RIGHT TO HEALTH AND THE WTO REGIME: LEGAL LINKAGES

Thesis submitted to Jawaharlal Nehru University

for award of the degree of

DOCTOR OF PHILOSOPHY

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2016

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DECLARATION

I declare that the thesis entitled "**Right to Health and the WTO Regime: Legal Linkages**" submitted by me for the award of the degree of Doctor of Philosophy of Jawaharlal Nehru University is my own work. The thesis has not been submitted for any other degree of this University or any other University.

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CERTIFICATE

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ACKNOWLEDGEMENT

My sincere thanks to Prof. B.S. Chimni and Prof. Y.K. Tyagi for enabling me to pursue this study. Without their benevolence, I would not have been able to embark on this study or to reach this stage. Earnest thanks to Prof. Chimni for encouraging me to take the thesis to this stage of submission.

Sincere thanks to Prof. Hegde for meticulously going through my synopsis in 2004 and enabling me to firm up the basic research direction. I am thankful to Prof. Bharat Desai and Prof. Murthy for their support in this 9(b) endeavour.

Thanks to the staff at the library in the Indian Society of International Law for their cooperation.

Thanks to my current organisation who provided me time to work on my thesis.

On the personal front, I am deeply indebted to my parents K.V. Varghese and Molina Varghese, who supported this research endeavour and who sent me to JNU in the year 2000 to pursue higher studies and supported me for several years thereafter. It was a big decision from them.

Thanks to Sheeba, Yohann, Mr. & Mrs. P.S. Thomas for their constant prayers and support.

Thank you Lord for enabling me to reach the stage of submission at Thine own time !

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GLOSSARY

1503 Procedure This is a procedure enabling individuals to directly brings their allegations on human rights violations to the Commission on Human Rights (Kedzia, Zdzislaw 2003: 69)

Bayh-Dole Act This is a legislation in US which enables research institutions and universities in the United States to obtain patent protection for their inventions which will in turn help them to enter into licensing agreements with the industry (WIPO 2009: 30).

Biosimilars Biosimilars which are sometimes called 'generic biologics', 'follow on biologics' or 'subsequent entry biologics' are products of different manufacturers which are similar in terms of quality, safety and efficacy to original products. However, unlike generic medicines which are interchangeable with reference products, biosmilars are not recognised as identical to reference products due to complex structures and variations in manufacturing processes. Biosimilars, require costly clinical trials and cannot be easily and inexpensively authorsied as generics ((WHO, WIPO and WTO 2013: 52).

Block Exemption Agreements which affect trade between Member States intended to restrict, prevent, distort competition within common market is prohibited by Article 81(1) of the EU Treaty. Article 81(3) of the same treaty provide for exemptions from such prohibition under Article 81(1) where the positive effects of such agreement outweighs the negative effects. This is facilitated through "block exemption" Regulations and Guidelines. The block exemption Regulation creates a safe harbor for most licensing agreements (WIPO 2009: 30).

Bolar Exceptions: This is named after a case in 1984 in the United States District Court launched by Roche Products Inc., against Bolar Pharmaceuticals a Nigeria based generic manufacturer. Bolar sought US federal approval for marketing a generic drug. The data for the same was based on a patent held by Roche. The District Court held that Bolar's use of the testing data associated with the patented compound was not an infringement of the law, but this decision was overturned in the decision of the Court of Appeals. The Court of Appeals did not agree with the argument of Bolar Pharmaceuticals Limited that they were covered under the American common law Experimental Use exception (Garrison, Christopher 2006: para 2.7). Later that year the United States Congress passed the *Drug Price Competition and Patent Restoration Act* which provided that it was not an infringement to make, use or sell a patented drug if it was done solely for uses reasonably related to the development and submission of information under a federal law regulating the manufacture, use or sale of the drugs. The rationale was that if the manufacturer of generic drugs had to wait until the expiry of a patent for a dug before being allowed to start developmental work, the patent term for the drug would be extended inadvertently (Walter 2003: 45).

Ever greening: This is a term used in denote a trifling change is made to an existing product and the same is claimed as a new product. The protection offered by the alleged new invention is used to extend the patentee's exclusive rights over the product (*Novartis A.G.* vs. *Union of India*, Justice Aftab Alam and J. Ranjana Praksh Desai, Supreme Court of India, Civil Appeal Nos. 2706-2716 of 2013: 55, para 100).

Exhaustion: By the term 'exhaustion' it means that if the trademarked goods are placed in the market by the owner or with his consent and once purchased legitimately, the IP owner or anyone deriving title from him cannot prevent the sale of such good as the exclusive right to sell the goods bearing the mark is exhausted by the first sale (Jain, Sneha 2009: 16). Under this there are three major classifications, national exhaustion, international exhaustion and regional exhaustion, all of which are briefly explained below.

Generic medicines: Generic drug means a pharmaceutical product which is not protected by a patent in force, and which is commercialized under a non-proprietary name or a brand name (See Correa Carlos 2000a: xiv). These are off-patent drugs, for which patent has run out, or non patented products for which patents were never taken. Therefore the drug may be manufactured and sold by many companies as a result of which the price competition is very severe resulting in lower prices (United Nations 1996: 328).

Human Rights Council: The Human Rights Council is an inter-governmental body within the UN system made up of 47 States responsible for strengthening the promotion and protection of human rights around the globe. The Council was created by the UN General Assembly on 15 March 2006 with the main purpose of addressing situations of human rights violations and make recommendations on them (See OHCHR URL: http://www2.ohchr.org/english/bodies/hrcouncil/)

International Exhaustion Regime: Under this regime the patent holder's right over the product is exhausted once the product is released into commercial space anywhere in the world (UNDP 2010: 39).Thereafter he cannot stop the subsequent sale of those

goods either in his own country or in any other country (Jain, Sneha 2009: 15).

International Reference Prices: International Reference Price are median prices of quality multi source medicines offered to low-middle income countries by non profit suppliers and where there is no supplier prices, international tender prices available from the Management Sciences for Health International Drug Price indicator Guide (United Nations 2012: 62).

JECFA: The JECFA functions as an international expert scientific committee body which is administered by FAO and WHO. JECFA evaluates the safety of food additives, contaminants, naturally occurring toxicants and residues of veterinary drugs in food and performs risk assessments as well provides advice to FAO, WHO and members countries of both organisations. Request for scientific advice from JECFA is channelled through the Codex Alimentarius Commission and the Codex also adopts international standards based on evaluations performed by JECFA (See *Canada – Continued Suspension of Obligations in the EC – Hormones Dispute*, WT/DS321/AB/R of 16 October 2008, para 457).

Least Developed Countries: The Fourth United Nations Conference on the Least Developed Countries held in Istanbul, Turkey in May 2011 identified that least developed countries consist of 48 countries with a total population of 880 million and that they represent the poorest and weakest segment of the international community (See A/CONF.219/3 2011, paragraph 1). The conference noted that least developed countries are characterized by constraints such as low per capita income, low level of human development, economic and structural handicaps to growth etc. and that in the past

three decades only three countries have graduated out of this category (See A/CONF.219/3 2011, paragraph 2)

Mail Box applications: This refers to a means by which applications for patents for pharmaceutical and agricultural chemical products can be filed and filing dates assigned to them. This was an interim measure to be made available by developing countries and least developed countries in order to facilitate precedence in filing dates, before their legal regime was amended to include product patents (See *India - Patent Protection for Pharmaceutical and Agricultural Chemical Products*, WT/DS50/AB/R, 19 December 1997, para 4).

National Exhaustion Regime: Here the rights of a patent holder are exhausted only when the product is released into the territory of a country (UNDP 2010: 39). However, if the goods are sold for the first time in a different country beyond the jurisdiction of the nation in which the trademark is registered, then the owner can invoke his trademark rights to prevent the import of the goods into the domestic market (Jain, Sneha 2009: 15).

Non-violation Complaints: Non violation complaints refereed to the complaints that are brought under Article XXIII:1(b) of GATT 1994 for preventing contracting parties from using non tariff barriers or other policy measures to negate the benefits of negotiated tariff concessions (See *India - Patent Protection for Pharmaceutical and Agricultural Chemical Products*, WT/DS50/AB/R, 19 December 1997, para 41).

Parallel importing: Parallel importing' is another measure, where a product sold by the patent owner more cheaply in one country is imported into another without the patent holder's consent.

Prebisch – Singer Thesis of Deteriorating Terms of Trade: International Trade replicating the patterns of colonialism may accentuate the dependency of developing countries on former colonial powers and make it impossible for these countries to overcome the obstacles to development (Joseph 2011: vi).

Ramsey Pricing: This is a method of price discrimination named after the economist Frank Ramsey (1903-1930) who suggested that utilities should allocate burden of high fixed costs among different customer to maximize welfare. For e.g. in the context of establishing telephone or electric network (Watal 2001:13).

Regional Exhaustion Regime: The patent holder's rights are extinguished once the product is released into the commerce in a certain region (UNDP 2010: 39).

Selection Patent: Here a single element or a small group within a large group is selected and independently claimed on the basis of a feature not mentioned in the large group. This is permitted is some jurisdictions where the small selected subset has a strong advantage. Certain jurisdictions like Germany have refused selection patents. Under the TRIPS Agreement broad discretion is provided to the Member states (Correa 2000a: 51-52).

Sui generis Sui generis means a term meaning a specialized regime of intellectual property rights, separate from copyright, patents and other chapters of intellectual property rights (See Correa Carlos 2000a: xv). Examples from the European tradition include *sui generis* industrial design laws (that protect appearance designs) and utility model laws that can

protect “minor” inventions generally (See Correa 2000a: 40).

Swiss Formula: This is an ever greening method used for the first time in 1984 before the European Patent Office and is used for getting an additional patent term for the second use of a patented substance. Countries may well reject these applications because it does not meet the traditional patent requirements such as novelty as the compound for the preparation of the medicament is the same as that used for the first pharmaceutical patent (See Correa 2000a: 23).

Tiered Royalty Method: The pricing methodology used in the context of compulsory licensing etc. in which the royalty is based not on the price of the generic product but on the price of the patented product in the high income country.

LIST OF ABBREVIATIONS

1961 Charter	1961 European Social Charter
1975 Declaration	1975 Declaration on the Use of Scientific and Technological Progress in the Interests of Peace and for the Benefit of Mankind
1996 Charter	1996 Revised European Social Charter
2003 EC Directive	Directive 2003/74/EC on 22 September 2003
2005 Report of the Task Force from Department of Chemicals and Fertilisers	Report brought out by the Department of Chemicals and Petrochemicals in September 2005
2005 Report of the Technical Expert Group on Patent Law Issues	Ministry of Commerce & Industry, Department of Industrial Policy & Promotion appointed Committee[1] in 2005 comprised of Dr. R.A. Mashelkar (Chairman), Prof. Goverdhan Mehta (Member), Moolchand Sharma (Member), Prof. N.R. Madhava Menon (Member) and Prof. Asis Datta (Member)
2005-06 Report of the Standing Committee on Chemicals and Fertilisers	The Standing Committee on Chemicals & Fertilizers (2005-06) (Fourteenth Lok Sabha) Ministry of Chemicals & Fertilizers (Department of Chemicals & Petrochemicals)
2007 Satwant Committee Report	Report issued by the Ministry of Chemicals and Petrochemicals, Government of India in May 2007
2010 WIPO Report	WIPO Standing Committee on the Law of Patents in 2010 (WIPO, SCP/14/1, December 11, 2009)
2002 Pharmaceutical Policy	2002 Pharmaceutical Policy from Government of India
2011 National Health Research Policy	2011 National Health Research Policy from Government of India
2011 WIPO Report	2011 Report of the WIPO Standing Committee on the Law of Patents
ADR	Adverse Drug Reactions
ADHR	1948 American Declaration of the Rights and Duties of Man
African Charter	1981 African Charter on Human and Peoples Rights
ALOP	Australia's appropriate level of protection
ANMAT	Medicines, Food and Medical Technology National Administration in Argentina
BVGH	Bio Ventures for Global Health

[1] Set up by Ministry of Commerce & Industry, Department of Industrial Policy & Promotion *vide* O. M. No. 12/14/2005-IPR-III dated April 5, 2005

BITS	Bilateral Investment Treaty's
CAFTA	2006 Central American Free Trade Agreement
CML	Chronic Myeloid Leukaemia
CAGR	Compound Annual Growth Rate
CDC	Centers for Disease Control and Prevention
CDSCO	Central Drugs Standard Control Organisation
CRC	1989 Convention on the Rights of the Child
Conference	The Workshop on Differential Pricing and Financing of Essential Drugs organized by the WHO, WTO and the Norwegian Foreign Ministry in April 2001
DPCO 2013	Drugs (Prices Control) Order, 2013 by the Ministry of Chemicals and Fertilizers dated May 15, 2013
DPCO 1995	Drug Price Control Order 1995
EAC	East African Community
EC Hormones Panel Reports	Appellate Body Report, WT/DS26/AB/R, WT/DS48/AB/R; the Panel Report, WT/DS26/R/USA; and the Panel Report, WT/DS48/R/CAN
EMA	European Medicines Agency
EMR	exclusive marketing rights
FDCA	Federal Food, Drug and Cosmetic Act
Food Act	Food Safety and Standards Act, 2006
FTA	Free Trade Agreement
GSK	GlaxoSmithKline
GAVI	Global Alliance for Vaccines and Immunisation
GCC	Gulf Cooperation Council
GHTF	Global Harmonisation Task Force
Guidelines	2008 Human Rights Guidelines for Pharmaceutical Companies in relation to Access to Medicines
Guiding Principles	2011 Guiding Principles on Business and Human Rights
HER/EFGR	Human Epidermal Growth Factor Type-I/Epidermal Growth Factor Receptor
HIV Guidelines	2006 International Guidelines on HIV/AIDS and Human Rights
HPAI	Highly Pathogenic Avian Influenza (HPAI) virus (H5N1)
IP	Intellectual Property
IPR	Intellectual Property Rights

IPR Policy 2008	Intellectual Property Rights Policy 2008
ICESCR	1966 International Covenant on Economic Social and Cultural Rights
ICH	International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use
IMDRF	International Medical Devices Regulators Forum
IRA	Import Risk Analysis (IRA)
KTKA	Kerala Traditional Knowledge Authority
MDRTB	Multi Drug Resistant TB
MEPE	Manufacturer's Margin
MOHFW	Ministry of Health & Family Welfare
MPPF	Medicines Patent Pool Foundation
MSF	Medicins san Frontieres
NADT	National Authority on Drugs and Therapeutics
NCE	New Chemical Entity
NLEM	National List of Essential Medicines
NME	New Medical Entity
NPPA	National Pharmaceutical Pricing Authority
NTB's	Non Tariff Barriers
OIHP	Office International d'Hygiene Public
OHCHR	Office of the United Nations High Commissioner for Human Rights
PANDRH	Pan American Network for Drug Regulatory Harmonisation
Paris Convention	Paris Convention for the Protection of Industrial Property 1883
PHA	Public Health Association of Australia
PRR	Protect, Respect and Remedy
PFC	Patent Facility Centre
PMPRB	Patented Medicines Review Board
PRT's	pathogen reduction treatments
PTA's	Preferential Trade Agreements
RTA's	Regional Trade Agreements
RCEP	Regional Comprehensive Economic Co-operation Agreement

SARS	Severe Acute Respiratory Syndrome
SARS	severe acute respiratory syndrome
SCoFCAH	EC Standing Committee on the Food Chain and Animal Health
SCVPH	Scientific Committee on Veterinary Measures relating to Public Health
SPS Agreement	Agreement on Sanitary and Phytosanitary Measures
TBT Agreement	Agreement on Technical Barriers to Trade of the WTO
TEG	2005 Technical Expert Group on Patent Law Issues
TPPA	2015 Trans Pacific Partnership Agreement
TRIPS Agreement	Agreement on Trade Related Aspects of Intellectual Property Rights
UDHR	1948 Universal Declaration of Human Rights
UN	United Nations
UN Charter	1945 Charter of the United Nations
Vienna Declaration	1993 Vienna Declaration and Programme of Action
ViiV	VIIV healthcare UK Limited
WHO	World Health Organization
WHO Constitution	1946 Constitution of the World Health Organization
WHO Expert Group Report	Expert Working Group on Research and Development Financing in December 2009 by the WHO
WIPO	World Intellectual Property Organization
WTO Agreement	Marrakesh Agreement Establishing the World Trade Organization

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CHAPTER 1
INTRODUCTION

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1. Introduction

[27] When Jesus departed from there, two blind men followed Him, crying out and saying, "Son of David, have mercy on us!"

[28] And when He had come into the house, the blind men came to Him. And Jesus said to them, "Do you believe that I am able to do this?" They said to Him, "Yes, Lord."

[29] Then He touched their eyes, saying, "According to your faith let it be to you."[30] And their eyes were opened.

(Mathew 9: 27-30)

The right to health is a well entrenched concept in international law and a basic human aspiration. As the above extract from the Bible seem to indicate, the creator also wills for human health.

There are various international instruments starting with the Charter of the United Nations, Constitution of the World Health Organisation and the Universal Declaration of Human Rights that firmly highlight the right to health. The challenge before international law today is to ensure that all individuals receive the fulfillment of this right.

Other than affordable access to medicines, another important area is the ability of sovereign nations to make necessary laws and regulations for protection of health of its population and a third aspect is the degree of involvement by the governments in the health sector. This study focuses on the impact on the right to health by various multilateral agreements under the WTO such as the 1995 *Agreement on Trade Related Aspects of Intellectual Property Rights* (hereinafter "TRIPS Agreement"), *Agreement on Sanitary and Phytosanitary Measures* (hereinafter "SPS Agreement"), the *Agreement on Technical Barriers to Trade of the WTO* (hereinafter "TBT Agreement") and the *General Agreement on Trade in Services* (hereinafter "GATS").

Earlier as a human right regime if there was single advancement of the right to health, now in the changed context of the WTO agreement we see that the movement is not

progressive alone. Rather there are two conflicting interest which are competing for space and precedence. The question is, whether WTO as a forum does justice to health interests. As the United Nations Conference on Trade and Development in its 2014 report notes:

> ..there are also valid concerns that the various legal obligations arising from multilateral, regional and bilateral agreements have reduced the national policy autonomy by affecting both the available range and efficacy of particular policy instruments. In addition, the effectiveness of national policies tend to be weakened – in some instances significantly – by forces of globalization (especially financial and globalization) and by the internalization of markets, which affect national economic processes. (UNCTAD 2014: viii)

1.1. TRIPS and Affordable Access to Medicines

Affordable access to medicines and medical technology is critical to human beings for good health and to ensure continuity of life.[1] In this regard, the TRIPS Agreement, which is a multilateral trade Agreement under the *1995 Marrakesh Agreement Establishing the World Trade Organization* (hereinafter "WTO Agreement") at its inception and initial operating years generated much concern throughout the developing world (See Xu Yi-Ching and Patrick Weller eds. 2004: 102). The stringent form of IPRs envisaged under the TRIPS Agreement and the requirement that the pharmaceutical sector be opened up for product patents makes cheaper access to medicines and medical intervention technologies very difficult. Through the years of implementation of TRIPS from 1995, this was found to be true on the ground in many cases.

Even the bench marks set through the TRIPS Agreement is now sought to be expanded through various bilateral and regional agreements which have received the epithet of 'TRIPS plus Agreements'. This is a troubling development as empirical studies reveal that prices of medicines under patent protection are higher (See Yamabhai, Inthira and Smith, Richard D 2015: 93). WHO (2014) notes that number of important antiretrovirals are still under patent protection and that this limits availability of cheaper generic versions in the countries concerned (WHO 2014: 3).

[1] Modern medicine in the form of tablets, syrups, injectibles etc. is widely used for effective treatment of diseases all over the world. Also there are various health technologies associated with medical intervention such as preventive (e.g. vaccine), diagnostic (stethoscope or thermometer), therapeutic (medicine, surgical equipment, surgical procedure, implant) and rehabilitative (physiotherapy equipment, a crutch etc.) (WHO, WIPO and WTO 2013: 34).

In the context of the TRIPS and TRIPS plus Agreements, it needs to be noted that it is not that the developed countries which today advocate stronger patent rights and commercialisation of health sector, always vouched for a strong patents system. Infact, in the 1870's Britain came close to abandoning the patent system altogether because it was considered to be protectionist in nature and was opposed by free trade advocates (Grubb, Philip W. 2004: 19). British industry pressed for the abolition of patents in the 1920's for as they were keen to imitate a German dye stuff appearing in the British market through alternative process rather than inventing new dye stuff themselves (Grubb, Philip W. 2004: 19).

Similarly, the United States had issued tens of thousands of patent related compulsory licenses in over 100 cases till the end of the 20th century (Yang, Deli 2012:77). In 1975 the Federal Trade Commission entered into a consent decree against Xerox for engaging in unfair trade practice by creating and maintaining patent structure of humongous size and complexity with obscure boundaries to defeat competition, as a result of which Xerox was asked to give compulsory license of office copier patents. Such compulsory license required three patents to be licensed free of cost and the rest at royalty of less than 0.5 per cent of net revenues which resulted in an accumulated royalty of only 1.5 percent to Xerox (Yang, Deli 2012:77).

Therefore the patent system did not always have all round support even from the ardent supporters of today and the flexibilities such as compulsory licenses which are questioned today were very much used by the developed nations in the past.

Further, when we look at the history of the WTO discussions, it emerges out that when the Uruguay Round of trade negotiations was launched, more than fifty countries did not confer patent protection on pharmaceuticals (Correa, Carlos 2000a: 11). Before the TRIPS Agreement, countries such as India where a strong manufacturing base for pharmaceuticals was created over time, could produce generic versions of the new molecules invented in the west with ease and without going through rigorous research and development programmes. This is no longer possible under the TRIPS and TRIPS plus agreements which require patent protection to be afforded to the inventors.

Sometimes patent holders may stop production of drugs of much consequence to developing countries but which do not offer profit margins to the pharmaceutical company in producing them. MSF points out that the production of eflornithine was apparently abandoned in 1994 by the manufacturer Aventis Pharmaceuticals because it did not guarantee adequate return on investment. Finally, upon request from MSF, Aventis Pharmaceuticals transferred the license to WHO (Orbinski, James 2001: 230).

Further, companies may seek to create patent thickets to stifle competition which in turn will impact access to medicines. For example, in the context of H5N1, for the manufacture of vaccines against such disease companies have sought to patent H5N1 genes, their sequences and/or their use, thus creating possibilities of patent thickets which will negatively impact further research on such disease (Hammond, Edward 2008: 7).

While the increase in the cost of the medicines for treatment of diseases may affect affordability, treatment of epidemics such as HIV, bird flu, swine flu etc. for the population at large may also suffer due to high medicinal prices etc. resulting from the stronger patent regime imposed under the TRIPS and TRIPS Plus agreements. Access to medicines becomes all the more important in the context of global pandemics like AIDS, EBOLA, zika etc.

UNAIDS noted that in 2014, 36.9 million people were living with HIV of which 22 million do not have access to HIV treatment including 1.8 million children (UNAIDS 2015: 3). At the end of 2009, the number was 33.3 million people with HIV (UNAIDS 2010: 23) of whom about 4.9 million are in Asia (UNAIDS 2010: 34). The number of people dying of AIDs related causes was estimated at 2.22 million in 2005 and 1.8 million in 2010 (United Nations 2012: 64). The number of people in need of antiretroviral therapy at the end of 2009 increased from 10.1 million to 15 million (WHO 2010: 1). Developing countries are worst hit, for e.g. in 2012 in Kenya close to 1.6 million people suffer from HIV/AIDS ("UNAIDS Welcomes Kenya High Court Judgment on Anti-Counterfeit Law", 2012). UNDP in 2010 stated that estimates reveal that the number of people suffering from diseases like AIDS will increase drastically with the figures reaching up to 55 million in 2030 (UNDP 2010: 14).

Another disease, of high concern is the highly pathogenic avian influenza (HPAI) virus (H5N1) affecting domestic and wild birds which was first identified in China in 1996 and which spread to 62 countries in Asia, Middle East, eastern and western Europe and sub-Saharan Africa by 2009. The virus has resulted in the death of millions of poultry and caused economic damage to the tune of billions of dollars (European Union 2010: 17). While HPAI rarely infects humans, if these viruses were to undergo genetic change and become capable of continuous transmission from one human to another it may result in millions of deaths and damage to the tune of billions of dollars. In case of any such malady, developing countries would be worst affected because of poverty, inadequate health care systems etc. (European Union 2010: 18).[2] The significance of the need to deal with such diseases is clear from that in the fight against HPAI which has not yet become a human pathogen by mutation, by December 2009, the international community had pledged a cumulative amount of 4.3 billion US dollars (European Union 2010: 18).

The outbreak of Ebola in the recent past and Zika now, is another instance which highlight the need for focusing on diseases which envelope the developing world. Zika virus for e.g., has potential to impact tens of millions of people and is now being transmitted in 33 countries with about 600 million inhabitants (McNeil Jr., Donald G, Romero, Simon and Tavernise, Sabrina 2016: 19). In today's economy where national boundaries are transcended by commercial activities with steady flow of people across national boundaries, the need to address the needs of all areas of the globe is critical. In countries where a large portion of the population lives below the poverty

[2] European Union 2010: 18

> The influenza A(H1N1) pandemic 2009 caused by a mild virus with a low (1.3 %) case fatality rate had caused 5700 deaths worldwide by 25 October 2009. However, another influenza pandemic virus, such as H5N1, could have higher pathogenicity and transmissibility and, therefore, be much more devastating in its impact on human lives and sustainable development globally. In a moderate pandemic flu scenario, studies have suggested that the economic losses from illness and death in the first year of the pandemic could amount to 1.3 % of world GDP or more. Combined with preventive costs of close to 2 % of GDP, total costs could exceed 3 % of world GDP in a moderate pandemic scenario (WB, 2009). Burns and others suggest that the cost of a global influenza pandemic could range from 0.7 to 4.8 % of global GDP according to the severity of the outbreak. The lower estimate is based on the Hong Kong flu of 1968–69, while the upper is benchmarked by the 1918– 19 Spanish flu. In the case of a serious flu, 70 % of the overall economic cost would come from absenteeism and efforts to avoid infection. Generally speaking, developing countries would be hardest hit, because higher population densities, relatively weak healthcare systems, and poverty accentuate the economic impacts in some countries

line, even small increases in prices can have catastrophic consequences. The price of medicines is of particular relevance to those in the developing and under developed countries where the health amenities are less, the economic strength of the ordinary citizen is low and where the conditions which spread diseases are prevalent.

It is relevant to note here that the scope of application and impact of the TRIPS Agreement extends beyond patents. While the TRIPS Agreement does not mention specific levels of data protection, it does require nations to ensure protection of test and regulatory data related to pharmaceutical and agricultural products which are submitted for approval to the government (See Verma S.K. 2013: 31). This is further sought to be expanded upon by the TRIPS plus agreements. If the data submitted to regulatory authorities cannot be used by generics manufacturers, then the cost for generating such data will need to be again borne by the generic manufacturers, thereby increasing their costs and in turn the pricing of the medicines.

1.2 SPS, TBT and GATS Agreements

From among the WTO Agreements, the SPS Agreement and the TBT Agreement are other multilateral trade agreements which have provisions impacting health as they deal with health standards and non-tariff barriers. The provisions have the impact of determining the extent to which countries can set required health standards, as the SPS Agreement seeks to establish a multilateral framework of rules and disciplines to guide the development, adoption and enforcement of sanitary and phytosanitary measures in order to minimize their negative impact on trade (Preamble to the SPS Agreement). The TBT Agreement in turn, seeks to ensure that technical regulations and standards, including packaging, marking and labelling requirement and procedures for assessment of conformity with technical regulations and standards do not create unnecessary obstacles to international trade (Preamble to TBT Agreement).

The SPS and TBT agreements have the scope to impact the right to health of a citizen, as governmental measures setting a high level of heath standard may be challenged as not being based on scientific norms through the WTO. Normally such high standards are prescribed by developed countries. This in one way prevents nations from raising the bars of the health standards, for e.g. the *EC Hormones* disputes, the *Japan - Apples* dispute before the DSB etc.. On the other hand, these health standards affect

countries in terms of their export potential. Even pharmaceutical exports from developing countries can be restricted through trade barriers created through packaging norms. Thus, the SPS and TBT Agreements can act both in favour of and against the developing countries. Under the WTO dispute resolution mechanism there have been several cases in relation to trade in products such as cigarettes, asbestos etc. which products have detrimental effect on the health of a population as a whole. Some of these disputes before the WTO DSB involving the SPS and TBT Agreements are examined to understand the impact of these decisions on the right to health.

Further, the GATS has provisions which impact commercialisation of the health sector, movement of people, transborder services etc. The impact of the opening up of sectors including health services under the GATS on the right to health is briefly considered and this is important considering that trade in services is on the upswing.

2. Review of Literature

There is much literature now on the topic of TRIPS Agreement and the right to health, while the literature on impact of SPS, TBT and GATS Agreement on the right to health is on a more limited scale. Most of the available literature as can be seen are standalone studies on patents and the right to health, data protection and the right to health or the SPS/TBT Agreement and the right to health etc. The expanse of study in this thesis gives a panoramic view on which direction the right to health is moving in the context of the WTO.

2.1 The Right to Health in International Law

The right to health, in the fact sheet brought out by the Office of the United Nations High Commissioner for Human Rights (hereinafter "OHCHR"), refers to the right to enjoy a variety of goods, facilities, services and conditions necessary for the realization of good health (United Nations 2008b: 5). The 2000 General Comment No. 14 noted that health is a fundamental human right indispensable for the exercise of other human rights (See United Nations (2000), Economic and Social Council, E/C.12/2000/4., para 1).

The *Report of the Special Rapporteur on the Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health* (Grover, Anand

(2011), UN Doc.A/HRC/17/43 of 16 March 2011) is an important document which looks into the conflict between the right to health and WTO.

Further, the *Report of the Special Representative of the Secretary General on the Issue of Human Rights and Transnational Corporations and Other Business Enterprises*, John Ruggie (hereinafter "Guiding Principles on Human Rights") (Ruggie, John (2011), UN Doc.A/HRC/17/31of 21 March 2011) contain the 'Protect, Respect and Remedy' (PRR) Framework which was adopted by the Human Rights Council in 2011. The Guiding Principles is grounded in the recognition of States' existing obligations to respect, protect and fulfill human rights and fundamental freedoms (Ruggie, John (2011), UN Doc.A/HRC/17/31 of 21 March 2011: 6, preamble (a)) and it notes the role of business enterprises as specialized organs of the society performing specialized functions, and which are required to comply with all applicable laws and to respect human rights (Ruggie, John (2011), UN Doc.A/HRC/17/31of 21 March 2011: 6, preamble (b)). The Guiding Principles further require that States should maintain adequate domestic policy space to meet their human rights obligations when pursuing business related policy objectives with other States or business enterprises such as through investment treaties or contracts (See Article 9 of the Guiding Principles, UN Doc.A/HRC/17/31of 21 March 2011).

Mabika, Aulline H and London, Leslie note that human rights are interdependent and the violation of one right frequently results in the violation of another. In addition, the international law instruments which provide for such rights are also seen to be interdependent (Mabika, Aulline H and London, Leslie 2007b: 12).

The 2006 UN Political Declaration on HIV/AIDS, recognized that diseases such as these constitute a global emergency and pose one of the most formidable challenges to the development, progress and stability of societies and world at large to which an exceptional and comprehensive global response is required (Political Declaration on HIV/AIDS, 2006, para 2). The UN also reaffirmed that medication in the context of pandemics such as HIV/AIDS is one of the fundamental elements to achieve progressively the full realization of the right of everyone to the enjoyment of the highest attainable standard of physical and mental health (Political Declaration on HIV/AIDS, 2006, para 12).

Granslandt Mattias, Maskus, Keither E and Wong, Elina V. (2001: 785) note that the South African GDP would be about 17 per cent lower in 2010 than it would be without AIDS, removing $ 22 billion in output from the economy and that in Botswana alone there could be 13-15 per cent reduction in the income of the poorest households.

Friedman, Eric A ., (2016) calls for the creation of a framework convention on global health with monitoring mechanism under it such as those under the International Covenant on Civil and Political Rights.

Chimni, B.S. (2004) argues that a network of economic, social and political international institutions are now established at the instance of the developed world which institutions together constitute a nascent global state seeking to implement the interests of transnational capital and of powerful states to the disadvantage of the third world states and peoples (Chimni 2004: 2). On global justice, he argues that the principle of redistributive justice calls for the establishment of a practice of social audit of international economic laws to assess their impact on the global poor and that the primacy of international human rights laws over economic laws need to be recognised, in particular over those which internationalise property rights (Chimni 2007: 217).

2.2. TRIPS, TRIPS Plus and the Right to Health

The preamble to the WTO Agreement emphasises that trade and economic endeavour should be conducted with a view to raise the living standards and in a manner consistent with the needs and concerns at different levels of economic development. The need for positive efforts to ensure that developing and least developed countries receive a share of growth in international trade commensurate with their economic needs is also emphasised. The patentability requirements and the flexibilities to the patentability criteria are mentioned in the TRIPS Agreement.

There are various ministerial declarations of the WTO which deal with public health such as the Doha Ministerial Declaration, Hong Kong Declaration, Geneva Declaration etc.. The Doha declaration provided time till January 2016 for the least

developed countries to provide product patents for pharmaceutical products. This transition period was extended till July 01, 2021 through the decision of the TRIPS Council in June 11, 2013 (WTO 2014: 194) and is now further extended till January 01, 2033 in the WTO Council for TRIPS decision of November 06, 2015 (WTO Document IP/C/73 of 6 November 2015).

Yamabhai, Inthira and Smith, Richard D (2015: 93) note that 'patenting is associated with higher prices relative to a regime where patents are not available'. The study which had a pro patenting approach on many counts, still note that the impact could range anywhere from 26-277% (Yamabhai, Inthira and Smith, Richard D 2015: 93).

Joseph, Sarah (2011) in her exhaustive study notes that 'a natural outcome of such monopoly rights is that prices from IP protected products are inflated' (Joseph 2011: 214). She calls the WTO rules imbalanced (Joseph, Sarah 2011: 292) and note that the TRIPS Agreement may compel States to adopt retrogressive measures with respect to the right to health and that the enforcement of certain unfair rules by the North against the South could constitute breach of extraterritorial human rights obligations (Joseph, Sarah 2011: 287).

As Correa, Carlos notes, "Patents work by providing government-sanctioned, limited-term monopolies as an incentive and reward for useful inventions" (Correa, Carlos 2000a: 2). He considers the significant impact of pharmaceutical patents on access to medicines, and opines that if developing nations as a whole were to take the stance to prohibit or suspend the patentability of certain pharmaceutical substances on the grounds of *ordre public*, then this could give rise to 'state practice' which WTO panels will have to take into account (See Correa, Carlos M. 2000b: 13). He also surveys the various legitimate steps available to the developing countries within the TRIPS framework to ensure access to medicines (Correa Carlos 2007a) and under Article 30 (Correa, Carlos M. 2007b).

The *WIPO Standing Committee on Law of Patents* (WIPO 2009) explores the linkages between the patent system and transfer of technology. While the report favoured patents as a means to facilitate transfer of technology, it did not find conclusive evidence of positive impact of patents on transfer of technology. The report noted that

the patent system transformed public good knowledge into a tradable property with defined ownership and limits (WIPO 2009: 23, para 91).

UNDP (UNDP 2010) conducted an elaborate study on improving access to medicines by making use of the flexibilities under the TRIPS Agreement. It noted that the initial attempts by low income countries to use the flexibilities under the TRIPS Agreement was fraught with challenges, highlighted the various options including compulsory licenses as options available under the TRIPS Agreement and further noted the concerns arising from TRIPS plus Agreements. Several other international organisations including WHO, WTO, ICTSD, UNCTAD etc. have come out with study reports on the topic of access to medicines and are elaborately examined.

The survey of these documents is critical as it forms a significant source of international law. Oppenheim (1996) notes that the international organisations in international life contributes to more rapid adjustment of customary law to developing needs of international community (Oppenheim 1996: 30-31). Besides the direct function of international organisations as potential source of international law, state practice as displayed in international organisations and the collective decisions and activities of these organisation form valuable evidence of the general practice accepted as law in the field of operation of these international organisations (Oppenheim 1996: 30-31).

Agitha, T.G., (2013:589) notes that the right to health is a universal and inalienable right and should have precedence over commercial interests and the governments have the duty to ensure universal health coverage. The incorporation of IPRs into the global trade regime has considerably impacted the right of the States to set health policies and priorities and the pharma industry has played a key role in incorporating the IP agenda into the GATT (Agitha, T.G., 2013: 589). She further notes that market driven research and development ignore the needs of the people with no purchasing power (Agitha, T.G., 2013: 589). Currently much of the research is directed to specific diseases placed on agenda by a few wealthy donors. In 2010-11 WHO's budgetary funding for infectious diseases had negligible allocation for non communicable diseases such as cardio vascular diseases, diabetes, cancer, chronic

respiratory disease which account for 63% of deaths world wide of which 80% occur in low and middle income countries (Agitha, T.G. 2013: 593).

Bryan Mercurio (2006) notes in his elaborate study on TRIPS plus agreements that the TRIPS is not a definitive agreement on IPRs that some hoped it would be, but instead it represents one part of a larger cycle in which developed countries engage in bilateralism, regionalism and multilateralism to engage their interests and secure concessions from other nations (Bryan Mercurio 2006: 216).

Review of certain decisions of the DSB pertaining to the TRIPS Agreement has also been done. In decisions such as *China – Measures Affecting the Protection and Enforcement of Intellectual Property Rights* (WT/DS362/R of 26 January 2009), the wide reach of the WTO dispute settlement process becomes evident when the content of national legislation is reviewed by the Panel for compliance with the TRIPS Agreement. *Canada – Patent Protection of Pharmaceutical Products* (DS114 of 17 March 2000) was an important decision for health rights, as the regulatory review exceptions under Canadian law were upheld by the Panel. However, the Panel did not uphold the stockpiling exception which does not advance the cause of the right to health.

On TRIPS plus Agreements, Hsu (2006: 528) states that there is even the practice of templates or standard terms for free trade agreements or Trade and Investments Framework Agreements that are used by developed countries like United States on the basis of which they may try to argue that the repeated use of such templates or standard forms reflect the customary international law position on certain provisions (Hsu 2006: 532). This may encourage powerful states to proactively enter into numerous bilateral treaties on certain terms which they wish to promote as customary international law. The question then arises as to whether economically less influential States would be bound by such provisions found in many regional trade agreements promoted by economically powerful and influential states (Hsu 2006: 538).

The *Trans-Pacific Partnership Agreement* entered into between United States, Canada, Australia, New Zealand, Malaysia, Singapore, Japan, Mexico, Peru, Vietnam, Brunei and Chile in October 2015 has significant TRIPS plus provisions. The TPPA

note that a Party may in formulating and amending its laws adopt measures necessary to protect public health and nutrition and promote public interest in sector of vital importance to their socio-economic and technological development to the extent they are consistent with the provisions of Chapter 18 of the TPPA on IPR (Article 18.3.1 of TPPA). The TPPA has TRIPS plus provisions such as patents for new uses of a known product, new methods of using a known product, new processes of using a known product (Article 18.37.2 of TPPA), patent extension for unreasonable delays in a Party's issuance of patents, adjusting the term to compensate for such delays (TPPA, Article 18.46.1) etc.

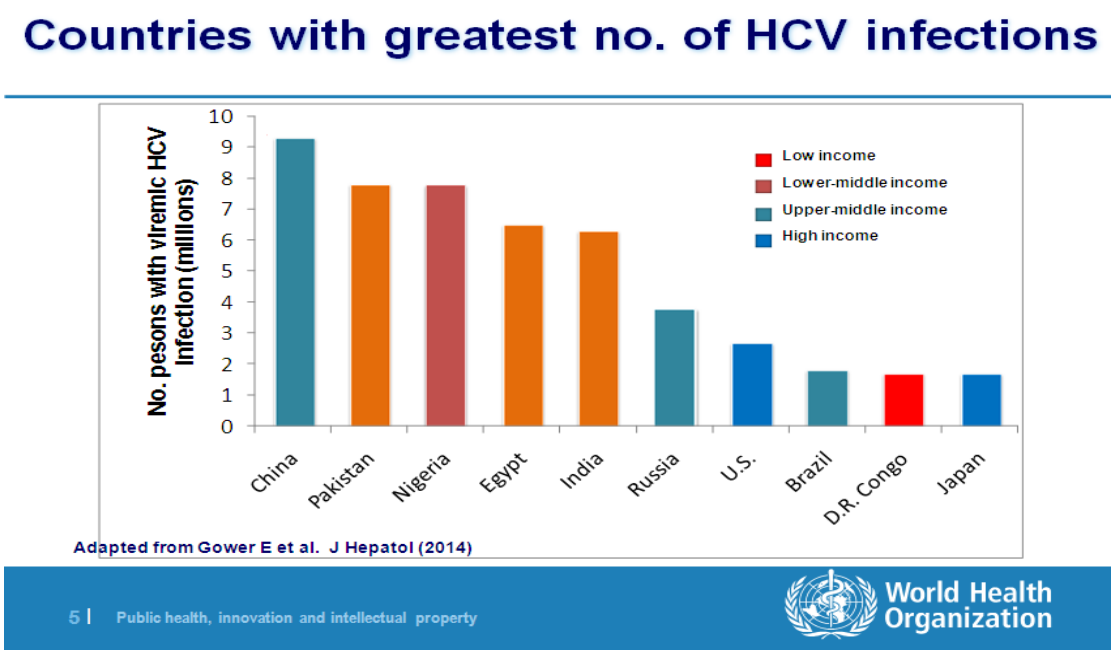
On similar lines is the currently under negotiation Regional Comprehensive Economic Cooperation Agreements ("RCEP") between Indonesia, Malaysia, Philippines, Singapore, Thailand, Brunei, Vietnam, Laos, Myanmar, Cambodia with ASEAN Plus Three i.e. China, Japan, South Korea and with India, Australia, New Zealand. India is currently in advanced stages of negotiation of the RCEP (Economic Times, February 17, 2016).

The study by Hoen *et.al* (2011) state that in 2011 only a third of the 33.3 million people living with HIV and requiring treatment receive such treatment. *Medicins san Frontieres* (hereinafter "MSF") pointed out in 2001 that millions were dying because of lack of access to medicines (Orbinski, James 2001: 223). It also reported that the United States had offered loans to 24 heavily indebted sub-Saharan states at reduced rates to buy patent protected drugs (Orbinski, James 2001: 226). Such loans will only add to the debt burden of these heavily debt stricken countries. Many developing countries may not be able to use the flexibilities available under the TRIPS Agreement as pharmaceutical companies actively discourage the use of compulsory licensing provisions by governments as it would reveal the actual cost of production and the true profit margins (Orbinski, James 2001: 228).

New drugs of consequence to developing countries such as drugs against malaria, tuberculosis etc. are not developed by pharmaceutical companies. Orbinski, James (2001) points out that there have been no new drugs developed for the treatment of tuberculosis after the development of rifampicin in 1967.

As the below graph from WHO as on December 2014 shows, the number of Hepatitis C patients in the developing world is much higher compared to the developed countries (See Beyer, Peter 2014). Countries with the greatest number of HCV infections are China, Pakistan, Nigeria, Egypt and India and the countries with least number of HCV infections include countries such as US, Brazil, Japan etc..

Table 1: Countries with Greatest Number of HCV Infections



A 2010 EU study notes that discrepancies exist in the availability of medicines to treat influenza A(H1N1). For e.g. the availability of stockpiles of Tamiflu was 71000 courses at Cambodia, 500000 in Thailand, 1000 in Uganda while United States had 70 million treatment doses by mid-2008. Even these numbers in the developing countries apparently were based on donations from pharmaceutical companies like Roche and from various other countries and after negotiations with pharmaceutical companies (European Union 2010: 59). The study recommends equity in the availability of health care (European Union 2010: 60).

An Oxfam study noted that in an eastern province of Zambia, poor rural women spend up to $7 to purchase antibiotics for the treatment of childhood pneumonia when majority of the people survive on less than $1 a day (Oxfam 2002: 215).

The EU study note an FAO estimate of 2008 that HPAI (H5N1) has resulted in USD 20 billion in economic losses and that an influenza pandemic by this virus will cost the global economy USD 2 trillion. Such an outbreak would impact service sectors such as tourism, retail trade, transport, entertainment etc. and the cost of the illness can include medication and hospitalization etc. (European Union 2010: 71).

The proponents of liberalisation note that intense foreign competition will bring overall gains to the economy while it may not be immediately obvious (Heydon, Kenneth, 2014: 1054). While the strong regime for IP has been pursued and enforced through TRIPS Agreement and TRIPS plus Agreements, scholars point out that if strong IP laws led to a strong economy, then Sub Saharan countries would have the strongest economies in the world since they have adopted some of the highest levels of protection (Farley, Christine Haight 2014: 102), which definitely is not the case.

2.3. TRIPS Agreement, India and the Right to Health

Mahajan, Madhur Mohit (2011: 322) notes that the Indian pharmaceutical market remained import dependent till the 1960's when the government implemented policies facilitating local production. The laws and policies of the Government of India in the 1970s enabled the increase in pharma production and pharma units in India. From about 2200 pharma manufacturing units in 1969-70 period the number of units in India increased to around 24,000 by 1995-96 (Mahajan, Madhur Mohit 2011: 323). The Government of India founded 5 state owned pharmaceutical companies namely, The Bengal Chemical and Pharmaceutical works (1930) which was the first public sector drug manufacturer, The Hindustan Antibiotic Ltd (1954), Indian Drugs and Pharmaceutical Ltd (1961, with Soviet assistance), Bengal Immunity Ltd., Smith Stanistreet Pharmaceutical, and Indian Drugs and Pharmaceutical Corporation (Mahajan, Madhur Mohit 2011: 329). The strong generic medicines manufacturing base and consequent cheap availability of medicines in India was due to such policies.

As Kadri, Harunrashid and Saykhedkar, Medha (2011) note, most of the patents in India are owned by foreign investors primarily from the United States which indicate that the United States has been a major beneficiary of the TRIPS Agreement in India (See Kadri, Harunrashid and Saykhedkar, Medha 2011:223).

Chimni, B.S. (1993), argue that the review of theoretical evidence shows that a positive association between strong protection and transfer of technology and foreign direct investment is at best uncertain and does not offer justification for introducing hard patents regime in India and other developing countries (Chimni, B.S. 1993: 238).

Lee Minsoo and Park Donghyun (2013) note that while intuitively appealing, evidence from empirical literature that tests the relationship between IPR protection and FDI is at best mixed (Lee Minsoo and Park Donghyun 2013:1). The study conclude that IPR protection promotes FDI inflows in countries with informal economies smaller than a threshold value, but not in the case of countries with GDP above the threshold value (Lee Minsoo and Park Donghyun 2013:13).

Various Govt. reports have been reviewed. The 2005 R*eport of the Task Force to Explore Options Other than Price Control for Achieving the Objective of Making Available Life-Saving Drugs at Reasonable Prices* considered various options other than price control to make life saving drugs available at reasonable prices (Government of India 2005b). In the matter of data protection, the 2007 Satwant Committee Report in India looked into data protection as required under Article 39.3 of TRIPS Agreement and noted that the TRIPS Agreement does not clearly state the manner in which data protection is to be provided (Government of India 2007: iv).

Various decisions of the courts in India on the matter of the right to health have been considered, including *Natco Pharma* v. *Bayer Corporation* (Compulsory License Application 1 of 2011) and *Natco Pharma Ltd.* v. *Union of India* (Supreme Court, Civil Appeal Nos. 2706-2716 of 2013).

The 1940 *Drugs and Cosmetics Act* in India define the term ‘drug’ and it includes medicinal devices as well. The 2013 *Drug (Prices Control) Order*, 2013 empowers the government to fix medicinal prices and the manner in which it is to be done. The 1970 *Patents Act* in India lays down the patentability criteria and among other things, the various means by which patent holders rights can be overridden. While the 1970 *Patents Act* do have some provisions to deal with above mentioned situations, but the same may not be adequate. The reality remains that price of medicines increase very

frequently and thereby making them unaffordable to a large section of the society. The 2002 *Competition Act* deals with cartelisation in India.

On protection of test data, in India there is no comprehensive legislation that is enacted to deal with the same, but the protection is afforded through a multiplicity of laws all of which partially deal with the subject. The 1968 *Insecticides Act* regulates insecticides and other related agro chemicals and provision of test data for regulatory approval while the 1940 *Drugs and Cosmetics Act* regulates the import, manufacture and sale of drugs and cosmetics and provision of test data in certain cases

2.4. TRIPS Agreement and Practices from Different Countries

The legislation in various developing countries such as South Africa, Namibia, Kenya, Thailand, Argentina etc. is reviewed. The perusal of the legislation in these developing countries reveals that some flexibilities such as compulsory licensing, price control, interchangeable medicines etc. have been mandated in these countries for public health considerations.

The legislation in developed countries such as Canada, U.S. is briefly surveyed. The 2010 *Patient Protection and Affordable Care Act* in the United States brought about by the Obama administration sought to bring about non-discriminatory access to health care to all in the insured sector in the United States. The legislation makes it mandatory for all individuals in the United States to maintain insurance coverage failing which they will be penalised.

The case proceeding before the NAFTA, *Eli Lilly and Company* vs. *Government of Canada* (UNCT/1/2) is a significant case in which the pharmaceutical company Eli Lilly has taken the Government of Canada to arbitration under the North American Free Trade Agreement. In this proceeding Eli Lilly and Company is attempting to relitigate the decisions in two Federal Court Proceedings in Canada.

2.5. The Right to Health and GATT 1994, SPS, TBT and GATS

The SPS, TBT and the GATS have provisions which impact the right to health. Article 3.1, 3.3 and 5.3 of the SPS Agreement have been the subject matter of many disputes under the SPS Agreement. Under Article 3.1 of the SPS Agreement, the

principle of harmonisation is laid down, which states that to achieve harmonisation of sanitary or phytosanitary measures as much as possible, Members are to base their sanitary or phytosanitary measures in international standards, guidelines, recommendation etc. where they exist. However, under Article 3.3 of SPS Agreement Member may introduce sanitary or phytosanitary measures which result in higher level of sanitary or phytosanitary protection than those achieved by measures based on international standards where there is scientific justification or where the Member determines such higher measure to be appropriate based on risk assessment and determination of appropriate level of sanitary or phytosanitary protection under article 5. However, such measures are not to be inconsistent with any other provision of the SPS Agreement.

The number of disputes pertaining to SPS Agreement is several and is increasing. The study of these disputes is important, especially as the developing countries and least developing countries do not have the same capability as the developed countries in dealing with these disputes. Zeng, Ka (2013) observe that there is strong evidence that members with greater government efficiency and regulatory quality are more likely to successfully absorb the legal costs associated with litigation at the WTO and also to obtain positive panel decisions (Zeng, Ka 2013: 204). Conflicting views are held by scholars like Mitchell (2013) who notes that there seems to be no inherent bias in the system against developing countries and that rules and procedures can prevent the most powerful states from dominating the smaller countries in these disputes (Mitchell 2013:102).

In *Argentina – Measures affecting the Import of Pharmaceutical Products* (WT/DS233/1 of 30 May 2001) India approached the DSB alleging that the Argentina's Law/Act No. 24.766 and Decree No. 150/92, constituted unnecessary obstacles to international trade and prevented Indian pharmaceuticals from entering into the Argentinean market. In *Indonesia – Measures Concerning the Importation of Chicken Meat And Chicken Products*, (WT/DS484/1) Brazil raised request for consultations against Indonesia that certain Indonesian measures on shipping and quarantine on importation of chicken meat and chicken products are ‘unnecessarily constraining and discriminatory against the exports’ and that they ‘are not based on relevant international standards, guidelines or expectations’, etc.

A review of the various decisions in the context of SPS and TBT Agreements is undertaken to understand the approach adopted by the various AB and Panel reports on trade and human rights. in *EC Measures Concerning Meat and Meat Products (Hormones)* (WT/DS26/AB/R, WT/DS48/AB/R of 16 Jan 1998) in the face of the argument by EC that precautionary principle is customary international law, the AB noted that precautionary principle at least outside the field of international environmental law still awaits authoritative formulation (WT/DS26/AB/R, WT/DS48/AB/R of 16 Jan 1998, para 123). In *Canada – Continued Suspension of Obligations in the EC – Hormones Dispute* (WT/DS321/R of 21 March 2008), the AB made several observations favouring health protection, but in the end the AB decided that the SCVPH Opinions do not constitute a risk assessment as they do not satisfy the definition of risk assessment contained in Annex A(4) second sentence and that the scientific evidence referred to in the opinions do not support the conclusion therein. The EC was required to remove its non-conforming measures.

With reference to the TBT Agreement and even otherwise, the decision in *European Communities - Measures Affecting Asbestos and Products Containing Asbestos* (WT/DS135/AB/R of 12 March 2001, para. 172) is the most important among the various decisions from a right to health perspective and in this decision the AB noted human health as being "important in the highest degree." The AB also noted that it is undisputed that WTO Members have the right to determine the level of protection of health that they consider appropriate in a given situation (WT/DS135/AB/R of 12 March 2001, para. 168). The Panel had also held that the French Decree was necessary to achieve the public health objective and did not constitute any arbitrary or unjustifiable discrimination (WT/DS135/R of 18 September 2000, para 8.237).

In the context of GATS, the Trade and Development Report by UNCTAD (UNCTAD 2014: III) noted that trade in services increased by 5% globally in 2013. In the context of increase in privatization and commercialisation of the health care sector, nations may not be able to achieve higher levels of health rights. Chapman, Audrey (2014) notes, with the exception of the few not for profit organisations, the private sector primarily comprises of entities which invest in health care to make money and not to provide affordable health care services. Such private health care facilities have inbuilt

incentives to pursue the most profitable treatment methodology and higher administrative costs (See Chapman, Audrey 2014: 129). In addition, there is now a general shift from viewing health system as a core social institution for the benefit of the society to being considered as a commodity (See Chapman, Audrey 2014: 129). However, public sector financing and delivery plays import role in achieving universal health coverage and no middle or low income country in Asia has achieved near universal health care without relying primarily on public or public funded health system (See Chapman, Audrey 2014: 129).

As can be seen from the above, there is much research now on the topic of the right to health and the TRIPS Agreement and the TRIPS plus Agreements, while there is less number of studies which examine the SPS, TBT Agreements and the GATS from the perspective of right to health. Of these the GATS is even less researched from the perspective of right to health. The comprehensive examination of these four agreements in this thesis is expected to contribute to the literature which can provide the developing country perspective on the outcome of the interface between the right to health and the major WTO agreements, in international law.

3. Objective and Scope

This study attempts to see:

a) How does the TRIPS, SPS, TBT, GATS agreements and TRIPS plus Agreements, affect the right to health of populations?

b) What are the options available to the nations to protect the right to health under the WTO Agreements?

The patentability of diagnostic, therapeutic and surgical methods, microorganisms etc. have not been researched in this thesis except briefly in Chapter 3 and 4. SPS and TBT related provisions in domestic law are only briefly surveyed. The coverage of the DSB decisions, TRIPS plus agreements etc. are done on indicative basis and not exhaustively.

4. Research Questions

The study proposes to address the following research questions:

1. What is the status of the right to health under international law?

2. Whether the right to health as established under various international legal instruments is adversely affected by the TRIPS Agreement, SPS, TBT and GATS Agreements under the WTO, with special reference to developing countries?
3. What is the status of the right to health under the various DSB decisions?
4. What are the options available under the TRIPS Agreement, SPS, TBT and GATS Agreements to uphold the right to health?
5. Whether the flexibilities under the TRIPS Agreement are sought to be by passed through TRIPS plus Agreements?
6. What are the changes in law in various States pursuant to the WTO obligations and whether they negatively impact the right to health?
7. What specific policy and legal steps can be taken by nations to ensure the availability and accessibility of medicines?

5. Research Methodology

For the purpose of this thesis, primary legal documents at the international, regional and bilateral level on the subject have been examined along with decisions rendered by international adjudicatory bodies such as the WTO DSB on the subject matter. Further, documents published by intergovernmental organisations such as the WHO, ICTSD, UN, WIPO, WTO, UNCTAD, EU etc. have been perused. Scholarly views by various authors such as expressed in academic journals, books, and reports etc., on the topic have been reviewed.

6. Chapterisation

In Chapter 2 the various human rights provisions are looked at to understand the concept of the right to health in law and its standing in international law.

In Chapter 3, the TRIPS Agreement and its impact on the right to health is examined. In addition to the provisions of the TRIPS Agreement, various decisions of the DSB dealing with TRIPS Agreement is reviewed. Studies by various intergovernmental organisations such as WHO, UNDP, ICTSD, UNCTAD, WTO etc. are also reviewed herein.

In Chapter 4 the Indian legal scenario is examined in detail. Various study reports by the Indian Government, legislative provisions and regulations there under,

government policies and various judicial decisions in India are examined. Examples from India bring out that the medicinal pricing by patent holders in many cases is several hundred times more than the price at which generic competitors are ready to sell the product.

In Chapter 5 the legal provisions on the topic in some developing countries and some developed countries are examined. This is imperative as under Article 38(1) of the Statute of the International Court of Justice, general principles of law recognised by civilized nations are a source of international law.

In Chapter 6, the SPS, TBT and GATS agreements are studied. Various decisions of the DSB on SPS, TBT and GATS agreements impacting the right to health are reviewed.

Chapter 7 is where the conclusions of the thesis are recorded.

CHAPTER 2

THE INTERNATIONAL LAW ON THE RIGHT TO HEALTH

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1. Introduction

Health is defined in Article I of the 1978 *Declaration of Alma-Ata* as below:

> …. health, which is a state of complete physical, mental and social wellbeing, and not merely the absence of disease or infirmity, is a fundamental human right and that the attainment of the highest possible level of health is a most important world-wide social goal whose realization requires the action of many other social and economic sectors in addition to the health sector.

The 1978 *Declaration of Alma-Ata* recognized that the promotion and protection of the health of the people is essential to sustained economic and social development and contributes to a better quality of life and to world peace (Article III of the *Declaration of Alma-Ata*). It also stated that Governments have a responsibility for the health of their people which can be fulfilled only by the provision of adequate health and social measures (Article V of the *Declaration of Alma-Ata*).

As per the report of the Secretary General of the Economic and Social Council of the United Nations, health is at the heart of the Millennium Development Goals and a critical precondition for progress on most of those Goals (See Report of the Secretary-General, Economic and Social Council 2009, E/2009/81, para.1). However, the right to health scenario in the world in far from satisfactory. According to Report of the Special Rapporteur[3] of the Human Rights Council of the United Nations General Assembly in 2011 (Grover, Anand (2011), UN Doc. A/HRC/17/43 of 16 March 2011: 3-4) despite recent progress, massive inequalities remained in access to medicines around the world, as nearly 2 billion people (or one third of the world's population) lack such access. Furthermore, more than 100 million people fall into poverty

[3] "Special Rapporteurs are special mechanisms/procures established by the Commission on Human Rights to deal with either selected substantive human rights problems or with the human rights situation in a given country. This competence originates from ECOSOC resolution 1235 (XLII) that has empowered the Commission on Human Rights in appropriate cases to make a thorough study of situations which reveal consistent pattern of violations of human rights, Started in 1967, special procedures are widely appreciated as one of the main pillars of the United Nations human rights programme…. The General Assembly has adopted *Regulations Governing the Status, Basic Rights and Duties of Officials other than Secretariat Officials, and Experts on Mission*, which could be applicable to the holders of the discussed mandates", Zdzislaw Kedia (2003) United Nations Mechanisms to Promote and Protect Human Rights, Janusz Symondies (ed.), *Human Rights: International Protection, Monitoring, Enforcement*, Aldershot, England: Ashgate Publishing Limited and UNESCO: 49-50

annually because of high health-care costs. This is inspite of that several international declarations, documents etc. over the past several decades emphasise the importance of health.

Rajkumar (2012: 351) notes that health is fundamental to one's existence and that public health crisis demonstrates that without a sound system of dealing with health care unnecessary sufferings and death could be caused. He further notes that rule of law in its modern sense encompass a number of things including protection and promotion of human rights (See Rajkumar 2012: 357).

In such context, it is relevant that the Report of the Special Rapporteur of the Human Rights Council of the United Nations General Assembly in 2011 noted that the right to health is negatively affected by the TRIPS Agreement. The report states as below (Grover, Anand (2011), UN Doc. A/HRC/17/43 of 16 March 2011, para 47):

> 47. While intellectual property rights have the important function of providing incentives for innovation, they can, in some cases, obstruct access by pushing up the price of medicines. The right to health requires a company that holds a patent on a lifesaving medicine to make use of all the arrangements at its disposal to render the medicine accessible to all. As patents create monopolies, limit competition and allow patentees to establish high prices, they consequently have a significant impact on access to medicines. While some countries lack sufficient awareness about the use of TRIPS flexibilities and have limited technical capacity to implement them, others have not streamlined their patent laws sufficiently to facilitate use of such flexibilities. Furthermore, pressure from developed countries and multinational pharmaceutical corporations have played a prominent role in shaping the implementation of TRIPS flexibilities in developing and least developed countries. For example, a number of developing countries, while attempting to implement TRIPS flexibilities to address public health concerns have experienced pressures from developed countries and multinational pharmaceutical corporations.

Given this background, the right to health as laid down in international legal instruments such as the *1946 Constitution of the World Health Organization* (hereinafter "WHO Constitution") and various resolutions by the WHO, *1948 Universal Declaration of Human Rights* (hereinafter "UDHR"), the *1966 International Covenant on Economic Social and Cultural Rights* (hereinafter "ICESCR"), the *1945 Charter of the United Nations* (hereinafter "UN Charter"), various regional instruments like the *1948 American Declaration on the Rights and*

Duties of Man, studies by the *Economic and Social Council* of the United Nations, resolution by the *Office of the High Commissioner for Human Rights*, reports by the Special Rapporteurs of the United Nations, decision of the International Court of Justice, some jurisprudential theories etc. are examined in this chapter and it is sought to be identified whether the status of the right to health in international law could be of some relief against the onslaught of various trade law requirements pursuant to the WTO.

2. International Instruments

Treaties are effective instruments for improvements of rights when there is opportunity for political and/or legal mobilization to demand effective implementation (Elkins Zachary, Ginsburg Tom and Simmons Beth, 2013: 64-64). International instruments have powerful coordinating effect on the contents of national constitutions and normative convergence has been accomplished by actual human rights practice (Elkins Zachary, Ginsburg Tom and Simmons Beth, 2013: 64-65). The following is a perusal of the various international instruments on the right to health.

2.1. 1946 WHO Constitution

The WHO was established as a specialized agency of the United Nation with the explicit purpose to promote the right to health. The Constitution was adopted by the International Health Conference held in July 1946 by the representatives of 61 States and entered into force on April 7, 1948. The WHO in some respects can be considered to be successor to the *Office International d'Hygiene Public* (hereinafter "OIHP") which was established in 1907.The WHO had accepted responsibility with respect to the OIHP assets, collected arrears from some of the member states and also accepted the pension responsibilities of some of the staff members of the OIHP (Klabbers, Jan 2009: 20).

The preamble of the WHO Constitution states that 'the enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social condition'. This WHO statement has been subsequently reaffirmed through the provisions of

international legal instruments of universal acceptance such as article 25 (1) of the UDHR and article 12 of the ICESCR.

The preamble to the WHO Constitution provides that health is a state of complete physical, mental and social wellbeing and not merely the absence of disease or infirmity. The preamble recognizes that the achievement of any state in the promotion and protection of health and control of disease is of value to all and that the unequal development in different countries in the promotion and control of disease is a common danger. The preamble emphasizes that the extension to all people of the benefits of medical, psychological and related knowledge is essential to the fullest attainment of health. The preamble also speaks of the responsibility of governments for the health of their people which can be fulfilled only by the provision of adequate health and social measures.[4]

Article 1 of the WHO constitution makes it clear that the objective of the World Health Organization shall be the attainment by all peoples of the highest possible level of health. Towards this end, WHO has made much contribution and the achievements of the organization in the last decade include WHO/UN

[4] Preamble of the WHO constitution states as below:

> The States parties to this Constitution declare, in conformity with the Charter of the United Nations, that the following principles are basic to the happiness, harmonious relations and security of all peoples:
>
> Health is a state of complete physical, mental and social wellbeing and not merely the absence of disease or infirmity.
>
> The enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social condition.
>
> The health of all peoples is fundamental to the attainment of peace and security and is dependent upon the fullest co-operation of individuals and States.
>
> The achievement of any State in the promotion and protection of health is of value to all.
>
> Unequal development in different countries in the promotion of health and control of disease, especially communicable disease, is a common danger.
>
> Healthy development of the child is of basic importance; the ability to live harmoniously in a changing total environment is essential to such development.
>
> The extension to all people of the benefits of medical, psychological and related knowledge is essential to the fullest attainment of health.
>
> Informed opinion and active co-operation on the part of the public are of the utmost importance in the improvement of the health of the people.
>
> Governments have a responsibility for the health of their people which can be fulfilled only by the provision of adequate health and social measures.

Accepting these principles, and for the purpose of co-operation among themselves and with others to promote and protect the health of all peoples, the contracting parties agree to the present Constitution and hereby establish the World Health Organization as a specialized agency within the terms of Article 57 of the Charter of the United Nations.

Prequalification of Medicines Programme which enabled treatment of 4 million HIV/AIDS patients, WHO/Health Action International (HAI) survey methodology, which facilitated survey of availability and affordability of heath care in over 50 countries as part of the monitoring of Millennium Development Goals (WHO 2010, WHO/EMP/2010.2: 1).

In the view of some scholars, the WHO inspite of all its weaknesses is the appropriate body to take leadership in global health issues including health research and development (Agitha, T.G. 2013: 593). The various resolutions passed by the WHO are useful to note in the context of this study.

2.1.1. Resolutions of the WHO

Several resolutions of the World Health Assembly of the WHO and report/decisions from the Executive Board also emphasise on the right to health and the impact of the TRIPS Agreement etc.

2.1.1.1. 2003 Resolution

A 2003 resolution adopted by the WHA reaffirms that public health interests are paramount in both pharmaceutical and health policies and urges member states to adapt national legislation in order to use to the full the flexibilities contained in the TRIPS Agreement (See WHO 2003, WHA56.27, para 1). The resolution noted that to tackle new public health problems such as severe acute respiratory syndrome (SARS) access to new medicines with potential therapeutic effect, health innovations and discoveries should be universally available without discrimination (See WHO 2003, WHA56.27, recital). Another issue highlighted by the WHO in this resolution is that the research by the pharmaceutical companies is geared to meet the diseases in the developed would than on the developing world (See WHO 2003, WHA56.27, para 1). The same WHA resolution note that of the 1400 new products developed by the pharmaceutical industry between 1975 and 1999 only 13 were for tropical diseases and 3 were for tuberculosis. It also noted that developed countries represent nearly 90% of the global pharmaceutical sales whereas of the 14 million global deaths due to infectious diseases 90% occur in developing countries (See WHO 2003, WHA56.27, recital).

2.1.1.2. 2005 International Health Regulations

The WHO has recommended through its resolution that member states should provide support to developing countries and economies in transition – if they so request – in building, strengthening and in the maintenance of the public health capacities as required under the 2005 International Health Regulations (WHO 2005, WHA58.3, para 5(3)).

Article 2 of the 2005 International Health Regulations states that the purpose and scope of the regulations is to:

> prevent, protect against, control and provide a public health response to the international spread of disease in ways that are commensurate with and restricted to public health risks, and which avoid unnecessary interference with international traffic and trade.

Further Article 3(4) provides that '*states have in accordance with the Charter of the United Nations and principles of international law the sovereign right to legislate and implement in pursuance of their health polices*' and that in doing so they shall uphold the purpose of the Regulations.

A WHO WTO joint study note that the basic principles which underlie these regulations is that there should be minimum interference with world traffic due to reasons such as epidemics and that there should be efficient response preparedness for epidemics, stockpiling of medicines etc. to achieve this goal (WHO and WTO 2002: 59, para 100).

2.1.1.3. 2008 Resolution

The WHA resolution *Global Strategy on Public Health, Innovation and Intellectual Property* adopted by the WHO in 2008 highlights that price of medicines is one of the factors that can impede access to treatment (WHO 2008, WHA61.21: para 11). However, this resolution does not portray the TRIPS Agreement as an impediment to the right to health, but highlights the requirement to use the flexibilities provided in the TRIPS Agreement.

2.1.1.4. 2008 Report of the Expert Working Group

The *Report of the Expert Working Group on Research and Development Financing by the WHO* (WHO 2008, WHA61.21, 24) studies the interface between patents and the right to health. The report does the following:

i. adopted the view that IPRs do not and should not prevent Member states from taking measures to protect public health (See (WHO 2008, WHA61.21,24, para 20).

ii. note that IPRs are an important incentive in the development of new health care products and further provides that this incentive does not meet the need of the development of new products to fight diseases where the potential of the paying market is small or uncertain (WHO 2008, WHA61.21,24, para 25).

iii. recommend that international negotiations on issues related to IPRs and health should be coherent in their approaches to promotion of public health (WHO 2008, WHA61.21,24, para 21).

iv. note that several factors contribute to the price of health products and medical devices and that competition and reduction or elimination of import tariffs on these products and devices can contribute to the reduction of prices. Countries are recommended to carefully monitor their supply and distribution chains and procurement practices to minimize costs that can adversely influence the price of the medical products and devices (WHO 2008, WHA61.21, para 26).

Innovative tax methods such as tax on arms trade market, financial transactions, internet usage, airline taxes etc. have been suggested by the WHO through its Report of Expert Working Group on Research and Development Financing in December 2009 (WHO 2009, EB126/6 Add.1, para 22-23).

2.1.1.5. 2009 Resolution

In its 2009 resolution the WHO calls for a global health research and innovation co-ordination and funding mechanism to be created with support from various sources such as business, government, consumer contributions etc. to target various health initiatives such as research and development of new drugs, vaccines, diagnostics and intervention strategies against priority health conditions of the poor; to support research in areas that are essential for improving health including health policy and health systems research, to enhance innovation capacities and environments in low

and middle income countries, to operate health research laboratory with regional expression to monitor disease and track research and development regularly (WHO 2009, EB126/6 Add.1, para 16).

2.1.1.6. Legal Recourse by WHO

In 1993 the General Assembly of the WHO passed a resolution in which it sought the opinion of the International Court of Justice as to whether the use of nuclear weapons would be in contravention of international law including the Constitution of the WHO. The International Court of Justice held that in order to determine so, it must satisfy two grounds i.e. it should be a question of legality and second it must be within the scope of work of such organization. The court refused to provide such advisory opinion on the ground that the though the question is one of legality, the WHO was not competent to raise such issue, since it was only a specialized body of the United Nations with a separate scope of work. However, inspite of the setbacks such as these, through the actual work of the WHO on the health front, it is definitely a pre-eminent body as far the health issues are concerned (Klabbers, Jan 2009: 6).

The decision is discussed in more detail in para 8.2 below.

2.2. Universal Declaration of Human Rights, 1948

The *Universal Declaration of Human Rights* (hereinafter "UDHR") was proclaimed by the United Nations General Assembly in Paris on December 10, 1948. The UDHR is a common standard of achievement for peoples and nations and represent the fundamental human rights to be universally protected.[5] Article 25(1) of the UDHR states that:

> Everyone has the right to a standard of living adequate for the health and well being of himself and of his family, including food, clothing, housing and medical care and necessary social services, and the right to security in the event of unemployment, sickness, disability, widowhood, old age or other lack of livelihood in circumstances beyond his control.

While Article 25(1) speaks explicitly of health, Article 22 speaks of right to social security. In the words of Mary Robinson, the United Nations High Commissioner for

[5] See [online: web] Accessed 29 January 2016 URL: http://www.ohchr.org/EN/UDHR/Pages/Introduction.aspx

Human Rights in 2001, the corner stone of economic, social and cultural rights is Article 22 of the UDHR, which provides that everyone is entitled to the realization of economic, social and cultural rights that are indispensable for his or her dignity and free and full personal development (Robinson, Mary 2001: 210). The five articles that follow elaborate on the economic rights, including the right to health.

2.3. 1966 ICESCR

As on April 19, 2015, there are 164 state parties and 70 signatories to the ICESCR.[6] The ICESCR entered into force in 1976. India acceded to the ICESCR on April10, 1979. India is yet to sign the ICESCR.

The preamble to the ICESCR states that the recognition of the inherent dignity and the equal and inalienable rights of all members of the human family is the foundation of freedom, justice and peace in the world. Also, the preamble states that ideal of free human beings enjoying freedom from fear and want can be achieved only if conditions are created where everyone may enjoy economic, social and cultural rights as well as civil and political rights. The preamble further also affirms that obligations of the States under the UN Charter to promote universal respect for and observance of, human rights and freedoms.

Thereafter Article 12 (1) of the ICESCR specifically refers to the 'right of everyone to the enjoyment of the highest attainable standard of physical and mental health'.[7] Article 12(2) (d) of the convention states that the steps to be taken by the State Parties to achieve the full realization of the right to health shall include those necessary for

[6] See [online: web] accessed on 19 April 2015 URL: http://treaties.un.org/Pages/ViewDetails.aspx?src=TREATY&mtdsg_no=IV-3&chapter=4&lang=en

[7] Article 12 states as below:

1. The State Parties to the present Covenant recognize the right of everyone to the enjoyment of the highest attainable standard of physical and mental health. (emphasis added)
2. The steps to be taken by the State Parties to the present Covenant to achieve the full realization of this right shall include those necessary for:
   (a) The provision for the reduction of the still birth rate and of infant mortality and for the healthy development of the child;
   (b) The improvement of all aspects of environmental and industrial hygiene.
   (c) The prevention , treatment and control of epidemic, endemic ,occupational and other diseases;
   (d) The creation of conditions which would assume to all medical service and medical attention in the event of sickness. (emphasis added)

the creation of conditions which would assume to all medical service and attention in the event of sickness.

Further, Article 15(1) (b) provides that the States which are parties to the Covenant recognizes the right of every one to enjoy the benefits of scientific progress and its applications. It further states that the steps to be taken by the State Parties to achieve the full realization of this right shall include those necessary for the conservation, development and diffusion of science and culture (Article 15(2) of the ICESCR).

Thus one can say that the right to health includes obligation of the State to enable full realisation of the right to health including medical service and benefits of science.

2.3.1 2008 Optional Protocol to the ICESCR

This protocol in its preamble:

a) recognized the inherent dignity and the equal and inalienable rights of all members of the human family as the foundation of freedom, justice and peace in the world.
b) reaffirmed that the UDHR proclaimed that all human beings are born free and are equal in dignity and rights and that everyone is entitled to all the rights and freedoms set forth therein, without distinction of any kind such as race, colour, sex, language, religion, political or other opinion, national or social origin, property, birth or status.
c) recalled that the UDHR and the ICESCR and the ICCPR recognize the ideal of free human beings enjoying freedom from fear and want can be achieved only of conditions are created whereby everyone may enjoy, civil, cultural, economic, political and social rights
d) reaffirmed the universality, indivisibility, interdependence and inter relatedness of all human rights and fundamental freedoms

From a right to health perspective all the above are important as this brings out the key rights of people irrespective of the nation, culture or society they are born in, the right to enjoy the right to health as well.

2.4. 1989 Indigenous and Tribal Peoples Convention (C169, International Labour Organisation)

Article 25 of the convention states that government shall ensure that adequate health services are made available to the indigenous and tribal people concerned or, the government is required to provide them resources to allow them to design and deliver such services under their own responsibility so that they may enjoy the highest attainable standard of physical and mental health. Further, Article 24 of the convention requires that social security schemes shall be extended progressively to cover the indigenous and tribal people concerned and applied without discrimination against them.

As on 21 September 2015, the convention is ratified by 22 states.[8]

2.5. 1989 Convention on the Rights of the Child

The 1989 *Convention on the Rights of the Child* (hereinafter "CRC") in its preamble note that the people of the United Nations have in the Charter reaffirmed their faith in fundamental human rights and have determined to promote social progress and better standards of life in larger freedom. The CRC note in the preamble that the United Nations has in the UDHR and ICESCR and the ICCPR proclaimed that everyone is entitled to the rights and freedoms set forth therein without distinction of any kind such as race, colour, sec, language, religion, political or other opinion, national or social origin, property, birth or other status.

The obligation to protect the right to health of children is mentioned in the Convention on the Rights of Child which entered into force in 1990. Article 24(1) of the Convention state that the State Parties recognise the right of the child to enjoyment of the highest attainable standard of health and also to the facilities for the treatment of illness and rehabilitation of health. The Convention requires State Parties to take appropriate measure to diminish infant and child mortality, ensure the provision of necessary medical assistance and health care to all children, to combat disease and malnutrition, ensure appropriate pre-natal and post natal health care

[8] See ratification status on http://www.ilo.org/dyn/normlex/en/f?p=1000:11300:0::NO:11300:P11300_INSTRUMENT_ID:312314, [Online: web] Accessed 21 September 2015

mothers, developing preventive health care etc. (Article 24(2) of CRC, 1989). Also, the state Parties are required to undertake to promote and encourage international co-operation with a view to achieving progressively the full realization of the rights mentioned in Article 24 and particular account is to be taken of the needs of the developing countries (Article 24(3) of CRC, 1989).

3. Regional Instruments

Provisions of regional instruments such as article 11 and 13 (1) Part I of the *1961 European Social Charter* (as revised in 1996), article 16 of the *1981 African Charter on Human and Peoples Rights* and article XI of the *1948 American Declaration of the Rights and Duties of Man* call for protection of the right to health.

3.1. 1948 American Declaration of the Rights and Duties of Man

The 1948 *American Declaration of the Rights and Duties of Man* (hereinafter "ADHR") was adopted by member states of the Organization of American States in Bogota, Columbia, on 2 May 1948. ADHR was the first international human rights instrument, preceding the UN's Universal Declaration of Human Rights by several months.[9] The OAS consists of 35 independent states and it has also granted observer status to 62 states including the European Union.[10] On the sixtieth anniversary of ADHR, the General Assembly of the OAS passed the resolution reaffirming that the ADHR is one of the fundamental instruments of the inter-American human rights system and urged all member states to continue its effective implementation and to step up activities geared toward its promotion (See article 1 and 2 of AG/RES. 2361 (XXXVIII-O/08) of the OAS).

Article IX of the ADHR states that every person has the right to the preservation of his health through sanitary and social measures relating to food, clothing, housing and medical care, to the extent permitted by public and community resources.[11]

[9] [Online: web] Accessed 21 September 2015 URL: http://www.cfr.org/latin-america-and-the-caribbean/american-declaration-rights-duties-man/p9603

[10] [Online: web] Accessed 21 September 2015 URL: http://www.oas.org/en/about/who_we_are.asp

[11] Art XI- Right to the preservation of health and to well being

> Every person has the right to the preservation of his health through sanitary and social measures relating to food, clothing, housing and medical care, to the extent permitted by public and community resources

Even the Charter of the OAS recognizes the importance of the right to health when Article 34 of the Charter of the OAS requires the state parties to devote their utmost attention to accomplish 'urban conditions that offer the opportunity for a healthful, productive, and full life'.

3.2. 1961 European Social Charter

The 1961 *European Social Charter* (hereinafter "1961 Charter") (See Appendix for the relevant provisions) deals with economic and social rights. The 1961 Charter was signed by all the 47 member states of the Council of Europe and had been ratified by 40 member states.

New rights were added to the 1961 Charter through the Additional Protocol to the European Social Charter of 1988 and the Amending Protocols of 1991 and 1995. The 1961 Charter is being replaced by the 1996 *Revised European Social Charter* (hereinafter "1996 Charter") (Secretariat of the ESC (March 2009: 1). The revised 1996 Charter is a single instrument in which all the rights granted by the 1961 Charter and the 1988 Additional Protocol are stated along with amending of certain of the rights and introducing new ones (Secretariat of the European Social Charter 2009: 1).

According to the resolution[12] adopted by the Parliamentary Assembly of the Council of Europe in 1998, the European Social Charter and its protocols must become a reference for the whole of Europe and serve as a basis for drafting new legislative and contractual instruments.

Part I (11) of the 1961 Charter states that "*everyone has the right to benefit from any measures enabling him to enjoy the highest standard of health attainable*". The same provision is stated in the 1996 Charter.

Article 11 of both the 1961 Charter and the 1996 Charter provides that in order to ensure effective exercise of the right to protection of health, Parties shall co-operate

[12] See Recommendation 1354 (1998) of the Parliamentary Assembly, Future of the European Social Charter

and remove as far as possible the causes of health, provide advisory and educational facilities for the promotion of the right to health etc.

Article 13(1) of both the 1961 Charter and the 1996 Charter has the same language on the right to social and medical assistance. It states that the Parties shall undertake with a view to ensure the effective exercise of the right to social and medical assistance ensure that any person who is without adequate resources and who is unable to secure such resources by his own or from other sources such as social security scheme be granted adequate assistance and in the case of sickness the care necessitated by his condition.

Several other provisions such as Article 12, Article14, and Article15 speak of social welfare measures, all of which contribute to the health of an individual.

Further Article14 of Additional Protocol to the European Social Charter adopted at Strasbourg on 5th May 1988 speaks of 'right of elderly persons to social protection'.

3.2.1. 2011 Council of Europe Recommendation

The Parliamentary Committee of the Council of Europe in the Recommendation titled *Preventive Health Care Policies in the Council of Europe Member States* note that effective preventive healthcare requires equal access to relevant services for all sectors of the population, regardless of their socio- economic standing (Council of Europe Member States 2011: para 4).

3.3.1981 African Charter on Human and Peoples Rights

1981 *African Charter on Human and Peoples Rights* (hereinafter "African Charter") was adopted in Nairobi in 1982 and entered into force as on 21 October, 1986. The African Charter has 53 state parties and is ratified by all 53 state parties. Article 16 of the African Charter states that every individual shall have the right to enjoy the best attainable state of physical and mental health and further that State parties to the African Charter shall take necessary measures to protect the health of their people and to ensure that they receive medical attention when they are sick.

In the context of protection of family, the Article 18 of the African Charter states that the family shall be the natural unit and basis of society and that it shall be protected by the State which shall take care of its physical health and moral.

Therefore it is clear from the above that at the international level the basic and universally accepted international instruments emphasize the importance of the right to health of the individual.

4. United Nations

4.1. 1945 Charter of the United Nations

Article 55(b) [13] of the Charter of the United Nations recognizes the right to health as an important factor towards creating conditions of stability and wellbeing which in turn are necessary for the peaceful and friendly relations among states.

Also, the specialized agencies like the Economic and Social Council has been given the mandate to study or initiate studies and report to the General Assembly in matters such as health (See Article 62 of the Charter of the United Nations.).

4.2. Resolutions of the United Nations General Assembly

4.2.1. 1969 Declaration on Progress and Social Development (Proclaimed by General Assembly Resolution 2542 (XXIV) of 11 December 1969)

This 1969 Declaration in its preamble:

- reaffirmed the faith in human rights and fundamental freedoms and in the in principle of peace, of the dignity and worth of human person and of social justice proclaimed in the United Nation Charter.

[13] Article 55 of the Charter of the United Nations states:
With a view to the creation of conditions of stability and wellbeing which are necessary for the peaceful and friendly relations among nations based on respect for the principle of equal rights and self-determination of peoples, the United Nations shall promote:
A. higher standards of living, full employment, and conditions of economic and social progress and development;
B. solutions of international economic, social, health, and related problems; and international cultural and educational co-operation; and
C. universal respect for , and observance of, human rights and fundamental freedoms for all without distinction as to race, sex, language, or religion.

- noted that man can achieve complete fulfillment of his aspirations only within a just social order and that it is consequently of cardinal importance to accelerate social and economic progress everywhere, thus contributing to international peace and security.
- recognized that the primary responsibility for the development of developing countries rests on those countries themselves and acknowledged the pressing need to narrow and eventually close the gap in the standards of living between economically more advanced and developing countries and to that end, that the Members States shall have the responsibility to pursue internal and external policies designed to promote social development throughout the world, and in particular to assist developing countries to accelerate their economic growth.

4.2.2. 1974 Declaration on the Establishment of a New International Economic Order

This declaration called for the establishment of a new international economic order based on equity, sovereign equality, interdependence, common interest and cooperation among all States irrespective of their social and economic systems to correct inequalities and to redress existing injustices, to make it possible to eliminate the widening gap between developed and developing countries and to ensure steadily accelerating economic and social development and peace and justice for present and future generations (Preamble to GA Res. (1974), 3201 (S-VI)). The declaration noted:

a) that the benefits of technological progress are not equitably shared by all members of the international community and that developing countries which constitute 70 percent of the world population account for only 30 per cent of the world's income (Article 1 of GA Res. (1974), 3201 (S-VI)).
b) that the gap between developed and developing countries continue to widen in a system which was established at a time when most of the developing countries did not exist as independent States and that such system perpetuated inequality (Article 1 of GA Res. (1974), 3201 (S-VI)).
c) that the developing world has become a powerful factor that makes its influence felt in all fields of international activity and that such irreversible changes in the relationship in the world necessitate active, full and equal

participation of the developing countries in the formulation and application of all decisions that concern the international community (Article 2 of GA Res. (1974), 3201 (S-VI)).

d) That there is close inter relationship between the prosperity of the developed countries and growth of international community as a whole depends on the prosperity of the constituent parts and that international co-operation for development is a shared goal and common duty of all countries (Article 2 of GA Res. (1974), 3201 (S-VI)).
e) That the political, economic and social well-being of present and future generations depends on co-operation between all members of the international community on the basis of sovereign equality and removal of disequilibrium between them (Article 3 of GA Res. (1974), 3201 (S-VI)).
f) That every country has the right to adopt the economic and social system that it deems appropriate for its own development and not as a result to be subjected to discrimination of any kind (Article 4(d) of GA Res. (1974), 3201 (S-VI)).
g) Giving to developing countries access to achievements of modern science and technology and promoting the transfer of technology and the creation of indigenous technology for the benefit if developing countries in form and in accordance with procedures that suit their economies (Article 4(p) of GA Res. (1974), 3201 (S-VI)).

This declaration ends with the note that the establishment of a new international economic order shall be one of the most important basis for economic relations between all peoples and nations (Article 7 of GA Res. (1974), 3201 (S-VI)).

4.2.3. 1975 Declaration on the Use of Scientific and Technological Progress

The 1975 *Declaration on the Use of Scientific and Technological Progress in the Interests of Peace and for the Benefit of Mankind* (*Proclaimed by General Assembly Resolution 3384(XXX) of 10 November 1975)* (hereinafter "1975 Declaration") starts with the recognition that scientific and technological progress has become one of the most important factors in the development of the human society. The 1975 Declaration proclaimed that all States shall:

a) take measures to ensure that scientific and technological achievements satisfy the material and spiritual needs of all sectors of the population
b) co-operate in the establishment, strengthening and development of the scientific and technological capacity of developing countries with a view to accelerating the realization of the social and economic rights of the peoples of those countries
c) take measures to extend the benefits of science and technology to all strata of the population and to protect them, both socially and materially from harmful effects of the misuse of scientific and technological developments….
d) take the necessary measures, including legislative measures to ensure that the utilization of scientific and technological achievements promotes the fullest realization of human rights and fundamental freedoms without any discrimination whatsoever on grounds of race, sex, language or religious beliefs.
e) take effective measures, including legislative measures to prevent and preclude the utilisation of scientific and technological achievements to the detriment of human rights and fundamental freedoms and the dignity of the human person.

Thus this 1975 Declaration emphasised on the need to use technological advancements for the benefit of mankind and to ensure that even the States supported this by ensuring required legislative measures.

4.2.4. 1993 Vienna Declaration and Programme of Action

Article 1 of the 1993 *Vienna Declaration and Programme of Action* (hereinafter "**Vienna Declaration**") states that human rights and fundamental freedoms are the birth right of all human beings and that their protection and promotion is the first responsibility of governments. Therefore, it is clear that governments cannot absolve or shirk away the responsibility to ensure the well-being of its citizens (See Article 1 of the 1993 Vienna Declaration, A/CONF.157/23). Also, the Vienna Declaration provides that the promotion and protection of all human rights is the legitimate concern of the international community and that the organs and specialized agencies related to human rights are to enhance the coordination of their activities based on

consistent and objective application of international human rights instruments (See Article 4 of the 1993 Vienna Declaration, A/CONF.157/23).

As per the Vienna Declaration all human rights are universal, indivisible, interdependent and indivisible and the international community is to treat human rights globally in a fair and equal manner on the same footing with the same emphasis. States regardless of their political, economic and cultural systems are to protect all human rights and fundamental freedoms (See Article 5 of the 1993 Vienna Declaration, A/CONF.157/23).

The Vienna Declaration requires promotion and protection of human rights and fundamental freedoms at the national and international level should be conducted without conditions attached (See Article 8 of the 1993 Vienna Declaration, A/CONF.157/23). The international community is to promote effective international co-operation for the realization of the right to development and the elimination of obstacles to development (See Article 10 of the 1993 Vienna Declaration, A/CONF.157/23). The Vienna Declaration makes clear that everyone has the right to enjoy the benefits of scientific progress and its applications (See Article 11 of the 1993 Vienna Declaration, A/CONF.157/23). States are required to eliminate all violations of human rights and their causes as well as the obstacles to the enjoyment of these rights. Also, the states and international organisations in co-operation with nongovernmental organisations are to create conditions at the national, regional and international level to ensure the full and effective enjoyment of human rights (See Article 13 of the 1993 Vienna Declaration, A/CONF.157/23).

States have an obligation under the Vienna Declaration to create and maintain adequate measures at the national level in various fields including health for the promotion and protection of person in vulnerable sections of their population and to ensure participation from those interested in finding solution to their own problems (See Article 24 of the 1993 Vienna Declaration, A/CONF.157/23). The Vienna Declaration requires states to refrain from any unilateral measure which is not in accordance with international law and the United Nations Charter and which impedes the full realization of human rights as set forth in the Universal Declaration of Human Rights with particular emphasis on the right of every one to a standard of living

adequate for their health and well-being (See Article 31 of the 1993 Vienna Declaration, A/CONF.157/23).

4.2.5.2006 Political Declaration on HIV/AIDS

Some resolutions of the United Nations General Assembly such as 2011 *Resolution The Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health* (GA Res. 2011, A/HRC/17/L.16,) discussed above, directly address the co-relation between the right to health and the TRIPS Agreement. The 2006 Political Declaration on HIV/AIDS (A/RES/60/262 of 15 June 2006) which was another significant document, while emphasizing the right to health and access to medicines as one of the key components to health, also state that the TRIPS Agreement does not and should not prevent members from taking measures in the present and in the future to protect public health. It states that the TRIPS Agreement can be and should be interpreted and implemented in a manner supportive of the right to protect public health and to promote access to medicines (A/RES/60/262 of 15 June 2006, para 43). This resolution adopted in 2006 by the General Assembly states in para 43:

> 43. Reaffirm that the World Trade Organization's Agreement on Trade-Related Aspects of Intellectual Property Rights does not and should not prevent members from taking measures now and in the future to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, reaffirm that the Agreement can and should be interpreted and implemented in a manner supportive of the right to protect public health and, in particular, to promote access to medicines for all including the production of generic antiretroviral drugs and other essential drugs for AIDS-related infections. In this connection, we reaffirm the right to use, to the full, the provisions in the TRIPS Agreement, the Doha Declaration on the TRIPS Agreement and Public Health and the World Trade Organization's General Council Decision of 2003 and amendments to Article 31, which provide flexibilities for this purpose;

4.2.6. 2006 International Guidelines on HIV/AIDS and Human Rights

The 2006 *International Guidelines on HIV/AIDS and Human Rights 2006* (GA Res. (2006), A/RES/60/262, hereinafter "HIV Guidelines") were formulated in the backdrop of the multiple declarations and charters adopted by the international community and were a revision of the similar international guidelines were adopted by the Second International Consultation on HIV/AIDS and Human Rights in 1996. These HIV Guidelines deal with the rights to be ensured to those suffering with

HIV/AIDS and the measures to be adopted for their health and well-being. The HIV Guidelines while it specifically dealt with people infected with HIV also affirmed the responsibility of State to protect human rights[14]. In the context of HIV, the HIV Guidelines also states that prevention, treatment, care and support is necessary to fulfil human rights related to health, including the right to enjoy the highest attainable standard of health (See UNAIDS 2006, para 28). The HIV Guidelines further noted that human rights and public health share the common objective to promote and protect the rights and well-being of all individuals (See UNAIDS 2006, para 95).

4.2.7. 2007 United Nations Declaration on the Rights of Indigenous Peoples

The 2007 *United Nations Declaration on the Rights of Indigenous Peoples* (Adopted by GA Res. 2007, 61/295) also speaks of the right to health. Article 24(2) of the declaration echoes the verbiage from the ICESCR when it says that indigenous individuals have an equal right to the enjoyment of the highest attainable standard of health and that the states shall take the necessary steps with a view to progressively achieves the full realization of this right. Article 24 further states that indigenous peoples have the right to their traditional medicines and to maintain their health practices and that indigenous individuals shall have the right to access with any discrimination to all social and health services. The declaration also states that states shall where appropriate take special measures to ensure continuing improvement of the economic and social conditions of the indigenous peoples (See Article 21(2) of GA Res. 2007, 61/295).

The Declaration was adopted by the General Assembly of the United Nations in 2007 by a majority of 143 states in favour.[15] Since its adoption Australia, New Zealand, Canada and United States which had voted against the declaration have reversed their position and endorsed the resolution.

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[14] Joint United Nations Programme on HIV/AIDS (UNAIDS) (2006), *International Guidelines on HIV/AIDS and Human Rights 2006 Consolidated Version*, para 100

> 100. The Vienna Declaration and Programme of Action, adopted at the World Conference on Human Rights in June 1993,37 affirmed that all human rights are universal, indivisible, interdependent and interrelated. While the significance of national and regional particularities and various historical, cultural and religious backgrounds must be borne in mind, States have the duty, regardless of their political, economic and cultural systems, to promote and protect universal human rights standards and fundamental freedoms.

[15] See http://undesadspd.org/IndigenousPeoples/DeclarationontheRightsofIndigenousPeoples.aspx, last accessed on April 20, 2015

4.2.8. 2010 Draft Outcome Document of the High-level Plenary Meeting

Resolutions of the General Assembly such as the resolution in 2010 on the Millennium Development Goals also reiterate the right to use the flexibilities under the TRIPS Agreement (GA Res. 2010, A/RES/64/299, paragraph 78 (t)) and also calls for the amendment of article 31 of the TRIPS Agreement.

> Reaffirming the right to use, to the full, the provisions contained in the World Trade Organization Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement), the Doha Declaration on the TRIPS Agreement and Public Health, the decision of the General Council of the World Trade Organization of 30 August 2003 on the implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, and, when formal acceptance procedures are completed, the amendment to article 31 of the Agreement, which provide flexibilities for the protection of public health, and, in particular, to promote access to medicines for all, and encourage the provision of assistance to developing countries in this regard. We also call for a broad and timely acceptance of the amendment to article 31 of the Agreement, as proposed by the General Council of the World Trade Organization in its decision of 6 December 2005.

4.2.9. 2011 Resolution

This 2011 General Assembly resolution on *The Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health* was adopted without vote on 17 June 2011, and was proposed from the Human Rights Council by Algeria, Armenia, Bangladesh, Bolivia (Plurinational State of), Bosnia and Herzegovina, Brazil, Chile, Colombia, Costa Rica, Cuba, Guatemala, Ecuador, Egypt, El Salvador, India, Nicaragua, Panama, Peru, South Africa, Turkey, Uruguay, Venezuela (Bolivarian Republic of). The resolution in its preamble states that 'access to medicines is one of the fundamental elements in achieving progressively, the full realization of the right of every one to the enjoyment of the highest attainable standard of physical and mental health and that it is the responsibility of States' to ensure access for all to medicines without discrimination and in particular medicines that are affordable, safe, effective and of good quality (See Preamble of GA Res 2011, A/HRC/17/L.16).

The resolution in its preamble recognised the need for States, in co-operation with international organisations, civil society including nongovernmental organisations and private sector to create favourable conditions at national, regional and international

levels to ensure full and effective enjoyment of the right of every one to the highest attainable standard of physical and mental health.

The Resolution noted with concern that for millions of people throughout the world, full realization of the right of everyone to the enjoyment of the highest attainable standard of health including access to safe, affordable, effective and good quality medicines, vaccines, other medical products and health care facilities and services still remain a distant goal and for those in poverty the goal remain remote (See Preamble of GA Res 2011, A/HRC/17/L.16).

The resolution further call upon the States to address the potential negative impacts of IPRs on the availability and affordability of medicines and to take advantage in full of the flexibilities provided in the TRIPS Agreement and to assess the human rights impact prior to the adoption of additional commitments and to recognize that as much IP protection is important for the development of new medicines it has its effects on prices (See paragraph 7(g), Preamble of GA Res 2011, A/HRC/17/L.16).

4.2.10. 2011 Fourth United Nations Conference on the Least Developed Countries

Resolutions adopted by various conferences of the United Nations also reiterate the right to use the flexibilities under the TRIPS Agreement. For example, the Fourth United Nations Conference on the Least Developed Countries at Istanbul, Turkey in May 2011 (See United Nations (2011), A/CONF.219/3) reaffirms the right to use in full the provisions in the TRIPS Agreement, the Doha Declaration on the TRIPS Agreement and Public Health (WT/MIN (01)/DEC/2), the decision of the WTO General Council on the implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement etc.[16]

[16] United Nations (2011), A/CONF.219/3, paragraph 76 (2) (c) states:

> (c) Reaffirm the right to use, to the full, the provisions contained in the World Trade Organization Agreement on Trade-Related Aspects of Intellectual Property rights (TRIPS Agreement), the Doha Declaration on the TRIPS Agreement and Public Health, the decision of the World Trade Organization General Council of 30 August 2003 on the implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, and, when formal acceptance procedures are completed, the amendments to article 31 of the Agreement, which provide flexibilities for the protection of public health and, in particular, to promote access to medicines for all and to encourage the provision of assistance to developing countries in this regard. We also call for broad and timely acceptance of the amendment to

4.2.11. 2012 MDG Gap Task Force Report

Inspite of the various international law commitments, access to essential medicines remains as issue. The 2012 report on the status of Millennium Development Goals states that there is little improvement in recent years in improving the availability and affordability of essential medicines in developing countries (United Nations 2012: xvi). The study note that only 51.8% of the public sector health facilities and 68.5% of the private sector health facilities are able to provide essential medicines to the patients (United Nations 2012: xvi). The study captures that the prices of essential medicines tend to be multiples of international reference prices and that as a result obtaining essential medicines remains prohibitive for low income households. In many cases several family members suffer from the illness at the same time and in such scenario treatment with even the lowest priced generic medicines becomes impossible for several low income households (United Nations 2012: xvi). The study identifies as a challenge generation of new and additional resources than only intermediating already committed ODA and private charitable contributions and to facilitate disease specific interventions with the national health programmes and polices of countries (United Nations 2012: xvi).

The study note that while various initiatives to improves access to essential medicines is being explored, some countries are yet to amend their national laws to incorporate TRIPS flexibilities fully and that a number of bilateral and regional free trade agreements include IP protection in excess of the minimum standards required by the TRIPS Agreement (United Nations 2012: xvi). The policy recommendations from the study were as below (United Nations 2012: xvi):

a) In addition to overseas development assistance, there should be donor commitments to support global initiatives for the treatment and prevention of acute and chronic diseases
b) The international community to assist developing countries in increasing the availability and use of medicines in the public sector and in proving these medicines at little or no cost through the public health system

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article 31 of the Agreement on Trade-Related Aspects of Intellectual Property Rights, as proposed by the World Trade Organization General Council in its decision of 6 December 2005;

c) The international community to further strengthen cooperation for supporting local production of generic medicines in developing countries
d) Encouragement to pharmaceutical industries to use voluntary license agreements and join patent pools
e) Developing countries to assess on the possible adverse impacts on access to medicines while adopting TRIPS plus provisions
f) International community to strengthen the developing country regulatory capacity on the quality of medicines
g) International community to continue efforts to increase funding for the research and development of new medicines especially for neglected diseases.

The study noted that while the global financial and economic crises of 2008 could have eroded international co-operation efforts, it did not and that the G20 was mindful of the impact of the crises on developing countries (United Nations 2012: 1). The study pointed out that there is positive feedback when economies of development partner countries achieve robust growth and becomes dynamic markets for world trade investment and that citizens in rich countries los stand to gain when welfare in poor countries improves and further that pressure on migratory flows will diminish when there are good jobs and improved living conditions at home (United Nations 2012: 5).

5. Economic and Social Council

5.1. 2000 General Comment No. 14

The Economic and Social Council in its 2000 General Comment No. 14 titled The Right to the Highest Attainable Standard of Health states that health is a fundamental human right indispensable for the exercise of other human rights (United Nations (2000), Economic and Social Council, E/C.12/2000/4., para 1). The 2000 General Comment No. 14 identifies that even in times of severe resource constraints, the vulnerable sections of the society must be protected by the adoption of relatively low-cost targeted programmes (United Nations (2000), Economic and Social Council, E/C.12/2000/4., para 18). It also noted that equity demands that poorer households should not be disproportionately burdened with health expenses compared to wealthier households (United Nations (2000), Economic and Social Council, E/C.12/2000/4., para 12(b) (iii)). It further states that States have a special obligation

to provide those who do not have sufficient means with necessary health insurance and health care facilities and to prevent any discrimination in the provision of health care and health services (See United Nations (2000), Economic and Social Council, E/C.12/2000/4., para 18).

The 2000 General Comment No. 14 identifies various facets to the right to health. They are:

a) Availability: This denotes availability of functioning public health care facilities, trained medical and professional staff, essential drugs etc.

b) Accessibility: The resolution identifies four sub factors on this.

b.1. Non-discrimination – That the health facilities and services must be available to all without discrimination

b.2. Physical Accessibility – that the health facilities and services must be within the physical reach of all sections of the population, especially the vulnerable and marginalised groups. Accessibility implies medical services and underlying determinants such as potable water and adequate sanitation.

b.3. Economic Accessibility - That the health care facilities must be affordable to all including socially disadvantaged groups and that poorer households should not be disproportionately burdened with health expenses compared to richer households.

b.4. Information Accessibility- this deals with the right to seek, receive and impart information and ideas concerning health issues.

c. Acceptability: that the health facilities and services must be respectful of medical ethics and culturally appropriate and as well respectful of confidentiality and health status of those concerned.

d. Quality: that health facilities and service must be scientifically and medically appropriate and of good quality which requires skilled medical personnel, unexpired drugs and medical equipment etc.

The 2000 General Comment No. 14 identifies three types of obligations with regard to the right to health on state parties (See United Nations (2000), Economic and Social Council, E/C.12/2000/4., para 33) namely, the obligation to respect, protect and to fulfil.

The obligation to 'fulfil' requires states to facilitate, provide and promote the right to health and requires states to adopt appropriate legislative, budgetary, judicial, promotional and other measures towards realization of the right to health. The obligation to respect requires States to refrain from directly or indirectly interfering with the enjoyment of the right to health. The obligation to protect requires States to take measures to prevent third parties from interfering with the guarantees mentioned in article 12 of ICESCR.

The 2000 General Comment No. 14 highlighted the importance of respecting the enjoyment of the right to health in other countries and to prevent third parties from violating such right in other countries. It stated as below (United Nations (2000), Economic and Social Council, E/C.12/2000/4., para 39):

> To comply with their international obligations in relation to article 12, States parties have to respect the enjoyment of the right to health in other countries, and to prevent third parties from violating the right in other countries, if they are able to influence these third parties by way of legal or political means, in accordance with the Charter of the United Nations and applicable international law

It further stated that in relation to conclusion of international instruments, State parties should take steps to ensure that these instruments do not adversely impact on the right to health (See United Nations (2000), Economic and Social Council, E/C.12/2000/4., para 39). Also while functioning as members of international institutions such as International Monetary Fund and the World Bank and regional development banks, state parties is to pay greater attention to the protection of the right to health in influencing lending policies, credit agreements and international measures of these institutions (See United Nations (2000), Economic and Social Council, E/C.12/2000/4., para 39).

The 2000 General Comment No. 14 identifies the obligation on the state parties to provide essential drugs as time to time defined under the WHO Action Programme on

Essential Drugs as a core obligation (See United Nations (2000), Economic and Social Council, E/C.12/2000/4., para 43(d)).

The 2000 General Comment No. 14 further stated that the adoption of a human rights-based approach by the United Nations specialized agencies and bodies will greatly facilitate the implementation of the right to health (See United Nations (2000), Economic and Social Council, E/C.12/2000/4., para 64). The report also required States to take appropriate steps to ensure that private business sector and civil society should be aware of and should consider the importance of the right to health in the course of conducting their activities (See United Nations (2000), Economic and Social Council, E/C.12/2000/4., para 55).

5.2. 2007 Study by the United Nations Economic and Social Commission

A 2007 study by the *United Nations Economic and Social Commission for Asia and the Pacific* (E/ESCAP/63/4) note that IP protection could have an adverse effect on the prices and the availability of the pharmaceuticals in the APAC region. The study elaborates that since significant portion of the exports from China and India are generic drugs which have been developed through reverse engineering and that their production could be adversely affected with the change in patent laws. The study however does not denounce the TRIPS Agreement and instead points out that there are flexibilities built into the TRIPS Agreement which can be used and that this has been clarified by the 2001 Doha Declaration on TRIPS Agreement and Public Health (WT/MIN(01)/DEC/2). The study highlights that the increasing prevalence of bilateral agreements between the countries in the APAC region and the developed countries has implications as the pharmaceutical related commitments in some of these bilateral agreements extend beyond the scope of the TRIPS Agreement (United Nations (2007), E/ESCAP/63/4, para 54). The study calls for a delicate balance to be maintained between encouraging innovation and providing affordable access to drugs. The study note that adopting regional approaches to matters such as using the flexibilities under the trade agreement as a creative solution based on collaboration and co-operation (United Nations (2007), E/ESCAP/63/4, para 55).

5.3. 2009 Report of the Secretary-General

The 2009 *Report of the Secretary-General* (United Nations (2009), E/2009/81) notes that patent protection of medicines and other health related products could lead to high prices for medicines thereby affecting affordability and accessibility. This report note that the WTO Agreements that have implications on the right to health include the TRIPS Agreement, the SPS Agreement, the TBT Agreement and the GATS agreement (United Nations (2009), E/2009/81, para 44). The report noted that even within a country, the inequities can be great and cites the example that the maternal mortality rate is four time higher among the poor than the rich in Indonesia (United Nations (2009), E/2009/81, para 46).

The report note that health systems are weak in many countries due to decades of poor planning and investment, poorly co-ordinated aid etc. Also, there is long-term failure to invest in basic health infrastructure, services and staff (United Nations (2009), E/2009/81, para 55). The report notes that the health systems that function well have the following characteristics (United Nations (2009), E/2009/81, para 56):

- Good health services that are available and affordable for all
- Well performing health work force
- Equitable access to essential medical products, vaccines and technologies of assured quality
- Dissemination of evidence based health information; effective monitoring of performance and outcomes, accountability to service beneficiaries
- Leadership and effective governance.

Thus the report highlights equitable access to essential medicines as an important aspect of the right to health.

6. United Nations High Commissioner for Human Rights

6.1.2001 Resolution of Sub Commission on the Promotion and Protection of Human Rights

The Sub Commission on the Promotion and Protection of Human Rights (hereinafter "Sub Commission") of the United Nations expressly recognized the conflict between

IPRs and human rights through resolution titled '*Intellectual Property and Human Rights*' (United Nations (2001), Resolution 2001/21). The resolution stated as below:

> Reiterating that actual or potential conflict exists between the implementation of the TRIPS Agreement and the realization of economic, social and cultural rights, in particular the rights to self determination, food, housing, work, health and education, and in relation to transfers of technology to developing countries [17].

Further, paragraph 5 of the said resolution urged all governments to ensure that the implementation of the TRIPS Agreement does not negatively impact on the enjoyment of human rights as provided for in international human rights instruments by which they are bound.

The said resolution was adopted in August 2001 before the Doha round of discussions at the WTO and sought observer status in the discussions in the Council on TRIPS. While the 2001 Doha Declaration (WT/MIN(01)/DEC/2) which came after this resolution emphasised the importance of public health and the measures that may be taken to facilitate the same, the contents of this declaration is still valid. This resolution specifically stated that human rights obligations of the states under international law has primacy over economic policies and agreements and that States should take international human rights obligations and principles in international economic policy formulation (See United Nations (2001), Resolution 2001/21, paragraph 3, emphasis added). The resolution highlighted that as declared in article 28 of the Universal Declaration of Human Rights, everyone is entitled to an economic and social international order in which the rights and freedoms set forth in the Universal Declaration on Human Rights can be fully realized (See United Nations (2001), Resolution 2001/21, recital). The resolution reaffirmed that under the International Covenant on Economic, Social and Cultural Rights the right to health (among the other rights mentioned therein) constitute legally binding obligation upon the State Parties (See United Nations (2001), Resolution 2001/21, recital). The resolution recalled that under article 27, paragraph 2 of the Universal Declaration of Human Rights and article 15, paragraph 1(c) of the International Covenant on Economic Social and Cultural Rights, the right to protection of moral and material

[17] See Sub-Commission on Human Rights Resolution 2001/21, Office of the High Commissioner for Human Rights, 16 August 2001, recital

interests resulting from any scientific, literary or artistic productions of which one is an author is subject to the limitations in public interest (See United Nations (2001), Resolution 2001/21, recital).

In addition, through resolution 2000/7, the Sub Commission requested the *United Nations High Commissioner for Human Rights* to undertake as analysis of the impact of the TRIPS Agreement on human rights, in pursuance of which a study report titled *The Impact of the Agreement on Trade Related Aspects of Intellectual Property Rights on Human Rights* (E/CN.4/Sub.2/2001/13) was brought out. Though the study primarily highlights that the developing countries must use the exemptions provisions under the TRIPS Agreement to their benefit, it also explicitly observes about the TRIPS Agreement that 'the various links with the subject matter of human rights- the promotion of public health, nutrition, environment and development- are generally expressed in terms of exceptions to the rule rather than the guiding principles themselves and are made subject to the provisions of the Agreement.' Thus it is clear that the conflict between IPRs and protection of the right to health is real.

6.2. 2008 OHCHR Fact Sheet No. 31

The Office of the United Nations High Commissioner for Human Rights came out with a fact sheet on the right to health in which document the outline of the right to health concept is captured (United Nations 2008b). The fact sheet noted that States have the primary obligation to protect and promote human rights (See United Nations 2008b: 22) and also noted access to medicines as one of the entitlements under rights to health (See United Nations 2008b: 3).

The fact sheet note that a number of instruments such as the 1965 *International Convention of the Elimination of All forms of Racial Discrimination* (Article 5 (e) (iv), 1966 *International Covenant on Economic Social and Cultural Rights* (Article 12), 1979 *Convention on the Elimination of All forms of Discrimination Against Women* (articles 1 (1) (f), 12 and 14(2) (b), 1989 Convention on the rights of the child (Article 24), 1990 *International Convention on the protection of the Rights of All Migrant Workers and Members of Their Families* (Article 28, 43(e) and 5(c)), the 2006 *Convention on the Rights of Persons with Disabilities* (Article 25), all recognize the right to health.

In the context of the right to health, the fact sheet recorded the principle of progressive realisation and noted that it is implicitly recognised that States have resource constraints and that it takes time to implement treaty provisions and that some of the aspects of the rights under the ICESCR is deemed to be subject to progressive realization (See United Nations 2008b: 23). Not all aspects of right top health may be realised immediately, but at minimum States are required to show that they are making all efforts within their available resources to promote all rights under the ICESCR(See United Nations 2008b: 23). The fact sheet noted that the Committee on Economic, Social and Cultural rights has stressed that States have a core minimum obligation to ensure the satisfaction of at least minimum essential levels of each of the rights under the ICESCR and that in the context of the right to health it includes right to access health facilities, goods and services on non-discriminatory basis, provision of essential drugs, equitable distribution of health facilities, goods and services, etc. (See United Nations 2008b: 25). Also, the States have obligation to prevent third parties from interfering with the right to health (See United Nations 2008b: 26).

This Fact Sheet No. 31 noted non-discrimination as key principle in human rights and as crucial to the enjoyment to the right to the highest attainable standard of health (See United Nations 2008b: 4) and identifies non-discrimination and equality as fundamental human rights principles and are critical components of the right to health (See United Nations 2008: 7). The document highlights that discrimination is 'any distinction, exclusion or restriction made on the basis of various grounds which has the effect or purpose of impairing of nullifying the recognition, enjoyment or exercise of human rights and fundamental freedoms' (See United Nations 2008b: 7). It refers to article 2(2) of International Covenant on Economic Social and Cultural Rights and article 2(1) of the Convention on the Rights of Child and identifies the following non exhaustive grounds of discrimination namely race, colour, sex, language, religion, political or other opinion, national or social origin, property, disability, birth and other status. It also notes that Article 5 of the *International Convention on the Elimination of All Forms of Racial Discriminatio*n stresses that States must prohibit and eliminate racial discrimination and guarantee the right of everyone to public health and medical care.

In the context of this thesis it is submitted that this requirement of non-discrimination requires that there should be no distinction between the citizens of developing/least developed countries and the citizens of developed nations who may be able to afford medicines. Even with a nation the rich and the poor alike should be able to realise the right to health without discrimination.

7. Special Rapporteur's of the United Nations on Health

7.1 Special Rapporteur Reports

The United Nations has identified the right to health as an area in which it has appointed and sought reports from multiple Special Rapporteur's and from Special Representatives to the Secretary General. Following are some of such reports.

7.1.1. 2008 Report of the Special Rapporteur, Paul Hunt

This report of 31 January 2008 by Mr. Paul Hunt, the *Special Rapporteur on the Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health*, examines the various facets of the right to health and states that at the heart of the right to health lies an effective and integrated health system encompassing health care and the underlying determinants of health, which is responsive to national and local priorities and accessible to all. The report notes that without such a health system the right to the highest attainable standard of health can never be realized and that it only through building and strengthening health systems that it will be possible to secure sustainable development, poverty reduction, economic prosperity, improved health for individuals and populations as well as the right to the highest attainable standard of health (Hunt, Paul (2008), UN Doc.A/HRC/7/11 of 31 January 2008, para 15 -16).

The report notes that the right health encompasses more than medical care and that the right to attain the highest attainable standard of physical and mental health is an inclusive right and extends not only to timely and appropriate medical care, but also underlying determinants of health such as safe water and adequate sanitation, adequate supply of safe food, nutrition and housing, healthy occupational and environmental conditions, access to health-related education and information, freedom from discrimination etc. (Hunt, Paul (2008), UN Doc.A/HRC/7/11 of 31 January 2008, para 45). The State should also have sufficient number of domestically

trained workers commensurate to the health needs of the population (Hunt, Paul (2008), UN Doc.A/HRC/7/11 of 31 January 2008, para 80).

The report tries to identify some of the core obligations as it applies to states with regard to the right to health (Hunt, Paul (2008), UN Doc.A/HRC/7/11 of 31 January 2008, para 51-52). They are:

a) Preparation of a comprehensive national plan for the development of the health systems
b) Ensuring access to health related services and facilities on a non-discriminatory basis with special emphasis and initiatives for those in poverty
c) Ensuring equitable distribution of health elated service and facilities i.e. balance of distribution between rural and urban areas
d) Setting up effective, transparent, accessible and independent mechanisms of accountability in relation to the duties arising from right to the highest attainable standard of health
e) Ensuring minimum basket of health related services and facilities including essential food to ensure freedom from hunger, basic sanitation and adequate water, essential medicines, immunization against community's major infectious diseases, sexual and reproductive health service etc.

The report notes that all States have a responsibility to cooperate on trans boundary health issues and do no harm to their neighbours. It also notes that high income States have an additional responsibility to provide appropriate assistance and co-operation in health for low income countries and that they should help low income countries with the fulfillment of their core obligations arising from the right to the highest attainable standard of health. The report also states that low income countries have a responsibility to seek appropriate international assistance and co-operation to help strengthen their health systems (Hunt, Paul (2008), UN Doc.A/HRC/7/11 of 31 January 2008, para 61).

The report notes that right to highest attainable standard of health gives rise to legally binding obligations and that a State is legally obliged to ensure that its health systems includes a number of features such as a comprehensive national plan, outreach programmes for the disadvantaged, minimum basket of health related services and

facilities, effective referral systems arrangements to ensure participation by those affected by health decision making, respect for cultural difference and so on (Hunt, Paul (2008), UN Doc.A/HRC/7/11 of 31 January 2008, para 66).

7.1.2.2008 Note by the Secretary General

This note by the Secretary General of the United Nations on the Report of the Special Rapporteur Mr. Paul Hunt, on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, was presented to the General Assembly on 11th August 2008 (United Nations (2008a), A/63/263 of 11 August 2008) and it annexes *Human Rights Guidelines for Pharmaceutical Companies in relation to Access to Medicines* (hereinafter "Guidelines"). Thus at the United Nations level there has been effort to evolve guidelines that will apply to private parties. The Guidelines state that almost two billion people lack access to essential medicines and that improving access to existing medicines can save ten million lives each year, with four million of them in Africa and South –East Asia (United Nations (2008a), A/63/263,: 15 of 11 August 2008, Preamble, para a).

The Guidelines noted that one of the Millennium Development Goal targets is to provide access to affordable essential drugs in developing countries in cooperation with pharmaceutical companies. The Guidelines stated that medical care and access to medicines are vital features of the right to the highest attainable standard of health (United Nations (2008a), A/63/263 of 11 August 2008: 15, Preamble, para d).

While the Guidelines clearly recognized that States have primary responsibility for realizing the right to the highest attainable standard of health and increasing access to medicines, the Guidelines also affirmed that in addition to States, numerous national and international actors share the responsibility to increase access to medicines (United Nations (2008a), A/63/263 of 11 August 2008: 15, Preamble, paragraphs f&g). The Guidelines emphasized that pharmaceutical companies, innovator, generic and biotechnology companies have human rights responsibilities in relation to access to medicines (United Nations (2008a), A/63/263 of 11 August 2008: 15, Preamble, para i). The Guidelines noted that pharmaceutical companies contribute in various ways to the realization of the right to the highest attainable standard of health and providing important information about public health issues to individuals and

communities (United Nations (2008a), A/63/263 of 11 August 2008: 15, Preamble, para l).

The Guidelines provide that the company should adopt a human rights policy statement which expressly recognizes the importance of human rights generally and that the company should integrate human rights including the right to the highest attainable standard of health into its strategies, polices, programmes, projects and activities of the company (United Nations (2008a), A/63/263 of 11 August 2008, Articles 1 and 2). The Guidelines require the company to always comply with national laws of the State where it operates and to refrain from any conduct that will or may encourage the State to act in any manner that is inconsistent with its obligations under national and international law including the right to highest attainable standard of health (United Nations (2008a), A/63/263 of 11 August 2008, article 13).

The Guidelines state that the company should have a governance system that includes direct board level responsibility and accountability for access to medicines policy and should have clear management systems including quantitative targets to implement and monitor its access to medicines policy (United Nations (2008a), A/63/263 of 11 August 2008, article 11). The Guidelines require that the company should publish comprehensive annual report enabling assessment of company's polices, programmes, projects and other activities that bear upon access to medicines (United Nations (2008a), A/63/263 of 11 August 2008, article 13). The Company is also to have effective monitoring mechanism which assesses the impact of the company's strategies, policies, programmes, projects and activities on access to medicines (United Nations (2008a), A/63/263 of 11 August 2008, article 14).

Interestingly, the Guidelines require the companies to respect the rights of the countries to use the provisions of the TRIPS Agreement which permit flexibility for the purpose of promoting access to medicines including the provisions relating to compulsory licensing and parallel importing (United Nations (2008a), A/63/263 of 11 August 2008, article 26). Also, companies are required not to make demand for more stringent IP provisions such as additional limitation on compulsory licensing (United Nations (2008a), A/63/263 of 11 August 2008, article 27). The Guidelines call upon the companies to respect the letter and spirit of the Doha Declaration on TRIPS

Agreement and Public Health and not to impede the implementation of the provisions of the Doha Declaration such as compulsory licenses for exports to countries without manufacturing capacity (United Nations (2008a), A/63/263 of 11 August 2008, article 28).

7.1.3. 2011 The Report of the Special Rapporteur, Anand Grover

The 2011 *Report of the Special Rapporteur on the Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health, Anand Grover*, concluded that access to medicines is an integral and fundamental part of the right to health, Governments and the international community as a whole have a responsibility to provide access to medicines for all (Grover, Anand (2011), UN Doc. A/HRC/17/43 of 16 March 2011: 13, para 45). It also noted that The Millennium Development Goals identify this as a shared responsibility with States, several national and international actors such as pharma companies etc. all of which have a role to play (Grover, Anand (2011), UN Doc. A/HRC/17/43 of 16 March 2011: 13, para 45).

The report mentions that the TRIPS Agreement is an impediment to the access to medicines (Grover, Anand (2011), UN Doc. A/HRC/17/43 of 16 March 2011: 4). Also, it is stated therein that there is pressure from the developed countries on the developing countries and the least developed countries from using the flexibilities provided for by the TRIPS Agreement (Grover, Anand (2011), UN Doc. A/HRC/17/43 of 16 March 2011, para 21). The report further stated that there are TRIPS plus free trade agreements which compound the problem further. To cite an example of TRIPS plus commitments, an Oxfam study note that as a result of this US-Jordan FTA a Jordanian law which provided that patent holders must provide large quantities at reasonable prices has been removed and that the looser wording in the treaty will make it more difficult for the government to introduce compulsory licensing and easier for the pharmaceutical industry to bring legal challenges (Oxfam 2002: 217).

While the right to health is mentioned as a right in the constitutions of most of the nations, only some of the constitutions expressly mention access to essential medicines as a fundamental right. As per the statistics made available by the WHO 135 of 186 national constitutions has provisions relating to the right to health, while

only 4 i.e. constitutions of Mexico, Peru, the Philippines and the Syrian Arab Republic mention access to essential medicines as a fundamental right. 95 constitutions mention right to access to health facilities (Grover, Anand (2011), UN Doc. A/HRC/17/43 of 16 March 2011: 5).

The report identified insufficient and ineffective drug supply chains, inequitable pricing, inappropriate prescriptions, poor medicine selection and information on access to medicines, weak accountability and low public participation as factors which affect the right to health (Grover, Anand (2011), UN Doc. A/HRC/17/43 of 16 March 2011: 11, para 41).

The report identified IPRs as the most significant obstacle to access to essential medicines. Competition was identified as a very effective mechanism to keep down the prices of medicines. The report identified that in 2001 the prices of antiretrovirals used for the treatment of HIV dropped from $15000 to $400 per patients per year due to the availability of cheaper generic[18] medicines from developing countries (Grover, Anand (2011), UN Doc. A/HRC/17/43 of 16 March 2011: 8, para 25).

In their zeal to enforce the ownership rights over patents, developed countries and multinational companies tend to conflate between generic medicines and counterfeit medicines. Netherlands confiscated medicines produced in India and which were in transit to Brazil. Such actions are called 'bottom measures'. The developed countries tend to subject such shipments to criminal prosecution. The report identified that such actions tend to disrupt the access to medicines (Grover, Anand (2011), UN Doc. A/HRC/17/43 of 16 March 2011: 9, para 27).

7.1.4. 2011 Addendum to the Reports of the Special Rapporteur

As identified in the report by the *Special Rapporteur of the United Nations in his mission to Guatemala in March 2011* (See Grover, Anand (2011), UN Doc. A/HRC/17/25/Add.2: 19, para 76:

[18] Generic drug means a pharmaceutical product which is not protected by a patent in force, and which is commercialized under a non-proprietary name or a brand name (See Correa Carlos 2000a: xiv)

> Access to essential medicines is a core obligation of the right to health. States parties to the International Covenant on Economic, Social and Cultural Rights have an obligation to provide safe, efficacious and affordable medicines and, in particular, to ensure access for marginalized populations, such as the rural poor. The right to health requires that health goods and services must be accessible, available, acceptable, and of good quality. Furthermore, the State is responsible to respect, protect and fulfil the right to health, which includes policy, legislative and regulatory changes that may take near immediate effect.

The report also identified that agreements such as Central America-Dominican Republic-United States Free Trade Agreement imposes TRIPS plus obligations and erodes the critical safeguards included in the WTO Agreement on TRIPS to protect public health and the public good. The report highlighted that since United States is the major trading partner with all the countries in the region there was significant inequality in bargaining power in the negotiations and that many countries in the region did not have sufficient legal expertise on IP matters to address the matters adequately (See Grover, Anand (2011), UN Doc.A/HRC/17/25/Add.2: 19, para 81).

7.1.5. 2013 Report of the Special Rapporteur, Anand Grover

The 2013 *Report of the Special Rapporteur on the Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health, Anand Grover*, specifically noted that access to medicines is an integral component of the right to health as stated in Article 12 of the ICESCR (Grover, Anand (2013), UN Doc. A/HRC/23/42 of 1 May 2013: 3, para 3). Medicines are to be made available in sufficient quantities within a country to meet the requirements of the population and also the medicines are to be accessible in terms of economic availability and physical distance from where the population lives (Grover, Anand (2013), UN Doc. A/HRC/23/42 of 1 May 2013: 4, para 4). The Rapporteur noted that States have the obligation to protect and fulfil the right to health including access to medicines and that the duty to protect also requires the States to ensure that third parties do not obstruct enjoyment of the right to health (Grover, Anand (2013), UN Doc. A/HRC/23/42 of 1 May 2013: 4, para 5). The Rapporteur has emphasised on the need to shift dominant market-oriented paradigm on access to medicines to a right to health paradigm and to reaffirm access to affordable and quality medicines as well as medical care (Grover, Anand (2013), UN Doc. A/HRC/23/42 of 1 May 2013: 5, para 7).

The Rapporteur emphasised that under the right to health framework States have the immediate obligation to take legal and administrative measures to ensure access to essential medicines for their populations and that the same is secured by all available means. It was disheartening to note from the Rapporteur's report that a third of the world population mainly living in developing countries do not have regular access to essential medicines (Grover, Anand (2013), UN Doc. A/HRC/23/42 of 1 May 2013: 6, para 11). From a geographical breakdown of the sales of new medicines during the period 2004-2008, it evolves that North America, Europe and Japan accounted for 95 percent of the sales, while Africa, Asia which represent two thirds of the world's population accounted for only 5 per cent of the market (Grover, Anand (2013), UN Doc. A/HRC/23/42 of 1 May 2013: 6, para 13).

7.1.6. 2014 Note by the Secretary General

This note by the Secretary General on *Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health*, noted that while transnational corporations have the ability to influence polices at domestic and international level, States have not been able to regulate such corporations from violating the right to health (United Nations (2014), A/69/299 of 11 August 2014: 3, para 4). The report also noted that the magnitude of violations by transnational corporations and the ease with which they evade responsibility mandate an international mechanism to hold such corporations liable for human rights abuses which will supplement the domestic law (United Nations (2014), A/69/299 of 11 August 2014: 12, para 37). The report recommended a declaration like the UDHR which mandate certain human rights obligations on private corporations (United Nations (2014), A/69/299 of 11 August 2014: 14, para 47). The report noted that agreements are concluded between States and that no obligations are imposed on transnational corporations to respect, protect and fulfil the right to health, though the corporations engage in profit making even if they have to violate human rights obligations (United Nations (2014), A/69/299 of 11 August 2014: 15, para 49).

7.2. Other Relevant Reports of Special Rapporteur's of the United Nations

7.2.1. 2011 Report of the Special Representative of the Secretary General, John Ruggie

This *Report of the Special Representative of the Secretary General on the Issue of Human Rights and Transnational Corporations and Other Business Enterprises, John Ruggie* (hereinafter "Guiding Principles on Human Rights") (Ruggie, John (2011), UN Doc.A/HRC/17/31of 21 March 2011) contain the 'Protect, Respect and Remedy' (PRR) Framework and was adopted by the Human Rights Council in 2011 and has three pillars. The first pillar is the responsibility of States to protect against human rights abuses by third parties including business enterprises through appropriate policies, regulation and adjudication (Ruggie, John (2011): 5, para 6). The second pillar is the corporate responsibility to respect human rights and that business enterprises should act with due diligence to avoid infringement of the rights of others and the third pillar is the need for greater access by victims to effective remedy, both judicial and non-judicial (Ruggie, John (2011), UN Doc.A/HRC/17/31 of 21 March 2011: 5, para 6).

As Prenkert, Jamie Davin and Scheckleford, Scott J. note, the Special Representative Mr. John Ruggie, during his mandate and thereafter as well referred to the PRR framework and also the Guiding Principles on Business and Human Rights as a polycentric governance system (Prenkert, Jamie Davin and Scheckleford, Scott J. (2014: 458). In a polycentric governance system, a top down approach is not adopted, instead there can be several local, regional and nongovernmental initiatives for e.g. for reduction of the carbon emissions, not only the United Nations Framework Convention on Climate Change is important, but also smaller initiatives such as the Major Emitters Forum which has limited membership. This brings in a flexible approach to the problem being addressed.

The Guiding Principles on Human Rights as per the introduction to the said document helps in elaborating the existing standards and practices for States and business and integrates them within a single, logically coherent and comprehensive template and identities where the current regime falls short and should be improved (Ruggie, John (2011), UN Doc.A/HRC/17/31, 21 March 2011: 5, para 14).

The Preamble to the Guiding Principles on Human Rights note that Guiding Principles on Human Rights are grounded in the recognition of States existing obligations to respect, protect and fulfill human rights and fundamental freedoms (Ruggie, John (2011), UN Doc.A/HRC/17/31 of 21 March 2011: 6, preamble (a)), the role of business enterprises as specialized organs of the society performing specialized functions, and which are required to comply with all applicable laws and to respect human rights (Ruggie, John (2011), UN Doc.A/HRC/17/31of 21 March 2011: 6, preamble (b)) and the need for rights and obligations to be matched to appropriate and effective remedies when the same are breached (Ruggie, John (2011), UN Doc.A/HRC/17/31of 21 March 2011: 6, preamble (c).

States are to protect against human rights abuse by third parties, including business enterprises within their territory and/or jurisdiction (Ruggie, John (2011), UN Doc.A/HRC/17/31of 21 March 2011, Article A.1). For this states are required to take appropriate steps such as effective policies, legislation, regulations and adjudication to prevent, investigate, punish and redress such abuse. In order to meet such requirement states are required to enforce the laws that are aimed at requiring the business enterprises to respect human rights and to ensure that the general laws and policies applying to the operation of business enterprises in the state do not constrain, but enable respect for human rights among the business enterprises (Ruggie, John (2011), UN Doc.A/HRC/17/31of 21 March 2011, article 3(a) and (b)). States are further required to provide effective guidance to business enterprises on how to respect human rights in their operation and where appropriate require the business enterprises to communicate how they address human rights impact (Ruggie, John (2011), UN Doc.A/HRC/17/31of 21 March 2011, article 3(c) and (d)).

States are required to protect against human rights abuse by third parties including business enterprises within their territory and are required to take appropriate steps to prevent, investigate, punish and redress such abuse (Ruggie, John (2011), UN Doc.A/HRC/17/31of 21 March 2011, article A(1)). Also, States are required to clearly set out the expectation that business enterprises domiciled in their territory and jurisdiction shall respect human rights throughout their operations (Ruggie, John (2011), UN Doc.A/HRC/17/31of 21 March 2011, article 3(b)). Further States are required to enforce laws that aim to require business enterprises to respect human

rights and to assess the adequacy of such laws and to address gaps (Ruggie, John (2011), UN Doc.A/HRC/17/31of 21 March 2011, article 3(a)). States are also required to ensure that the laws and policies governing business enterprises such as business law do not constrain but enable the respect for human rights (Ruggie, John (2011), UN Doc.A/HRC/17/31of 21 March 2011, article 3(b)). Also, States are required to provide guidance to business enterprises to respect human rights throughout their operations (Ruggie, John (2011), UN Doc.A/HRC/17/31of 21 March 2011, article 3(c)).

States are required to take additional steps to protect against human rights abuses by business enterprises that are owned or controlled by the State and also those which receive substantial support and services from the State in the form of export credit agencies, official investment insurance or guarantee agencies (Ruggie, John (2011), UN Doc.A/HRC/17/31of 21 March 2011, article 4).

Article 5 of the Guiding Principles on Human Rights require that when States contract with or legislate for business enterprises to provide services, they should exercise adequate oversight in order to meet their international human rights obligations. Further States are required to promote respect for human rights by business enterprises with which they conduct commercial transactions (Ruggie, John (2011), UN Doc.A/HRC/17/31of 21 March 2011, article 6). When States contract with or legislate with business enterprises to provide services, they are required to exercise adequate oversight in order to meet their international human rights obligations (Ruggie, John (2011), UN Doc.A/HRC/17/31of 21 March 2011, article 5).

Article 9 of the Guiding Principles on Human Rights require that States should maintain adequate domestic policy space to meet their human rights obligations when pursuing business related policy objectives with other States or business enterprises such as through investment treaties or contracts. This is important in the context of the discussion in this thesis.

Article 10 elaborates on this and states that when States acting as members of multilateral institutions that deal with business related issues should seek to ensure that those institutions neither restrict in the ability of their member states to meet their

duty to protect nor hinder business enterprises from respecting human rights. Further, the same article requires States to encourage the multilateral institutions acting within their mandates and capacities to promote respect for human rights by the business enterprises including through technical assistance, capacity building and awareness raising.

Article 11 of the Guiding Principles on Human Rights note that business enterprises should respect human rights and that they should avoid infringing on human rights of others and that they should address adverse human rights impacts with which they are involved. Article 12 provides that the responsibility of business enterprises to respect human rights refers to the minimum as those stated in the International Bill of Rights and in the International Labour Organizations' Declaration on Fundamental Principles and Rights at work.

The Guiding Principles on Human Rights states that the responsibility to respect human rights requires business enterprises to avoid causing or contributing adverse human rights impacts through their own activities and to address such impacts when they occur (Ruggie, John (2011), UN Doc.A/HRC/17/31of 21 March 2011, article 13(a)). It also requires business enterprises to prevent or mitigate adverse human rights impacts that are directly linked to their operations, products or services by their business relationships, even if they have not contributed to those impacts (Ruggie, John (2011), UN Doc.A/HRC/17/31of 21 March 2011, article 13(b)). The Guiding Principles require that in all contexts, business enterprises should comply with all applicable laws and respect internationally recognized human rights, wherever they operate and seek ways to honour the principles of internationally recognized human rights when faced with conflicting requirements and to treat the risk of causing or contributing to gross human rights abuses as a legal compliance issue wherever they operate (Ruggie, John (2011), UN Doc.A/HRC/17/31of 21 March 2011, article 23). Also, where business enterprises identify that they have caused or contributed to adverse impacts, Guiding Principles on Human Rights requires that states should provide for or co-operate in their remediation through legitimate processes (Ruggie, John (2011), UN Doc.A/HRC/17/31of 21 March 2011, article 22).

7.2.2. 2012 Report of the Special Rapporteur, Grover Anand

The 2012 *Report of the Special Rapporteur on Extreme Poverty and Human Rights*, (hereinafter "Report of the Special Rapporteur on Extreme Poverty and Human Rights") note that the indivisibility, interdependence and interrelatedness of human rights is often highlighted and reiterated in human rights instruments and by various human rights bodies, but in practice the same is disregarded.

Further, the interdependence of all human rights is without doubt (Report of the Special Rapporteur on Extreme Poverty and Human Rights, UN Doc.A/67/278 of 09 August 2012, para 4). The report further notes that the vulnerability of the poor increases because of the inability of the poor to pursue justice remedies through existing systems (Report of the Special Rapporteur on Extreme Poverty and Human Rights, UN Doc.A/67/278 of 09 August 2012, para 5). The report notes that the lack of effective remedies for violations of human rights such as discrimination is still a pressing reality in many jurisdictions as much as the lack of judicial protection for economic, social and cultural rights (Report of the Special Rapporteur on Extreme Poverty and Human Rights, UN Doc.A/67/278, 09 August 2012, para 8). The report notes that States should take the required steps for the removal of obstacles caused by the unequal economic or social status of those seeking redress based on principles of equality etc.(Report of the Special Rapporteur on Extreme Poverty and Human Rights, UN Doc.A/67/278 of 09 August 2012, para 12). Where there is much disparity in economic and social status of litigants, then there is high risk of unequal trial (Report of the Special Rapporteur on Extreme Poverty and Human Rights, UN Doc.A/67/278 of 09August 2012, para 13). Therefore, States are to take all the necessary measures to reduce or eliminate the deficiencies that impair or diminish the effective protection of rights (Report of the Special Rapporteur on Extreme Poverty and Human Rights, UN Doc.A/67/278 of 09 August 2012, para 14). Also, poor functioning of judicial systems particularly affects the poor because pursuing justice requires much more effort in terms of money and time, with chances for a favourable outcome grim (Report of the Special Rapporteur on Extreme Poverty and Human Rights, UN Doc.A/67/278 of 09 August 2012, para 15).

7.2.3. 2012 Report of the Special Rapporteur in the Field of Cultural Rights

The *Special Rapporteur in the Field of Cultural Rights: The Right to Enjoy the Benefits of Scientific Progress and its Applications, Farida Shaheed*, in her 2012 report noted that:

a) the right of everyone to share in the scientific advancement and its benefits is enshrined in the UDHR and the right to benefit from scientific progress and its applications in the ICESCR (United Nations A/HRC/20/26 of 14 May 2012:3, para 1).
b) Various international and regional provisions demonstrate general consensus on the need to ensure right to science to all persons (United Nations A/HRC/20/26 of 14 May 2012:3, para 6).
c) That many constitutions speak about the right to enjoy the benefits of scientific progress and its applications, right to have access to science, promotion of dissemination and/or use of science and technology etc. (United Nations A/HRC/20/26 of 14 May 2012:5, para 14).
d) That right to science means right to access, that scientific knowledge, information and advances are to be made accessible to all as provided for in Arctioel2 of the ICESCR without discrimination as to race, colour, sex, language, religion, political or other opinion etc. and that access must to be science as whole and not to specific scientific outcomes or applications (United Nations A/HRC/20/26 of 14 May 2012:9, para 26).
e) That new scientific knowledge and innovations increase available options, thereby strengthening people's capacity to envisage for a better future for which access to certain technologies may be critical (United Nations A/HRC/20/26 of 14 May 2012:7, para 20).
f) That the Supreme Court of Venezuela held that the failure of the Venezuelan Institute of Social Security to ensure regular and consistent supply of drugs for HIV-positive people covered by it amounted to violation of the right to enjoy the benefits of scientific progress (United Nations A/HRC/20/26 of 14 May 2012:8, para 23).
g) That States should ensure that the benefits of science are physically made available and also economically affordable on a non-discriminatory basis (United Nations A/HRC/20/26 of 14 May 2012:10, para 30).

h) That concern has been widely expressed about the conflict between right to science and intellectual property rights in particular since the adoption of the TRIPS Agreement and also in the context of the TRIPS plus provisions. The Rapporteur noted that the potential of IPR regimes to obstruct new technological solutions critical to human problems including food, water, health etc. need attention (United Nations A/HRC/20/26 of 14 May 2012:15, para 56).

The Rapporteur in her final conclusions recommended among other things that:

a) States should guard against promoting the privatisation of knowledge to an extent that it deprives individuals of opportunities to take part in cultural life and to enjoy the fruits of scientific progress. That the current maximalist IP approach should be reconsidered and the virtues of a minimalist approach to approach protection should be explored (United Nations A/HRC/20/26 of 14 May 2012:21, para 74(o)).
b) That States should use the TRIPS flexibilities and take legislative and policy advice from WIPO where required (United Nations A/HRC/20/26 of 14 May 2012:21, para 74(p)).
c) That States should implement the recommendations of the Special Rapporteur on the right o very one to the enjoyment of the highest attainable standard of physical and mental health and the Special Rapporteur on the right of food on the issue of intellectual property rights(United Nations A/HRC/20/26 of 14 May 2012:21, para 74(q)).

7.2.4. 2015 Report of the Special Rapporteur in the Field of Cultural Rights

In her 2015 report (United Nations 2015 A/70/279) the Rapporteur Farida Shaheed noted that:

a) The tension between patent protection and broad public access is common in all areas of essential technologies, beyond health, food etc. (United Nations 2015 A/70/279: 4, para 4)
b) Innovation essential for a life with dignity should be accessible for everyone (United Nations 2015 A/70/279: 4, para 4)
c) The TRIPS Agreement makes a departure from the Paris Convention as it establishes patent protection for a minimum term of 20 years and ignores the

diversity of human needs, the flexibility provided by the Paris Convention and the subsequent agreements that built upon it (United Nations 2015 A/70/279: 7, para 19).

d) Many academic and other analyses strongly reject the premise in the TRIPS Agreement that minimum standards of protection are of equal benefit to various countries with various socio-economic and developmental needs (United Nations 2015 A/70/279: 7, para 24).
e) Aggressive patenting practices exploit administrative weaknesses. High number of low quality patents hinder research, legitimate competition and access (United Nations 2015 A/70/279: 9, para 26).
f) While the human right to property has been the basis for patent protection within the European human rights system (United Nations 2015 A/70/279: 10, para 33), the equation of IP regimes with human right to protection of the moral and material interests of the authors is false and misleading (United Nations 2015 A/70/279: 10, para 32).
g) The appropriation of scientific knowledge through patents such as patents of genes, patenting of pre-existing information versus inventions, patenting of frivolous inventions, misappropriation of the innovations of indigenous and local communities are all of concern (United Nations 2015 A/70/279: 9, para 26).
h) Patents while properly structured expand the options and well-being of all people by making available new possibilities (United Nations 2015 A/70/279: 13, para 47).
i) That human rights perspective demand that patents do not extend so far as to interfere with individuals dignity and well-being, for e.g. strong patent rights making compulsory licensing of medicines impractical or unduly cumbersome (United Nations 2015 A/70/279: 13, para 47).
j) Alternate mechanism such as tax incentives for corporate investments in research and development, public funding, government purchasing etc. can be used to stimulate research than relying on patenting alone (United Nations 2015 A/70/279: 15, para 57).
k) Antitrust competitions laws should be used to impose limits on patents such as prohibiting patent owners from refusing to grant licenses without justification, preventing originator firms from buying out generic manufacturers, preventing

attempts to switch patients from a drugs on which patent is about to expire to another drugs which is under patent etc. (United Nations 2015 A/70/279: 21, para 86).

In her final recommendation the Rapporteur noted that international patent instruments, should be subject to human rights impact assessments (United Nations 2015 A/70/279: 22, para 95), that the WTO bodies should take account of human rights standards and obligations and review the rules that have native impact on the realisation of human rights (United Nations 2015 A/70/279: 22, para 96) and that States should complete human rights assessment of their domestic law and policy (United Nations 2015 A/70/279: 22, para 97).

8. International Organisations

8.1. International Organisations

Various international organisations have been formed in the recent times to facilitate access to medicines. They include:

- **Global Fund to Fights AIDS, Tuberculosis and Malaria**: This is a public private partnership and international financing institutions aimed to attract and disburses additional resources to prevent and treat AIDS, TB and malaria. The model is based on country ownership and performance based funding with the receipts implementing their own programmes as per their priorities provided verifiable results are achieved (WHO, WIPO and WTO 2013: 208).
- **South Centre:** This is an intergovernmental organisation of 52 developing countries which provides policy advice to the developing countries and contributes to collaboration in promoting common interest and common participation by developing countries in international forums (WHO, WIPO and WTO 2013: 209). The three main activities undertaken by the South Centre are policy advice, capacity building and training.
- **United Nations:** Various initiatives by the United Nations include those by United Nations Human Rights Council and Office of the United Nations High Commissioner for Human Rights[19], Joint United Nations Programme on

[19] The UNHRC is a subsidiary body of the United Nations General Assembly while the OHCHR provides substantive and technical support in all areas of its work. The Special Rapporteurs appointed by the UNHRC address country specific situations or thematic issues in various parts of the world.

HIV/AIDS, United Nations Conference on Trade and Development, United Nations Development Programme, United Nations Children's Funds, UNITAID, United Nations Industrial Development Organisation ("UNIDO") etc.

- Organisations such as the World Bank, UNCTAD and ICTSD also have done work in this field. Certain reports from UNCTAD and ICTSD clearly note that IPRs have been much controversial in the recent days and that considerable increases in royalty payments and licensing fees in many areas of the world as well the inclusion of IP related provisions in many bilateral trade and investment agreements illustrate the importance of IPRs as a major economic, trade and investment issue (UNCTAD (2009), UNCTAD/PCB/2009/13: iv).

8.2. Decision of the ICJ in 1996 Legality of the Use by a State of Nuclear weapons in Armed Conflict, Advisory Opinion

The WHO had approached the ICJ with the request to give an advisory opinion on whether the use of nuclear weapons by a State in war or other armed conflict be a breach of its obligations under international law including the WHO Constitution ((1996), ICJ Reports, 66).

The WHO relied on (1996, ICJ Reports, 66- 67) the principles laid down in the WHO Constitution, the report of the Director General on health and environmental effects on nuclear weapons, WHA resolutions 36. 28, 40.24, 42.26, 45.31 on the effects of nuclear war on health and health services, that there is no health service in the world which can alleviate in any significant way a situation resulting from the use of even on single nuclear weapon, role of the WHO as mentioned in Article 2(a) of its Constitution to act as the directing and co-coordinating authority on international health work, to take all necessary action to attain the objectives of the Organisation etc.

The Court held that three conditions must be satisfied to find the jurisdiction of the Court when a request for an advisory opinion is submitted to it by a specialized agency namely, the agency requesting the opinion must be duly authorised under the

Charter to request opinion from the Court; the opinion requested must be on a legal question, and the question must be one arising within the scope of activities of the requesting agency (1996, ICJ Reports, 71-72, para 10). Some of the States raised the objection that conditions necessary for the jurisdiction of the Court are not met in this case and that the question that has been raised is essentially a political one and that it goes beyond the scope of WHO's proper activities and that the same would deprive the Organization of any competence to seize the Court of it (1996, ICJ Reports, 73, para 13).

The Court however noted that the fact that a question has political aspects, as in the nature of things and is the case with some many questions in international life does not suffice to deprive of its character as a legal question and to deprive the Court of the competence expressly conferred on by its Statute (1996, ICJ Reports, 73). The Court noted its own observation in the 1980 decision in the Interpretation of the Agreement of 25 March 1951 between the WHO and Egypt where it held:

Indeed, in situations in which political considerations are prominent it may be particularly necessary for an international organisation to obtain an advisory opinion from the Court as to the legal principles applicable to the matter under debate, especially those which include the interpretation of its constitution (1996, ICJ Reports, 74, para 16).

However, the Court noted that in the light of the object and purpose of the WHO Constitution as well as the practice followed by the WHO, Article 2 may be read as authorizing the WHO to deal with the effects of health on the use of nuclear weapons, or any other hazardous acidity and to take preventive measures aimed at protecting the health of populations in the event of such weapons being used. However, the question that was put to the court is 'not the effects on the use of nuclear weapons on health' but the 'legality of the use of such weapons in view of their health and environmental effects' (1996, ICJ Reports, 76, para 21). The Court held that:

> Whatever those effects might be, the competence of the WHO to deal with them is not dependent on the legality of the acts that caused them. Accordingly, it does not seem to the Court that the provisions of Article 2 of the WHO constitution, interpreted in accordance with the criteria referred

> above, can be understood as conferring upon the WHO competence to address the legality of the use of nuclear weapons (1996, ICJ Reports, 76, para 21).

The Court noted that whether nuclear weapons are used legally or illegally, their effects on health would be the same and that while it is probable that the use of nuclear weapons might seriously prejudice WHO's material capability to deliver all necessary services, this does not raise an issue falling within the scope of Organisations activities (1996, ICJ Reports, 77, para 22).

The Court further noted that international organisations are subjects of international law and that unlike States they do not possess a general competence. On the other hand international organisations are governed by the 'principle of specialty' i.e. they are invested by the States which create them with powers, the limits of which are a function of the common interests whose promotion those states entrust to them (1996, ICJ Reports, 78, para 25). The Court held as below:

> … to ascribe to the WHO the competence to address the legality of the use of nuclear weapons – even – in view of the health and environment effects would be tantamount to disregarding the principle of specialty for such competence could not be deemed a necessary implication of the Constitution of the Organisation in the light of the purposes assigned to it by the Member States (1996, ICJ Reports, 79, para 25).

The Court held that the essential condition of founding its jurisdiction is absent in the case as it has arrived at the view that the request for advisory opinion submitted by the WHO does not relate to a question within the scope of activities of the Organisation in accordance with Article 96, paragraph 2 (1996, ICJ Reports, 84, para 31).

In sum, this is one case where the ICJ did not take up the opportunity to give a decision in favour of protection of human health as a whole.

8.3. 2000 UN Global Compact

The UN Global Compact is a UN initiative for corporate sustainability. It lays down ten principles which are derived from the UDHR, *International Labour Organisation's Declaration on Fundamental Principles and Rights at Work*, *Rio Declaration on Environment and Development* and the *United Nations Convention*

Against Corruption. Of these principles 1 and 2 deal with human rights in general and business, while the rest deal with labour, environment and anti-corruption.

Principle 1 and 2 of the United Nations Global Compact provides certain operational guidelines for businesses states as below on the responsibility of business with regard to human rights. Principle 1 states that "*businesses should support and respect the protection of internationally proclaimed human rights*" and Principle 2 require that businesses should "*make sure that they are not complicit in human rights abuses*".

Thus the UN Global Compact calls upon the private sector as well to take note of and adhere to the human rights obligations. This is relevant in the context of the current discussion.

9. Jurisprudence

In the subsequent discussions in this thesis, the scope of conflict between the right to health and the trade law instruments is being attempted. Before we proceed to such discussion, what it is critical to examine the perspective which should apply to any interpretation of legal provisions in the context of this important topic, i.e. whether legal provisions should be seen literally and in isolation or whether the same needs to be seen holistically in the context of existing law.

9.1. Positivist Approach

Under a positivist approach to law, law is not tested for morality, but all that is tested is whether there is a law on the matter being addressed. Exclusive positivism holds that there is separation between law and morality and that moral criterion cannot play a role in validating law (Padmanabhan, Vijay M. 2014: 571). Also, exclusive positivism holds that a separation between law and morality fosters greater predictability regarding the content of the law which is important to avoid fragmentation in a legal regime which does not have an universal and organized settlement system (Padmanabhan, Vijay M. 2014: 571). In the Hobbesian view, a sovereign could be said to act unjustly or wrongly if he violated a covenant to the subject. But Hobbes contends that no covenants are made by a sovereign with the subjects. The subjects grant unlimited power to the sovereign, or at least the sovereign

accepts no limits by any covenant or agreement with the subjects (Goldsmith, M.M. 2005: 8).

9.2. Natural Law Theory

Under the natural law theory advocated by Locke, morality is important. It is pertinent to note the summarization made by Snyder (2005) on the Lockeain theory as below:

> Locke begins the Second Treatise by describing the state of nature, which is human society as it exists apart from the civil state. Although there is no government in this natural condition, that does not mean that there is no moral law which ought to be obeyed. Indeed the *State of Nature* has a Law of Nature to govern it, which obliges everyone. Furthermore, this law of nature wills the Peace and Preservation of all Mankind. Later we are told that the preservation of Man is the 'Fundamental Law of Nature (Snyder 2005: 9).
> …

Now the state of nature, is for Locke, a condition of equality and freedom, at least it is initially. Since no one enjoys a legitimate political power over another, all men order their Actions, and dispose of their Possessions, and persons as they think fit. But even this state of nature is limited, for the rational law which governs it decrees principles of action which promote peace and presentation. One may not simply do as one wishes, if what one wishes to do is contrary to the laws of nature, for everyone is morally bound by that law. One principle, derivable from the law, for example, is that 'no one ought to harm another in his Life, Health or Possessions'. Since this principle is derivable from the law of nature – it is necessary for peace and preservation – and so is part of that law observing is obedience to the rational will of God and is one expression of human rationality (Snyder, David C. 2005: 9).

When it comes to the matter of human rights, a positivist view may not be the best. This position is echoed by other scholars such as Padmanabhan (2014) who hold that it is a foundational principle of human rights law that all humans enjoy rights by virtue of being human and that a role for moral obligation in the validation of human rights is critical to achieving human rights (Padmanabhan, Vijay M. 2014: 571).

Also, as noted by Gomez and Ramacharan by quoting other authors, Constitutional liberalism developed in Western Europe and the US as a defence of individual's right to life and property and the freedoms of religion and speech (See Gomez, James and Ramacharan, Robin 2014b: 3). For securing these rights it was imperative to have

checks on the powers of the Government, to have equality under law, impartial courts and tribunals and separation of church and the State. In Constitutional liberalism it is argued that human beings have natural and inalienable rights and that governments need to protect such rights, even if it requires curtailing the powers of the government (See Gomez, James and Ramacharan, Robin 2014b: 3).

Therefore, even assuming or where there are legal instruments or customary practices which uphold trade at the cost of human rights, they will have to be examined on the touchstone of morality. This may seem to espouse uncertainty, however, the goal of protecting the right of the human being, being of absolute criticality, this approach will need to be embraced. Therefore a court examining an apparent contradiction between the right to health and trade interests should rely on this foundational principle in jurisprudence.

As Niger Rodley (2010: 783-784) Professor of International Law and Special Rapporteur on Torture of the UN Commission on Human Rights, Member of the UN Human Rights Committee, established under the International Covenant on Civil and Political Rights (Chairperson 2013-2014) and also President of the International Commission of Jurists, note that the original notion of human rights refer to the rights that the individual assert against the organised power of the State. It grew in the seventeenth and the eighteenth centuries when feudalism was being replaced by mercantilism and religion began to lose its position as counterweight to royal power which was giving way to the industrialising State. But thereafter it evolved that the leviathan itself needed to be tamed and that from Locke to Rosseu and Thomas Paine and from the Magna Carta and the English Bill of Rights to the Virginia Bill of Rights and the *Declaration des droits de l'homme et du citogen*, the idea of individual human domain reserve was born and consecrated.

10. Methodology for Enforcement of Human Rights

10.1. Behavioural Approach to Human Rights

Where there are a plethora of human rights instruments, it needs to be seen what will be the best mechanism to enforce human rights. Under the positivist approach a treaty will need to be enforced and any breach of the same will result in sanctions, or other international measures. It is seems that inspite of having such regime in place, there

are a large number of nations which do not comply with the treaty obligations, especially on the front of economic, social and cultural rights.

Under the behavioural approach, rather than assuming an international norm and asking how that norm can be enforced as a rule on states, the focus is on how the international human rights regimes could pay more attention to the social situations that give or deny its norms social meaning (Woods, Andrew K. 2010: 71). For this one needs to focus attention on nature of norms, social situations and human behaviour. Woods (2010) notes that in the matter of economic, social and cultural rights a behavioural approach will be better than an expose and shame model of advocacy (Woods, Andrew K. 2010: 87).

10. 2. Conflict Redressal under International Law on the Right to Health

It is stated by many that the principle of State sovereignty is being violated by the TRIPS obligations as nations no longer seem to be able to determine national health policies as they wish to. The question is which will prevail in case of conflict of obligations arising under international IPRs regime and under the international human rights law dealing with the right to health and what are the redressal mechanisms under international law.

To answer this question it is useful to peruse the relevant provisions of the 1969 *Vienna Convention on Law of Treaties* which provides the guidelines on interpretation of the provisions of treaties. As evident from the decisions of the DSB of the WTO many a time the DSB has referred to the 1969 *Vienna Convention on Law of Treaties* in its decisions.

10.3.1969 Vienna Convention on Law of Treaties

Article 31 of the Vienna Convention of the Law of Treaties provide for the general rule of interpretation and states that a treaty is to be interpreted in good faith in accordance with the ordinary meaning given to the terms of treaty in their context and in the light of the object and purpose of the treaty. Article 31(2) elaborates that the context for the purpose of the interpretation of a treaty shall comprise in addition to its text the preamble and annexes and any agreement relating to the treaty which was made between the parties in connection with the conclusion of the treaty. Also, any

instrument which is made by one or more of the parties in connection with the conclusion of the treaty and accepted by the other parties as an instrument related to the treaty is to be looked into. Any subsequent agreement between the parties regarding the interpretation of the treaty or the application of its provisions and any subsequent practice in the application of the treaty which establishes the agreement of the parties regarding its interpretation is also to be looked into. Relevant rules of international law applicable in relation between the parties are also to be examined. Further a special meaning can be ascribed to a term of it is established that the parties so intended.

Under Article 31, when the interpretation under the provisions of article 31 as elaborated above leads to a result which is manifestly absurd or unreasonable or leaves the meaning ambiguous or obscure, recourse may be had to the supplementary means of interpretation such as preparatory work of the treaty and the circumstances of its conclusion.[20]

Under Article 32, recourse may be had to supplementary means of interpretation such as preparatory work of the treaty and the circumstances of the conclusion of the treaty to arrive at the meaning arising from the application of article 31. This can be done also when the meaning arising from interpretation of article 31 leaves it ambiguous or obscure or leads to a result which is manifestly absurd or unreasonable. Therefore when trade law provisions result in absurd meaning negatively impacting the health of

[20] **Article 31-General Rule of Interpretation**

1. A treaty shall be interpreted in good faith in accordance with the ordinary meaning to be given to the terms of the treaty in their context and in the light of its object and purpose. (emphasis added)
2. The context for the purpose of the interpretation of a treaty shall comprise, in addition to the text, including its preamble and annexes:
   a) any agreement relating to the treaty which was made between all the parties in connexion with the conclusion of the treaty;
   b) any instrument which was made by one or more parties in connexion with the conclusion of the treaty and accepted by the other parties as an instrument related to the treaty.
3. There shall be taken into account, together with the context:
   a) Any subsequent agreement between the parties regarding the interpretation of the treaty or the application of its provisions;
   b) Any subsequent practice in the application of the treaty which establishes the agreement of the parties regarding its interpretation;
   c) Any relevant rules of international law applicable in the relation between the parties. (emphasis added)

A special meaning shall be given to a term if it is established that the parties so intend.

a population, there is a need to refer to the preparatory work and /or the circumstances of its conclusion and then arrive at a sane conclusion.

The Panel in *China – Measures Affecting the Protection and Enforcement of Intellectual Property Rights* (WT/DS362/R of 26 January 2009) reiterated (See para 7.500) the decision of the AB in the 1996 *United States - Standards for Reformulated and Conventional Gasoline* (WT/DS2/AB/R of 29 April 1996: 17) and also *Japan - Taxes on Alcoholic Beverages* (4 October 1996, WT/DS8/AB/R: 10) that the general rule of interpretation, expressed in Article 31 of the Vienna Convention and the rules on supplementary means of interpretation in Article 32 of the Vienna Convention have attained the status of rules of customary or general international law. The Panel held as below (See para 7.500):

> In accordance with Article 3.2 of the DSU, the Panel applies "the customary rules of interpretation of public international law" to its task of interpreting the TRIPS Agreement in this dispute. The general rule of interpretation, expressed in Article 31 of the Vienna Convention, and the rules on supplementary means of interpretation in Article 32 of the Vienna Convention, have attained the status of rules of customary or general international law. The Panel will apply the general rule of interpretation and, to the extent warranted, supplementary means of interpretation. The Panel is mindful that Article 3.2 of the DSU also provides that "recommendations and rulings of the DSB cannot add to or diminish the rights and obligations provided in the covered agreements".

Under Article 46 of the treaty, it is not open to a state to dispute the provision of a treaty stating that the said provision is in violation of a provision of its internal law unless such violation was manifest and concerned a rule of its internal law of fundamental importance. Therefore domestic law provisions in breach of the international human rights treaties entered into by any nation need to be streamlined with the international human rights obligations and customary law. Internal law cannot require states to set aside international human rights obligations and customary law.[21]

[21] See Article 46-Provisions of Internal Law Regarding Competence to Conclude Treaties

1. A State may not invoke the fact that its consent to be bound by a treaty has been expressed in violation of a provision of its internal law regarding competence to conclude treaties as invalidating its consent unless that violation was manifest and concerned a rule of its internal law of fundamental importance.
2. A violation is manifest if it would be objectively evident to any State concerning itself in the matter in accordance with normal practice and in good faith.

Under Article 52 of the treaty, a treaty is void if at the time of its conclusion it conflicts with a peremptory norm of international law (*Jus Cogens*).[22] A peremptory norm of international law is explained as a norm accepted and recognized by the international community of States as a whole from which no derogation is permitted and which can be modified only by a subsequent norm of general international law having the same character. The unflinching exposition made by the international community that the right to health is a fundamental right indispensable for the exercise of other human rights and that even in times of severe resource constraints the vulnerable sections of the society must be protected ((United Nations (2000), Economic and Social Council, E/C.12/2000/4., para 1)) etc. all point out to that the right to health is customary international law. It may even be argued that the right to health is *jus cogens* from which no derogation is feasible and that treaties in conflict with the same are void. Therefore provisions in any of the trade law instruments that conflicts with the right to health the same must be held void.

Chapter Summation

Broadly, the right to health is well entrenched in international law and is upheld by the international community as a basic human right to be fulfilled. There are various international instruments in place which enumerate on the right to health.

Key international instruments such as the 1975 *Declaration on the Use of Scientific and Technological Progress in the Interests of Peace and for the Benefit of Mankind* (GA Res. (1975), 3384(XXX)) and the 2011 Resolution on *The Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health* (GA Res 2011, A/HRC/17/L.16) emphasise the need to use technological advancements for the benefit of mankind and to ensure that even the States supported this by ensuring required legislative measures. The 1974 *Declaration on the Establishment of a New International Economic Order* (GA Res. (1974), 3201 (S-VI)) mention the need to give developing countries access to achievements of modern science and

[22] Article 52-Treaties Conflicting With A Peremptory Norm of General International Law (Jus cogens)
A treaty is void if, at the time of its conclusion, it conflicts with a peremptory norm of general international law. For the purposes of the present Convention, a peremptory norm of general international law is a norm accepted ad recognized by the international community of States as a whole as a norm from which no derogation is permitted and which can be modified only by a subsequent norm of general international law having the same character. (emphasis added)

technology and to promote transfer of technology and for creation of indigenous technology for the benefit of developing countries in accordance with the forms and procedures which suit their needs (Article 4(p) of GA Res. (1974), 3201 (S-VI)). Resolutions of the General Assembly such as the 1969 *Declaration on Social Progress and Development* noted that the primary responsibility for development of the developing countries rests on the developing countries themselves and that all Member States have the responsibility to pursue internal and external policies designed to promote social development throughout the world and in particular to assist the developing countries to accelerate their economic growth. The potential to use right to development to reinforce the human rights in the context of the right to health is much (See UN Doc. A/HRC/15/WG.2/TF/CRP.2 of 19 November 2009: 4, para 6). Therefore the jurisprudence is in favour of a legal regime enabling the development of the developing nations.

An examination of various international instruments above bring out that the world community has held at certain times that there is no conflict between the right to health and IPRs under international law and that instead what is required is the presence of adequate legal mechanism to ensure that accessibility and affordability to medicines is ensured. The international community has at times stated that the IPRs do not impair the right to health and also many of the instruments recognise that IPRs foster innovation. However, the very fact that there are various intergovernmental initiatives intended to improve the access to medicines is a confirmation of the fact that there is conflict between the right to health and international trade initiatives under the WTO.

In addition, the reports of the Special Rapporteurs of the United Nations clearly bring out that there is conflict between IP and human rights. The *Special Rapporteur on the Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health* in 2011 noted that the right to health is negatively affected by the TRIPS Agreement (*The Report of the Special Rapporteur* 2011, A/HRC/17/43: 13, para 47). The *Special Rapporteur in the Field of Cultural Rights* noted in her 2015 report that international patent instruments, should be subject to human rights impact assessments (United Nations 2015 A/70/279: 22, para 95), that the WTO bodies should take account of human rights standards and obligations and review the rules

that have negative impact on the realisation of human rights (United Nations 2015 A/70/279: 22, para 96) and that States should complete human rights assessment of their domestic law and policy (United Nations 2015 A/70/279: 22, para 97).

While the right to health is firmly entrenched in several international instruments and even if there are various exceptions to the enforcement of patent provisions, the poverty of the people who are impacted by lack of access to essential medicines on the ground nullifies the recognition of the right in legal instruments. Poverty, bad governance etc. prevent the actual victims from realising their human rights even where there are legal instruments available to protect their rights.

On the other hand, if the instruments of protection in treaty form or softer forms such as various resolutions, reports etc. discussed in this chapter are not available then the risk of human rights violations are much more. This is all the more high in the case of issues which are not clear cut violations through the criminal acts, but is more of deprivation of benefits. Therefore where the deprivation can impact the life of a person of a population as a whole, then the law will need to take corrective steps to prevent such deprivation and even enable access to those basic necessities, in this case, medicines.

It also needs to be noted that in spite of the established position of the right to health under international law, there are limited redressal mechanisms or case precedents with regard to protection of the right to health. Elkins, Ginsburg and Simmons (2013) note that international law matters where people, courts and others are able to utilise it in domestic practice and that constitutional incorporation is one mechanism by which international legal regime for human rights has local impact (Elkins Zachary, Ginsburg Tom and Simmons Beth 2013: 69). Accordingly, incorporation in domestic law and translating its actual benefit to the people on the ground is the key.

The study done in this chapter brings out that justiciability of the right to health of individuals under international law is something which is not clearly available. International bodies such as the ICJ do not normally act as forum for litigation on the violations of an individual's right. This is rightly so in keeping with their charter documents and national mechanisms need to address such individual issues, first.

Therefore some scholars have opined that a framework convention on global health with monitoring mechanisms under it like the Special Rapporteurs should be considered (Friedman, Eric A. 2016). In any case, in the matter of justiciability of health rights, a positivist view may not be the best, as it is a foundational principle of human rights law that all humans enjoy rights by virtue of being human and that role for moral obligation in the validation of human rights is critical to achieving human rights (Padmanabhan, Vijay M. 2014: 571).

The success of international law will be when it can evolve methodologies to put pressure on the national mechanisms through monitoring etc. However, this is a grey area in which there will be resentment from nations as being interference on their sovereignty. International law is most effective when it works through domestic institutions, international and constitutional levels of governance being mutually reinforcing and complementary (Elkins Zachary, Ginsburg Tom and Simmons Beth 2013: 65).

One thing is clear i.e. the repeated and unwavering exposition made by the international community that the right to health is a fundamental right in various human rights instruments discussed above, such 1948 *Universal Declaration of Human Rights*, 1948 *American Declaration of the Rights and Duties of Man*, 1979 ICESCR, United Nations (2000), Economic and Social Council, E/C.12/2000/4., para 1, various reports of the Special Rapporteurs's etc. all lend credence to the argument that the right to health is customary international law from which no derogation is permissible . Therefore if there are provisions in any of the trade law instruments that conflict with the right to health the same need to be denounced as void.

CHAPTER 3
TRIPS AGREEMENT AND THE RIGHT TO HEALTH

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1. Introduction

The 1995 WTO Agreement expanded the scope of coverage from goods under the *1947 General Agreement on Tariffs and Trade* to trade in IP, services, textiles, agriculture, sanitary and phytosanitary measures, remodelled dispute resolution mechanism etc. (WHO and WTO Secretariat 2002: 25, para 8). Of the many multilateral agreements under the WTO regime, the maximum concern was with TRIPS Agreement as the strong IP regime was expected to significantly impact the availability of medicines and therefore the right to access to medicines in the developing countries. Scholars and international organisations have always highlighted such concern. Joseph, Sarah (2011) notes that a natural outcome of monopoly rights is that prices from IP protected products are inflated (Joseph 2011: 214).

As noted in an Oxfam study, patents were introduced by Venetians at the end of the fifteen century to encourage the development of new inventions in water technology (Oxfam 2002: 208). In the hands of the absolutist monarchs in Europe the patent systems was corrupted into an arrangement designed to enrich the monarchy and its favourites at the expense of the society and in Britain as the system was so badly abused by the monarchy that the Parliament passed the legislation – *Statute of Monopolies* – which restricted the duration of patent protection and also required that the invention should be new and of benefit to the public (Oxfam 2002: 208).

Also, history tells us that certain inventions in the medicinal field are of such cardinal importance to the public that any restriction on its usage will be criminal for e.g. restrictions on the use of ether after the discovery of the its anaesthetic properties in the 1930's. It is noted that physicians resented any restrictions on its use (Garrison, Christopher 2006: para 4.10). In the 1990's the American medical fraternity had strong concerns when a medical method patent was granted to Samuel L. Pallin relating to a form of incision for use in cataract surgery and the patent holder attempted to enforce the patent (Garrison, Christopher (2006: para 4.10).

Sarah (2011) notes that prices will be artificially inflated for the patented 20 year term as the patent holders seek to maximise their returns. She gives the example of the anti HIV drug Atripla which costs US $ 1300 per month and that such expensive medicines will be affordable only in industrialised countries due to government benefits and that it will be impossible for people in the developing world to pay such prices (Joseph 2011: 217).

However, the advocates of a strong IP regime in the pharma industry suggest that research and development is extremely cost intensive ranging between USD 650-800 million in developed countries and Rs. 150-200 crores in India (Chandran, Sajeev, Roy, Archna and Jain, Lokesh 2005: 277). This encompasses the cost of failures etc. (E. Kettler, Hannah and Collins, Chris*:* 3). Granslandt Mattias, Maskus, Keither E and Wong, Elina V. 2001: 787) noted that the cost in 1999 for development of a new pharmaceutical drug is approximately 300 million or higher. However, once launched, most pharma products are easy to reproduce. A weak IPR regime is considered a disincentive for FDI and technology transfer. Where a strong domestic capacity exists and where such country does not have a strong IPR regime, pharmaceutical companies may refuse to bring their products into such market. For example, in a 1996 study only 45 out of the 434 pharmaceuticals in patent in UK were made available in India by Pfizer (E. Kettler, Hannah and Collins, Chris).

Scholars such as Correa Carlos have also recognized the use of patents in fostering innovation and technology transfer. He states that there is broad recognition of the role that IPRs can play in stimulating research and development in health sector, especially in the developed countries. Patents are considered important due to the high costs and the risks of R&D and that there is recognition that the level of protection may influence foreign investment, technology transfer and research (See Correa, Carlos 2000a: 2).

Sarah (2011) highlights that there are various other avenues to ensure R&D than patents. She also argues that certain national case studies have not revealed that patents have generated any substantial advancement of R&D and drug innovation by Italian drug companies post patent protection, though Italy started providing strong patent protection from 1978 (Sarah 2011: 233). Further, Pusceddu, Piergiuseppe

(2014) opine that the revenues from developing countries constitute only small portion of the total profit for drug companies (Pusceddu, Piergiuseppe 2014: 107).

There is no concrete evidence on the benefits from patents for developing countries as research for treatment of tropical diseases is neglected. Out of 1,223 new medicines in the market between 1975 and 1997 only 13 were for tropical disease and half of these resulted from veterinary research (Orbinski, James 2001: 233). Treatment of drug resistant variations of TB such as multi drug resistant TB (MDRTB) can be expensive which will deter majority of people in poor countries from treatment. This study of 2001 by MSF points out that of majority of the income generated from pharmaceutical sales is spent on marketing in viable markets and not on R&D (Orbinski, James 2001: 234).

However, writers such as Jayashree Watal notes that the TRIPS Agreement was not simply about maximizing the level of IP protection, but that it emerged from a negotiating process where the need for balance was very much noted (Watal, Jayashree 2001: 26). This view is countered by other writers such as Willem Pretorius who has highlighted that the developing countries were left with no option due to the enormous pressure that was exerted on them by the developed countries (Pretorius, Willem 2002: 188). He elaborates that the stick and carrot method was used to ensure acceptance of the developed country position on the TRIPS agreement, the stick being threat of trade sanctions if the developing countries did not comply and the carrot being favourable consideration such as aid, preferential trade benefits in future bilateral agreements, etc. (Pretorius, Willem 2002: 188).

Given this backdrop, the impact of international IPR regime on the realisation of health as a legal right of the individual citizen is the focus of study in this chapter. Towards this, a descriptive study of the TRIPS Agreement with reference to the right to health is done to identify the key provisions of the TRIPS Agreement which have bearing on the right to health. The various ministerial declaration of the WTO such as the 2001 Doha Ministerial Declaration, 2011 Geneva Ministerial Conference etc. is surveyed. Various decisions of the DSB pertaining to the TRIPS Agreement in the context of the right to health are also explored. Thereafter the chapter surveys the

work of various international bodies such as the WTO, WHO, ICTSD, UNCTAD, WIPO, UNDP etc. on the linkages between the right to health and WTO.

Such survey is important under Article 38(1) (a) and (d) of the Statute of the international Court of Justice.[23]

2. Arguments against a Strong Patent System in Pharmaceutical Sector

The implementation of the TRIPS Agreement has given pharmaceutical companies more rights than before and the developing nations are left with the challenge of addressing cure for disease that create health emergencies (Pusceddu, Piergiuseppe 2014: 104). Even among the developing countries, the prices may vary depending on various factors. For e.g. WHO (2014) notes that for antiretrovirals, people in China, Cuba, Ecuador, Thailand and Ukraine paid more than US$300 per patient per year for first line treatment in 2012 while in Brazil, Kazakhstan, the Russian Federation the same drug cost more than US$1000 per patient per year, as the latter countries were sourcing their medicines from originator companies where part or all the treatment regimen was patent protected (WHO 2014: 9).

Patents in the pharmaceutical sector can have significant impact not only on pricing but also further research in the sector. Patent thickets may result from pharma patents which impede further research as various genetic sequences, protein strains etc. all are being sought to be patented. For example, MedImmune's PCT Application WO2006098901 of September 21, 2006 claimed sequences from at least 29 influenza strains and in many cases entire gene sequences in the research connected to H5N1 influenza (Hammond Edward 2009: 11). Patent litigations are lengthy, expensive and are based on the slightest slice of rationality (Hammond Edward 2009: 11) and this prevents many researchers and institutions, generic manufactures from venturing into such research which in turn would negatively impact the availability of medicines. In order to expand the span of patent rights, patent attorneys for their corporate clients also do 'homology fishing' in which they make very broad patent claims such as claims on influenza virus sequence X and any influenza virus which has the sequence

[23] Article 38(1) (a) mentions international conventions, whether general or particular, establishing rules expressly recognised by contesting states, as source of international law. Further Article 38(1) (d) mentions judicial decisions, as subsidiary means for determination of rules of law.

95% or more the same as the sequence of the current claim (Hammond Edward 2009: 30-31).

Some studies note that stronger IPRs regime need not benefit developing countries. For example, a study funded by the funded by the Commission on Intellectual Property Rights, Innovation and Health (CIPIH) of the World Health Organization in 2005 states that IPRs promote research into drugs and therapies with large returns (Padmashree Gehl Sampath 2005: 53). The study noted the findings of a 2001 study which found that large firms in India perform R&D on global illnesses which may also be found in developing countries for e.g. diabetes (Padmashree Gehl Sampath 2005: 54). The study noted that it is unlikely that higher levels of IP protection in India will translate into higher incentives for firms to conduct R&D into health priorities of Indian or other developing countries (Padmashree Gehl Sampath 2005: 54).

A study published by the United Nations University notes that the existence of IPR protection in developing countries before the TRIPS Agreement does not provide any concrete empirical evidence on the impact of IPR protection on development either generally or for individual developing countries (Michalopoulos, Constantine 2001: 131). Also, the study points out that as a result of stronger IPR regime developing countries with limited inventive and innovative capabilities will become net importers and users of technology (Michalopoulos, Constantine 2001: 131). The 2001 study further noted that the expectation that increased IPR protection would enhance the effort from the pharmaceutical industry to engaging in developing drugs against disease which are developing country specific, has also not been realized (Michalopoulos, Constantine 2001: 135).

The WHO Secretariat had noted in 2003 in its report to the World Health Assembly that IPRs may have an adverse impact on innovation. This was in the context of biomedical research and the report noted that the current situation has gone too far in

promulgating a culture of ownership and that if it is allowed to continue will inevitably lead to inequalities in health care.[24]

A factor to note here is that product patents in the pharmaceutical industry is a recent phenomenon even among the developed countries. For e.g., Kumariah Balasubramaniam points out that France, Germany, Italy, Japan Sweden, Switzerland etc. which today have very strong pharmaceutical sector had resisted providing pharmaceutical patents until their industries had reached sufficient degree of development (Balasubramaniam, Kumariah 2002: 105). France introduced product patents in 1960, Germany in 1968, Japan in 1976, Switzerland in 1977, Italy and Sweden in 1978 (Pretorius, Willem 2002: 184). Also, during the first hundred years, the United States had also refused to have patent protection in place arguing that it was freely entitled to copy foreign works in furtherance of its social and economic development (Pretorius, Willem 2002: 184).

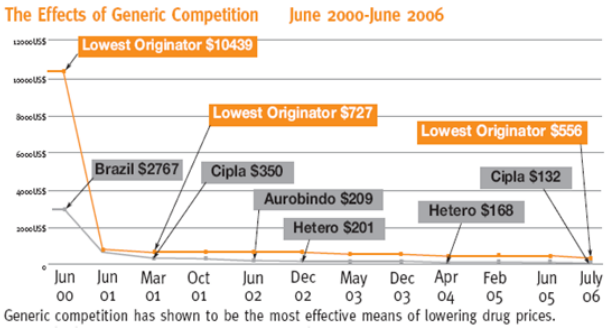
The need to ensure competition from generic manufacturers is clear from the data made available by MSF and which is hosted by the WIPO (Balasegaram, Manica 2014), which is as below:

[24] See *Intellectual Property Rights, Innovation and Public Health, Report by the WHO Secretariat*, Fifty-Sixth World Health Assembly, A56/17, May 12, 2003, para 20. The report noted as below:

> 20. Adverse effects on future innovation. In some circumstances, intellectual property rights might have a perverse effect on innovation. Much depends on the stage of product development at which protection is applied, and what, in different jurisdictions, is admissible under patent law as an invention. The recent report of WHO's Advisory Committee on Health Research notes that: "The current situation has gone too far in promulgating a culture of ownership, and if it is allowed to continue it will inevitably lead to further inequalities in health care". It further suggests that unless the "complex and chaotic situation" which currently prevails is addressed, protection of intellectual property could stifle the very innovation it is designed to stimulate. As a result "both the biomedical research community and industry will be severely disadvantaged in their efforts to translate the potential of genomics into improvements of global health." A prudent approach is needed to ensure that legitimate concerns do not give rise to "solutions" that have undesirable effects. For example, the exclusion from patentability of genes would act as a strong disincentive to the biotechnology industry, just at a time when significant numbers of new biotechnology-based pharmaceuticals are coming onto the market. The way in which current law on intellectual property rights and regulatory systems operate therefore need to be carefully examined before changes are sought.

Generic competition needed

Graph 1: *Sample of ARV triple-combination: stavudine (d4T) + lamivudine (3TC) + nevirapine (NVP). Lowest world prices per patient per year.*



Generic competition has shown to be the most effective means of lowering drug prices.

MSF Access Campaign

Further, an Oxfam study noted that the TRIPS Agreement will add to the financial burden of developing nations in terms of license fee payments and royalties linked to technology transfers and that in the case of the countries with balance of payments deficits, limited reserves etc. such as the sub-Saharan Africa the TRIPS Agreement will present a formidable barrier to technological development (Oxfam 2002: 211). The study says that the widely held assumption that stronger IP protection will promote foreign investment is not rooted in credible evidence and that foreign investors tend to downgrade the R&D activities of their affiliates in developing countries even where those countries offer string IP protection (Oxfam 2002: 212).

It is useful to note here that the 2015 WIPO study does not recommend imposing criminal sanctions against patent infringement, but rather surveys the topic. The study noted that if criminal process were to be applied against patent infringement, then the uncertainties about the scope of protection may deter potential competitors from even considering activities which are outside the scope of the patent (2015 WIPO: 6, para 14). The risk of over deterrence may be expensive for the society since fear of criminal sanctions, may hinder development in sectors such as public health which are of critical importance (2015 WIPO: 6, para 14).

Studies reveal that a strong patent regime causes the prices of the medicines to increase substantially (E. Kettler, Hannah and Collins, Chris). Carlos Correa shares this view when he notes that patents have a substantial effect on competition and on the prices of medicines (Correa, Carlos (2007a: 1).

It helps to note that developed countries are also susceptible to challenges caused by patent protection over lifesaving drugs. For example in October 2001 there was an anthrax scare in US when the patent holder for the drug Bayer was unwilling or unable to offer enough supplies to meet the demand. While the US government considered imposing compulsory licensing, it also received proposals from Indian manufacturers like Cipla to make the drug available in a shorter timescale and at cheaper prices. In the end the US government managed to procure the drug in adequate quantities from the patent holder Bayer (E. Kettler, Hannah and Collins, Chris). Certain studies bring out that the German company Bayer was forced to sell its anti-anthrax drug Cipro to both US and Canada at heavily discounted prices after both States threatened to issue compulsory licenses (Joseph 2011: 224).

Studies reveal that pharmaceutical companies engage in inequitable pricing methods as well. For e.g. a study of the prices of thirty most prescribed patented drugs in South Africa revealed that the pricing in South Africa was 98 percent more than the prices available within the European Union (Pretorius, Willem 2002: 189). Another example is Mongolia, a least developed country, where the prices were recorded at nine times that of Australia and New Zealand (Pretorius, Willem 2002: 189). From these and other examples, it is suggested that the pharma industry engages in a policy of charging what the market can bear. In poor countries, the pharma companies may pursue a high price, low volume strategy while in rich countries they may pursue a lower price, high volume strategy (Pretorius, Willem 2002: 189).

A study in the context of Zambia notes that the protection of patents offered by the TRIPS Agreement results in excessive prices for essential drugs and places such drugs beyond the reach of the majority in Zambia. The study also noted that excessive pricing of drugs is directly responsible for the premature, predictable and avoidable death of people living with HIV/AIDS. The study also noted that by limiting access to drugs the TRIPS Agreement has undermined the scientific gains and which would

have made AIDS a medically manageable disease (Mabika, Aulline H and London, Leslie 2007a: 12).

Another study highlighted that though least developed countries such as Malawi has time till 2016[25] to make its laws TRIPS compliant still there are obligations under the bilateral agreements which it may have entered into and also TRIPS compliance by other countries such as India will impact the availability of key generic pharmaceuticals in Malawi. Therefore according to the study though LDC's do not have to comply with TRIPS yet, they still are impacted by the TRIPS obligations (Mabika, Aulline H and London, Leslie 2007b: 5). The study further noted that patent protection through TRIPS while it is argued to promote and stimulate R&D, technology transfer and research, foreign investment etc., still these advantages are criticised as theoretical in many cases while in practice TRIPS application has resulted in higher drug prices and therefore restricted the access of the poor to medicines (Mabika, Aulline H and London, Leslie 2007b: 5).

Having set this background the provisions of the TRIPS Agreement are discussed below.

3. TRIPS Agreement

3.1 Provisions of the TRIPS Agreement

The TRIPS Agreement provides for stringent protection of IPRs which are geared towards protecting rights of an individual vis-a-vis the requirements for developing or undeveloped economies to have the benefits of the various inventions without having to pay huge royalties etc.. The strong international regime on IPR protection under TRIPS Agreement compels more uniform and minimum standards of protection, which may result in higher medicinal pricing etc. for developing and underdeveloped countries. While the supporters of a strong IPR regime argue that the stringent implementation of IPRs as envisaged in the TRIPS Agreement will enhance the right to health in one way by rewarding those investing in the research and development of new drugs and thereby foster fresh research and development of vital drugs, at the same time the strong IPR regime negatively affects the accessibility and affordability

[25] As per the decision of the TRIPS council in June 11,2013, this transition period for least developed countries has been extended till July 01, 2021

of the medicinal drugs especially for those in developing and least developed countries.

The TRIPS Agreement recognizes in its preamble that IPRs are private rights and also recognizes the public policy objectives of national systems such as technological and developmental objectives for the protection of IP. The TRIPS Agreement further recognizes in its preamble the special needs of the least developed country members in respect of maximum flexibility in the domestic implementation of laws and regulation in order to enable them to create a sound and viable technological base.

Article 27(1) of the TRIPS Agreement requires product patents as well as process patent to be granted. No discrimination as to the field of technology is permissible under this clause. Further, Art 27 (3)(b) of the TRIPS Agreement requires nations to provide protection for plant varieties through patents or effective *sui generis*[26] system or combination thereof. Some exceptions are provided in Article 27(2) and (3) to the blanket statements in 27(1).

Article 28 of the TRIPS Agreement details the scope of the rights to be granted to a patent owner. Article 28(1)(a) states that where the subject matter of a patent is a product, the patent owner shall have the right to prevent third parties not having the owner's consent from making, using, offering for sale, selling or importing that product for these purpose. Further Article 28(1) (b) says that where the subject matter of a patent is a process, the patent owner will have the right to prevent third parties not having the owner's consent from the act of using the process, and from the act of using, offering for sale, selling or importing at the least the product obtained directly by that process for these purposes.

Such stringent obligations creates difficulties for the developing countries and least developed countries from making available to their population cheap access to the medicines by enabling local production without the patent holder's consent. For example, in South Africa such patent law obligations created difficulties for the government in providing affordable medicinal care to people suffering from AIDS. In

[26] Sui generis means a term meaning a specialized regime of intellectual property rights, separate from copyright, patents and other chapters of intellectual property rights. See Correa Carlos 2000a: xv.

November 1997, the South African Government had enacted a law enabling it to undertake parallel importing along with other measures in the interest of public health. The move was intended to enhance the government's ability to provide the country's 4.5 million HIV/AIDS victims with access to affordable medicines. The law was challenged by 39 pharmaceutical companies alleging breach of WTO principles. The pharmaceutical companies withdrew their action in face of an international campaign by civil society (Oxfam 2002: 216).

UNAIDS estimated that 33.3 million people were living with HIV at the end of 2009 (UNAIDS 2010: 23) of whom about 4.9 million are in Asia (UNAIDS 2010: 34). Also, the report noted that in 2009 about 2.6 million people were newly infected with HIV (UNAIDS 2010: 16). The report further noted that 10 million people with HIV and who are eligible for treatment is still in need (UNAIDS 2010: 8) and that about 1.9 million people died of HIV related reasons in 2009 (UNAIDS 2010: 19). The vast majority of people living with HIV did not have access to AIDS medication. The number of people in need of antiretroviral therapy at the end of 2009 increased from 10.1 million to 15 million as per WHO estimates.[27]

Outright purchase by governments of the medicines developed by the pharmaceutical companies might be impossible in situations where the government is reeling under financial crunches as is the case in most of the developing countries. It is here that the local production of the costly new medicines or alternate methods for production of these costly medicines becomes important. Also, local working of the patent grant is crucial for the developing countries as it brings in new technical know- how.

Measures such as local production, compulsory licensing, parallel importing and clauses addressing public interest concerns can make available lifesaving drugs at affordable prices to the public. 'Compulsory licensing' is a measure by which governments can issue compulsory licenses to allow a competitor of the patent holder to produce the products or to use the process under license in case of events like lack of sufficient availability of drugs and medicines in the market. It is noted by some that compulsory licenses for patented inventions has been an established practice in most

[27] WHO 2010: 1

of the countries and that even developed countries like the United States have such provisions in place (M.D. Nair 2004: 422). Nair notes that compulsory licenses are issued when patents result in anti-competitive practices or when the patent holder refuses to work the patent to beat competition in the market place (M.D. Nair 2004: 417).

However, the procedures associated with compulsory licensing may well make compulsory licensing impossible. For example in July 19, 2007 Rwanda intimated the WTO of its intent to import compulsory licensed pharmaceuticals for health reasons and Canada in September 2007 became the first country to issue compulsory license and export TriAvir a combination AIDS drug to Rwanda, by Apotex a Canadian generic drug manufacturer (See Thapa, Rojina (2011: 473). However, the process associated with such export has been so complex that the Canadian Company that exported such drug has publicly stated that it would not be willing to do so again because of the procedure which was very cumbersome (See Thapa, Rojina (2011: 473). In 2008 when Nepal applied for import license for generic versions of two anticancer drugs, Indian manufacturer Natco Pharma responded and sought compulsory license to the same to produce 45000 doses and to pay the patent holders five percent royalty. The proceedings were delayed when one of the patent holders was permitted to lobby for right to attend full hearing (Thapa, Rojina (2011: 473).

Parallel importing' is another measure, where a product sold by the patent owner more cheaply in one country is imported into another without the patent holder's consent. By such measures or threat of such measures, the price of the patented product is sure to come down.

3.2. Flexibilities for Protection of Public Health under the TRIPS Agreement

a) The *1994 General Agreement on Tariffs and Trade* (hereinafter "1994 GATT") does have certain provisions which provides for measures to protect human life or health. Article XX (b) of the 1994 GATT does provide for human welfare.[28] It permits

[28] 1947 *General Agreement On Tariffs And Trade* - Article XX-General Exceptions
Subject to the requirement that such measures are not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail, or a disguised restriction on international trade, nothing in this Agreement hall be construed to prevent the adoption or enforcement by any contracting party of measures:

the contracting parties to adopt measures necessary to protect human, animal or plant life or health to the extent such measures are not arbitrary or unjustifiable discrimination between countries or a disguised restriction on trade. Similar exception was stated in Article XX of the 1947 General Agreement on Tariffs and Trade which provided that nothing in the Agreement shall be construed to prevent the adoption or enforcement by any contracting party of measures necessary to protect human, animal or plant life or health provided, such measures are not applied in a manner constituting an arbitrary or unjustifiable discrimination between countries where the same conditions prevail, or a disguised restriction on international trade.

b) Article 7 of the TRIPS Agreement mentions that the protection and enforcement of IPRs should contribute to the promotion of technological innovation and transfer and dissemination of technology. It further provides that the protection and enforcement of IPRs should be to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare and to a balance of rights and obligations.

c) Further, article 8(1) of the TRIPS Agreement states that "*Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition and to promote the public interest in sectors vital to their socio- economic and technological development…*" It also notes that appropriate provisions consistent with the provisions of the TRIPS Agreement may be needed to prevent the abuse of IPRs by rights holders and to prevent practices which unreasonably restrain trade or adversely affect the international transfer of technology (TRIPS Agreement, Article 8(2)).

d) Article 27(2) is to the effect that members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect *odre public* or morality, including to protect human, animal or plant life or health. Further, under 27(3) members may exclude from patentability diagnostic, therapeutic and surgical methods necessary for the treatment

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(b) necessary to protect human, animal or plant life or health;

of humans and animals. Similarly plants and animals other than microorganism, and biological processes for the production of plants and animals other than non-biological and micro biological processes can be excluded from patenting. The reason for such exclusion is to ensure that patents do not impede doctors from fulfilling their duties towards patients, which duty is of paramount importance (E., Asif 2013: 243). E., Asif (2013) is his article on implementation of exclusions on medical, diagnostic and therapeutic methods under TRIPS Agreement, note that there is no uniform global position on such patentability exclusion if one examines the domestic law provisions of various countries. He note that while developing countries have sought to take advantage of this flexibility, some of the developed nations have not provided patentability exclusion to medical, diagnostic and therapeutic methods (E., Asif 2013: 244). He further note that there is public policy requirement that to ensure the best possible treatment of health, physicians should always be free in the choice of treatment(E., Asif 2013: 243).

e) Article 30 of the TRIPS Agreement provides that members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exception do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interest of the patent owner, taking account of the legitimate interest of third parties.

f) Article 31 provides for other use of the subject matter of a patent without the authorization of the patent holder, including use by the government or third parties authorized by the government subject to the following conditions.

i. The authorization for the use is to be considered on individual merits (TRIPS Agreement, Article 31(a)).
ii. The proposed user should have made efforts to obtain authorization from the patent holder on reasonable commercial terms and such efforts are not successful within a reasonable period of time. This requirement can be waived in the case of national emergency or other circumstances of extreme urgency or in the cases of public non-commercial use. However, in such situations of national emergency or other circumstances of extreme urgency the right holder is to be notified as soon as reasonably practical ((TRIPS Agreement, Article 31(b)).

iii. The scope and duration of such use shall be limited to the purpose for which it was authorized (TRIPS Agreement, Article 31(c)).

iv. Such use shall be nonexclusive[29] and non-assignable ((TRIPS Agreement, Article 31(e)).

v. Any such authorization shall be for predominantly for the supply of the domestic market of the member authorizing such use (TRIPS Agreement, Article 31(f)).

vi. Such authorization is to be terminated when the circumstances which lead to such authorization cease to exist or are unlikely to occur (TRIPS Agreement, Article 31(g)).

vii. The right holder is to be paid adequate remuneration in the circumstances of each case and after taking into account the economic value of the authorization (TRIPS Agreement, Article 31(h)).

viii. The obligation to make reasonable efforts to obtain the license from the right holder on reasonable commercial terms and the obligation to restrict such use predominantly for the domestic market shall not apply where the use is permitted to remedy a situation determined in a judicial or administrative process to be anti-competitive (TRIPS Agreement, Article 31(k)).

The relevant provisions of the TRIPS Agreement and GATT in the context of this study can be summarised as below:

Table 2: Relevant Provisions of the TRIPS Agreement and GATT

Provision	**Content**
Preamble	• IPR's are private rights and also recognize the public policy objectives of national systems such as technological and developmental objectives for the protection of IP. • Recognizes the special needs of the least developed country members in respect of maximum flexibility in the domestic implementation of laws and regulation in order to enable them to create a sound

[29] See article 31(d) of the TRIPS Agreement

	and viable technological base
Article 7	• the protection and enforcement of IPRs should contribute to the promotion of technological innovation and transfer and dissemination of technology. • the protection and enforcement of IPRs should be to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare and to a balance of rights and obligations
Article 8(1) of TRIPS	• Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition and to promote the public interest in sectors vital to their socio- economic and technological development…
Article 8(2) of TRIPS	• Appropriate provisions consistent with the provisions of the TRIPS Agreement may be needed to prevent the abuse of IPRs by rights holders and to prevent practices which unreasonably restrain trade or adversely affect the international transfer of technology
Article 27(1)	• Product patents as well as process patent to be granted. • No discrimination as to the field of technology is permissible under this clause
Article 27(2)	• Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect *odre public* or morality, including to protect human, animal or plant life or health
Article 27(3)	• Members may exclude from patentability diagnostic, therapeutic and surgical methods necessary for the

	treatment of humans and animals. Similarly plants and animals other than microorganism, and biological processes for the production of plants and animals other than non-biological and micro biological processes can be excluded from patenting[30].
Art 27 (3)(b)	• Nations to provide protection for plant varieties through patents or effective *sui generis* system or combination thereof. • Some exceptions are provided in Article 27(2) and (3) to the blanket statements in 27(1)
Article 28	• Covers the scope of the rights to be granted to a patent owner.
Article 28(1)(a)	• Where the subject matter of a patent is a product, the patent owner shall have the right to prevent third parties not having the owner's consent from making, using, offering for sale, selling or importing that product for these purpose
Article 28(1) (b)	• Where the subject matter of a patent is a process, the patent owner will have the right to prevent third parties not having the owner's consent from the act of using the process, and from the act of using, offering for sale, selling or importing at the least the product obtained directly by that process for these purposes
Article 30 of TRIPS	• Provides that members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exception do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interest of the patent owner, taking account

[30] Carlos Correa (2000b) opines that if developing nations as a whole were to take the stance to prohibit or suspend the patentability of certain pharmaceutical substances on the grounds of *ordre public*, then this could give rise to 'state practice' which WTO panels will have to take into account. Such position may compel a temporary expansion of the *ordre public* exception beyond its traditional interpretation (See Correa, Carlos M. 2000b: 13).

	of the legitimate interest of third parties. Carlos Correa suggests that the following can be considered to be legitimate acts within the scope of article 30 (Correa, Carlos M. (2007b: 303). a) Import of the product that is put in the market elsewhere by the patentee with his consent, or by a person authorized by the patentee b) Private acts on a non-commercial scale or for non-commercial purpose c) Use of the invention for research and experimentation and for teaching purposes d) Seeking regulatory approval for marketing of the product before expiry of the patent e) Preparation of medicines for individual cases according to prescription f) Use of the invention by a third party who started or undertook bonfire proprietary acts before the application for the patent (or its publication)
Article 31 of TRIPS	• For other use of the subject matter of a patent without the authorization of the patent holder, including use by the government or third parties authorized by the government subject to the following conditions. i. The authorization for the use is to be considered on individual merits (TRIPS Agreement, Article 31(a)). ii. The proposed user should have made efforts to obtain authorization from the patent holder on reasonable commercial terms and such efforts are not successful within a reasonable period of time. This requirement can be waived in the case of national emergency or other circumstances of extreme urgency or in the cases of public non-

	commercial use. However, in such situations of national emergency or other circumstances of extreme urgency the right holder is to be notified as soon as reasonably practical ((TRIPS Agreement, Article 31(b)). iii. The scope and duration of such use shall be limited to the purpose for which it was authorized (TRIPS Agreement, Article 31(c)). iv. Such use shall be nonexclusive (See article 31(d) of the TRIPS Agreement) and non-assignable ((TRIPS Agreement, Article 31(e)). v. Any such authorization shall be for predominantly for the supply of the domestic market of the member authorizing such use (TRIPS Agreement, Article 31(f)). vi. Such authorization is to be terminated when the circumstances which lead to such authorization cease to exist or are unlikely to occur (TRIPS Agreement, Article 31(g)). vii. The right holder is to be paid adequate remuneration in the circumstances of each case and after taking into account the economic value of the authorization (TRIPS Agreement, Article 31(h)). viii. The obligation to make reasonable efforts to obtain the license from the right holder on reasonable commercial terms and the obligation to restrict such use predominantly for the domestic market shall not apply where the use is permitted to remedy a situation determined in a judicial or administrative process to be anti-competitive (TRIPS Agreement, Article 31(k)).
Article XX (b) of the	• Provides for human welfare. Contracting parties to

1994 GATT	adopt measures necessary to protect human, animal or plant life or health to the extent such measures are not arbitrary or unjustifiable discrimination between countries or a disguised restriction on trade
Article XX of the 1947 GATT	• Provided that nothing in the Agreement shall be construed to prevent the adoption or enforcement by any contracting party of measures necessary to protect human, animal or plant life or health provided, such measures are not applied in a manner constituting an arbitrary or unjustifiable discrimination between countries where the same conditions prevail, or a disguised restriction on international trade.

While through the content of the TRIPS Agreement, the WTO regime is capable of dictating the provisions of the health policy and health law of nations in a manner unprecedented, the question is whether the flexibilities provided under the TRIPS Agreement is sufficient to meet the public health requirements. This is because the TRIPS Agreement is primarily oriented towards promotion of trade interests.

Carlos M. Correa (Correa, Carlos M 2000b: 89-121)) observes that, "the exception under article XX (b) of the GATT, as interpreted has in practice left States with little room to design and implement public health measures." On the TRIPS Agreement specifically, Carlos Correa observes that article 8.2 of the Agreement "incorporates the "necessity" test, but seems to subject it to an additional "compatibility" test (not present in article XX of the GATT) that, if broadly interpreted, may nullify a possible exception based on public health or other grounds. There are several instances when the developed nations exert pressure on the developing and least developed nations not to use the flexibilities made available under the TRIPS Agreement. All these adversely affect the enabling of the right to health. It is also pointed out by some nongovernmental organizations like *Treatment Action Campaign* in South Africa that the scope of TRIPS is sufficiently complex to allow pharmaceutical companies to

pursue time consuming, costly legal action with the goal of delaying the implementation of alternatives (E. Kettler, Hannah and Chris Collins: 38).

In his report to the WHO to enable developing nations make policy decisions with regard to the options they have before them in the context of TRIPS compliance, Carlos Correa looks at whether an exception to patentability of medicines may be justified under the general GATT where article XX (b) permits exceptions necessary to protect public health. However, he opines that while Article XX(b) recognizes the importance of sovereign nations to be able to promote domestic health interests even of contrary to their general obligations under the WTO Agreement, till the date of the report Article XX(b) has be interpreted and applied in a narrow manner under WTO case law and that it is doubtful whether GATT Article XX(b) would apply in the TRIPS context (Correa, Carlos M 2000b: 14).

The situation of high medicinal prices arising from stringent patent regime cannot be agreed to be left without regulation as alternatives such as drugs donations/price reductions etc. from pharma companies leave countries dependent on charity for ensuring public health. Sometimes drugs donations or price reductions from pharma companies comes attached with conditions that are untenable. For example, the pharma company Abbot offered its reduced price AIDS drugs to South Africa provided South Africa does not import any generic medicines (E. Kettler, Hannah and Chris Collins: 44).

A 2010 EU study concludes that the opportunity offered by this influenza pandemic should be used to increase the availability of vaccine, drugs and science, which the study refers to as global public goods and that there should be research, transfer of technology and increased capacity building for developing countries (European Union 2010: 75) . The study:

a) recommended the need for a balance between political and economic concerns of individual states or pharmaceutical companies with ‘global public health solidarity movement’ which results in ‘sharing of information, viruses, science and technologies as international public goods’ for the benefit of all (European Union 2010: 70).

b) recognized the global scene of limited and unequal access to drugs and vaccine for developing countries and the need for solutions.
c) noted that by September 2009, countries such as Australia, Brazil, France, Italy, New Zealand, Norway, Switzerland, United Kingdom and United States had given away 300 million doses of influenza A(H1N1) vaccine to the WHO for distribution among developing countries (European Union 2010: 70).

The second exception to Article 27(1) is public order or *ordre public* as stated in Article 27(2). Carlos Correa opines that if developing nations as a whole were to take the stance to prohibit or suspend the patentability of certain pharmaceutical substances on the grounds of *ordre public*, then this could give rise to 'state practice' which WTO panels will have to take into account. Such position may compel a temporary expansion of the *ordre public* exception beyond its traditional interpretation (See Correa, Carlos M. 2000b: 13).

With regard to Article 30, Carlos Correa suggests that the following can be considered to be legitimate acts within the scope of article 30 (Correa, Carlos M. 2007b: 303).

a) Import of the product that is put in the market elsewhere by the patentee with his consent, or by a person authorized by the patentee
b) Private acts on a non-commercial scale or for non-commercial purpose
c) Use of the invention for research and experimentation and for teaching purposes
d) Seeking regulatory approval for marketing of the product before expiry of the patent
e) Preparation of medicines for individual cases according to prescription
f) Use of the invention by a third party who started or undertook bonafide proprietary acts before the application for the patent (or its publication)

3.3. Amendment to the TRIPS agreement adopted on December 08, 2005

The Amendment to the TRIPS agreement adopted on December 08, 2005 provided for exports of the medicines to the least developed countries which do not have

adequate manufacturing facilities. Such compulsory licenses would have several conditions attached to it. The same are[31]:

(i) only the amount necessary to meet the needs of the eligible importing Member(s) may be manufactured under the licence and the entirety of this production shall be exported to the Member(s) which has notified its needs to the Council for TRIPS;

(ii) products produced under the licence shall be clearly identified as being produced under the system through specific labelling or marking. Suppliers should distinguish such products through special packaging and/or special colouring/shaping of the products themselves, provided that such distinction is feasible and does not have a significant impact on price; and

(iii) before shipment begins, the licensee shall post on a website the following information:

— the quantities being supplied to each destination as referred to in indent (i) above; and

— the distinguishing features of the product(s) referred to in indent (ii) above;

(c) the exporting Member shall notify the Council for TRIPS of the grant of the licence, including the conditions attached to it. The information provided shall include the name and address of the licensee, the product(s) for which the licence has been granted, the quantity(ies) for which it has been granted, the country(ies) to which the product(s) is (are) to be supplied and the duration of the licence. The notification shall also indicate the address of the website referred to in subparagraph (b)(iii) above.

4. Ministerial Declarations

The Ministerial Declarations are the declarations made by the Ministerial Conferences of the WTO. As detailed in Article IV (1) of the Marrakesh Agreement, the Ministerial Conference is composed of representatives of all the Members which meet

[31] See clause 2 (b) and (c) of the Annex to the TRIPS Agreement, Amendment of the TRIPS Agreement, Decision of 6 December 2005, WT/L/641, 8 December 2005

once in very two years and the Ministerial Conference carries out the functions of the WTO. Article IV (1) further states that the Ministerial Conference has the authority to take decisions on all matters under any of the Multilateral Trade Agreements, if so requested by a member and in accordance with the specific requirements for decision making as provided in the Marrakesh Agreement and the Multilateral Trade Agreement. The Ministerial Declarations which has majorly mentions of the right to health majorly are discussed below.

4.1. 2001 Doha Ministerial Declaration

The conflict between the TRIPS Agreement and the public health concerns of the developing countries were recognized by the *2001 Declaration on the TRIPS Agreement and Public Health* adopted at the Doha Ministerial Conference (WT/MIN(01)/DEC/2), as well as many of the subsequent ministerial declarations. This is important as Article IX (2) of the Marrakesh Agreement states that the Ministerial Conference and the General Council shall have the exclusive authority to adopt interpretations of the Marrakesh Agreement and of the Multilateral Trade Agreements. In the case of a Multilateral Trade Agreement in Annex1 (the TRIPS Agreement is Annex 1C), the Ministerial Conference exercises the authority based on the recommendation by the Council overseeing the functioning of the Agreement (the Council for TRIPS in the context of the TRIPS Agreement). Such decision to adopt an interpretation is to be taken by a three-fourth majority of the members.

The Doha Declaration (WT/MIN(01)/DEC/2) while recognizing the importance of IP protection also noted that such protection shall have impact on medicinal prices. The Doha Declaration (WT/MIN(01)/DEC/2) stated that the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health. The declaration while reiterating its commitment to the TRIPS Agreement affirmed that the TRIPS Agreement can be and should be interpreted in a manner supportive of the WTO member's right to protect public health and to promote access to medicines to all. The declaration reaffirmed the right of the WTO members to use to the full the flexibilities provided under the TRIPS agreement. The flexibilities under the TRIPS Agreement were identified as below:

> In applying the customary rules of interpretation of public international law, each provision of the TRIPS Agreement shall be read in the light of the object

and purpose of the Agreement as expressed, in particular, in its objectives and principles.

Each Member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted.

Each Member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency.

effect of the provisions in the TRIPS Agreement that are relevant to the exhaustion of intellectual property rights is to leave each Member free to establish its own regime for such exhaustion without challenge, subject to the MFN and national treatment provisions of Articles 3 and 4

A discussion on the various types of exhaustion namely international, national and regional exhaustion is done in the glossary section of this thesis. India recognizes 'national exhaustion' vide section 30 of the 1999 Trademarks Act.

The Doha Declaration (WT/MIN(01)/DEC/2) further noted that the least developed country members will not be obliged with respect to pharmaceutical products to implement or apply Sections 5 and 7 of Part II of the TRIPS Agreement or to enforce the rights provided under these sections till January 01, 2016. Thereafter, as per the decision of the TRIPS council in June 11, 2013, this transition period has been extended till July 01, 2021 (WTO 2014: 194). This exception is without prejudice to the rights of least developed nations to seek other extensions of the transition period. This deadline is now further extended till January 01, 2033 in the WTO Council for TRIPS decision of November 06, 2015 (WTO Document IP/C/73 of 6 November 2015).

However, with regard to the declaration certain studies note that 'declaration' has no specific legal status in the framework of WTO law, but that given the content and the mode of approval the same can be argued as an authoritative interpretation (Mabika, Aulline H and London, Leslie 2007: 8).

4.2. 2003 Cancun Ministerial Declaration

The Cancun Ministerial declaration of the WTO in 2003 reaffirmed the commitment of the WTO members to the Doha Declaration (WT/MIN(01)/DEC/2).[32] Article 31(f) of the TRIPS Agreement says that production under compulsory licensing must be predominantly for the domestic market. The concern was that this could limit the ability of countries that cannot make pharmaceutical products from importing cheaper generics from countries where pharmaceuticals are patented. As per the Cancun Ministerial declaration, also called the 2003 waiver, the permanent amendment will allow any member country to export pharmaceutical products made under a compulsory license for this purpose. They may need to change their own laws in order to do so.[33]

4.3. 2005 Hong Kong Ministerial Declaration

While the focus in this Ministerial Declaration was on agriculture, it also affirmed the commitment under the Doha Round. The Ministerial Declaration reaffirmed the importance of the General Council Decision of 30 August 2003 on the Implementation of Para 6 of the Doha Declaration on TRIPS Agreement and Public Health (WT/MIN(01)/DEC/2) and for an amendment to the TRIPS Agreement. The Ministerial Declaration welcomed the work in the Council for TRIPS and the Decision of the General Council of 06 December 2015 for amendment to the TRIPS Agreement (See Paragraph 40 of *Doha Work Programme*, WTO Document WT/MIN(05)/DEC of 22 December 2005).

4.4. 2011 Geneva Ministerial Conference

In this Conference there was no single Ministerial Declaration that was adopted, but there was declarations adopted by various groups of Ministers as common ground could not be reached among all. In the Chairman's Concluding Statement (See WTO Document WT/MIN (11)/11 of 17 December 2011: 2), it was noted that the Ministers reaffirmed the positive link between trade and development and that the Ministers have taken decision for extension of the LDC transition period under Article 66.1 of the TRIPS Agreement. In the Chairman's Concluding Statement (See WTO

[32] See paragraph 6 of the Cancun Ministerial Declaration adopted on Sep 14, 2003, WT/MIN(03)/20
[33] See paragraph 6 of the Cancun Ministerial Declaration adopted on 23 September 2003, WT/MIN(03)/20 [Online: https://www.wto.org/english/tratop_e/trips_e/wtl641_e.htm] Accessed 20 April 2015

Document WT/MIN (11)/11 of 17 December 2011: 2), it was also noted that ministers reaffirmed the intergrality of special and differential treatment provisions and to make them more precise, effective and operational. There was no specific focus on health that was made in such Chairman's Concluding Statement. However, the statement noted that inspite of full and intensified efforts to conclude the Doha Development Agenda, the negotiations are at impasse (See WTO Document WT/MIN (11)/11 of 17 December 2011: 3).

5. DSB Decisions

The DSB has made decisions which are important with reference to TRIPS and the right to health. For example, the *Canada – Patent Protection of Pharmaceutical Products* (WT/DS114/R) is a significant decision for the developing countries, as the case discussed the lawfulness of the act of preparing a generic version[34] of a patented drug by a competitor to the patent holder while the patent is in force, so that the competitor can market the generic drug as soon as the patent on the original drug expires. Following is a brief survey of some of such important decisions.

5.1. 1996 Portugal - Patent Protection

In *Portugal - Patent Protection under the Industrial Property Act* (WT/DS37/2 of 8 October 1996), in May 1996, United States raised request for consultation with Portugal with regard to the patent term provided under the Portuguese Industrial Property Act. United States submitted that the term provided by the Portuguese Industrial Property Act was inconsistent with the TRIPS requirements that the patent be provided for a term of not less than twenty years. Both countries entered into consultations and the matter was settled by mutual consent when Portugal issued Decree Law 141/96 confirming that all patents that were in force on 1 January 1996, and all patents granted after this date based on applications that were pending on 1 January 1996, will receive a term of protection that lasts either 15 years from the date of grant of the patent or 20 years from the effective filing date of the patent, whichever term is longer.

[34] Generic medicines are off-patent drugs, for which patent has run out, or non-patented products for which patents were never taken. Therefore the drug may be manufactured and sold by many companies as a result of which the price competition is very severe resulting in lower prices. (See United Nations 1996: 328)

5.2. 1997 India – Patent Protection

In *India – Patent Protection for Pharmaceutical and Agricultural Chemical Products* (WT/DS50/1 of 5 September 1997), in July 1996, the United States sought consultations with India regarding the absence in India of either patent protection for pharmaceutical and agricultural chemical products or formal systems that permit the filing of patent applications for pharmaceutical and agricultural chemical products and that provide exclusive marketing rights in such products (WT/DS50/1 of 5 September 1997). The EC and member states also made third party submissions that, India did not provide for the mailbox mechanism and the mechanism for the granting of exclusive marketing rights as foreseen under Articles 70.8[35] and 70.9[36] of the TRIPS Agreement and was therefore not living up to its obligations under the WTO Agreement. Article 70.8 (a) deals with the requirement to make available a means to file patent applications from the date of entry into force of the WTO even where such matters are under the transitional period while Article 70.8 (b) deals with the criteria for patentability to be made applicable to these applications. Article 70.8 (c) states that patents protection is to be accorded for the remainder of the term once the patent is granted. Article 70.9 deals with the details of the exclusive marketing rights that are to be provided.

The facts of the dispute included that, India had promulgated the Patents (Amendment) Ordinance 1994 to meet the obligations under Article 70.8 and 70.9 of the TRIPS Agreement. The Ordinance provided for pharmaceutical patents and allowed for filing of patent applications of such substances and processing of such applications by the

[35] Article 70.8 states: Where a Member does not make available as of the date of entry into force of the WTO Agreement patent protection for pharmaceutical and agricultural chemical products commensurate with its obligations under Article 27, that Member shall:

a) Notwithstanding the provisions of Part VI, provide as from the date of entry into force of the WTO Agreement a means by which application for patents for such inventions can be filed;
b) Apply to these applications, as of the date of application of this Agreement, the criteria for patentability as laid down in this Agreement as if those criteria were being applied on the date of filing in that Member or, where priority is available and claimed, the priority by the date of the application; and
c) Provide patent protection in accordance with this Agreement as from the grant of the patent and for the remainder of the patent term, counted from the filing date in accordance with Article 33of this Agreement, for those of these applications that meet the criteria for protection referred to in subparagraph (b).

[36] Article 70.9 states: Where a product is the subject of a patent application in amber in accordance with paragraph 8(a), exclusive marketing rights shall be granted, notwithstanding the provisions of Part VI, for a period of five years after obtaining marketing approval in that Member or until a product patent is granted or rejected in that Member, whichever period is shorter, provided that, subsequent to the entry into force of the WTO Agreement, a patent application has been filed and a patent granted for that product in another Member and marketing approval obtained in such Member.

Patent Office. The Ordinance also provided for exclusive marketing rights to be granted with respect to the products that were the subject matter of such applications. Under the Indian law, the validity of such ordinance expires in six weeks after the reassembly of the Parliament. The Patents (Amendment) Ordinance 1994 lapsed on March 26, 1995. The Patents (Amendment) Bill 1995 which had been introduced into the Parliament to implement the contents of the Ordinance on a permanent basis lapsed as the Parliament was dissolved on May 1996. Thereafter no legislative measures were adopted to formalise the receipt of applications and grant of exclusive marketing rights, commonly called mailbox application. This was the ground for the dispute raised by the United States. The United States made the following claims[37]:

(a) That India had failed to implement the obligation under Article 70.8 to establish a mechanism that preserves the novelty of applications for pharmaceutical and agricultural chemical product patents during the TRIPS transition period, regardless of when those applications are filed during that period.

(b) That Article 70.8 of the TRIPS Agreement requires India to ensure that persons who filed or would have filed "mailbox" applications had the "mailbox" been in place on time and maintained can file such applications and receive the filing date they would have received.

(c) That, if the Panel finds that India has a valid mailbox system[38] in place, that India has failed to comply with its transparency obligations under Article 63 of the TRIPS Agreement.

(d) That the obligation to provide for EMR's arose on January 01, 1995 and that since India had failed to provide for EMR's through legislation it was not in compliance with the TRIPS Agreement.

(e) That India has failed to implement the obligation in Article 70.9 that marketing rights be granted so that competitors of the owner of such right will not be permitted on the market absent the owner's consent.

The United States requested the Panel to recommend India to bring its measures inconformity with the TRIPS Agreement and that India should implement its

[37] WT/DS50/R 5 September 1997: 4-5

[38]The term "mailbox system" is used as shorthand for provisions to be put in place which allow for the filing of patent applications for pharmaceutical and agricultural chemical products as required by Article 70.8.

obligations under Article 70.8 and 70.9 in the way Pakistan implemented these obligations.

India disputed the submissions of the United States and stated that section 6 of the 1970 *Patents Act* in India provided for receipt of the applications and that it did not specify that the application should be for a patentable matter (WT/DS50/R of 5 September 1997, para 5.2). India also specified that these patent applications in the pharmaceutical sector were not being forward to the Controller General of Patents, Trademarks and Designs and therefore there was no rejection of these patent applications in the pharmaceutical sector (WT/DS50/R of 5 September 1997, para 5.2). India highlighted that under Article 1 and 70 of the TRIPS Agreement both legislative and administrative measures were available to India to become TRIPS compliant and therefore it was incorrect to maintain that India should provide for the mailbox mechanism under law (See WT/DS50/R of 5 September 1997, para 5.2). India maintained that the administrative mechanism that it had provided was sufficient and that the number of filings made by the companies showed that the companies did not face difficulties in filing patent applications in the pharmaceutical sector (See WT/DS50/R of 5 September 1997, para 5.2).

The United States countered the submissions made by India and stated that the very fact that India promulgated the Patents (Amendment) Ordinance 1994 made it clear that legislative changes were required and that the Ordinance would not have been issued unless the government deemed it necessary to take action under Article 123 of the Indian Constitution which provided for the Ordinance route (See WT/DS50/R 5 of September 1997, para 5.3). The United States also submitted that Indian law did not permit the Patent Office to treat one set of applications differently and that once that patent applications are filed it must be forwarded to the patent examiners for examination. The United States further submitted that India's informal mechanism through administrative instructions was untenable under Indian law that in a review before the court of law in India, the court could hold that this informal mechanism could be held *ultravires* and that such applications filed could not result in a valid patent (WT/DS50/R 5 of September 1997, para 5.3). The United States also submitted that this informal route was not publicly known and that it failed the transparency obligations under Article 70.8 of the TRIPS Agreement (WT/DS50/R 5 September 1997, para 5.3).

It also submitted that a mailbox system unknown to the world as useless (WT/DS50/R 5 of September 1997, para 5.3).

The European Communities and their Member States made third party submission in the matter and stated that while India made bonafide attempt to be compliant with the WTO requirements for a mail box system through the Patents (Amendment) Ordinance 1994, India was not presently compliant with the WTO requirements as the Ordinance had lapsed and was in breach of Articles 70.8 and 70.9 of the TRIPS Agreement (WT/DS50/R of 5 September 1997, para 5.3).

India stated in its response that no other developing country had notified a system for the grant of EMR's under its domestic law and that this indicated that Article 70.9 was not understood by other developing countries as well as casting an obligation to change their domestic law before the entry into force of the TRIPS Agreement (WT/DS50/R 5 of September 1997, para 7.17)

Panel Decision

The Panel concluded that India had failed to comply with its obligations under Article 70.8(a) because India failed to establish a mechanism that sufficiently persevered novelty and priority in respect of product patents in pharmaceuticals and agricultural chemicals sector. The Panel further concluded that India had not complied with its obligations under Article 70.9 of the TRIPS agreement as it had failed to establish a system for the grant of exclusive marketing rights (WT/DS50/R 5 September 1997, para 9.1). The Panel recommended the DSB to request India to bring its transitional regime in conformity with the obligations under the TRIPS agreement and take into account the interest of those persons who had filed patent applications under the Patents Amendment Ordinance 1994 and thereafter (WT/DS50/R 5 September 1997, para 9.2).

AB Report

India contested the decision of the DSB panel before the AB. India asserted that it has established through administrative instructions a means by which applications for patents for pharmaceutical and agricultural products can be filed and filing dates assigned to them (*India - Patent Protection for Pharmaceutical and Agricultural Chemical Products*, WT/DS50/AB/R of 19 December 1997, para 4). With regard to the

second requirement that patent applications and patents based on them not be rejected or invalidated in future, India maintained that the same was a creation of the panel and not a requirement under the TRIPS Agreement (WT/DS50/AB/R of 19 December 1997, para 5). India maintained that it's essentially for a Member to determine the methodology by which it sets outs the mail box system in place in terms of its municipal laws (WT/DS50/AB/R of 19 December 1997, para 9).

The Appellate body concurred with findings of the DSB and upheld the Panel's conclusion that India has not complied with its obligations under Article 70.8(a) to establish 'a means' that adequately preserves novelty and priority in respect of the applications for product patents in respect of pharmaceutical and agricultural chemical inventions during the transitional period provided for in Article 65 of the TRIPS Agreement. The AB also upheld the Panel's conclusion that Indi has not complied with its obligations under Article 70.9 of the TRIPS Agreement. The AB reversed the Panel's alternative finding that India has not complied with paragraphs 1 and 2 of Article 63[39] of the TRIPS Agreement. Article 63 deals with transparency requirements with regard to a Member's laws, rules and regulations.

The United States in its submission held the Panel decision as correct and pointed out that the Panel had held that India could not rebut that submission of the United States that such administrative instructions and patents based on them could be invalidated by a legal challenge.

[39] Article 63 states:

1. Laws and regulations, and final judicial decisions and administrative rulings of general application, made effective by a Member pertaining to the subject matter of this Agreement (the availability, scope, acquisition, enforcement and prevention of the abuse of intellectual property rights) shall be published, or where such publication is not practical made publicly available, in a national language, in such manner as to enable governments and right holders to become acquainted with them. Agreement concerning the subject matter of this Agreement which are in force between the government or a governmental agency of a member and the government or a governmental agency of another Member shall also be published.
2. Members shall notify the laws and regulations referred to in paragraph 1 to the Council for TRIPS in order to assist that Council in its review of the operation of this Agreement. The Council shall attempt to minimize the burden on Members in carrying out this obligation and may decide to waive the obligation to notify such laws and regulations directly to the Council if consultations with WIPO on the establishment of a common register containing these laws and regulations are successful. The Council shall also consider in this connection any action required regarding notifications pursuant to the obligations under this Agreement stemming from the provisions of Article6ter of the Paris Convention (1967)

The Panel held that they are not persuaded that the administrative instructions will prevail over contradictory provisions of the *Patents Act* 1970 and that in issuing these instructions, India did not avail of the provisions of section 159 of the 1970 *Patents Act* which allows the Government to make rules for carrying out the provisions of the Act or section 160 of the 1970 *Patents Act* which requires that such rules be laid before each House of the Parliament (WT/DS50/AB/R of 19 December 1997, para 69). The AB therefore held that they were not persuaded that the administrative instructions provide a sound legal basis to preserve novelty of inventions and priority of applications as of the relevant filing and priority dates (WT/DS50/AB/R of 19 December 1997, para 70). The AB agreed with Panels conclusion that the administrative instructions for receiving mail box applications were inconsistent with Article 70.8(a) of the TRIPS Agreement (WT/DS50/AB/R of 19 December 1997, para 71).

5.3. 1998 India – Patent Protection

In *1998 India – Patent Protection for Pharmaceutical and Agricultural Chemical Products* (WT/DS79/R of 24 August 1998), the European Communities and their member States raised request for consultations with India regarding the absence in India of either patent protection for pharmaceutical and agricultural chemical products or formal systems that permit the filing of patent applications for pharmaceutical and agricultural chemical products and that provide for the grant of exclusive marketing rights for such products. The issues raised were similar to the ones raised by the US in the dispute WT/DS50/AB/R of 24 August 1998. No mutually satisfactory solution was reached in the consultations between India and EC, held on 14 May 1997.

Thereupon the EC and its member states requested the Panel to extend its findings in the earlier dispute with US, to the EC and its member states namely that India had not complied with its obligations under Article 70.8(a) of the TRIPS Agreement to establish a means that adequately preserved the novelty and priority in respect of applications for product patents in respect of pharmaceutical and agricultural chemical inventions during the transitional period, that India had not complied with its obligations under Article 70.9 of the TRIPS Agreement and that India should bring its legal regime for patent protection on pharmaceutical and agricultural chemical products into conformity with India's obligations under the TRIPS Agreement.

It was brought to the note of the Panel that inspite of the AB decision on the matter three months earlier (WT/DS50/AB/R of 24 August 1998) which called upon India to take the necessary actions to be in conformity with its obligations the matter, no amendment had been enacted to the 1970 *Patents Act* to comply with the obligation (WT/DS79/R 24 of 24 August 1998, para 4.1).

India requested the Panel to dismiss the matter stating that the complaint of the EC and the member states was an unnecessary re-litigation on the same matter (WT/DS79/R 24: 9, para 4.2). India also submitted that the EC's complaints amounted to unwarranted harassment entailing a waste of WTO's limited human and financial resources as well as those of India (WT/DS79/R 24 of 24 August 1998, para 4.2).

The United States made third party submission in the matter and stated that the precise measures and provisions of the WTO Agreement in this dispute had been subject of a previous WTO dispute settlement proceeding that had concluded very recently and that the AB had thoroughly analysed the legal issues in the case and it was neither necessary not appropriate for the Panel to repeat that work. The United States submitted that the Panel may rule that India had failed to comply with Articles 70.8 and 70.9 of the TRIPS agreement and that India should amend its laws to comply with its obligations (WT/DS79/R 24 of 24 August 1998, para 5.1).

The Panel considered whether it is bound by the previous panel reports or AB decisions, even of on the same subject matter and concluded that the Panel is not bound by the previous panel or AB reports. The Panel noted Article 3.2 of the DSU which stresses the role of the WTO dispute settlement system in providing security and predictability to the multilateral trading system and the need to avoid inconsistent rulings(WT/DS79/R 24 of 24 August 1998, para 7.30).

The Panel concluded that a Member not making available as of January 01, 1995 patent protection for pharmaceutical and agricultural chemical products commensurate with its obligations under Article 27 cannot avail itself of transitional period under Article 65 (WT/DS79/R 24, para 7.36) and that in order to prevent the loss of novelty of an invention filing and priority dates need to have a sound legal basis and that without legally sound filing and priority dates, the mechanism to be

established on the basis of Article 70.8 will be rendered inoperational (WT/DS79/R 24 of 24 August 1998, para 7.39).

The Panel adjudicated the matter in favour of the EC and held that India has failed to establish a legally sound system for enabling applications for product patents in respect of pharmaceutical and agricultural chemical inventions and that India has not established a system for grant of exclusive marketing rights. India was asked to bring its transitional patent regime in line with the TRIPS obligations.

The Panel disagreed with the Indian argument that administrative instructions issued by the government provided sound legal basis for the filing of the applications and that the Panel also noted the principle of Indian administrative law that administrative instructions cannot be issued on any matter which is the subject of legislation and that administrative instructions can be made where there is no statutory provisions or where there is a gap in an enactment and that there should be no statutory provision expressly or by implication to the contrary (WT/DS79/R 24 of 24 August 1998, para 7.50).

In conclusion the Panel held that India had failed to implement its obligations under Article 70.9 to establish a system for the grant of exclusive marketing rights to be made available at any time after the entry into force of the WTO Agreement (WT/DS79/R 24 of 24 August 1998, para 7.74). The Panel concluded that India had not complied with the obligations under Article 70.8(a) because it had not provided a sound legal basis for adequately preserving novelty and priority in respect of the applications for product patents in respect of pharmaceutical and chemical inventions during the transitional period (WT/DS79/R of 24 August 1998, para 9.1). The Panel further recommended the DSB to request India to being its transitional regime for patent protection of pharmaceutical and agricultural chemical products into conformity with the TRIPS Agreement (WT/DS79/R of 24 August 1998, para 9.2).

5.4. 1999 South Africa – Anti-Dumping Duties

In *South Africa – Anti-Dumping Duties on Certain Pharmaceutical Products from India* (WT/DS168/1 of 13 April 1999), South Africa initiated anti-dumping proceedings against the import of ampicillin and amoxycillin 250 mg. capsules from

India. The *Board on Tariffs and Trade* of South Africa made a preliminary determination on 26 March 1997 that ampicillin and amocycillin 250 mg. and 500 mg. capsules exported by M/s Ranbaxy Laboratories Ltd., India, were being allegedly dumped into South Africa Customs Union. This was followed by the recommendation to impose final duties on these products by the above mentioned *Board on Tariffs and Trade*, reported on 10 September 1997.

The Government of India responded that the definition and calculation of the normal values is inconsistent with the provisions of the WTO and an erroneous methodology was used for determining the normal value and the resulting margin of dumping. The method of arriving at constructed export price was also not reasonable which resulted in a higher margin of dumping. The Government of India stated that the determination of injury was not based on positive evidence and did not include an evaluation of all relevant economic factors and indices having a bearing on the state of the industry which led to an erroneous determination of material injury suffered by the petitioner. India also submitted that the South African authorities' establishment of the facts was not proper and that their evaluation was not unbiased or objective. Moreover, the South African authorities have not taken into account the special situation of India as a developing country.

As on 16 September 2015, the mater was pending consultations.

5.5. 1999 Argentina - Patent Protection

In *Argentina - Patent Protection for Pharmaceuticals and Test Data Protection for Agricultural Chemicals* (WT/DS171/1 of 10 May 1999), the United States raised the issue that the Argentinean law does not conform to the TRIPS requirement that all Members of the World Trade Organization (WTO) that do not provide for product patents for pharmaceutical inventions as on the date of entry into force of the WTO Agreement establish a system of exclusive marketing rights whereby exclusive marketing rights will be granted for products that are the subject of applications for patents for such inventions, subject to certain stated requirements.

The second issue that was raised by the United States was that paragraphs 1, 2, 3 or 4 of Article 65 of the TRIPS Agreement to ensure that any changes in its laws,

regulations and practice made during the transitional period do not result in a lesser degree of consistency with the provisions of the TRIPS Agreement. The United States submitted that while earlier Argentinean law provided for a term year term of protection for test data that was submitted, such provision was revoked whereby there was no protection to such test data.

A mutually agreed solution was entered into between the Parties in this matter.

5.6. 2000 Argentina-Protection of Patents and Test Data

In *Argentina-Certain Measures on the Protection of Patents and Test Data* (WT/DS196/1 of 6 June 2000), the US requested consultations with Argentina concerning Argentina's legal regimes governing patents. The US position was that Argentina's patent law regime did not meet the TRIPS requirements such as protection against unfair commercial use of undisclosed or other test data, exclusion of microorganisms against patentability, failure to provide effective provisional measures such as preliminary injunctions against patent infringement, failure to provide safeguards against arbitrary invocation of compulsory licensing rights such as the time period for such compulsory licensing, justification for compulsory licensing etc., denial of rights of patentees to amend the patent applications in view of the rights granted by the TRIPS Agreement, denial of certain patent rights such as denial of rights of importation, process patents etc. The two countries raised an agreement on the issues raised and in 2002 reached at a settlement.

5.7. 2000 Canada - Pharmaceutical Products

In this case *Canada – Patent Protection of Pharmaceutical Products* (DS114 of 17 March 2000), the EC and its member States approached the Panel to make the determination that Canada by allowing manufacturing and stockpiling of pharmaceutical products without the consent of the patent holder and during the six month period prior to the expiration of the twenty year patent term by virtue of section 55.2(2) and 55.2(3). of the *Patent Act* together with the *Manufacturing and Storage of Patented Medicines Regulations* violated Article 28.1 and 33 of the TRIPS Agreement and that Canada treated the patent holder in the pharmaceutical sector less favourably than the patent holders in other field of technology violated the obligations

under Article 27.1 of the TRIPS Agreement which does not make any discrimination in the field of technology (WT/DS114/R of 17 March 2000, para 3.1).

Further the Panel was to determine that the development and submission of information needed to receive marketing approval for pharmaceutical products violated Article 28.1 of the TRIPS Agreement and that Canada by virtue of section 55.2(1) of the Patent Act which provided for development and submission of information required for obtaining marketing approval of pharmaceutical products without the consent of the patent holders also violated the provisions of Article 28 of the TRIPS Agreement. The Panel was asked to determine that these constituted prima facie nullification or impairment under Article 64.1 of the TRIPS Agreement, Article XXIII of GATT1 994 and Article 3.8 of the DSU.

Section 55.2(1) and 55.2(2) of Canada's *Patent Act* provided as below:

> 55.2(1). It is not an infringement of a patent for any person to make, construct, use or sell the patented invention solely for uses reasonably related to the development and submission of information required under any law of Canada, a province or a country other than Canada that regulates the manufacture, construction, use or sale of any product (emphasis added).
>
> 55.2(2). It is not an infringement of a patent for any person who makes, constructs, uses or sells a patented invention in accordance with subsection (1) to make, construct or use the invention, during the applicable period provided for by the regulations, for the manufacture and storage of articles intended for sale after the date on which the term of the patent expires (emphasis added).

The EC alleged that the European research based pharmaceutical industry had suffered losses of $100 million in per year on a conservative estimate based on sales of top 100 original pharmaceutical products sold in Canada between 1995 and 1997 (WT/DS114/R of 17 March 2000, para 4.7) and that the exceptions unreasonably conflicted with the normal exploitation of patent and unreasonably prejudiced the lawful interest of patent holders on account of interests of third parties (WT/DS114/R of 17 March 2000, para 4.8).

Canada refuted these allegations and stated that:

a) these provisions were limited exception to the exclusive rights granted to patent holder under Article 30 of the TRIPS Agreement and that there is no technology based discrimination as the prohibition against discrimination does not apply to allowable limited exceptions.

b) these exceptions do not reduce the term of patent provided under Article 33 of the TRIPS Agreement (WT/DS114/R of 17 March 2000, para 3.2).

c) these did not conflict with the normal exploitation of the patent or prejudice the legitimate interest of the patent owner as they affected the patent holders commercial exploitation, only after the expiry of the patent term and that the measures took into account Canada's national interest and measures conducive for social welfare where were recognised in Article 7 of the TRIPS (WT/DS114/R of 17 March 2000, para 4.10).

d) that this allowed the potential competitors to compete freely with the patentee after the patent term in consonance with the requirement under Article 29 (WT/DS114/R of 17 March 2000, para 4.10).

e) that the measures sought to protect public health a value recognised in Article 8.1 of the TRIPS Agreement through promoting generic medicines following patent expiry and that this took into account the legitimate interest of individual, private insurers and public sector entities which financed health care (WT/DS114/R of 17 March 2000, para 4.10).

f) that the process of development of drug and regulatory approval for newly patented pharmaceuticals takes about 8 to 12 years and that because of this long period the actual period during which the patent holder is enabled to exclusively cater to the market is about eight to 12 years. In the case of generics the development period is about two to four years and the regulatory process about one to two and half years. Unless the development process is permitted during the period of the patent, the generic manufacturers could be forced to wait for another three to six and half years before their product can come to the market. The regulatory review exception in section 55.2(1)was to enable generic manufacturers to complete development and regulatory approval during the patent term so that they could enter the market as soon as the patent term ends (WT/DS114/R of 17 March 2000, para 7.3).

The Panel in its decision noted that the Vienna Convention in Article 31 and 31 require the treaty to be interpreted in good faith in accordance with the ordinary meaning of the terms of the treaty in their context and in the light of their object and purpose (WT/DS114/R of 17 March 2000, para 7.13).

The Panel held that:

a) the very existence of Article 30 amounts to recognition that the definition of patent rights as in Article 28 need certain adjustments (WT/DS114/R of 17 March 2000, para 7.26).

b) Article 30 require three criteria to qualify for an exception *viz.* 1) the exception must be limited, 2) the exception must not unreasonably conflict with the normal exploitation of the patent and 3) the exception must not unreasonably prejudice the legitimate interest of the patent owner, taking account of the legitimate interest of third parties (WT/DS114/R of 17 March 2000, para 7.20).

c) it could not accept Canada's argument that the curtailment of the patent owner's legal rights is limited so along as the exception reserves the exclusive right to sell to the ultimate consumer during the term of the patent (WT/DS114/R of 17 March 2000, para 7.33). Canada seemed to argue that while exclude sales to consumers during the patent term is an essential right conveyed, while the rights to exclude making and using the patented products are in some was secondary (WT/DS114/R of 17 March 2000, para 7.33). The panel held that the stockpiling exception of section 55.2(2) constitute a substantial curtailment of the exclusionary rights granted to patent owners under Article 28.1 of the TRIPS Agreement (WT/DS114/R of 17 March 2000, para 7.36).

d) Canada's regulatory review exception is a limited exception within the meaning of Article 30 because of the narrow scope of its curtailment of the rights under Article 28.1. The Panel held that the patent owner's rights are not impacted by substantial amounts of test production to demonstrate reliable manufacturing and that the patent owners' rights are not impaired by the size of such production runs as long as they are for regulatory purposes and no commercial use is made of the resulting final products, (WT/DS114/R of 17 March 2000, para 7.45) during the patent term.

The Panel after examining the various arguments concluded that Section 55.2(2) of Canada's *Patent Act* is not consistent with Canada's obligations under Article 28.1 of the TRIPS Agreement and that Section 55.2(1) is not inconsistent with Article 27.1 and Article 28.1 of the TRIPS Agreement (WT/DS114/R of 17 March 2000, para 8.1). In sum, the Canadian laws, known as Bolar exceptions, which permitted the testing of generic drugs prior to the expiry of a patent to ensure marketing of such generic drugs as soon as the patent expired, was valid. However, the stock piling of such generic drugs by the generic drug manufacturers were not permitted. Canada was required to bring Section 55.2(2) of Canada's *Patent Act* in line with the TRIPS requirements (WT/DS114/R of 17 March 2000, para 8.1).

The parties went to arbitration over the time period required to implement the DSB's recommendations. Canada submitted before the arbitrator that it needed 14 months and 2 days for the implementation considering the complexity of the issue and the impact it will have on the health care system in Canada (WT/DS170/10 of 28 February 2001, para 19). United States on the other hand argued for 6 months as the possible implementation time. The arbitrator held that 10 months is the reasonable time for implementing the DSB recommendations (WT/DS170/10 of 28 February 2001, para 67)

5.8. 2000 Canada –Term of Patent Protection

In *2000 Canada –Term of Patent Protection* (WT/DS170/AB/R of 18 September 2000) the United States submitted that Canada which is obligated to implement the provisions of the TRIPS Agreement from January 11, 1996 is required to provide a minimum term of protection to all patents existing as of the date of application of the Agreement. The United States further submitted that the 1985 Canada *Patents Act* which provides the for terms of the patents provides for only 17 years as the term for applications filed before October 01, 1989 and that this term of 17 years is inconsistent with Canada's obligations under Articles 33 and 70 of the *TRIPS Agreement*. Article 33 of the TRIPS Agreement requires that the term of protection shall not be less than 20 years from the filing date.

Sections 44 of Canada's *Patent Act* stated that where an application for a patent is filed on or after October 01, 1989 the term of patent protection shall be twenty years from the filing date. Section 46 stated that where the application if filed before October 01, 1989 the term of patent protection shall be seventeen years from the date on which the patent is issued. The Amendment to the Canada Patent Act (known as Bill C-22) provided in section 27 that applications for patents filed before the coming into force of the Amendment Act shall be dealt with and disposed according to the provisions of the Patent Act as it read immediately before the coming into force of the amendment. Patents granted on applications filed on or after October 01, 1989 are referred to as New Act Patents and patents granted on applications filed before October 01, 1989 are referred to as Old Act Patents.

As per statistics made available by the Canadian Patent Office 142494 or over 60 percent of the Old Act patents then in existence had terms that expire until or well after the 20 year period following the application dates (WT/DS170/R of 5 May 2000, para 2.6). Just under 40 per cent of the old Act patents in force on January 01, 2000 will expire in less than 20 years measured from their application dates (WT/DS170/R of 5 May 2000, para 2.9).

The United States contended that since a large number of the existing Old act patents in Canada expired before 20 years from the date of filing, the Panel conclude that Canada is in violation of Article 33 and 70 of the TRIPS Agreement and that recommendation be made that Canada should bring its measures to be in conformity with the obligations under the TRIPS Agreement (WT/DS170/R of 5 May 2000, para 3.1). The United States pointed out that in addition to itself, Australia, Germany, Greece, New Zealand and Portugal have all revised their laws to conform to the 20-year protection term as of the filing date.

After hearing both the parties the panel held that the term provided by the 1985 Canada *Patents Act* is insufficient and does not meet the mandate in Article 33 of the TRIPS Agreement and recommended the Dispute Settlement Body to request Canada to bring its measures into conformity with its obligations under the WTO Agreement.

5.9. 2000 Brazil – Measures Affecting Patent Protection

In *Brazil – Measures Affecting Patent Protection* (WT/DS199/1 of 8 June 2000), US initiated request for Consultations with Brazil regarding Article 68 of Brazil's 1996 industrial property law (Law No. 9,279 of 14 May 1996; effective May 1997) and other related measures, which established a 'local working' requirement for the enjoyment of exclusive patent rights. By such provision only local production of the patented subject matter and not the importation can satisfy local working requirement.

By this provision a patent shall be subject to compulsory licensing if the subject matter of the patent is not 'worked' in the territory of Brazil. Brazil then explicitly defined 'failure to be worked' as 'failure to manufacture or incomplete manufacture of the product', or 'failure to make full use of the patented process'. The United States submitted that such a requirement is inconsistent with Brazil's obligations under Articles 27 and 28 of the TRIPS Agreement, and Article III of the GATT 1994.

A DSB panel was established with Dominican Republic, Honduras, India and Japan as third parties. However, Brazil and US reached a mutually agreeable solution to the matter when Brazil agreed that in the event it deems necessary to apply Article 68 to grant compulsory license on patents held by the U.S. companies, it will hold prior talks on the matter with the U.S. Government (WT/DS199/4 G/L/454 IP/D/23/Add.1 of 19 July 2001, para 2).

5.10. 2009 China –Intellectual Property Rights

The copyright law in China as adopted by the Standing Committee of the National People's Congress and promulgated in 1990 and amended in 2001 stated in the first sentence of Article 4 that "Work the publication of dissemination of which are prohibited by law shall not be protected by this law" (WT/DS362/R of 26 January 2009, para 7.1).

Further to this and certain related provisions, the United States initiated consultations and thereafter panel proceedings against China, in *China – Measures Affecting the Protection and Enforcement of Intellectual Property Rights* (WT/DS362/R of 26

January 2009), the United States initiated Panel proceeding against China alleging that:

- China has not provided for criminal procedures and penalties to be applied in cases of wilful trademark counterfeiting or copyright piracy on a commercial scale that fail to meet certain thresholds (WT/DS362/R of 26 January 2009, para 2.2).
- China's measures for disposing of confiscated goods that infringe IPRs are inconsistent with China's obligations under the TRIPS Agreement (WT/DS362/R of 26 January 2009, para 2.3)
- China is acting inconsistently with its obligations under the TRIPS Agreement by denying the protection of its Copyright Law to creative works of authorship that have not been authorized for, or are otherwise prohibited from, publication or distribution within China (WT/DS362/R of 26 January 2009, para 2.4)

The United States further alleged that the compulsory sequences of steps set out in the Chinese measures mean that Chinese customs authorities lack the authority to order destruction or disposal of infringing goods in accordance with the principles set out in Article 46 of the TRIPS Agreement, and that the measures at issue are therefore inconsistent with China's obligations under Article 59 of the TRIPS Agreement (WT/DS362/R of 26 January 2009, para 3.1).

The United States submitted that China during a review of the legislation in the Council for TRIPS in 2002 had explained that this clause refereed to the works the publication of which was prohibited by certain Chinese laws such as the *Criminal law*, the *Regulation on the administration of Publishing Industry*, the *Regulation on the Administration of Broadcasting*, the *Regulation on the Administration of Audiovisual Products*, the *Regulation on the Administration of Films and Regulation on Telecommunication*. United States argued that because of such bar the authors of such works do not get the minimum rights that are specially granted by the Berne Convention (TRIPS Agreement (WT/DS362/R of 26 January 2009, para 7.16).

In its submissions, while China argued that there is a distinction between copyright and copyright protection, the United States argued that this distinction is not laid down in the Berne Convention and is therefore irrelevant and that Article 4(1) of the Chinese law created significant commercial uncertainty to works which are denied copyright protection as it allows pirates to profit and that Article 17 of the Berne Convention does not permit Members to deny copyright protection to authors (TRIPS Agreement (WT/DS362/R of 26 January 2009, para 7.23).

Among the third party submissions, Argentina agreed that China has the right to prohibit the publication or distribution of certain kinds of works and that Article 17 of the Berne Convention contemplates such as possibility (TRIPS Agreement (WT/DS362/R of 26 January 2009, para 7.24). Canada submitted that Members can prohibit the publication and distribution of works but submitted that Members do not have right to deny copyright protection to such works (TRIPS Agreement (WT/DS362/R of 26 January 2009, para 7.25). The EC stated that such denial of protection is not covered by the exemption or limited exemptions under the Berne Convention and the TRIPS Agreement (TRIPS Agreement (WT/DS362/R of 26 January 2009, para 7.26).

The Panel in its report concluded that (WT/DS362/R of 26 January 2009, para 8.1):

- the Copyright law in China and specifically clause 41 of the said law is inconsistent with China's obligation under the Berne Convention (1971) and as incorporated by Article 9.1 of the TRIPS Agreement and with Article 41.1 of the TRIPS Agreement.
- while the United States has not established that the Custom measures are inconsistent with Article 59 of the TRIPS Agreement, the custom measures are inconsistent with Article 59 of the TRIPS Agreement as it incorporates the principle set out in the fourth sentence of Article 46 of the TRIPS Agreement (i.e. insufficiency of simple removal of trademarks on counterfeit trademark goods, for permitting removal of goods into channels of commerce).

- to the extent that the Copyright Law and the Customs measures are inconsistent with the TRIPS Agreement, they nullify or impair benefits accruing to the United States under the Agreement.

The Panel recommended that China should bring its copyright law and measures in conformity with the obligations under the TRIPS Agreement (WT/DS362/R of 26 January 2009, para 8.2).

5.11. 2010 European Union - Seizure of Generic Drugs in Transit

In *European Union and a Member State – Seizure of Generic Drugs in Transit* (WT/DS408/1 of 19 May 2010), India approached the DSB stating that based on complaints of alleged infringement by alleged owners of patents over the last two years from the date of raising the request for consultations, customs authorities in the Netherlands seized a substantial number of consignments of generic drugs from India in transit through the Netherlands. As per the terms of the request for consultation initiated by India, these seizures were made by applying the so-called "manufacturing fiction" under which generic drugs actually manufactured in India and in transit to third countries were treated as if they had been manufactured in the Netherlands. These consignments were initially detained and later, either destroyed or returned to India. In a few cases, the consignments were permitted to proceed to the destination country after considerable delay. India submitted that as per available evidence the customs authorities seized at least 19 consignments of generic drugs in 2008 and 2009 while in transit through the Netherlands, 16 of which originated in India.

Brazil also raised a similar request for consultation on the same occasion when a shipment of the generic drug Losartan Potassium, produced in India and destined to Brazil, was seized when in transit at Schipol Airport, in the Netherlands, in December 2008, and later returned to India (DS 408, WT/DS408/1 G/L/921 IP/D/28 19 May 2010: 1). The Dutch authorities seized the shipment pursuant to the European Communities Council Regulation No 1383/2003 (EC Regulation No 1383/2003).

As on 16 September 2015, the matter was pending consultations.

5.12. Summary of TRIPS Related Case Laws

The summary of the case laws as discussed above are as below:

Table 3: Summary of TRIPS Related Case Laws

Case	Gist of the decision
1. *Portugal - Patent Protection under the Industrial Property Act* (WT/DS37/2 of 8 October 1996)	US submitted that the Portuguese Industrial Property Act was inconsistent with the TRIPS requirement that the patent term be for a term of not less than twenty years. Both the parties settled the matter by mutual consent.
2. *India – Patent Protection for Pharmaceutical and Agricultural Chemical Products* (WT/DS50/R of 5 September 1997)	India was taken before the DSB for not having a valid law providing for mailbox mechanism and exclusive marketing rights as per TRIPS requirement. The recommended the DSB to request India to beings its laws in conformity. The AB also affirmed the Panel decision.
3. *India – Patent Protection for Pharmaceutical and Agricultural Chemical Products* (WT/DS79/R of 24 August 1998)	EC brought the matter before the WTO that India had not complied with its obligations to establish a means that adequately preserved novelty and priority in respect of applications for product patents in respect of pharmaceutical and agricultural chemical inventions during transitional period. Panel ruled in favour of EC that India failed to implement its obligations to establish grant of exclusive marketing rights.
4. *South Africa – Anti-Dumping Duties on Certain Pharmaceutical Products from India* (WT/DS168/1 of 13 April 1999)	South Africa initiated anti-dumping proceedings against import of ampicillin and amoxicillin 250 mg. from India. As on 16 September 2015, the mater was pending consultations.
5. *Argentina - Certain Measures on the Protection of Patents and Test Data* (WT/DS196/1 of 6 June 2000)	US brought the matter alleging that Argentina's legal regime did not meet TRIPS requirements such as protection against unfair commercial use, failure to provide effective provisional measure etc. The

	two countries reached a settlement on the matter.
6. *Argentina - Patent Protection for Pharmaceuticals and Test Data Protection for Agricultural Chemicals* (WT/DS171/1 of 10 May 1999)	US maintained that Argentinean law did not conform to TRIPS by not establishing a system for exclusive marketing rights. A mutually agreed solution was entered into between the Parties in this matter.
7. *Canada – Patent Protection of Pharmaceutical Patents* (WT/DS114/R of 17 March 2000)	The WTO panel noted that the Canadian laws, known as Bolar exceptions, which permitted the testing of generic drugs prior to the expiry of a patent to ensure marketing of such generic drugs as soon as the patent expired, was valid. However, the stock piling of such generic drugs by the generic drug manufacturers were not permitted
8. *Canada –Term of Patent Protection* (WT/DS170/AB/R of 18 September 2000)	US submitted that the Canadian law provided for term of the patent for only 17 years which was inconsistent with the TRIPS. Panel held that 1985 Canada *Patents Act* is insufficient in meeting the TRIPS requirement under Article 33.
9. *Brazil – Measures Affecting Patent Protection* (WT/DS199/1 of 8 June 2000)	US submitted that Brazil's 1996 Industrial Property Law which required local working for enjoyment of exclusive marketing rights as inconsistent with TRIPS obligations. Brazil and US entered into a mutual agreement that in event it was to grant compulsory license for not having local working, then it will hold prior talks with US government.
10. *China – Measures Affecting the Protection and Enforcement of Intellectual Property Rights* (WT/DS362/R of 26 January 2009)	US submitted that China's copyright law is inconsistent with China's obligations under the TRIPS Agreement. Panel recommended that China should bring its copyright law and measures in conformity with the obligations under the TRIPS Agreement.
11. *European Union and a Member State – Seizure of Generic Drugs in*	Customs authorities in Netherlands seized substantial consignments of generic drugs from

Transit (DS 408, WT/DS408/1 of 19 May 2010)	India in transit through Netherlands, against which India approached the DSB. As on 16 September 2015, the matter was pending consultations.

6. International Initiatives

There are various international initiatives such as study reports by international organisations, intergovernmental initiatives etc. happening over the past many years to deal with the issues of medicinal access and pricing in the context of the WTO obligations. Some of them are examined below in a chronological fashion.

6.1. 2001 Workshop on Differential Pricing and Financing of Essential Drugs

In this conference organized by the WHO, WTO and the Norwegian Foreign Ministry in April 2001 ("**Conference**"), 'Differential Pricing' was defined as "*adaption of prices charged by the seller to the purchasing power in different countries*" (See WHO, WTO and Norwegian Ministry 2001: 11) The Conference concluded that differential pricing could and should play an important part in ensuring accessibility to essential drugs at affordable prices and that in order to ensure that the drugs are actually received by the people in poor countries much financing is required and that most of the additional financing will need to be provided by the international community (WHO, WTO and Norwegian Ministry 2001: 2). The Conference noted that differential pricing of essential drugs is fully compatible with the TRIPS Agreement (WHO, WTO and Norwegian Ministry 2001: 25).

The Conference:

i. noted that much of the world's poor purchased the medicines required for their health care privately (WHO, WTO and Norwegian Ministry 2001: 7).

ii. recognized that the prices of the essential drugs matters to the poor countries and the poor people, it was also noted that availability of health services locally, adequate staffing, equipment, financing, orientation to local needs, distribution systems, taxes etc. are some of the other factors which are important in the context of enabling access (WHO, WTO and Norwegian Ministry 2001: 2, 7). Also, under utilization of many relatively inexpensive

essential drugs, which are not under patent protection was also noted in the Conference (WHO, WTO and Norwegian Ministry 2001: 9).

iii. recognised that there could be political fallout within the industrialized nations of the differential pricing in favour of poor countries and it was suggested that industrialized countries should not use the differential prices meant only for the poor countries as benchmarks for their own pricing (WHO, WTO and Norwegian Ministry 2001: 4).

iv. noted that market segmentation through prohibition of parallel trade to facilitate differential pricing is not violative of the provisions of the TRIPS Agreement. The Conference further noted that patent system is not sufficient to ensure adequate R&D into the neglected disease of the poor and that additional measures to support R&D is necessary (WHO, WTO and Norwegian Ministry 2001: 5).

v. noted that governments have a special role in ensuring access to essential drugs and that public purchasing of essential drugs is necessary on behalf of the poor populations and further that tariff's, taxes, local distribution costs etc. contribute much to the retail price of many medicines (WHO, WTO and Norwegian Ministry 2001: 9).

vi. noted that both for patented and for non-patented drugs price reductions of more than 90% from developed country prices could be achieved through bulk purchasing, competitive tenders and skilful negotiation (WHO, WTO and Norwegian Ministry 2001: 14). The Conference noted that UNFPA obtains reductions of up to 99 percent of the US market prices for some contraceptives through bulk purchasing and sell the contraceptives at a standard low price to developing countries. The Conference further noted that regional bulk purchasing funds such as Gulf Cooperation Council, African Association of Central Medical Stores (ACAME) etc. have obtained price reductions of up to 30 percent through negotiation (WHO, WTO and Norwegian Ministry 2001: 15). However on bulk purchasing, the Conference noted that it could result in imbalances such as that the international funding is used only for purchase

only from certain global manufacturers, thereby depriving the local manufacturers of their business (WHO, WTO and Norwegian Ministry 2001: 18 and 20).

vii. On donations, the Conference noted that donations suffer from certain disadvantages such as that donations are not always sustainable or available and that donations could come with conditions resulting from the imbalance in negotiating power between the donor and the recipient (WHO, WTO and Norwegian Ministry 2001: 16).

viii. noted the possibility of public private partnership to ensure availability of medicines for the people in developing countries by having arrangements for allocation of IPRs under the IAVI i.e. International AIDS Vaccine Initiative. Under this model, the private partners would retain all IPRs over the HIV vaccines for OECD countries and the IAVI would have march-in rights for HIV Vaccines in developing countries in case the private partner is unable or unwilling to produce and distribute vaccines to the developing countries at accessible prices (WHO, WTO and Norwegian Ministry 2001: 19).

ix. also noted that arrangements or agreements between competitors to have differential pricing for developing countries will not be treated as anti-competitive as the actions are not to lessen competition and that alternatively, international price differentiation independent of competitors would not be anti-competitive (WHO, WTO and Norwegian Ministry 2001: 20). The Conference also noted that middle income countries should be required to pay prices proportionate to their income levels and that such countries could be required to pay more than the least developed countries using the Human Development Index from the UNDP as a reference point (WHO, WTO and Norwegian Ministry 2001: 24).

6.2. 2002 WTO WHO Report

This Joint study report brought out by the WTO and the WHO in 2002 ("**2002 WTO WHO Report**") provided an outline of the impact of the TRIPS, SPS, GATS agreements etc. on the right to health and noted:

i. that the trade restrictions initiated from the WHO front are unlikely to conflict with WTO rules and that they try to minimize disruption to international trade and that this is one of the fundamental principles underlying the WHO's International Health Regulations which serves as legal framework to prevent the spread of diseases globally (WTO WHO Report 2002: 13, para 12). In the context of the Framework Convention on Tobacco Control, that it purposes to facilitate multilateral co-operation and action at the international level to address transnational tobacco control strategies (WTO WHO Report 2002: 13, para 16) and that none of the provisions of the same are WTO inconsistent and that many of the restrictions in the FCTC may been be determined to be necessary for health protection under the WTO rules (WTO WHO Report 2002: 13, para 16).

ii. That the TRIPS Agreement provide for the protection of trademarks including service marks and also for protection undisclosed information, such information including test data submitted to governments to obtain marketing approvals for new pharmaceuticals or agricultural chemicals in the area of pharmaceuticals (WTO WHO Report 2002: 39, box 2). Reasonable steps are to be adopted to protect such information from dishonest commercial practices (WTO WHO Report 2002: 39, box 2). These requirements are anticipated to deal with the problem of counterfeit drugs as well.

iii. that patent protection provides incentives for invention of new drugs by enabling its owners of trademarks to obtain protection for trademarks in the boundaries of the WTO members, by specifying procedures and remedies to the right holders for the effective enforcement of their rights, facilitating exchange of information and cooperation between customs authorities to deal with counterfeit trademarked goods (WTO WHO Report 2002: 40-41, para 49).

iv. that the term compulsory licensing is not used under the TRIPS Agreement, instead it is covered under Article 31 under the usage 'other use without authorisation of right holder' in Article 31 of the TRIPS Agreement (WTO WHO Report 2002: 45, para 60). According to this report only about twenty

developing nations namely Angola, Argentina, Bangladesh, Brazil, Cuba, Egypt, Guatemala, India, Kuwait, Madagascar, Morocco, Pakistan, Paraguay, Qatar, Tunisia, Turkey, United Arab Emirates and Uruguay did not have product patent protection at the time of entry into force of the TRIPS Agreement (WTO WHO Report 2002: 47, para 65).

6.3. 2002 WHO Report for China

A WHO report for China in 2002 (German Velasquez, Correa Carlos, Robert Weissman 2002) suggests several mechanisms to control medicinal pricing, such as:

i. **International Open Tendering**: In this method open tenders are floated for competitive prices from manufacturers locally and aboard. The report suggested that internationally such procurement process reduces costs of medicines by 40-50%. However, such mechanism can help in the case where competition exists and may not work for patented products (German Velasquez, Correa Carlos, Robert Weissman 2002: 6).

ii. **Voluntary Discount Agreements:** Here the supplier firms and the governments may enter into agreements hereunder differentially priced products may be supplied by various suppliers. Prices may be negotiated internationally by global alliances such as Global Alliance for Vaccines and Immunization and Green Light Committee or between supplier and countries (German Velasquez, Correa Carlos, Robert Weissman 2002: 7).

iii. **Voluntary Licensing:** Under voluntary licensing the patent holder and certain parties may enter into licensing agreements under which the patents holders may license rights to manufacture, import, distribute pharmaceutical products on an exclusive or non-exclusive basis. Depending on the negotiating strength of the parties etc., there could be significant reduction in prices or no reduction in prices at all (German Velasquez, Correa Carlos, Robert Weissman 2002: 7).

iv. **Compulsory Licensing:** Where the patent holder refuses to enter into licensing agreement ion reasonable commercial terms, in cases of national emergency, extreme urgency, governmental non-commercial use etc. the TRIPS Agreement through Article 31 provides for grant of compulsory licenses (German Velasquez, Correa Carlos, Robert Weissman 2002: 7).

v. **Local State Production:** The study notes that in 1998 there was an Asian financial crises and several privately owned local and foreign companies

almost halted production for several weeks due to collapse of local currency and uncertainty in foreign exchange rates which prevented them from importing necessary raw materials. Hover, the Government was still able to supply medicines to hospitals etc. due to the existence of state owned local pharmaceutical manufacturers. The presence of a strong local manufacturing basis increases negotiation strength with patents holders etc. (German Velasquez, Correa Carlos, and Robert Weissman 2002: 8).

vi. **Government Price Controls**: Government may choose to institute price controls where the pharmaceutical markets are not competitive. The price control may be based on actual costs, controlling companies' profit margins, comparison with prices in other countries or prices of medicines in similar therapeutic category. In order to effectively controls costs governments may choose to have control on the reimbursement amounts, economic evaluation of whether the magnitude of benefit from the new medicines justifies the costs and to subsidise those medicines which give the greatest output in improved health in return for lowest cost (German Velasquez, Correa Carlos, Robert Weissman 2002: 10).

vii. **Reduction of Import and other taxes for essential medicines and rational dispensing Practices**: Reduction in various taxes may help to reduce the prices, though it may not be the case always. After considering a number of factors such as whether price controls are in place, products are patented or not, pricing discretion available to pharmacies and dispensing agents etc. governments may choose to adopt this mechanism where appropriate (German Velasquez, Correa Carlos, Robert Weissman 2002: 10).

viii. **Public Investment in R&D for New Medicines**: With strengthening and expansion of the R&D base significant costs advantages may be fructified (German Velasquez, Correa Carlos, Robert Weissman 2002: 11).

6.4. 2006 ICTSD Report

The ICTSD in collaboration with the UNCTAD undertook a project on IPR's and Sustainable Development in which it considered the problems raised in the context of the TRIPS Agreement and among the plausible solution. The major problems identified are as below:

Table 4: 2006 ICTSD Report

Exception to Patent Rights	**Nature of Policy Problem Addressed**
Private and Non – commercial Use	De minimis activity should be shielded from patent infringement
Experimental Use	Scientific/technical progress must not be hindered by the patent system
Prior Use	Prior users should be treated fairly vis-s vis patent holders
Pharmacy	Pharmacists should be free to make medicines for supply to patients on the basis of individual medical prescriptions submitted to them by doctors without fear of patent infringement
Foreign Vessel	Freedom of international movement of foreign vessels must not be hindered by patents
Regulatory Review (Bolar)	Competition between patented medicines and generic medicines must be enabled as swiftly as possible after the expiry of the medicine patent
National Exhaustion	Once a patent holder has sold a patented product, they ought not to be able to control subsequent dealings with the product e.g. resale or repair
European Regional Exhaustion	Once a patented product has been sold on the European market, freedom of movement of goods throughout the rest of the market must not be hindered by patents.

Table extracted from ICTSD 2006).

The study in its conclusion notes that if a country is member of an international community such the commonwealth, it should examine the practices in the other member states and that where there are no appropriate models of exceptions already in existence thane a new exception may have to be developed (ICTSD 2006, para 5.5).

6.5. 2007 WHO - ICTSD – UNCTAD Report

Carlos Correa in this report prepared through a collaborative effort between WHO – ICTSD and UNCTAD, noted that patents can have substantial effect of competitions and therefore on the prices as well and that patent examiners should be conscious that their decisions relating to patent grants will affect the health and lives of the people of the country (Correa Carlos 2007a: 1). This report prepared by him details the mechanism available for utilization of flexibilities under the TRIPS Agreement.

6.5.1.Utilisation of the Flexibilities under the TRIPS Regime

One of the strategies that can be adopted to meet with challenge established by the patent regime is to utilize the flexibilities under the TRIPS regime. Adopting high thresholds for the standard of patentability is one useful mechanism to ensure that patents are not granted frivolously. As noted in one study grant of a large number of patents made on low standards of patentability may lead to unnecessary limitation on competition without much encouragement to innovation to meet the society's needs (Correa Carlos 2007a: 3). The study notes that while thousands of patents are granted in the pharmaceutical sector, the number of patents that are granted on genuine drugs are very less. The study notes that much of the patents are for minor modifications and that according to a report of the National Institute for Health Care Management in the United States, in the 12 year period 1989-2000 only 15% of all drugs approvals were medicines involving significant clinical improvements (Correa Carlos 2007a: viii). He notes that the following should be areas where patents are denied to prevent evergreening:

a) **Formulations:** This could be developing pharmaceutically viable products in different forms such as using particular stabilizing agents, or some compounds to improve bio-availability. These could be known to a person skilled in the art and need not include an inventive step (Correa Carlos 2007a: 7).
b) **Combinations:** This would be different combinations of previously known active ingredients (Correa Carlos 2007a: 8).
c) **Dosage:** Some patents claims consist of different dosage of existing product to different patients, such as paediatric doses. These should come under the exclusions i.e. methods of medical treatment and should not be patentable (Correa Carlos 2007a: 8).

d) **Salts, ethers and esters**: Salts are normally formed to increase stability or solubility of the drug. Different salts result in different solubility and different bioavailability. Patents applications on salts is a method for ever greening of pharmaceutical products (Correa Carlos 2007a: 9).

e) **Polymorphs:** Polymorphism is a natural property in which a therapeutically active ingredient may exist in different physical forms. Polymorphs are discovered normally as a part of experimentation and are not created or invented (Correa Carlos 2007a: 10).

f) **Markush claims:** These refer to a chemical structure with multiple functionally equivalent chemical entities allowed in one or more parts in a compound. Markush claims include large number of possible compounds including vast number of compounds whose properties have not been tested but which have been theoretically inferred from the equivalence with other compounds within the claim. Acceptance of Markush claims generates rights over an extremely broad set of compounds without prior testing or experimentation (Correa Carlos 2007a: 12).

g) **Selection Patents:** A selection patent is a method wherein a patent claim is raised over a small element or segment within a large known group. An independent claim is made out based on some feature not mentioned in the large group and if the larger group is patented then the patent owner may use the selection patent to extend the term of the patent protection for the selected sub set beyond the expiration of the original patent (Correa Carlos 2007a: 14).

h) **Analogue process:** Manufacturing processes that are not by themselves novel or inventive but which are used for the preparation of new or inventive compounds that are unpatented are considered patentable in some jurisdictions. This has the scope of expanding the span of patentability (Correa Carlos 2007a: 16).

i) **Enantiomer:** These are compounds that behave in relation to one another as an image does to its mirror image. In the patent field, sometime claims are raised on a mixture of both enantiomer and then later on a patent claim is raised on the most active enantiomer. This is an ever greening method (Correa Carlos 2007a: 16).

j) **Metabolite/Prodrug:** Metabolites are derivatives of active ingredients that are produced in the body and are not ‘created’ or ‘invented’. When metabolized in the body inactive compounds can be formed which can produce therapeutically active ingredients called prodrugs. A prodrug is sometimes mentioned as a drug in disguise. A patent over the prodrug may have the effect of extending control by

the patentee in the market on the active ingredient that is not metabolized (Correa Carlos 2007a: 18).

k) **Methods of treatment:** Certain patent applications may claim patents over methods of treatment such as diagnosis and surgical methods, cure, pain relief etc. (Correa Carlos 2007a: 19). Methods of treatment are considered an exception to patentability under the TRIPS agreement and therefore countries have considerable latitude not to grant such patents.

l) **First and Second Indications:** Certain patent applications may be for patenting of the second use of a medical product. Under the TRIPS Agreement, the obligation is only to provide product and process patents and not any use based claims (Correa Carlos 2007a: 21).

Carlos Correa opines that special rules for examination and grant of pharmaceutical patents may be adopted at the national level, considering the public health impact of pharmaceutical patents and the importance ascribed to public health requirements through the Doha declaration (Correa Carlos 2007a: 25). Carlos Correa maintains that such justified differentiation is maintainable under TRIPS (Correa Carlos 2007a: 25). Carlos Correa recommends that patent examiners should be adequately trained and be made aware of the impact of granting wrong patents which may unduly restrict competition and limit access to medicines (Correa Carlos 2007a: 26).

Carlos Correa notes that the Indian patent office issued guidelines stating criteria for the examination of applications dealing with hydrates, salts and other derivatives and that the 2005 Amendment had a specific provision to deal with patent claims on salts, esters etc. of existing products (Correa Carlos 2007a: 9).

6.6. 2009 Study by WIPO Report on the International Patent System

The World Intellectual Property Organization ("**WIPO")** has made studies in the matter of the relationship between health and IP. As pointed out in this 2009 study by the WIPO, titled *Report on the International Patent System* the effect of patents on innovation is not conclusive.[40] Higher patent protection alone may not foster

[40] See WIPO (2009), *Report on the International Patent System, Standing Committee on the Law of Patents*, Twelfth Session, June 23 to 27, 2008 SCP/12/3 Rev.2, February 3, 2009 (Geneva) 9 -10. It states as below:

innovation, while it may provide an incentive for engaging in R&D activities in countries with high level of economic development, education and economic freedom. The study however states that the requirement for public disclosure in patent law makes available in the public domain much information which would otherwise never come into the public domain. Thus patents as per this report helps in information disclosure and dissemination. Also, it ensures that there is no duplication of R&D as companies or researchers can focus their attention on areas which are yet to be researched (WIPO 2009a: 10).

The report also states that patent rights help in technology transfer in the form of trade, FDI, licensing and joint ventures and that a 2005 study estimated that technology transfer generates about USD 45 billion annually in US and around USD 100 billion worldwide (WIPO 2009a: 1). It is interesting to note that half of the worldwide patents are filed from the United States and Japan (WIPO 2009a: 12). Also, in most of the patent offices, the share of the non-resident patent filings is higher in the recent years when compared to the 1990's (WIPO 2009a: 14).

The report states that the availability of technical information through patents is a stimulus for further innovation (WIPO 2009a: 24). The report acknowledges that strong patents protection rights in the early stage of industrialization in a country can impede transfer of technology and also increase the cost of licenses, as developing economies learn advanced technology through reverse engineering etc. (WIPO 2009a: 29).

Licensing agreements can be used for anti-competitive practices by using a license agreement to divide the market between competitors etc. Various forms of abuse

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35. There is also ample evidence on the limitations of the patent system in encouraging innovation activities. Sakakibara and Branstetter (2001)9 analysed the impact of the 1988 patent reform in Japan and concluded that R&D effort and innovative output in Japan was unresponsive to the change in patent scope. Hall and Ziedonis (2001)10 studied the semiconductor industry of the United States of America and concluded that stronger patent protection did not drive the innovative effort of firms.

36. Inconclusive empirical evidence on patent strength and innovation relationship makes it difficult to draw any conclusion about the effectiveness of patent system to encourage R&D investments. For example, a recent study concluded that stronger patent protection provided for in "patent laws by itself do not promptly stimulate domestic innovation". However, implementation of patent laws will stimulate innovation in countries with high level of economic development, education and economic freedom (Qian, 2007).11

include tie-in clauses, export bans, tied royalties, grant backs, conditions preventing challenges to validity, coercive package licensing etc. (WIPO 2009a: 31). Tie- in clauses are clauses that require that materials are purchased only from certain sources while grant back clauses provide exclusive rights over the improvements to the licensor (WIPO 2009a: 32).

The TRIPS Agreement permits member states to specify in their legislation that certain licensing practices or conditions constitute abuse of IPRs and adopt appropriate measures to prevent or control such practices to the extent that such measures are consistent with the other provisions of the Agreement (WIPO 2009a: 32).

In order to ensure that public health concerns the reports suggest a Medical Research and Development (R&D) Treaty which would provide obligations and economic incentives to invest in priority research projects, agreements that member countries reduce IP protection in certain areas such as to permit research exceptions for patents, exceptions to patentability relation to certain open source medical databases etc. (WIPO 2009a: 38). The report suggests that such treaty can facilitate medical R&D through public sector funding, tax credit, as well as through newer methods, such as medical innovation prize funds, competitive intermediaries, or various open source collaborative research projects (WIPO 2009a: 38).

6.7. 2009 WIPO Report on Transfer of Technology

Transfer of technology as per the Report of the WIPO Standing Committee on the Law of Patents in 2009 is a series of processes for sharing of ideas, knowledge, technology and skills with another individual or institution and the acquisition by the other side of such ideas, knowledge and skills (See (WIPO (2009b), SCP/14/4: 4, para 16). The report noted that technology transfer promotes dissemination and further creation of knowledge and technology in the society (WIPO (2009b), SCP/14/4: 5, para 17).

Interestingly, this 2009 WIPO Report (WIPO (2009b), SCP/14/4: 23, para 91) which explored the linkage between patents and transfer of technology, states that:

> …the Patent system has transformed public good knowledge into a tradable property with defined ownership and limits of rights.

This 2009 WIPO Report notes that:

a) the patent system aims to improve the efficiency of the flow of knowledge and facilitates transfer of technology through a legal framework in which technology owners disclose their inventions and license or sells their patents without fear of infringement (WIPO (2009b), SCP/14/4: 13, para 50).

b) the patent system provides an exclusive right that prevents others from using a patented invention without the consent of patentee. Since the patentee is obliged to disclose the invention to the public in a clear and complete manner, a transparent system is embedded in the patent system (WIPO (2009b), SCP/14/4: 26, para 102).

c) in addition to the full description of the technology, the published patents require disclose the scope of protection, the owners, mention of the associated rights such as licenses and other relevant information relating to the legal status of patents and patent applications (WIPO (2009b), SCP/14/4: 26, para 102).

d) third parties can identify the public domain technology which can be freely used by anyone by combining the technical information and legal information disclosed in patents (WIPO (2009b), SCP/14/4: 26, para 103).

e) that published patent applications and patents are a significant source of technological knowledge as it contains the claims which define the scope of patent protection, bibliographical data relating to inventors, patent applicant etc. (WIPO (2009b), SCP/14/4: 13, para 51)

However, the report also noted that the effectiveness of Article 66.2 of the TRIPS for the transfer of technology has been questioned by some studies and that no assessment has been made of the nature and magnitude of the incentives made till now. Article 66.2 of the TRIPS Agreement provides for transfer of technology and requires developed country members to provide incentives to enterprises and

institutions to promote and encourage transfer of technology to least developed country members.[41] The Doha Ministerial Declaration reaffirmed that the provisions of Article 66.2 are mandatory and that the TRIPS Council shall put in place a mechanism for ensuring the monitoring and implementation of obligations under Article 66.2.[42] However, the 2009 WIPO Report also noted that certain studies have suggested that the submissions made by the developed countries to the TRIPS Council with regard to Article 66.2 were irregular, did not specifically target any LDC's and did not provide sufficient detail to determine whether Article 66.2 provided any additional incentives at all (WIPO (2009b), SCP/14/4: 20, para 78).

The report also noted a linkage between patent systems and transfer of technology lacks clear evidence though certain elements in the patent systems could have implications on transfer of technology (WIPO (2009b), SCP/14/4: 23, para 90).

6.8. 2010 UNDP Report

In 2010 UNDP came out with an elaborate study on improving access to medicines by making use of the flexibilities under the TRIPS Agreement (UNDP 2010) The report noted that lack of access to essential medicines is a public health crisis and a human rights challenge (UNDP 2010: 3). The report:

i. noted that right to access essential medicines is a part of the right to everyone to the enjoyment of the highest attainable standard of physical and mental health as is recognized by the Committee on Economic, Social and Cultural Rights (UNDP 2010: 3)

ii. highlighted the importance of generic medicines and highlights the case of antiretroviral (ARV) combination Triomune (stavudine + lamivudine +

[41] Article 66.2 of TRIPS Agreement states as below:

> Developed country members shall provide incentives to enterprises and institutions for the purpose of promoting and encouraging technology transfer of least-developed country members in order to enable them to create a sound and vital technological base.

[42] Article 11.2 of the Doha Ministerial Declaration states as below:

> 11.2 Reaffirming that the provisions of Article 66.2 of the TRIPS Agreement are mandatory, it is agreed that the TRIPS Council shall put in place a mechanism for ensuring the monitoring and full implementation of the obligations in question. To this end, developed country members shall submit prior to the end of 2002 detailed reports on the functioning in practice of the incentives provided to their enterprises for the transfer of technology in pursuance of their commitments under Article 66.2. These submissions shall be subject to a review in the TRIPS Council and the information shall be updated by members annually.

nevirapine) being made available by the Indian generic manufacturer Cipla at less than 365 dollars per day when the patent holders were charging USD 10,000 to USD 15,000 per year. This resulted in massive price reduction by the patent holders. The report also notes that in the present day majority of the ARV's supplied by government programs such as US President's Emergency Plan for AIDS Relief (PEPFAR) and by global funds such as Global Fund to Fight AIDS, tuberculosis and Malaria (GFATM) are of generic nature (UNDP 2010: 4).

iii. noted that high prices is one of the significant factors which inhibit access to essential medicines and that one of the prominent reasons for the high prices is IP protection which prevent generic manufacturers from entering the market. The report notes that in low income countries the people spend 50-90% of their health related expenses in buying medicines (UNDP 2010: 4-5).

iv. noted that the TRIPS Agreement is alleged to be negotiated in favour of high income, knowledge based economies and that these high income, knowledge based economies dominate the WTO system and decision making process though they are a minority in the WTO; and that two thirds or over 100 out of the 153 WTO Member states are low and middle income countries and that about 30 are least developed countries (UNDP 2010: 6).

v. noted that in 1999, the UNDP Human Development Report (HDR) stated that "the relentless march of IPRs needs to be stopped and questioned (UNDP 2010: 6).

vi. noted that initial attempts by low income countries to use the flexibilities in the TRIPS Agreement were fraught with challenges and notes that when South Africa amended its Medicines and Related Substances Act in 1997 to facilitate parallel imports and compulsory licensing 39 pharmaceutical companies and the South African Manufacturers Association challenged the amendment before the South African Court of Appeal' (UNDP 2010: 7). The report also notes that the US Government had initiated a complaint against Brazil before the DSB of the WTO when Brazilian law authorized the grant of compulsory

licenses where patent holders had not worked their inventions locally (UNDP 2010: 7).

vii. stated that many of the developing countries are yet to make use of the flexibilities provided by the TRIPS Agreement such as compulsory licensing or making use of international exhaustion regime or use of Bolar exceptions (UNDP 2010: 8).

viii. negated the argument that IPR's in the pharmaceutical sector fosters much innovation and states that since the signing of the TRIPS Agreement in 1995, consumers have not witnessed a significant increase in the output of medicines inspite of the substantially higher level of IP protection on the global level. The report notes the 2006 finding of the WHO Commission on Innovation, IPR and Public Health that while developing countries are bearing the cost of implementing the TRIPS Agreement, there are no documented cases of impact on innovation in the medical field as yet (UNDP 2010: 9).

ix. noted that the number of patents granted to protect genuinely new pharmaceuticals is small and declining and that at the same time thousands of patents are granted for minor modifications of already existing drugs in pharmaceuticals. The report cites statistics from the US National Institute for Health Care Management that 'in the period 1989-2000 only 15% of all new drug approvals were for medicines that provide a significant clinical improvement' (UNDP 2010: 9).

x. that since pharmaceutical companies produce medicines for markets that can pay for the same, their focus is on medicines that affect the developed world. For example, the pharmaceutical companies focus their research on lifestyle drugs such as medicines for erectile dysfunction, rejuvenation etc. than for fatal diseases like kala azar or sleeping sickness which affect the developing world (UNDP 2010: 10-11).

xi. stated that estimates reveal that the number of people suffering from diseases like AIDS will increase drastically with the figures reaching up to 55 million in 2030 (UNDP 2010: 14). This being the case the availability of generic

medicines is critical and it is important for nations to utilize the TRIPS flexibilities while putting in place or fine tuning their IPR regimes to ensure availability to affordable generics (UNDP 2010: 14).

xii. noted that nations must adopt and use the exclusions from the patentability regime as provided by the TRIPS agreement for e.g. non patentability of diagnostic, therapeutic and surgical methods, plants and animals other than microorganisms, biological processes for the production of plants and animals other than non-biological and microbiological processes, should all be kept outside the patents regime as patents in these areas may have the effect of making treatments more expensive (UNDP 2010: 17-18).

xiii. noted that the criteria for patentability as set in Article 27 of the TRIPS Agreement i.e. novelty, inventive step and industrial applicability, should be suitably defined under national law so as not to lower the threshold of patentability (UNDP 2010: 18-19).[43]

xiv. noted that by adopting strict criteria for patentability nations will be able to prevent secondary features from patentability, ever greening etc.(UNDP 2010: 20). The report notes that while developed countries may permit patenting of new forms and/or known uses, developing countries have taken active measures to prevent such low threshold of patenting and notes section 3(d) of the *Patents Act* in India (UNDP 2010: 20). Section 3 of the 1970 *Patents Act* states what inventions are not patentable and section 3(d) states that 'the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such process results in new

[43] The UNDP (2010: 18-19) notes:

> In a footnote to Article 27, the TRIPS Agreement allows member states to interpret "inventive step", which is the terminology used in most European countries, as "non-obvious", which is the standard applied in the US. Similarly, countries could define 'capable of industrial applicability' (the common European standard) as a synonym to 'useful' (the US standard). The standards of "non-obviousness" and "usefulness" set a lower threshold and make many more inventions patentable than the standards of inventive step and industrial applicability.

product or employs at least one new reactant' is not patentable (UNDP 2010: 21).[44]

xv. stated that excluding new uses of known substances from patentability would prevent a large number of old drugs from receiving another period of patent protection and noted the case of AZT which was known since 1964 as a cancer medicine but which was approved in 1987 for treatment of HIV. The report notes that if countries where AZT was initially patented had excluded new uses of known substances from patentability then AZT would have been available in generic form much earlier (UNDP 2010: 21).

xvi. recommended pre grant and post grant opposition to patents and provision of locus standi to civil society members in pre grant opposition as effective measures to improve patent quality and to reduce situations of patent challenges in courts (UNDP 2010: 22-23).

xvii. noted that the TRIPS Agreement in Article 39 provides for test data protection of pharmaceutical or agricultural chemical products and does not require data exclusivity, the latter regime which prevents drug regulatory authorities' from accepting applications for registration of generic medicines during period of exclusivity unless the applicants for the generic medicines submit their own test data. The report highlights that repetition of clinical trial contradicts the ethical principles for medical research involving human subject as adopted by the World Medical Association and that traditionally authorities have relied on

[44] The UNDP (2010:1) notes:

> In 2007, the Indian Patent Office, following an opposition filed by a patient organization, relied on this section in its refusal to grant the pharmaceutical company Novartis a patent for the cancer drug imatinib mesylate. The patent office considered the beta-crystalline form of imatinib mesylate to be a new form of a known substance without the enhancement in efficacy required under Section 3d and thus rejected the patent application under India's revised Patent Act. Novartis filed two lawsuits. In one lawsuit the company challenged the decision of the Patent Office, claiming that imatinib mesylate fulfils the patentability requirements under the Indian Patent Act as it enhances the efficacy of a known substance. In a second lawsuit Novartis claimed that Section 3d does not comply with the TRIPS Agreement and violated the Indian Constitution. On August 6, 2007 the High Court in Madras rejected the constitutional challenge, decided that it was not the forum to address questions on compliance with the TRIPS Agreement and upheld the validity of India's 2005 Patents Amendment Act. On 6 June 2009 the Intellectual Property Appellate Board of Chennai rejected the lawsuit against the decision of the Patent Office. This judgement was appealed by the patent applicant and a decision is pending. The decision on whether a new form of a known substance can be patented has major implications for many drugs used in HIV care, now and in the future.

data submitted by the originators instead of having to repeat the tests on animals and humans (UNDP 2010: 24).

xviii. noted that data exclusivity regimes will have a negative impact on generic manufacturers and their manufacture of medicines as the high cost of test data and the low margins of generic medicines will deter them from entering the market. The report further notes that data exclusivity provisions under a US-Jordan FTA has delayed the introduction of generic drugs into the market and also increased the costs of the medicines in the country (UNDP 2010: 25-26).

xix. highlighted compulsory licenses, parallel imports etc. as effective mechanisms to curb high prices in medicines. The report further highlights the need to make sure that anti-counterfeit laws do not declare generic medicines as counterfeit. The report cautions against TRIPS plus commitments which are thrust through free trade agreements between countries and cautions developing countries against such provisions in the FTA's which they hay enter into with the developed world. The report recommends use of competition laws to ensure fair pricing of medicines within national jurisdictions.

xx. observed that the Brazilian policy of providing free ARV treatment as announced in 1996 was made passable by the production and import of generic first and second line medicines. Post 2005 when the TRIPS obligations kicked in, Brazil used the threat of compulsory licensing with the pharmaceutical MNC's Abbot, Merck and Roche (manufacturers of lopinavir, indinavir, nelfinavir and saquinavir respectively) to reduce prices of the medicines as generics could no longer be used (UNDP 2010: 27, f.n.87).

xxi. emphasized that compulsory licenses need not be restricted to situations of national emergency and that the Doha Declaration (WT/MIN(01)/DEC/2) has clarified that each Member has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are issued and that each Member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency and that public health crises including HIV/AIDS, tuberculosis, malaria and other epidemics can

represent national emergency or other circumstances of extreme urgency (UNDP 2010: 31).

xxii. noted that the purchase of expensive patented medicines on large scale for a country health programme can have a very detrimental effect on a nations' health budget as much of the resources would have to be allocated for the purchase of such medicines (UNDP 2010: 32-33). The report highlights as a case in point the HIV treatment program in Brazil which provided free access to ARV's nationwide. In order to meet this objective the Brazilian government used the flexibility under TRIPS for 'government use' to manufacture or import cheaper generic medicines. Under this flexibility countries can implement simple procedures whereby government officials can authorize the use of a patented invention for government purposes subject to payment of monetary remuneration to the patent holder. The US government has also retained such powers under its domestic legislation (UNDP 2010: 32-33).

xxiii. highlighted that on August 30, 2003 the WTO General Council issued a decision (hereinafter "30 August Decision") which introduced a waiver of the requirement in Article 31(f) of the TRIPS Agreement which required predominant domestic use of the medicines produced under compulsory incensing an allowed WTO member states to issue compulsory licenses for export of generic medicines to countries with insufficient or manufacturing capacity (UNDP 2010: 35). The 30 August Decision also provided the waiver that for countries which are parties to a regional trade agreement in which half of its membership consists of LDC's export restrictions shall be waived to the extent necessary to enable a pharmaceutical product produced or imported under a compulsory license to one member state to be exported to those other developing or east developed countries party to the regional trade agreement which share the same health problem (UNDP 2010: 36).

xxiv. recommended the use of competition laws to prevent anti-competitive behaviour that could hamper access to affordable medicines (UNDP 2010: 41). The report highlights that these flexibilities are built into Article 8.2., 31(k) and 40 of the TRIPS Agreement and that as the TRIPS Agreement does not define what an anti-competitive behaviour is, it provides policy space to

nations to determine what anti-competitive behaviour is. Unreasonable restraint of trade or adversely affecting the international transfer of technology could be used as grounds which prove anticompetitive behaviour (UNDP 2010: 41).

xxv. highlighted compulsory licenses as a very effective measure to counter anti-competitive practice as under Article 31(k) compulsory licenses does not require prior negotiations with the patent holder and that there is no need even to inform the patent holder when compulsory licenses are used for government use authorizations. Further the sole requirement is too have a proper procedure administrative or judicial and if the anti-competitive practice is likely to recur, then the compulsory license may be continued with by the government (UNDP 2010: 41-42). The report points out that Article 31(k) of the TRIPS agreement waives the restriction for predominant local use in the context of a compulsory license issued as a measure to counter an anti-competitive practice and that thus the local producers would be able to achieve economies of scale and lower the cost (UNDP 2010: 42).

xxvi. noted that while the TRIPS Agreement sets only the minimum requirements with respect of enforcement of IPR rights, there have been several initiatives to impose IPR enforcement at levels which is far beyond the WTO requirements. For example there is pressure on developing countries to impose criminal sanctions on IPR violations which under the TRIPS Agreement is limited to only a class of wilful trademark counterfeiting and copyright piracy at a commercial scale (UNDP 2010: 45-46). The Report noted that such initiatives will deter generic manufacturers from entering the domain. Further as per the report various bilateral and regional agreements further erode the flexibilities under the TRIPS Agreement (UNDP 2010: 49). For example LDC's being forced to forgo the transition period available till 2016, FTA's negotiated by US which permit patenting of new uses of known substances, requiring longer periods of patent protection than 20 years, restricting ability of countries to permit pre-grant opposition etc. (UNDP 2010: 50).

xxvii. Called for against coercing developing countries to join the Patent Co-operation Treaty which facilitates the ability of foreign companies to file patent applications in such country, pressuring developing countries to provide for data exclusivity which is not required under the WTO, compelling countries to link their patent systems with US drug regulatory systems and forbidding the drug regularity authorities of such countries from approving generic drug as long as there is a valid patent for the drug in US, limiting counties from granting compulsory licenses only to cases of national emergency or extreme emergency etc. (UNDP 2010: 51). Limiting parallel imports though permitted through the Doha Declaration (WT/MIN(01)/DEC/2), compelling enforcement requirements which go beyond that required under the TRIPS are some other measures adopted by the developed countries (UNDP 2010: 52).

6.9. 2013 WTO, WHO and WIPO Joint Study

In 2013 the WTO, WHO and WIPO came out with a joint study titled "*Promoting Access to Medical Technologies and Innovation: Intersections between Public Health, Intellectual Property and Trade*" thus once again acknowledging the impact of the WTO regime on health. The study notes that lack of equity in the supply of essential medicines, high prices, informal payments and out-of-pocket expenses for the medication required exclude the poor and vulnerable and do not facilitate the realisation of the right to health (WHO, WIPO and WTO 2013: 42). The study notes that the millennium development goals are a set of eight international development goals to be achieved by 2015, all of them relate in some way to improving physical, mental and social well-being (WHO, WIPO and WTO 2013: 42).

The study noted that there are a number of regional and inter regional regulatory harmonisation initiatives on the regulation of medicines and medicinal devices including:

i. East African Community's project of harmonization of medicines registration in five member states which seeks to improve public health by increasing rapid access to good quality medicines through harmonisation of technical requirements and procedures for medicines registration which will in turn enable shorter registration periods for priority medicines to treat

communicable and non-communicable diseases (WHO, WIPO and WTO 2013: 49).

ii. European Medicines Agency which is responsible for scientific evaluation of applications to market certain medicine categories on Europe both for human and veterinary medicines. The system is based on EU wide harmonisation of certain areas of pharmaceutical legislation including technical requirements for marketing authorisation and that the system enables companies to apply for simultaneous registration of medicines in different EU member states (WHO, WIPO and WTO 2013: 50).

iii. Gulf Cooperation Council's drug registration established in 1999 which comprises of countries of Bahrain, Kuwait, Oman, Qatar, Saudi Arabia an United Arab Emirates and that the GCC registers pharmaceutical companies, products, inspects companies for GMP compliance, approves quality control laboratories, review of technical and post market surveillance reports, responsible for bio equivalence studies etc. (WHO, WIPO and WTO 2013: 50).

iv. Pan American Network of Drug Regulatory Harmonisation ("PANDRH") which was established to deal with regulatory harmonisation of medicines and comprises of representatives of drug regulatory authorities in Pan American region. The PANDRH set up the Pan American Forum of Drug Regulatory Agencies to discuss and explore solutions to common problems.

v. Regional initiatives such as Andean Quality System, Southern Common Market (MERCOSUR), Association of Southeast Asian Nations (ASEAN), African Medicines Regulatory Harmonisation (AMRH) initiative etc.

vi. Inter-regional regulatory harmonization initiatives such as (see (WHO, WIPO and WTO 2013: 50-51):

vii. International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use and related initiatives established in 1990 which brings together regulatory authorities and pharmaceutical industries of Europe, Japan and United states to discuss scientific and technical aspects of medicines registrations specially focusing on new and innovative medicines.

viii. Global Harmonisation Task force created in 1992 and which was founded by Australia, Canada, European Union, Japan and United States to achieve uniformity between national medical devices regulatory systems.

ix. International medicines regulators forum established in 2011 to discuss future directions in medical devices harmonisation and which comprises of group of medical devices regulators from Australia, Brazil, Canada, European Union, Japan, United States, and the WHO.

6.10. 2013 WHO UNDP Study

The WHO UNDP document titled *Using TRIPS Flexibilities to Improve Access to HIV Treatment*[45] suggests the following options to for low and middle income countries (WHO UNDP 2013: 9-10):

i. Revision of national IP laws in order to ensure that TRIPS flexibilities specifically geared to promote access to medicines are incorporated into national laws without delay.

ii. Parliamentarians to ensure that new trade agreement are not contradictory to the Doha Declaration (WT/MIN(01)/DEC/2)

iii. Least developed countries to use the necessary legislative action and where appropriate to use the transitional period and not to grant pharmaceutical patents till 2016[46] as provided for in the Doha Declaration (WT/MIN(01)/DEC/2)

iv. Encourage regional co-operation to develop IP and trade policies that promote innovation consistent with TRIPS

v. Strengthen the capacity of national regulatory regimes to ensure that quality, safety and efficacy of health products and to fast track the registration of drugs pre-qualified by the WHO

vi. Invest in regional and national production capacity in pharmaceutical sector.

6.11. Non-Governmental Initiatives

Among the non-state actors, alliances such as Global Alliance for Vaccines and Immunisation (GAVI) also play important roles such as providing basic vaccines to

[45] [Online: web] Accessed 21 September 2015, URL: http://www.who.int/phi/phi_trips_policybrief_en.pdf,

[46] As per the decision of the TRIPS council in June 11, 2013, this transition period for least developed countries has been extended till July 01, 2021.

children in the developing world. In 2008, the Special Rapporteur on the Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health himself commented on the utility of such initiatives (Hunt, Paul (2008), UN Doc.A/HRC/7/11 of 31 January 2008, para 31).[47]

6.11.1. Pricing Agreement by Medicines Patent Pool Foundation with Roche

Medicines Patent Pool Foundation is a nongovernmental organisation created by UNITAID in 2010 (United Nations 2012: 68). MPPF has sought to facilitate the availability of high cost medicines for the treatment of the poor in developing countries. On August 05, 2013, the MPP entered into a pricing agreement with F. Hoffmann-La Roche Ltd. for supply of *valganciclovor* medicines for the treatment of HIV- related cytomegalobirus infections (CMV) in developing and least developed countries through various non-profit organizations. Under this agreement Roche offered to enter into good faith negotiations with MPP on licensing of the medicine *sanquinavir* for use in developing countries.[48] The price agreed is 250 CHF for a pack of *vulganciclovir* tablets 450 mg 60 and the orders are not to be less than 40 packs per order per country for term of the Agreement (Exhibit A of 2013 Agreement between MPP and Roche). This agreement was valid till July 01, 2013 and could be extended by mutual agreement between the Parties (Section 13.1 of 2013 Agreement between MPP and Roche). The list identified countries i.e. 138 countries is attached as Exhibit B to the agreement and includes India.

The various non-profit organisations identified are to place orders with Roche or third party distributors designated by Roche (Section 4.1 of 2013 Agreement between MPP and Roche). The identified organizations are to be responsible for the necessary import and other licenses, payment of import and sales taxes, insurances, duties and levies under the agreement and for providing documentation s applicable (Section 5.3

[47] Hunt, Paul (2008), *Promotion and Protection of All Human Rights, Civil, Political, Economic, Social and Cultural Rights: Report of the Special Rapporteur on the Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health*, A/HRC/7/11, 31 January 2008, para 31. The report notes:

> 31. In 2005, recognizing that inadequate health systems were impeding progress towards improved immunization coverage, GAVI decided to support health system strengthening with an initial commitment of US$ 500 million for 2006-2010. Launched in 2007, the International Health Partnership - a global compact for achieving the health Millennium Development Goals - aims to build health systems in some of the poorest countries in the world. It is hoped that the Partnership will go beyond making better use of existing aid and also generate additional resources.

[48] Section 3 of the Agreement dated August 05, 2013 between MPP and Roche

of 2013 Agreement between MPP and Roche). Roche is to invoice the non-profit organisations and the organisations are to pay Roche the respective unit price for each product purchased under the agreement (Section 7 of 2013 Agreement between MPP and Roche).

The agreement also provided that after one year of the effective date Roche and MPP is to review the extent and scale up of the sue of the products within the identified territories and that at such time Roche and MPP is to enter into good faith negotiations regarding licensing and technology transfer to suitable appropriate third parties in the territory in order to ensure supply of low cost generic version of *vulganciclovir* (Section 8.1 of 2013 Agreement between MPP and Roche). Also, the agreement stated that one year after the effective date and upon request from MPP, Roche and MPP will enter into good faith negotiations for the licensing and technology transfer to suitable third parties in developing countries outside the identified territory to ensure the supply of low cost generic version of *vulganciclovir* (Section 8.2 of 2013 Agreement between MPP and Roche).

6.11.2. 2013 License Agreement by Medicines Patent Pool Foundation with ViiV

Under this Agreement dated February 13, 2013 between VIIV healthcare UK Limited (ViiV) and the MPF, MPPF received license from ViiV to allow it to grant sub licenses to various third parties in order to promote access to paediatric formulations of antiretroviral drugs in a number of low and middle income countries.

The license provided to the sub licensee is a nonexclusive, royalty free, non-sub licensable, non-transferable license to:[49]

a) manufacture, use, sell, supply, import or export in the territory raw materials for use in the manufacture of products to be supplied in the territory solely for use in the anti-retroviral therapy for HIV/AIDS and to
b) manufacture, use, sell, supply, import or export products in the territory and solely for use in antiretroviral therapy for HIV/AIDS.

[49] Section 2.1 of format of license agreement between MPPF and licensee annexed to the license agreement dated February 02, 2013 between ViiV and MPPF

Also, the license is granted to the licensee for a nonexclusive, royalty free, non-sub licensable and non-transferable license under non-territory patents to:[50]

a) manufacture, use, sell, supply, import or export outside the Territory products exclusively for use, sale, supply, import or export of such products in the territory and solely for use in the antiretroviral therapy for HIV/AIDS
b) manufacture, use, sell, supply, import or export outside the Territory raw materials exclusively for supplying to the territory for use in the manufacture of products in the territory and solely for use in the anti-retroviral therapy for HIV/AIDS
c) manufacture, use, sell, supply, import or export outside the territory raw material for the manufacture of the products outside the territory exclusively for use, sale, supply, import or export in the territory and solely for use in antiretroviral therapy For HIV/AIDS.

The agreement makes it clear that non IP right is conferred on the license than the license permissions as expressly stated in the agreement. The license agreement also has a non-diversion clause which makes it clear that the licensee is not to directly or indirectly sell or supply:[51]

a) products or raw materials outside the Territory
b) raw materials to any third party in the territory that the license knows, believes or ought to reasonably suspect will sell or supply raw materials outside the territory and
c) products to any third party in the territory that the licensee knows, believes or ought to reasonably suspect will sell or supply products outside the territory

The agreement is of use to the ViiV as well as the same provides that if at any time during the term of the Agreement if the Licensee or any of its employees, agents or other persons acting under its authority makes, develops, conceives, acquires, reduces to practice or becomes entitled to or secures control over any improvement it shall communicate such improvement to the licensor and ViiV in full together with all available information concerning the mode of working of the same. Also the licensee

[50] Section 2.2 of format of license agreement between MPPF and licensee annexed to the license agreement dated February 02, 2013 between ViiV and MPPF
[51] Section 7 of format of license agreement between MPPF and licensee annexed to the license agreement dated February 02, 2013 between ViiV and MPPF

is to grant the licensor and ViiV a perpetual, irrevocable, worldwide royalty free nonexclusive license to use such improvement, improvement patent and related know how.[52]

The following is a table on the list of license agreements as made available by WHO in December 2014 (Beyer, Peter Dr. 2014):

Table 5: List of License Agreements

Voluntary license agreements & non-assert declarations: HIV adults					
INN	**Licensor**	**Year**	**Scope**	**No countries**	**Licsees**
EFV	MSD	2007	South Africa	1 (allows export to SSA)	Several
d4T	BMS	2001	SSA, India. country list	50	Several
DDL	BMS	2006	SSA; India; country list	50	Several
RAL	MSD	2011	LIC; SSA	56	2
SQV	Roche	2006	LDC; SSA	65	Several
DRV	Tibotec (Janssen/J&J)	2012	Non-assert: LDC; SSA License: India	65	1+non-assert.
ZDV; ZDV/3TC	ViiV Healthcare	2010	LDC; LIC; SSA	69	Several
TPV	Boehringer-Ingelheim	2004/07	LIC; LDC; Africa, India	78	Several
NVP	Boehringer-Ingelheim	2004/07	LIC; LDC; Africa; India	78	Several
DTG; DTG/ABC	**MPP:** ViiV Healthcare	2014	Country list	73 (+ no patent count.)	MPP
EVG; QUAD TDF+FTC+EVG	**MPP:** Gilead Sciences	2011	Country list	100	Several
EVG; QUAD TDF+FTC+EVG	Gilead Sciences	2011	Country list	100 + 9 semi-exclusive licenses for MICs	4
ATV	**MPP:** BMS	2013	Country list	110 (+ 34 no patent count.)	MPP
RPV/TDF/3TC or FTC; RPV	Tibotec (Janssen/J&J)	2011	Country list	112	5
TDF	Gilead Sciences	2006/11	Country list	112	Several
TDF; TAF; FTC	**MPP:** Gilead Sciences	2011/14	Country list	112	Several

6.12. WIPO Re:Search

There are certain initiatives such as WIPO Re:Search, which attempts to bring together Member States, institutions, corporates etc. on the same platform for collaborative efforts on dealing with neglected diseases. This consortium was started in 2011 and has 94 organisations as members from 26 countries currently (Partnership Hub Report, 2014:2). The database of this consortium provides details of IP assets available for licensing royalty free for the sole purpose of addressing public health needs in the world's least developed countries in the matter of neglected tropical

[52] Section 7 of format of license agreement between MPPF and licensee annexed to the license agreement dated February 02, 2013 between ViiV and MPPF

diseases.[53] Re: Search initiative facilitates academic and non-profit researcher's access to industry assets and there are collaborations facilitated between researchers and industry members. In 2014 there were sixty six per cent partnerships between academic and non-profit members facilitated through the Re: Search consortium (Partnership Hub Report, 2014: 2).

7. TRIPS Plus Agreements

Any study of on the TRIPS Agreement and its impact on developing countries will be incomplete without review of the various bilateral agreements that are signed which exceed the obligations cast under the TRIPS Agreements. Various studies such as the ESCAP 2007 study covered in chapter 2, the United Nations 2012 report and the UNCTAD 2009 report covered in this chapter noted the dangerous trend of imposing higher obligations than the TRIPS through bilateral agreements.

As Heydon, Kenneth (2014: 1049) notes there has been a proliferation of PTA's and that in 2014 there were 379 PTA's including bilateral agreements compared to 30 in 1990. He notes that the PTA'S have attained a critical mass and that they now take place on a preferential basis than the multilateral agreements. The principal reason for the wide acceptance of PTA's is that they accurately by pass the political economy dilemma in trade liberalization by excluding difficult sectors, carefully selected partners are involved, avoid MFN commitments and secure reciprocity from partners (Heydon, Kenneth 2014: 1049).

While the FTA's are envisaged to act as building blocks, studies such as those by Kang, Jong Woo (2015) notes that these need not be building blocks, but can rather be stumbling blocks due to noodle bowl effect.

Bryan Mercurio (2006) while looking TRIPS and FTA's in detail, notes that TRIPS should never have been viewed as a final statement on international IPR's but as merely a stage in a larger cycle alternating between bilateral, regional and multilateral forums. He observes that the world has moved beyond the multilateral phase into a

[53] "Neglected Diseases Research Gets a Boost As Merck KGaA Joins Consortium", http://www.pharmaceutical-journal.com/news-and-analysis/news-in-brief/neglected-diseases-research-gets-a-boost-as-merck-kgaa-joins-consortium/20067283.article [Online: web] Accessed 11 September 15

bilateral phase in which there is negotiation increased IPR's (Bryan Mercurio 2006: 216). According to him TRIPS is not a definitive agreement on IPRs that some hoped it would be, but instead the TRIPS represent one part of a larger cycle in which developed countries engage in bilateralism, regionalism and multilateralism to engage their interests and secure concessions from other nations (Bryan Mercurio 2006: 216). Importantly, he observes on the US approach on FTA's as below:

a) when US is unable to gain concessions through multilateral negotiations due to various reason including consensus decision making, it simply shifts these parameters and sidesteps multilateral impediments through bilateral/regional agreements with those 'can do' countries which are willing to make concessions in order to secure potentially lucrative agreement with US (Bryan Mercurio 2006: 220). For example Nicaragua agreed to forgo its implementation period and instead immediately comply with TRIPS obligations in exchange for preferential access to us market and increased prospect of FDI (Bryan Mercurio 2006: 222).
b) the practice of negotiating TRIPS – plus provisions is not limited to FTA's with developing countries, but also include FTA's with developed countries such as Australia US FTA (Bryan Mercurio 2006: 222).
c) many of the US FTA's explicitly commit the parties to provide adequate and effective protection of IPR's in accordance with 'highest international standards', instead of terms as under the TRIPS or otherwise (Bryan Mercurio 2006: 223).
d) several US FTA's introduce provisions which prevent national drug regulatory authorities form registering generic version of drugs that is under patent in the country without consent of patent holder (Bryan Mercurio 2006: 224), which is a major shift from the current practice where the regulatory approval of a drug for its safety, efficacy etc. is not linked to a drugs patent status. This newly formed role of the regulatory authority as enforcer of private rights constitutes a significant benefit to the right holder (Bryan Mercurio 2006: 225).
e) the US FTA's brings its patterns in line with domestic law by preventing other applicant and national authority from relying on clinical studies and data provided by original applicant when seeking to register the generic version of the drug for a given period of time following first registration (Bryan Mercurio

2006: 227). Such data exclusivity can also act as a *de facto* patent ensuring minimum period of monopoly for pharmaceutical companies preventing competition and in some instances prohibit a generic manufacturer from seeking registration in a country (Bryan Mercurio 2006: 228). Further exclusivity provisions can effectively prevent use of compulsory licensing during patent terms as we as extend life of the patent (Bryan Mercurio 2006: 229).

f) Several US FTA's also effectively prohibit generic manufacturers from using evidence of registration of the originator drug in another country to provide the safety and efficacy of their version (Bryan Mercurio 2006: 227).
g) Some FTA's require pharmaceutical companies to be compensated for 'unreasonable delay' caused by national drug regularity authority in examining and application for registration or such delay from patent office on assessing the application for patent by extending the patent term by the same amount of time of 'unreasonable delay' which is often mention as five years form he date of filing or three years form request for extension (Bryan Mercurio 2006: 229).

Restrictions are imposed on the ground of issuing compulsory license to specific grounds such as remedying an anti-competitive practice, public non-commercial requirements, national emergency, other cases of extreme emergency and failure to meet working requirements (Bryan Mercurio 2006: 231). The inability to import ingredient or pharmaceutical products in situations other than those stated in the FTA could greatly undermine the accessibility of generic medicines (Bryan Mercurio 2006: 232).

On the US-Singapore FTA, the level of compensation to be provided in the context of compulsory licensing need to be 'reasonable and entire' than the TRIPS language of 'adequate' (Bryan Mercurio 2006: 231). While the Doha Declaration (WT/MIN(01)/DEC/2) confirmed the existing rights in TRIPS that each WTO member may establish its own regime of exhaustion of IPR's and parallel importing is itself not a violation of TRIPS. However, US FTA's with Morocco, Australia etc. prohibit parallel importation (Bryan Mercurio 2006: 233). This is another measure which will limit the options to reduce medicinal pricing.

Mercurio (2006: 235) summarises that the newly granted IPR's through the FTA'S pose threat to public health and welfare by removing the flexibilities granted in TRIPS. He rightly observes that the TRIPS Plus provisions negotiated by the US illustrate how the US is raising the minimum standards by progressively building upon the level of IP protection through development of FTA models or prototypes (Bryan Mercurio 2006: 224). If enough FTA's are negotiated containing TRIPS plus provisions, then these provisions will essentially become the new minimum standard from which any new WTO trade round would proceed (Bryan Mercurio 2006: 223).

Trebilcock, Michael, Howse, Robert and Eliason, Antonia (2013: 808) note that there is need to address the relationship between the WTO and the Preferential Trade Agreements. They conclude that it is not possible that there should be or could be any reversal of the trend towards bilateral or regional trade agreements, but the trend requires the WTO to play the role that is envisaged by Article XXV of the GATT to effectively monitor and scrutinise that arrangements to ensure that they do not undermine multilateral norms. Trebilcock, Michael, Howse, Robert and Eliason, Antonia (2013: 808) goes on to note that the proliferation of rules and dispute settlement decisions in different forums needs to be addressed and that while WTO jurisprudence is often cited by the regional tribunals, many of the tribunals make rulings and interpretations that could be inconsistent with one another and that there is need to consider a final appellate court for international trade which could consider the appeals from the rulings of diverse regional and bilateral dispute settlement mechanisms and ensure consistent jurisprudence on issue common to various forums.

Valdes, Raymundo and McCann, Maegan (2014) in their detailed analysis of the presence of IP provisions in Regional Trade Agreements (hereinafter "RTA's"), note:

a) that all regional trade agreements between Americas and Europe contain commitments to IP protection (Valdes, Raymundo et.al 2014: 14)
b) that such commitments are more common in RTA's involving Europe than in other agreements Valdes, Raymundo et.al 2014: 14)
c) that this type of commitment is more frequent in RTA's involving developed economies and less usual in RTA's involving only developing economies (Valdes, Raymundo et.al 2014: 14).

d) 90% of the RTA's signed by the United States or EFTA members and about three quarters of European Union's or Japan's agreements contain patent provisions
e) That inclusion of pharma related provisions in RTA's is not common, even in those agreements that otherwise contain other type of IP provisions (Valdes, Raymundo et.al 2014: 30)
f) That RTA's containing pharma related provisions are common for agreements involving only developed countries and to a lesser extent for agreement between developed and developing/transition economies (Valdes, Raymundo et.al 2014: 30)
g) That great majority of the US RTAs incorporate pharma related provisions and that some provisions can result in longer than normal periods of market exclusivity (Valdes, Raymundo et.al 2014: 30)

Farley, Christine Haight (2014: 103) notes that each of these new bilateral agreements results in further ratcheting up of IP provisions and a whittling down of TRIPS flexibilities. Even a danger is brought to the fore front, as to whether a TRIPS member stat that obligates itself to TRIPS plus protection in a bilateral agreement will then be obligated to extend these standards to all members of the WTO due to the MFN clause and thus it might be possible for a WTO member to take advantage of a TRIPS plus standard in a bilateral agreement to which it is not a party (Farley, Christine Haight 2014: 104). Further there could be decisions made under the investment arbitration tribunals which might determine a TRIPS compliant mechanism to be breach of an BIT, for example, a compulsory license for a necessary pharmaceutical being held as constituting indirect expropriation under the BIT (Farley, Christine Haight 2014: 106).

7.1. 2006 CAFTA and RCEP

CAFTA was entered into between US, Dominican Republic, Nicaragua, Guatemala, Costa Rica, El Salvador and Honduras and is in force from 2006. It required the Parties to ratify or accede to 1970 *Patent Cooperation Treaty* and the 1980 *Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure* by January 01, 2006 (Article 15(3) of CAFTA) and to the 1991 *International Convention on Protection of New Varieties of Plants* etc. by

January 01, 2008 (Article 15(4) of CAFTA). Further, it required the Parties to make reasonable efforts to ratify or accede to the 2000 *Patent Law Treaty*, affirmed commitments under the TRIPS and also to the various IP agreements concluded or administered under the auspices of the WIPO (Article 15(6) of CAFTA). In the case of developing countries becoming party to the same, additional time ranging from six months to four years were provided for compliance with some of the IPR provisions (Article 15(12) of CAFTA). As a result of CAFTA, several TRIPS plus provisions had to be acceded to even by the developing countries party to it including extension of patent extensions for unreasonable delays in granting patents, restoration or extension of patent term for unreasonable curtailment of patent term in the marketing approval process for pharmaceutical patents (Pusceddu, Piergiuseppe 2014: 106), exclusive rights over test data for atleast five years from the date of approval of the product whether or not patent is granted and whether or not data is undisclosed or not (Pusceddu, Piergiuseppe 2014: 107). Such patent extension will impact public health, as community will have to bear the burden of paying for administrative delays with no additional benefits to patients in developing countries (Pusceddu, Piergiuseppe 2014: 107).

The Regional Comprehensive Economic Co-operation Agreement (hereinafter "RCEP") currently being negotiated between Indonesia, Malaysia, Philippines, Singapore, Thailand, Brunei, Vietnam, Laos, Myanmar, Cambodia with ASEAN Plus Three i.e. China, Japan, South Korea and with India, Australia, New Zealand IS reported to have significant TRIPS plus provisions.. The Public Health Association of Australia (hereinafter "PHA") which is a non-governmental body came across certain leaked proposal by Japan to Australia on strong IP provisions under the RCEP, by which Japan was asking Australia and other negotiating countries to (Public Health Association of Australia 2015: 5):

- Expand the scope of patentability to new forms and new uses of known substances, even where there was no enhanced efficacy
- Patent term extension to compensate for delays in marketing approval process
- providing six years of protection for clinical trial data

- Introducing stringent enforcement of IPRs, including seizure of medicines in transit from one country to another which are suspected of infringing the rights in the transit country

In response to the RCEP, the PHA came out with recommendation to the government asking the government of Australia to oppose the inclusion of stringent IP measure in the RCEP and highlighted a number of examples of the impact of high levels of IP protection on access to medicines. They quoted that:

a) Australian Generic Medicines Industry Association found that delays in entry of generic competition for 39 listed medicines due to secondary patenting cost tax payer's 37.8-48.4 million dollars over a 12 month period between Nov 2001 and Nov 2012 (Public Health Association of Australia 2015: 5).
b) In US secondary patenting of HIV medicines ritonavir and lopinavir/ritonavir could delay generic entry for additional 19 years beyond original patent term (Public Health Association of Australia 2015: 5).
c) Investment related clauses in trade agreement enable companies to sue governments if they enact laws which affect their profits (Public Health Association of Australia 2015: 10).
d) In Thailand extending market exclusivity for five years was found to increase medicine outlays between 9 to 45%, as per 2002 data (Public Health Association of Australia 2015: 6).
e) In Jordan, data protection delayed introduction of generic medicines for 79% of new medicines (Public Health Association of Australia 2015: 6).

7.2. 2015 Trans Pacific Partnership Agreement

The Trans-Pacific Partnership Agreement was entered into between United States, Canada, Australia, New Zealand, Malaysia, Singapore, Japan, Mexico, Peru, Vietnam, Brunei and Chile in October 2015. The TPPA seeks to establish a comprehensive regional agreement that promotes economic integration to liberalise trade and investment, to bring economic growth and social benefits, to create new opportunities for workers and businesses, to contribute to raising of living standards, to benefit consumers and to reduce poverty and to promote sustainable growth (Preamble, TPPA). It also seeks to build on the respective rights and obligations under the Marrakesh Agreement establishing the World Trade Organisation (Preamble, TPPA).

Interestingly, the preamble also affirms the rights of the Parties to adopt, maintain or modify health care systems (Preamble, TPPA) and the inherent right of the Parties to regulate and to preserve the flexibility to set legislative and regulatory priorities to safeguard public welfare, to protect legitimate public welfare activities such as public health, safety, integrity and stability of financial systems and public morals.

Article 18.1 which is the opening paragraph in the Chapter on IP takes note of the Doha Declaration as well as many other treaties on IPR. A Party may in formulating and amending its laws adopt measures necessary to protect public health and nutrition and promote public interest in sector of vital importance to their socio-economic and technological development to the extent they are consistent with the provisions of Chapter 18 of the TPPA (Article 18.3.1 of TPPA). Also, appropriate measures may be taken by a Party to the extant they are consistent with Chapter 18 of the TPPA as may be needed to prevent abuse of the IPRs by right holders or practices which unreasonably restrain trade or adversely impact international transfer of technology (Article 18.3.2 of TPPA).

Article 18.6 notes that the obligations of the Chapter do not and should not prevent a party from taking measures to protect public health and that while reiterating their commitments under the Chapter the Parties affirms that this Chapter can and should be interpreted and implemented in a manner supportive of each Party's right to protect public health and in particular to promote access to medicines for all (See Article 18.6.1(a) of TPPA). The various WTO decisions affirming public health such as the Doha Declaration et al. are noted and that the Chapter should not prevent the effective utilisation of such public health solution (See Article 18.6.1(b) of TPPA).

With such language in the background, the TPPA introduces TRIPS plus provisions such as patents for new uses of a known product, new methods of using a known product, new processes of using a known product (Article 18.37.2 of TPPA), patent extension for unreasonable delays in a Party's issuance of patents, adjusting the term to compensate for such delays (TPPA, Article 18.46.1) etc. Unreasonable delay is defined as delay of more than five years in the issuance of the patent from the date of filing the patent application in the territory of the Party or three years after a request for examination application is made. However, in calculating such delay the Party can

exclude the periods of time that do not occur during the processing of or the examination of the patent application by the granting authority and the periods of time that are not directly attributable to the granting authority and the periods of time that are attributable to the applicant of the patent application (TPPA, Article 18.46.2).

Significantly the TPPA has provisions on protection of test data that are TRIPS plus provisions. If a Party has the requirement of submission of undisclosed test or other data concerning the safety and efficacy of the product, such Party is not to permit third persons to market the same or similar product on the basis of such information or marketing approval granted to the person who has submitted such information without the consent of the party that submitted such information, for at least five years from the date of marketing approval of the new pharmaceutical product in the territory of such Party (TPPA, Article 18.50.a).

On pharmaceutical patents it is specifically mentioned that each party shall make available adjustment of the patent term to compensate the patent owner for unreasonable curtailment of the effective patent terms as a result of market approval process (TPPA, Article 18.48.2). The exemption provision in the TPPA is interesting, as it further limits the exception and states that a party may provide limited exceptions to the exclusive rights conferred by a patent to the extent that such exceptions do not unreasonably conflict with the normal exploitation of the patent and do not unreasonably prejudice the legitimate interest of the patent owner while taking into account the legitimate interest of third parties (TPPA, Article 18.40).

The PHA had earlier came out with recommendation to the government in the context of the RCEP and asked the government of Australia to oppose the inclusion of stringent IP measure in the RCEP and had highlighted a number of examples of the impact of high levels of IP protection on access to medicines such as that if Vietnam was to agree to the IP measures proposed by US, in the TPPA, more than half of the HIV population currently receiving anti-retroviral treatment out of the eligible 68% under the WHO guidelines of those having HIV, would no longer have access (Public Health Association of Australia 2015: 10).

In sum, the enforcement of higher levels of IP protection through RTA's, PTA's, FTA's, IIA's, bilateral treaties etc. are situations against which developing and least developed countries need to be on the guard. As Hsu, Locknie (2006: 533) notes, there is concern raised that the language repeated in multiple RTA's may have impact on customary international law, if such oft repeated and stated language is to be considered as instant customary international law. That being a dangerous position to be in, it is all the more important that signing on 'templates' of RTA's, PTA's, FTA's, bilateral treaties etc. should be avoided by developing and least developed countries.

UNCTAD in its annual report in 2014 noted that policy space is reduced by free trade agreements and also by International Investment Agreements. While in the 1990's such loss of policy space was considered as a small price for the expected increase in FDI, this view has changed in the early 2000s when it became clear that the investment rules obstruct a wide range of public policies including those intended to improve the impact of FDI on economy. Also, there is ambiguity as to whether the bilateral investment treaties and investment chapters in RTA's actually stimulate FDI's or not. Also, concern has come up from the lack of transparency of the tribunals formed to adjudicate on the disputes arising from such agreements and also from the investor bias seen in these adjudicating forums (UNCTAD 2014: x). Among the range of possibilities suggested to achieve a rebalance, is even a retreat from investment treaties and reverting to national law (UNCTAD 2014: xi).

Chapter Summation

The very fact that multiple international agencies such as WTO, WHO, UNDP, ICTSD, WIPO have all addressed the issue of the impact of medicinal prices etc. due to TRIPS Agreement shows the reality and the international recognition of the impacts of patents and medicinal prices. The 2001 Doha Ministerial Declaration, 2003 Cancun Ministerial Declaration etc. all noted this issue.

One of the reasons why the TRIPS Agreement was opposed by the developing countries and the civil society is the tremendous impact of the TRIPS Agreement on human rights and in the initial drafting it focused on protection of IPRs than on the human rights impact. In the words of Mary Robinson, the United Nations High

Commissioner for Human Rights, 'the legal regimes of trade and human rights have developed more or less independently from one another' (Robinson, Mary 2001: 210).

Sarah (2011) notes that 'the development rationale for global IP protection is highly suspect especially since Northern States did not respect such rights during their path to development' (Joseph, Sarah 2011: 244). WIPO in its studies (2009a and 2009b) pointed out that the effect of patents on innovation and transfer of technology, respectively, is not conclusive. In the context of implementation of the TRIPS Agreement domestic national trade and IP protection regulations must abide by and respect the provisions of international trade law and human rights obligations should be made subordinate to the trade agreements or IP regimes (Mabika, Aulline H et. al 2007).

Irrespective of the arguments of the R&D expenses always put forward by the pharmaceutical companies, the profits they reap are several times over the investments they have made. Pharma companies show little interest in dealing with the diseases of the developing world, unless it makes commercial sense for them. Further, they keep the prices high in developing countries as well, as they feel that lower prices in some countries could result in pressure on them to reduce the prices in developed countries where the products are sold at a higher price. From a right to health perspective, the lower pricing of essential drugs in developing countries can become the benchmark for the pricing of the drugs in developed countries and this can help with improving the health scenario of developed nations as well, though some studies recommend the opposite.

Article XX(b) of GATT 1994 provides that the parties may adopt measures to protect human, animal or plant life or health to the extent such measures are not arbitrary or unjustifiable discrimination between countries or a disguised restriction on trade. TRIPS Agreement provides for various flexibilities such as Article 30 for limited exceptions to exclusive rights under patents, Article 31 for other use of the subject matter without authorisation of patent holder etc. Countries should use the flexibilities provided, including adoption of a *sui generis* regime under Article 27.3 (b) as is appropriate for each country's needs such as price controls, compulsory licensing, parallel imports, competition policies etc. (Michalopoulos, Constantine 2001: 150).

Various methodologies such as formulations, combinations, dosage, slats, ethers and esters, polymorphs, Markush claims, selection patents, analogue process, enantiomer, metabolite/prodrug, methods of treatment, firsts and second indications etc. are various areas to be focused to reduce the scope of patentability and thereby increasing access to medicines (Carlos Correa 2007a).

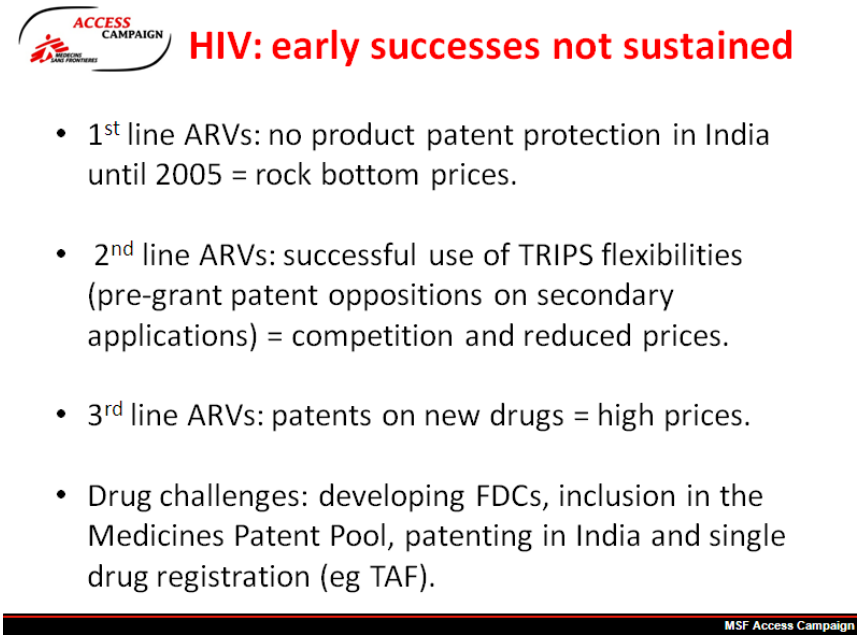
Organisations such as the WHO noted that relaxation of patent requirements, tiered pricing, voluntary licensing, compulsory licensing, bulk purchasing, corporate donations, regional capacity building etc. are all effective mechanisms to achieve the most favourable pricing of patented medicines in developing countries. The WHA recommended that these approaches be evaluated individually and in combination to ensure the balance between exclusive patent rights to facilitate investment stimulus and the objective of reducing prices (WHO 2003, para 18). The WHO report for China in 2002 mentioned various other mechanisms as well, such as international open tendering, voluntary discount agreements, local State production, Government price controls etc. as various options to ensure affordability of essential medicines. Further, it is recommended to adopt the compulsory licensing provisions under the 30 August 2003 Decision, where required (Padmashree Gehl Sampath 2005: 66) and not to adopt TRIPS plus provisions. Interestingly, compulsory licensing provisions have been looked at even by developed countries as a solution for bringing down the cost of pricing, for e.g. the United States and Canada in the context of the anthrax scare which resulted in three deaths in the United States and none in Canada, in 2001 (Joseph 2011: 224).

These recommendations have merit and can go a long way in protecting the interests of the developing countries. While developing countries have attempted to take benefit from such provisions, there are concerns on the efficiency of functioning of such methodologies.

On the TRIPS flexibilities and its utility, the 2010 UNDP Report noted that initial attempts by low income countries to use the flexibilities in the TRIPS Agreement was fraught with challenges (UNDP 2010: 7). As per the data made available by MSF, presence of TRIPs flexibilities alone may not be sufficient to ensure the availability of medicines at affordable prices. The data as below suggests that while the TRIPs

flexibilities were useful to bring down the prices of medicines which were modifications to existing ones, the same has not been effective in the case of new medicines (Balasegaram, Manica 2014).

Table 6: TRIPS flexibilities and ARV's



Countries need to be careful not to agree to TRIPS plus provisions in bilateral and regional trade agreements. Many countries while negotiating bilateral agreements may end up agreeing to stronger provisions than what is required under the TRIPS Agreement, for example, longer patent term, limiting the grounds for issuing compulsory licenses, restrictions on the use of clinical test data on pharmaceutical products, limiting the grounds on which patents may be revoked, looser criteria for patentability, restrictions on parallel imports etc. In fact, the enlargement of IP agreements may result in such a complexity of agreements that one is not able to determine as to what will apply except with specialised and detailed legal assistance which in turn may work against advancing business interests for e.g. Chile which is party to over one hundred IP agreements, multilateral and otherwise (Farley, Christine Haight (2014: 109).

The TPPA and other such regional agreements has several TRIPS plus provisions such as patents for new uses of a known product, new methods of using a known product, new processes of using a known product (Article 18.37.2 of TPPA), patent extension for unreasonable delays in a Party's issuance of patents, adjusting the term

to compensate for such delays (TPPA, Article 18.46.1) etc. These will have detrimental impact on ensuring access to medicines.

We are faced today with a potent problem of patenting, which is not easy to overcome. While the flexibilities can be put use, every effort needs to be exercised to reduce the expanse of patenting. In view of the human rights requirements all nations need to do the best to reduce the scope and span of patenting within the options available with the TRIPS Agreement and also not agree to TRIPS plus requirements.

Further, with regard to the WTO decisions analysed, an important function of the WTO dispute settlement system is "to clarify the existing provisions of [covered] agreements in accordance with customary rules of interpretation of public international law" (DSU, Article 3.2). This has been reaffirmed by the decisions from the DSB such as the panel report on the dispute *India – EU: Patent Protection for Pharmaceutical and Agricultural Chemical Products* (WT/DS79/R 24, para 5.4). Therefore any decision by the WTO dispute settlement process cannot contradict or go against the provisions of public international law. However, the study of the various decisions yields the conclusion that the DSB being a trade dispute settlement body does not give primacy to health concerns. For e.g. the decision of the Panel and the AB in *Canada – Patent Protection of Pharmaceutical Products* (DS114 of 17 March 2000), was clearly a decision where health concerns were over ridden by trade concerns when the stockpiling exemption was not upheld, though it was definitely heartening that the regulatory review exceptions under Canadian law was upheld by the Panel. The DSB has to be conscious in its decision making so that it does not make its decisions in isolation from the human rights provisions so that there is no violation of the expansive human rights instruments in place.

CHAPTER 4
TRIPS AGREEMENT, INDIA AND THE RIGHT TO HEALTH

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1. Introduction – The Right to Health under Indian Law

The right to health is a constitutional right in India. Article 47 of the Constitution of India states that the State shall regard the raising of the level of nutrition and the standard of living of its people and the improvement of public health as among its primary duties.

Further, India has various pieces of legislation and rules including the 1940 *Drugs and Cosmetics Act*, 1995 *Drug Price Control Order*, 2013 *Drugs (Prices Control) Order*, 1970 *Patents Act*, 1897 *Epidemic Diseases Act*, 2006 *Food Safety and Standards Act*, 2002 *Competition Act* etc. all of which a have bearing on public health. Further, various policy documents such as the 2002 *Pharmaceutical Policy*, 2011 *National Health Research Policy*, 2012 *National Pharmaceutical Pricing Policy* etc. have been formulated by the Government of India. State governments have also come out with policy documents such as 2005 *Essential Medicines Policy* in Haryana, 2008 *Intellectual Property Rights Policy* by the Government of Kerala, etc.. The same are examined in this chapter.

The right to health is a firmly established principle in Indian jurisprudence through various courts decisions such as *Vincent Panikulamgara vs. Union of India and Others*, (1987, 2 Supreme Court Cases 165), *Indian Network for People living with HIV/AIDS* v. *Union of India* (MANU/TN/1217/2008), *Novartis A.G. v. Union of India & Ors* (Civil Appeal Nos. 2706-2716 of 2013), *Union of India and Anr.* vs. *Swiss Garnier Life Sciences and Ors.* (MANU/SC/0664/2013) etc.. These have been also been briefly reviewed in this chapter.

Availability of affordable medicines is one of the most important issues in India in relation to the right to health. Concerns have been raised whether the WTO regime to which India is a party have adversely impacted the right to health of the individual citizen through increased patent protection to private players within India which strengthens the rights of pharmaceutical companies on their formulations, which in

turn will adversely affect other companies from manufacturing the same medicines and would affect the medicinal prices. The need to make modern medicine available at affordable costs to the population further arises from the fact that alternative mechanisms of treatment like traditional medicine suffer from many drawbacks like lack of standardization, lack of delivery infrastructure, lack of integrations - intra or interdisciplinary (Bhushan Patwardhan, 2005: 5).

The strong pharmaceutical industry in India which had helped curb the medicinal costs in the past is now impacted by the obligations under the TRIPS Agreement. In 2011 the Planning Commission noted that the Indian pharmaceutical industry is the 3rd largest in the world by volume and 13th in value (Govt. of India 2011: 8) while another study noted that it is the 14th in value in the global pharmaceutical market (Kallummal, Murali and Bugalya, Kavita 2012: 4). According to the *Pharmacovigilance Programme of India for Assuring Drug Safety*, the pharmaceutical industry in India, was valued at Rs. 90,000 crores and that it is growing at the rate of 12 – 14 % per annum (Government of India in collaboration with Indian Pharmacopoeia Commission 2010b). Exports in the pharmaceutical sector were growing at 25 % Compound Annual Growth Rate (CAGR) every year and the total export of pharmaceutical products from India was valued at Rs. 40,000 crores (Government of India in collaboration with Indian Pharmacopoeia Commission 2010b). However, recent studies indicate that there is a surge in the import of pharmaceuticals in India from China (Kallummal, Murali and Bugalya, Kavita 2012: 44) and that China's dominance in the import market in India will exceed that from other competitors in the pharmaceutical sector (Kallummal, Murali and Bugalya, Kavita 2012: 45). Therefore, clearly, India's position as the supplier of generic medicines to the world is on the wane.

On a different note, healthcare facilities in the country are far below the requirements of the population. Nearly 80 per cent of all outpatient care and 60 percent of all hospital care is through private health facilities (Selvaraj, Sakthivel et. al 2014: 19) The Ministry of Statistcs, Govt. of India as per the data made available in their website states that in 2009 the country had 17463 government hospitals and 10,75,000 beds in government hospitals (Government of India 2009b). There is real concern

that such provision from the government will not substantially increase given the commercialisation of the health sector.

Given this background, in this chapter a survey of the Indian law on the right to health is done in the context of the obligations under the TRIPS Agreement and suggestions are made on the best options available for India to protect the right to health of the population.

2. India's Concerns about TRIPS obligations

2.1. Medicinal Pricing

As the 1970 *Patents Act* in India before the current amendments did not permit patenting of pharmaceutical formulations, the Indian pharmaceutical industry had become very strong and had enabled cheap access to almost all of the medicinal formulations from across the globe at a very cheap price. Sarah (2011) notes that India's abolition of pharmaceutical patents in the 1970's catalysed its generic drug industry and transformed it from a drug importing country into a major generic exporter (Joseph 2011: 233).

As defined by the US Food and Drug Administration, generic drugs are copies of brand-name drugs and are the same as those brand name drugs in dosage form, safety, strength, route of administration, quality, performance characteristics and intended use.[54] In US generic drug products are required to meet the same rigid standards as the innovator drug. All generic drugs approved by FDA have the same high quality, strength, purity and stability as brand-name drugs. In US the generic manufacturing, packaging, and testing sites must also pass the same quality standards as those of brand name drugs.[55] With the amended patent regime in place, which permit for

[54] See US Food and Drug Administration, "Understanding Generic Drugs", [Online: Web] Accessed 24 October 2015, URL: http://www.fda.gov/drugs/resourcesforyou/consumers/buyingusingmedicinesafely/understandinggenericdrugs/default.htm

[55] US Food and Drug Administration states as below:

> In US the FDA through review of bioequivalence data, assures that the generic product will perform the same as its respective brand name (or reference) product. This standard applies to all generic drugs, whether immediate or controlled release. A generic drug must be shown to be bioequivalent to the reference drug; that is, it must be shown to give blood levels that are very similar to those of the reference product. If blood levels are the same, the therapeutic effect will be the same. In that case, there is no need to carry out a clinical effectiveness study and they are not required.

product and process patents Indian manufacturers will not be able to copy the formulations of the foreign pharmaceutical companies. This impacts and the medicinal pricing and thereby negatively affect the right to health of the citizens.

In India it is estimated that at any given point of time there are about 20 to 25 lakh people suffering from various kinds of cancer and that every year about 700,000 people are detected with cancer. The conservative estimate for the cost of anti-cancer medicines per patient is about Rs. 25,000 per annum. Therefore the sales of cancer drugs in India in a year should come to Rs. 5000 crores. However the statistics reveal that the anti-cancer drug sales amount on only Rs. 150 crores in a year. This big gap in statistics could due be the inaccessibility of the medicines to these patients due to high medicinal pricing (Government of India 2010a: 5, paragraph 16).

There are about 25 lakh people in India who are affected by AIDS. For those who are treated for this disease the NACO purchases medicines and distributes the medicines free of cost through its Centres and State Aids Control Societies. Currently, only those patients with a CD 4 below 200 per cu ml of blood, numbering about 3 lakh are being treated under this programme. Higher medicinal prices would negatively affect even the current public health initiatives from the government (Government of India 2010: 5, paragraph 17). Even when product and process patents were not in place, availability of medicines has been a serious issue for the Indian public due to the cost of the medicines etc.

Post the grant of exclusive marketing rights through the Patents (Amendment) Act 1999, there was increase in the medicinal pricing in India. For e.g. Novartis' Glivec which is used for treatment of Chronic Myeloid Leukaemia ('CML'), there was an increase in the price of the drug from $90 to $2610 after the grant of EMR (Cuts International Jaipur 2006: 36). The Indian company NATCO Pharma Ltd. had

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As per the recent study made available by the FDA, the FDA evaluated the results of 38 published clinical trials that compared cardiovascular generic drugs to their brand-name counterparts. There was no evidence that brand-name heart drugs worked any better than generic heart drugs. [Kesselheim et al. Clinical equivalence of generic and brand-name drugs used in cardiovascular disease: a systematic review and meta-analysis. JAMA. 2008: 300(21)2514-2526

launched in early 2003 an alternative version (named Veenat) of the aforementioned drug of Novartis. This generic version[56] was made available to patients at one tenth the price set by the original manufacturer (estimated annual cost of treatment for Glivec at $27000 and for Veenat at $2700) (Cuts International Jaipur 2006: 37).

The following is the table on the medicinal pricing for the same formulations across various countries as made available by a study in 2005 (Dr. R.D. Lele 2005):

Table 7: International Prices vis-a-vis Indian Prices of Select Products

International prices vis-à-vis Indian prices of select products (2005)						
Drug & Dosage	**Pack**	**India (Rs.)**	**Price in Pakistan (Rs.)**	**Price in Indonesia (Rs.)**	**Price in USA (Rs.)**	**Price in UK (Rs.)**
Adefovir 10 mg tab	10's	190.00	N.A.	-	7817.48	7980.00
Alendronate Sodium 10 mg	10's	49.00	539.52	N.A.	1017.72	627.00
Alprazolam 0.5 mg	10's	7.00	46.52	212.50	1034.88	-
Amlodipine	10's	5.90	87.05	228.78	696.96	353.40

[56] Generic drug is a copy of a brand name drug whose patent has expired. The original manufacturer of a drug receives a patent on the drug and is the only manufacturer who can produce and sell the drug during this patent period. Once the patent expires, other manufacturers may produce and sell the drug. These manufacturers usually sell the drug under its common or *generic* name. Most drugs have three names: a chemical name, a generic name, a brand name. Since chemical names are usually long and complicated, the drugs are given a standard, shorter generic name.

Manufacturers will usually give drugs brand names to identify that manufacturer's version of the product. An example of these three names, using a well-known prescription drug is as follows:

- chemical name — 7-chloro-1,3-dihydro-1- methyl-5-phenyl-2H-1,4-benzodiazepin-2-one;
- generic name — diazepam; and
- brand name — *Valium*.

…

In US All drugs considered to be generically equivalent to a brand name product must meet strict manufacturing requirements set by the Federal Food and Drug Administration (FDA). These requirements include tests which assure that the product is bioequivalent to the brand name product. Bioequivalent means that the same amount of active ingredient is delivered to the body at the same time, and used by the body, in the same way as the brand name product. Therefore, generically bioequivalent drugs should produce the same results as the brand name product.

See Texas State Board of Pharmacy (Source [Online: web] Accessed on 23 April 15 URL: https://www.pharmacy.texas.gov/consumer/broch3.asp

Besylate 5 mg						
Atenolol 50 mg		5.60	62.42	322.56	809.60	NA
Atorvastatin 10 mg tabs	10's	24.00	483.85	565.95	1087.68	489.44
Cetirizine 10 mg	10's	7.80	31.03	166.67	928.40	193. 04
Ciprofloxacin 500 mg	10's	29.00	368.36	926.75	2552.44	1079.20
Ciprofloxacin 0.3% eye drops		5.88	157.67	256.00	2035.44	375.44
Diclofenac 50 mg	10's	4.34	36.79	161.12	733.48	191.52
Imatinib Mesylate 100 mg caps	10's	850.00	8516.66	9821.96	9329.76	9863.28
Lansoprazole 30 mg	10's	35.00	425.15	462.78	2097.04	542.64
Montelukast 4 mg tabs	10's	59.25	364.99	NA	1321.76	487.92
Ondansetron						
HCl 8 mg injn	4 ml	20.00	N.A.	665.50	11285.12	911.24
Pioglitazone 15 mg tabs	10's	9.00	N.A.	–	1522.40	655.12
Ranitidine 150 mg	10's	5.19	64.39	216.33	1012.44	16.72
Salmeterol 25 mcg + Fluticasone 50 mcg inhaler	120 doses	210.50	598.60	782.65	N.A.	1378.64
Tamsulosin 0.4 mg caps	10's	53.13	N.A.	-	875.16	522.88

Note:

1. Retail prices in India & wholesale prices in other countries considered.
2. Conversion rate of exchange considered: 1 USD = Rs. 44.00, 1 GBP = Rs. 76.00
   1 Pak Rs. = Rs. 0.73, 1 Indonesian Rp = Rs. 0.005 and 1 Bht = Rs. 1.04 as on 12-7-2005
3. Conversion rate of exchange considered: 1 USD = Rs. 44.00, 1 GBP = Rs. 76.00
   1 Pak Rs. = Rs. 0.73, 1 Indonesian Rp = Rs. 0.005 and 1 Bht = Rs. 1.04 as on 12-7-2005 .

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*** Indian Drug Manufacturers' Association Bulletin, 30th October 2005 , 36(40): 42-51.*

Pharma companies tend to employ various methods to prevent the generic companies from entering into the manufacture of the generic medicine which competes with the patented product such as litigation against the generic competitors alleging patent infringement etc[57]. Sometimes the pharma companies themselves enter the generic market or may enter into co-marketing agreements with the generic producers. Entry of the major pharma companies into the generic market may have a positive effect, however co-marketing agreements etc. may adversely affect other generic

[57] Aventis Pharmaceuticals Inc. faced a federal lawsuit on the charge of firstly filing a patent infringement suit against Andrx, to delay their marketing of the generic version of Aventis' popular heart drug Cardizem CD and thereafter using another delaying tactical arrangement by paying Andrx Corp., not to market their generic alternatives. This case originated in the United States, but practices such as these may well pervade the Indian market as well, if it has not already given that companies such as Aventis have a substantial foothold in the Indian pharmaceutical market. Aventis is ranked third amongst the MNC pharmaceutical companies of India in terms of market share. (Financial Express, May 16th, 2001)

manufacturers etc. Sometimes pharma companies even engage in collusive conduct such as pay offs to generic manufacturers to prevent them from entering the market.[58]

It is to be noted here that the position adopted by the Government of India is not to weaken IPRs, but to "promote a holistic and conducive ecosystem to catalyse the full potential of intellectual property for India's economic growth and socio-cultural development" (Draft National IPR Policy 2014: 1).

2.2. Evergreening of Patents

Pharma companies in the name of life-cycle management try to maximize revenues from their products through evergreening and prevent generic competition. A number of strategies are adopted such as changes in methods of treatment, mechanism of action, derivatives, isomeric forms, delivery profiles, dosing regimen, dosing route, combinations, screening methods, biological targets, field of use etc. to extend the term of the patent (Inderjeet Singh Bansal, Deeptymaya Sahu, Gautam Bakshi and Sukhjeet Singh 2009: 300).

Ever greening strategies, study may include (Inderjeet Singh Bansal, Deeptymaya Sahu, Gautam Bakshi and Sukhjeet Singh 2009: 300):

a) Redundant extensions and creation of "next" generation drugs which result in superfluous variation to a product and then patenting it as a new application
b) Switching a prescription drug to over the counter drug
c) Exclusive partnerships with generic players in the market prior to patent expiry to significantly enhance the brand value and royalties on the product
d) Defensive pricing strategies wherein innovator companies decrease the price of the product in line with the generic players for healthy competition
e) Establishment of subsidiary units by innovator companies before the advent of generic players

The *1970 Patents Act* in India deals with ever greening when section 3(d) of the legislation states that the mere discovery of any new property or new use for a known

[58] The pharmaceutical company Schering-Plough Corp spent US$90mn in pay offs to generic drug manufacturers as part of a scheme to avoid facing generic competition in the market, which not only distorts the competitive process but also has serious repercussions on access to affordable medicines. (Financial Express, May 16th, 2001)

substance or the mere discovery of any new property or new use for a known substance or the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least a new reactant shall not be patentable. However, as seen from above the ever greening strategies are many and the patent office need to be vigilant and further, the law needs to evolve where deficient to deal with all these strategies.

2.3. Counterfeit

Numerous initiative exists at the international level on anti-counterfeit such as the *Anti-Counterfeiting Trade Agreement*, *G-8 Countries Initiatives on Counterfeits*, *WIPO Advisory Committee on Enforcement, Security and Prosperity Partnership between Canada, Mexico and US* (Shukla, Nitin and Sangal, Tanushree 2009: 237) etc. It has been argued that the legal changes due to TRIPS Agreement will significantly help to deal with counterfeit drugs. The WHO has come out with a figure of USD 50 billion or 13.7%, as the annual quantum of substandard/spurious/falsely-labelled/falsified/counterfeit medical products, which figure is disputed by many developing countries (Gopakumar K.M. 2015a).

Falsified medicines are those which are fraudulently mislabelled, the source has been fraudulently altered etc. while substandard medicines are those which do not meet the standard under law and may contain incorrect doses, contaminants etc. (See Malache, Allan and Day, Emma Ely, 2014: 102). Importantly, there is much difference between falsified and substandard medicines. In India the 1940 *Drugs and Cosmetics Act* used various terms such as misbranded drugs, adulterated drugs, spurious drugs etc (See section 9A, 9B and 9C respectively of the 1940 *Drugs and Cosmetics Act*).

However, the counterfeit is sometimes a broadly used term and may tend to cover generic drugs as well. Generics exported from India were seized in a few instances under *EC Council Regulation No. 1383/2003* when the cargoes of these generic medicines were in transit to other developing countries. The drugs, losartan potassium on export to Brazil from Dr. Reddy's laboratories in India in December 2008, shipments from Ind-Swift Laboratories to Venezuela and from Cipla Ltd. to Peru have all been subjected to such seizures. Also UNITAID funded shipment consisting of 49 kilograms of abacivir sulfate from the Indian company Aurobindo were seized at

Schiphol Airport by the Dutch authorities under the claim that it contained counterfeit goods (Shukla, Nitin and Sangal, Tanushree 2009: 238). Such seizures are not as per the terms of the TRIPS agreement. Article 52 of the TRIPS Agreement provides for seizure only if the consignment is in violation of the IP rights in the final destination of the import.

The TRIPS and the TRIPS plus agreements are sometimes used to enforce IP on a draconian manner impeding the right to health. While anti counterfeit law while it may help with dealing with falsified medicines, it need not necessarily ensure the availability of good medicines to the population, which is critical for a large country like India.

2.4. Acquisitions

The quality of products from the Indian pharmaceutical industry is recognized globally (Sanjay Pingle 2005: 14) and the Indian pharma companies have been a target of takeovers. Following are the large takeovers in the 2006-10 periods in the Indian pharmaceutical sector (Sinha, Koutenya 2011: 9):

	Year	**Indian Company**	**Acquiring foreign company**	**Purchase price in USD**
a.	August 2006	Matrix	Lab Mylan, US	736 million
b	April 2008	Dabur	Pharma Fresenius Kabi, Singapore	219 million
c.	June 2008	Ranbaxy	Labs Dalichi Sankyo , Japan	4600 million
d.	July 2008	Shanta Biotech	Sanofi Aventis, France	783 million
e.	December 2009	Orchid	Chemicals Hospira, USA	400 million
f.	May 2010	Piramal Healthcare	Abbott, USA	3720 million

Some reports reveal that the market share of the foreign MNC's in the Indian domestic pharmaceutical market has increased to 25% from 15% five year ago (See

Sinha, Koutenya 2011: 9). At present 100% FDI is permitted in the pharmaceutical sector through the automatic route i.e. without any requirement to take permission from the government of India. The Government of India is considering to bring foreign investments in the pharmaceutical sector under the permission route i.e. after getting the necessary permission from the Foreign Investment Promotion Board. While such takeover's may enable pharmaceutical companies to draw upon each other's research expertise and to bring products to market more rapidly and effectively, it may also cause the pricing of the medicines produced by the acquired companies to be on the higher side.

Some of the large mergers in the global pharmaceuticals industry, in the last few years are Sanofi-Aventis, Glaxo-Wellcome-SmithKline Beecham;Hoechst-Marion-Merrell Dow-Roussel; Pfizer-Warner Lambert; Ciba-Sandoz (to form Novartis); and Hoechst Marion Roussel-Rhone Poulenc (to form Aventis). These mergers raise competition concerns (Cuts International Jaipur 2006: 44-45). An example of a merger which raised competition concerns in some countries is the one between the two pharmaceutical giants Glaxo Wellcome and SmithKline and Beecham to form GlaxoSmithKline (GSK). The merged entity had sales of 18.1 billion in the year 2000. GSK supplied products to 140 countries. Not many countries raised competition concerns, however South Africa, EU etc raised competition concerns. The Competition Commission in South Africa held that the merger should be prohibited on competition and public interest grounds as the merged would result in the merging entity having high market shares. The merger, it was pointed out, would result in unacceptable levels of concentration with respect to Bactroban, Zelitrex and Famir and there were no appropriate substitutes to these medicines to prevent overpricing. Finally, the merger was conditionally permitted after the merging entities reached an agreement with the Competition Commission in South Africa to outlicense some of their products identified by the Commission (Cuts International Jaipur 2006: 49). The EC also reached similar conclusion on the matter. In sum, these mergers and acquisitions while it may be beneficial to the concerned pharmaceutical companies eliminates competitors and affect the availability and accessibility of medicines as far as the public are concerned.

2.5. India as an Outsourcing Facility

Interestingly, some studies noted that the Indian pharmaceutical industry will continue to grow inspite of the introduction of product patents and that Indian pharmaceutical industry will become part of the global research industry and that much work will be outsourced to India (Manthan D Janodia, J. Venkata Rao, Sureshwar Pandey, D Sreedhar, Virendra S Ligade and N Udupa 2009: 434). Various strategies are adopted by the Indian pharmaceutical industry to meet the post TRIPS scenario. They include in-licensing and out licensing alliances wherein MNC's allow Indian companies to launch the MNC products in India for royalty; co-marketing alliances where two companies market the same product under different brand names to build up a larger share of the market; outsourcing where Indian companies do the research for foreign companies; international acquisitions by Indian companies in order to increase presence in export markets and marketing alliances with foreign companies to market in foreign markets the drugs produced by the Indian companies from their facilities abroad (Padmashree Gehl Sampath 2005: 55-56).

Mahajan, Madhur Mohit (2011) notes that post 2005 Indian companies are investing more into research for the development of new chemical entities (or in common parlance new drugs) and modifications on new chemical entities. Earlier, much of the research from the Indian industry was to develop new processes for manufacturing existing drugs formulated by foreign companies (Mahajan, Madhur Mohit 2011: 325). The study further says that India is rapidly emerging as a trusted outsourcing location to manufacture difficult to manufacture high quality drugs for the US companies. The US FDA compliances of these plants are found to more than 6 times expensive than the normal manufacturing facilities in India costing between 3 million to 20 million USD, which many large pharmaceutical firms in India are investing in (Mahajan, Madhur Mohit, 2011: 328). India has the largest number of US FDA approved bulk drug plants outside of the USA and that in the period between 1998 and 2005 119 such production facilities have come up in India, while in the period 1985 - 1995 the number of such production facilities started in India was only 11 (Mahajan, Madhur Mohit 2011: 328). The study concludes that while the TRIPS Agreement and the related change in patent law in India raised enormous challenges for the Indian pharmaceutical industry, many of the pharma firms in India are now pursuing R&D practices to develop new drugs (See Mahajan, Madhur Mohit 2011: 328-329).

Thus there is apprehension about the nature of work the pharmaceutical firms in India will be engaged in post TRIPS, i.e. whether the pharmaceutical industry will be engaged in formulating new drugs or whether the Indian pharmaceutical industry will just become an outsourcing facility for major pharmaceutical MNC's. Post 2005, Indian drug manufacturing concerns have been target of take over's etc., which could affect the ability of the country to have its own efficient domestic pharma industry, than an outsourcing facility.

2.6. Patenting of Traditional Knowledge

Another issue of grave concern to the developing nations is the patenting by private sector of the centuries old traditional knowledge used by communities for curative purposes. Such patents effectively bar those communities from using such traditional medicines without permission/payment of royalty to the patent holder. To cite examples, turmeric, neem, bittergourd, jamun, brinjal, gurmar, etc. which have been in use for innumerable centuries in India for treatment of various diseases have been subjected to various U.S patents.

*T*he *1970 Patents Act* does not permit patenting of traditional medicines in India [section 3(p)]. Further, India has tried to address the problem through the legislation, *Biological Diversity Act, 2002*. The *Biological Diversity Act, 2002* specifically deals with the issue of patenting of biological resources through sections 6, 7, 18(4), 19, 20 etc. Section 6(1) of the *Biological Diversity Act, 2002* states:

> No person shall apply for any intellectual property right, by whatever name called, in or outside India for any invention based on any research or information on a biological resource obtained from India without obtaining the previous approval of the National Biodiversity Authority before making such application.

State governments have also made some initiatives in this direction. For example, the Government of Kerala has come out with 2008 *Intellectual Property Rights Policy* (hereinafter "**2008 IPR Policy**") to protect the traditional knowledge base. The 2008 IPR Policy suggest the setting up an authority at the state level called the Kerala Traditional Knowledge Authority (hereinafter "**KTKA**") with which all practitioners of traditional knowledge will need to be registered and which body will also be

responsible for enforcing the rights created under the new legal arrangement by recommending legal action against the violators of the rights. Two types of traditional rights are identified in this 2008 IPR Policy: a) right to a brand name associated with the unique practice of an institution, community or family such as Kottackal massage and b) the right to use the traditional knowledge. This 2008 IPR Policy recommends using various provisions of the 2002 *Biological Diversity Act* such as section 3 and 7 to prevent misappropriation of the biological resources associated with the traditional knowledge. Section 3 of the 2002 *Biological Diversity Act* requires foreigners to get previous approval of the National Biodiversity Authority and section 7 requires all entities in India to provide prior intimation to the State Biodiversity Board before obtaining biological resources for commercial utilization, bio-survey and bio-utilization for commercial purposes. The policy also speaks of setting up a specialised governmental body known as the Supervisory Council on Intellectual Property with the chief minister as the chairman and the law minister as the vice chairman and various experts such as scientists and also the chairpersons of the State Biodiversity Board and the KTKA to provide overall supervision in matters relating to IPRs and to follow up the recommendation of the KTKA with regard to prosecutions for the violation of knowledge users rights.

Some solutions also lie outside the IP laws. For example, Peru passed a legislation in 1999 which banned the non-value added export of some botanical species with known healing properties such as the plants 'cat's claw' and 'maca' which are indigenous to Peru and which had been targeted by foreign laboratories (Correa, Carlos 2000a: 30).

2.7. Adverse Drug Reactions (ADR's)

The introduction of drugs into India without proper regulatory verification throws up challenges in monitoring Adverse Drug Reactions (ADR's). As per government of India data about 1,144 people died during clinical drug trials in 2010 and 2011 (Economic Times, (Delhi Edition), Aug 21, 2012: 1). Of the 483 people who died in India in 2011, compensation was paid to only 16 volunteers In India as the deaths were attributed to the normal progression of the existing illness and where the compensation was paid it was as low as Rs. 50,000/- (Economic Times, (Delhi Edition), August 21, 2012:1). The clinical research market in India is expected to cross USD 16 billion by 2016 (Economic Times, (Delhi Edition), August 21, 2012:1).

In order to protect the health of the patients by assuring drug safety, the Pharmacovigilence Programme was set up by the *Central Drugs Standard Control Organisation* (CDSCO) in collaboration with the *Indian Pharmacopeia Commission*. The objectives of the Pharmacovigilance Programme of India are to (Government of India 2010(b)):

a) monitor Adverse Drug Reactions (ADRs) in Indian population
b) create awareness amongst health care professionals about the importance of ADR reporting in India
c) monitor benefit-risk profile of medicines
d) generate independent, evidence based recommendations on the safety of medicines
e) support the CDSCO for formulating safety related regulatory decisions for medicines
f) communicate findings with all key stakeholders
g) create a national centre of excellence at par with global drug safety monitoring standards

As a result of globalization, multinational pharmaceutical companies transferred clinical trial stage of their research to countries like Brazil, India, China, Eastern European countries etc., as the laws in the developed nations are stringent on such clinical trials. The cost of conducting clinical trials in India and other developing countries is much lesser than the developed countries and also, the patients from such countries are less likely to question the doctor's recommendations and suggestions (Terwindt, Carolijn 2014: 86). As a result of the lax controls that India had on this sector, HPV vaccination against cervical cancer done on about 23000 girls in India under Government project in Andhra Pradesh and Gujarat, without proper confirmation on the benefits of the vaccine, which vaccine was sponsored by the Bill and Melinda Gates Foundation. The vaccines used for this project were developed by Merck (vaccine Gardasil) and GlaxoSmithKline (vaccine Cervarix). Proper consent was not obtained by the girls who took this vaccination and the project was finally suspended after the health activist and doctors raised concerns (Terwindt, Carolijn 2014: 86).

As a result of direction from the Supreme Court in India, the clinical trial guidelines were recently revised by the Government of India and the clinical trials in India is now regulated by the 2014 *Good Clinical Practice Guidelines* issued by the CDSCO.

2.8. Medicinal Devices

Devices comes under the broad definition of 'drugs' under section 3 (b) of the 1940 *Drugs and Cosmetics Act*. However, the cost of many of these devices in India is exorbitant. Medical devices such as stents inserted in human heart during angioplasty is reported to be costing double the price in India than in developed countries. A March 2012 newspaper report noted that in Germany the upper limit for heart stents is amount Euro 350 which is less than the price level in India (Priyanka Golikeri 2012). The report notes that the price in other Europeans nations is in the range of 600 to 700 Euro.

Certain reports suggest that cardiologists routinely use drug coated stents etc. which are more expensive than normal bare metal stents for patients, even though such patients are at low risk for another blockage. This is done on the ground of giving the best technology to the patients costing considerable burden on the patients who are paying for such devices or causing such burden on the exchequer in the developed countries where the government pays for such procedures (Deborag Kotz 2012).

This sector is in need of serious regulation and the Government of India may set up a regulator to control the medicinal devices sector which regulator may control quality, price etc. The Planning Commission in its 2011 report recommended amendment to the provisions of the Dugs and Cosmetics Act to have separate provision on medical devices providing for definition of medical devices, their risk classification, clinical trial details etc. (Govt. of India 2011: 15).

2.9. Patenting of Microorganisms

For over a hundred years, however, living organisms were excluded from patent laws. Life forms were considered a product of nature and not human invention. This non patentable status of living organisms changed with the *Chakraborty* vs *Diamond* case, says a study done by the Patent Facility Centre (PFC), under the Technology Information Forecasting and Assessment Council (M. Somasekhar 2005: 2).

In India, under the amended 1970 *Patents Act* microorganisms are patentable[59]. In *Dimminaco AG vs. Controller of Patents,* the Calcutta High Court held in 2002 that a patent on a micro-organism is valid and that the Act did not preclude a living end product from being patented.

The *2005 Technical Expert Group on Patent Law Issues* appointed by the Government of India after examining the issue of whether it is TRIPS compatible to exclude microorganisms from patenting concluded that Article 27.3 of the TRIPS Agreement does not permit such exclusion and that excluding micro-organisms *per se* from patent protection in India would be violative of TRIPS Agreement (Government of India 2009, para 5.45). However, the TEG recommended that strict guidelines need to be formulated for examination of the patent applications involving micro-organisms from the point of view of substantial human intervention and utility. The TEG also pointed out that there have been instances of patenting of Indian biological materials by other countries and that it would be in India's interest to document, protect and modify new micro-organisms isolated from various parts of our country and find their new and improved industrial uses. This step, the TEG recommended that it would help Indian biotech industry.

As per the data in 2005, of the 600 applications filed in India, 24 relate to bacteria, 189 to virus and 13 to fungi. Pharma companies like Dr. Reddy's Research Foundation (11), Novo Nordisk (10), Gist Brocades (10), Procter and Gamble (7) and Biocon India (6) are active in exploiting the versatile world of bacteria. Again, CSIR (48) applications dominate the field (M. Somasekhar 2005: 2).

National laws vary on patenting of biological materials and microorganisms. In the United States an isolated or purified form of a natural product, including genes, is patentable. The *European Directive on Biotechnological Inventions* (*No. 96/9/EC of March 11, 1996)39* which is essentially declaratory of the long standing law

[59] See section 3 of the 1970 Patents Act states what is not patentable. It reads:

> 3 (c): "the mere discovery of a scientific principle or the formulation of an abstract theory or discovery of any living thing or non-living substances occurring in nature."
> 3(j) : "plants and animals in whole or any part thereof other than micro-organisms but including seeds, varieties and species and essentially biological processes for production or propagation of plants and animals."

throughout much of Europe, provide that 'biological material' and substances isolated from nature (such as new antibiotics) will be considered patentable (Correa Carlos 2000a: 17).

Hammond, Edward (2009) noted in his study on patents on H5N1 influenza virus, that in some cases companies have filed patent applications on the entire genes as well and in some others, a gene or a modified gene sequence is claimed when used in a specified manner (Hammond, Edward 2009: 8). He mentions PCT Application WO2006098901of September 21, 2006 in which MedImmune claimed gene sequences of atleast 29 influenza strains and in some cases entire HA and/or NA genes (Hammond, Edward 2009: 11). Such huge patent claims may result in a microbial resource being locked up and there may arise thickets comprising of dozens of patent applications which cause overlapping and confusing mess of claims impeding further research (Hammond, Edward 2009: 20).

3. Legal Changes in India pursuant to TRIPS

Modifications to the domestic law of member nations of the WTO are necessitated by the obligations cast upon the member nations by the TRIPS Agreement. Estimates by scholars had revealed that the changes required to Indian IPR law to make it TRIPS compatible include:

a) application of principles of national treatment (Article 3)
b) and most favoured nation treatment (Article 4),
c) provision of process and product patents in all fields of technology (Article 27.1),
d) importation of the patented product to be counted as working of the patent (Article 27.1),
e) term of patent protection to be 20 years counted from the filing date (Article 33),
f) the burden of proof in case of process patent infringement to rest with the party accused of infringement (Article 34.1),
g) availability of enforcement procedures which permit effective action in case of infringement of IPRs (Article 41.1),
h) permit the granting or registration of the IPR within a reasonable period of time (Article 62.2) and provision of Exclusive Marketing Rights (hereinafter

"EMRs") during transition period in developing countries (Article 70.8 and 70.9).

3.1. India Taken before WTO DSB for Non-Compliance of Patent Obligations

As the pace of effecting changes to Indian law to ensure TRIPS compatibility was slow in India, India was taken by the U.S. before the DSB in 1997 resulting in the trade dispute titled *India – Patent Protection for Pharmaceutical and Agricultural Chemical Products* (WT/DS50/R).[60] The complaint raised by the U.S. was that India was in violation of the obligations under Article 70.8 and 70.9 of the TRIPS Agreement dealing with exclusive marketing rights (hereinafter "EMRs"). The DSB Panel as well as the AB found that India was in violation of the obligations under Article 70.8 and 70.9 of the TRIPS and India was asked to amend her laws to become TRIPS compatible. This decision has been discussed in more detail in Chapter 3.

In order to become TRIPS compatible on EMR's, amendments were made in 1999 to the *1970 Patents Act* by inserting sections 24 (A) to 24 (F) to provide for EMRs in the area of pharmaceutical products in India. Thereafter the Patents Second (Amendment) Act 2002, Patent Ordinance 2004 and finally Patents (Amendment) Act, 2005 were enacted in India to become TRIPS compatible.

3.2. The Amendments to *1970 Patents Act* for TRIPS Compatibility

3.2.1. 1999 Patents (Amendment) Act

The Patents (Amendment) Act 1999 provided for Exclusive Marketing Rights which is the transitional measure recommended under the TRIPS Agreement till grant of product patents in the pharmaceutical sector. EMR's could be granted where[61]:

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[60] The GATT organization (1947) undertook the responsibility of settling differences among contracting parties as soon as it was created. Gradually over almost four decades, the GATT developed a set of dispute resolution procedures based on informal, political, and diplomatic procedures rather than legal ones… The WTO procedure gives government's access to tribunals, make legal rulings of the tribunals automatically binding, introduces an appellate review, and makes trade sanctions automatically available in case of noncompliance. See Xu Yi-ching and Patrick Weller (eds.), (2004), *The Governance of World Trade: International Civil Servants and the GATT/WTO*, Cheltenham, UK: Edward Elgar Publishing Limited: 197.

[61] Section 24 b of the *1970 Patents Act* as amended by the Amendment Act 1999 stated as below:

1) Where a claim for patent covered under sub-section (2) of section 5 has been made and the applicant has,-

a) where an invention has been made whether in India or in a country other than India and before filing such a claim, filed an application for the same invention claiming identical article or substance in a convention country on or after the 1st day of January, 1995 and the patent and the

First ground:

a) A claim for a patent of a medicine or drug has been made.
b) Invention has been made in India or in a country other than India.
c) Before filing such a patent claim, has filed an application for the same invention claiming identical articles or substance in a convention country on or after the 1st day of January 1995.
d) Patent and the approval to sell or distribute the article or substance on the basis of appropriate tests conducted on or after the 1st day of Jan 1995 in that country have been granted on or after the date of making a claim for patent of the medicine or drug in India.

Second ground:

a) A claim for a patent of a medicine or drug has been made.
b) Invention has been made in India.
c) Before filing such a claim made a claim for patent on or after the 1st of Jan 1995 for method or process of manufacture for that invention relating to identical article or substance.
d) Such claim mentioned above has been granted in India the patent therefore on or after the date of making a claim for patent for medicine or drug.

In both cases, such claim should have received the approval to sell or distribute the article or substance from the authority specified in this behalf by the Central govt. Once such approval has been received by the claimant, then he shall have the exclusive right by himself, his agents or licensees to sell or distribute the article or the

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approval to sell or distribute the article or substance on the basis of appropriate test conducted on or after the 1st day of January, 1995, in that country has been granted on or after the date of making a claim for patent covered under sub –section (2) of section 5; or

b) where an invention has been made in India and before filing such a claim, made a claim for patent on or after the 1st day of January, 1995 for method or process of manufacture for that invention relating to identical article or substance and has been granted in India that patent therefore on or after the date of making a claim for patent covered under sub section (1) of section 5.

and has received the approval to sell or distribute the article or substance form the authority specified in this behalf by the Central Government, then he shall have the exclusive rights by himself, his agents or licensees to sell or distribute in India the article or the substance on and from the date of approval granted by the Controller in this behalf till a period of five years or till the date of grant of patent or the date of rejection for the grant of patent, whichever is earlier.

substance on and from the date of approval granted by the Controller for a period of five years or till the date of grant of patent or that date of rejection of the application for the grant of patent, whichever is earlier.

EMR's are now done away with as pharma patents are permissible in India.

3.2.2. 2002 Patents Second (Amendment) Act

In order to become TRIPS compatible India enacted the *Patents Second (Amendment) Act 2002* to the *1970 Patents Act*. These amendments while it did not make India fully TRIPS compliant, were welcomed by the pharmaceutical industry in India who opined that in India there is undue worry about medicinal prices going up due to an overhauled patent regime in line with the TRIPS obligations (*Chronicle Pharmabiz* (Mumbai), 5(12), 03/03/2005: 9). They maintained that India with a large number of US FDA approved facilities outside USA will emerge as a significant player in the area of generics (*Chronicle Pharmabiz* (Mumbai), 5(12), 03/03/2005: 9).

3.2.3. 2004 Patent Ordinance

In 2004 India promulgated an ordinance to make the patent legislation compatible with the TRIPS requirements. Through this ordinance section 3(d) of the *1970 Patents Act was* amended to substitute the words "new use" with "mere new use". Also, a new section 25 was proposed which provided for pre grant opposition i.e. where an application for a patent has been published but the patent has not been granted, any person may in writing oppose the patent application on the grounds such as non-disclosure or wrongful mentioning in the specification. The new provision also provided for post grant opposition i.e. at any time after the grant of the patent but before one year from the date of the publication of the grant of the patent, any person may give a notice of opposition on the ground that the invention as claimed in the complete specification was publicly known or used in India before the priority date of the claim. Importation of a product made by the process concerned before the priority date of the claim was sufficient to constitute as publicly known or publicly used in India. Also, section 92 A providing for compulsory license for the export of patented pharmaceutical products in certain exceptional situations was inserted. It stated that compulsory license shall be available for the manufacture and export of patented products to any country having insufficient or no manufacturing capacity in the

pharmaceutical sector in order to address public health problems provided compulsory license has been granted in such country.

However, the Ordinance lapsed as the lower house of the Indian Parliament was dissolved before the Ordinance could be converted into an amendment Act.

3.2.4. 2005 Patents (Amendment) Act

In 2005, India brought about the 2005 *Patents (Amendment) Act* which provided for pharmaceutical patents. The 2005 *Patents (Amendment) Act* deleted section 5 which earlier in section 5(1) mentioned that in the case of inventions claiming substances intended for use or capable of being used as food or as medicine or drug no patent shall be granted in respect of claims for the substance themselves, but claims for the methods or processes of manufacture shall be patentable. Through the Patents (Amendment) Act 1999, exclusive marketing rights could be granted under section 5 (2). Both section 5(1) and 5(2) were deleted through the Patents (Amendment) Act, 2005.

There is no bar on patenting of pharmaceutical substances under the amended *Patents Act*. Section 2(ta) of the 1970 *Patents Act* defines pharmaceutical substance as '*any new entity involving one or more inventive steps*'.

Upon the enactment of the Patents (Amendment) Act 2005, informed sections of the society and also the WHO had raised concern that the implementation of the TRIPS obligations shall adversely affect the availability of medicines in India at affordable prices to the poor. Reports noted that access to critical medicines such as those for HIV/AIDS treatment is greatly facilitated by Indian generic manufactures which decrease the cost of medicines to even about 98 per cent, and that Indian manufacturers export medicines to about 200 poor countries.(See (2005), "International AIDS NGOs oppose patent amendments in India", *Chronicle Pharmabiz* (Mumbai), 5(6): 5)

WHO noted that several member states including Ghana, Lesotho, Malawi, Namibia, Bangladesh, Cambodia, China, Indonesia, Korea, Laos, Thailand, Papua New Guinea and Vietnam expressed their concern that in future generic antiretroviral drugs from

India may no longer be available to them. Also, from the African Union comprising over 44 member countries, in a declaration signed in 2005 at Ethiopia flagged off the issue that access to generic drugs especially from India may be impacted by the steps taken for TRIPS compliance (See Mathew, Joe C 2005: 3).

The provisions of the *1970 Patents Act* are discussed in detail below in this chapter. G Nair, Gopakumar et. al (2014b: 16) note that the *1970 Patents Act* and Patents Rules, 2003 as amended provide a model for the rest of the world. He concludes that the threshold for patentability for inventions in pharmaceutical and biotech world has been raised in the amended *1970 Patents Act* to prevent frivolous patenting and evergreening and interestingly, that the patentability filters as provided in Section 3 and especially 3(d) has contributed to restricting patentability to genuine inventions.

The list of non-patentable inventions in Section 3 of the 1970 *Patents Act* such as discovery of mere new use of known substance, computer programme, business method, traditional knowledge, method of treatment, mere arrangement and rearrangement of substances, substance which is admixture of two or more substances etc. reduces the scope of patentable subject matter in India compare to that in the United States (Kadri, Harunrashid and Saykhedkar, Medha (2011: 222). However, in the United States there are various scenarios such as absence of pre grant opposition, wider scope of patentable subject matter, identical definitions of inventions and discovery, liberal and favourable interpretation by judiciary, patenting of bushiness methods, software, discovery of new use of known substance etc. (Kadri, Harunrashid and Saykhedkar, Medha (2011: 221) which expand the scope of patenting in the United States compared to India.

3.3 Government Study Reports in the Context of Legal Changes from TRIPS

3.3.1. 2007 Satwant Committee Report on Data Protection

The report issued by the Ministry of Chemicals and Petrochemicals, Government of India in May 2007 (hereinafter "2007 Satwant Committee Report") addressed the issue of data protection as required by Article 39.3 of the TRIPS Agreement which mandates protection to be provided for the test data submitted for market approval by

the pharmaceutical and agro-chemical industries.[62] The report observed that while the TRIPS Agreement mandates data protection for pharmaceuticals and agricultural chemicals which contain a new chemical entity, the agreement does not clearly state the manner in which data protection is to be provided (Government of India 2007: iv).

With regard to the regulatory scenario in India, the report noted that in India there is no separate legislation to protect undisclosed test data submitted to the regulatory authorities in the pharmaceutical and agricultural sector and that protection of undisclosed information in India is through the provisions of common law, law of torts, Indian Contract Act, 1872 (compensation, injunction etc) and section 5 of the Official Secrets Act which declares unauthorized disclosure of official secrets as a punishable offence. The report noted that both the 1940 *Drugs and Cosmetics Act* which regulates the manufacture and marketing approval of drugs and traditional medicines and the Insecticides Act, 1968 which deals with agricultural chemicals, require submission of test data to verify the safety and efficacy of the new drugs and agricultural chemicals before the grant of marketing approval (Government of India 2007: iv).

The report noted that the data protection requirements are different for agro-chemicals, traditional medicines and pharmaceuticals and recommended different approaches for the three types of products. For agro-chemicals the report recommended data protection for three years and for traditional medicines the report recommended data protection for five years (Government of India 2007: v). In both cases the regularity is not to rely on the data submitted by the originator while processing the second and subsequent applications.

In the case of pharmaceuticals, a calibrated approach was recommended with measures to be taken to implement the minimum standards of data protection through

[62] Article 39.3 of the TRIPS Agreement states as below:

> Members when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilize new chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use. In addition, Members shall protect such data against disclosure, except where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use.

explicit legal provisions in the 1940 *Drugs and Cosmetics Act* and the 1968 *Insecticides Act* and the Rules there under (Government of India 2007: v).

The report concluded that there is enough flexibility in the provisions of TRIPS Agreement for a country to determine appropriate means of protecting test data and that there is no need for separate statute for data protection in India (Government of India 2007: v).

3.3.2. 2005-06 Report of the Standing Committee on Chemicals & Fertilizers

The issue of availability and price management of drugs and pharmaceuticals has been studied by the Government of India at various levels. The Standing Committee on Chemicals & Fertilizers (2005-06) (Fourteenth Lok Sabha) Ministry of Chemicals & Fertilizers (Department of Chemicals & Petrochemicals) (hereinafter "2005-06 Report of the Standing Committee on Chemicals & Fertilizers") addressed this issue and the solutions suggested by the Report does not say that availability of medicines can be ensured by not providing patents in the pharma sector. This committee report does identify a number of other issues such as that the National List of Essential Medicines (hereinafter "NLEM") does not cover the medicines which are actually required to be covered, but is an obsolete list which does not cover the critical diseases which affect the Indian population and even includes names of banned medicines etc. The Government has addressed this to some extent by coming out with the revised list in June 2011.

The Report recommended:

a) Strengthening the NPPA sufficiently and to enable state level cells and to strengthen the drug regulatory authorities to ensure proper checking at production/ distribution level. Revival of the Public Sector Industries in the pharma sector has also been recommended.
b) Revival of many of the pharma companies in the public sector which are either closed down or are facing liquidation.
c) Increasing the spending of the government on public health from the current 0.9 % of the GDP. The WHO recommended level is 5% of the GDP.
d) Evolving a system as formulated by the Government of Tamil Nadu to procure medicines in bulk through a tender process at prices less than MRP and then

making them available in public heath institutions and have Government run dispensaries distributing medicines at reasonable costs as facilitated by the government of Rajasthan.

e) Enhance the budget for the traditional system of medicines in India and to provide adequate publicity for the same.
f) A single authority to be set up to deal with the medicinal issues. Currently it is spread over multiple ministries. For e.g. while the issue relating to pricing of drugs and pharmaceuticals policy comes under the Ministry of Chemicals & Fertilizers (Department of Chemicals & Petrochemicals), the Health Policy is framed by the Ministry of Health and Family Welfare. The Ministry of Science and Technology deal with the Research & Development while patent issue is being looked after by the Ministry of Commerce and Industry.
g) Setting up of a fund to facilitate R&D in the pharma sector to counter the effects of the stronger patent regime that has come in place.
h) Strengthening the State Drug Control Administration, bringing out publications by NPPA, bringing lifesaving drugs like anti-cancer and Anti-HIV drugs under price control, strengthening R&D in pharma sector, curbing spurious drugs etc.

3.3.3. 2005 Report of the Task Force

The Report of the Task Force to Explore Options Other than Price Control for Achieving the Objective of Making Available Life- Saving Drugs at Reasonable Prices brought out by the Department of Chemicals and Petrochemicals in September 2005 (hereinafter "2005 Report of the Task Force from Department of Chemicals and Petrochemicals") considered the options other than price control to make available lifesaving drugs at reasonable prices. This Task Force concluded that for any price regulatory mechanism to be effective there has to be a credible threat of price controls to be imposed and enforced and further noted that the current system is inappropriate (Government of India 2005b, chapter 7, para 1.1.). This 2005 Report of the Task Force from Department of Chemicals and Petrochemicals made the following recommendations (Government of India 2005b, chapter 7, para 1):

a) Price controls should be based on the essentiality of a drug and that it should be on the medicines actually used by the consumer and not on the bulk drugs.

b) Only a ceiling of the prices was to be prescribed and that such ceiling must be based on the cost of production.
c) All drugs were recommended to be brought under a comprehensive price monitoring system.
d) There should be a unified regulatory structure to regulate the quality, quantity and price of the drugs.
e) Generic drugs to be encouraged through a process of active promotion and public health facilities be required to prescribe and dispense generic drugs.
f) For proprietary drugs such as those for HIV and cancer, government to actively pursue access programs including differential pricing and alternative packaging.
g) Revival of public sector enterprises involved in the manufacture of drugs
h) Fiscal incentives for research and development of drugs
i) Financial support for dedicated generic manufacturers and small scale units
j) Drug regulator to maintain data base on drugs and their compositions and registration of drugs to be compulsorily approved by the regulator with nu further changes to be permitted to the composition of the drugs.
k) Ensuring availability of drugs through public health facilities
l) Insurance companies to be encouraged to cover price of medicines as well.

The Task Force recommended conversion of the present Drug Prices (Control) Order (DPCO) which is a regulation under the Essential Commodities Act, 1995 into a legislation which will (Government of India 2005b, chapter 7, para 2):

a) empower the government or its designated authority to do price control on any individual, class or category of drug or therapeutic product for any period as required in public interest,
b) require principles of price control to be laid down by the government or such authority,
c) authorise the government or its designated authority to compel data relevant to its functioning from the manufacturers, marketers, distributors or retailers of drugs and therapeutic products,
d) require companies manufacturing or marketing drugs and therapeutic products to submit authenticated price lists on a periodic basis,

e) enable government to approve the brand name and composition of a specific product to prevent changes in the composition,
f) enable imposition of penalties for noncompliance with the provisions of the Act, greater accountability and role of State Drug Controllers.

The Task Force endorsed the proposal by the Planning Commission in its Mid Term Appraisal of the Tenth Five Year Plan to establish a National Authority on Drugs and Therapeutics ("NADT") through an amendment to the 1940 *Drugs and Cosmetics Act*. The Task Force recommended that the NADT was to be:

- formed by the integration of the Drug Controller General of India, the Central Drugs Standard Control Organisation (CDSCO) and the National Pharmaceutical Pricing Authority (NPPA) (Government of India 2005a, chapter 7, para 3).
- made responsible for regular updation and revision of the National List on Essential Medicines to be approved by the Government in consultation with the states and to do price negotiations on drugs.
- responsible for quality certification and marking, promotion of generic drugs and maintenance of a public website/database on drug prices etc.

As an immediate measure it was recommended that the NPPA should be made more effective through some fundamental changes in the NPPA such as fixing a minimum tenure of two years for the Chairman of the NPPA, strengthening the monitoring system of the NPPA through proper computerisation and software and establishing live electronic linkage between the NPPA and the State Drug Controllers. Simultaneously a National Drug Authority as to be created for safety, quality and efficacy aspects.

Also an appellate authority was to be created for appeals on the decisions from the NADT (Government of India 2005b, chapter 7, para 4).

The Task Force laid down the following principles on price regulation (Government of India 2005b, chapter 7, para 5):

i. The NLEM to be made the basis for intensive price monitoring, ceiling prices, imposition of price controls etc.

ii. The government to announce the ceiling price of all drugs on the basis of weighted average of the top three brands by value of single ingredient formulations prevailing in the market as on a 01.04.2005 The Org-IMS data to be used for this purpose with a 20 percent retail margin. However, it was recommended that the Org-IMS data needs to be updated.

iii. Till the time the ceiling prices are fixed, prices of all essential drugs to be frozen.

iv. Price ceiling to be specified on per dosage basis, per capsule basis or standard volume of injections and on individual pack for syrups etc.

v. For formulations having combination of more than one drug, the ceiling price to be the weighted average of the ceiling price of all the constituents.

vi. For the combinations containing a drug in the NLEM and any other drug, the ceiling price as applicable to the essential drug to apply. However, company can approach the price negotiations committee for any relaxation.

vii. Companies to be permitted to represent for any price increase based on valid grounds.

viii. An intensive monitoring to be carried out for drugs falling into a pre-specified list of therapeutic categories with the price as in the NLEM being the reference price.

ix. The NLEM to be revised on a periodic basis such as every five years.

x. The MRP price to be made inclusive of all taxes as required under the Packaged Commodities Rules, 1977.

xi. All patented drugs and their formulations to be compulsorily brought under price negotiation prior to grant of marketing approval. Where there is failure of such negotiation, then price control or compulsory licensing to apply. The reference price for such negotiations would be the premium enjoyed by such drug in the lowest priced market abroad as compared with its closest therapeutic equivalent in such country.

xii. Bulk purchase mechanism to be streamlined to curd malpractices in order to ensure that the pieces of the drugs reflect the true value and not more.

xiii. For bulk purchase, procurement should be only from pre-qualified manufacturers of drugs, GMP compliance by the manufacturers, assessment of

the manufacturing and financial capacity of the manufacturer through review of its balance sheets, post ward inspection of the manufacturing facilities, procurement in the generic form etc. (Government of India 2005b, chapter 7, para 7).

xiv. Small manufacturers not to be excluded because of their financial size.

xv. For any new formulation based on existing API marketing approval would be granted only if the indicated price is consistent with the relevant ceiling price (Government of India 2005b, chapter 7, para 6.1).

xvi. The reference price to be used for price negotiations (Government of India 2005b, chapter 7, para 6.3) to be based on the premium enjoyed by the drug in the lowest priced market abroad compared to the closest therapeutic equivalent in that same country. Such premium to be then compared to the reasonable price under Indian conditions.

xvii. While price monitoring of generic drugs should be done no control or price margins should be specified for generic drugs.

xviii. Quality certification of generic drug manufacturers to be done free of cost (Government of India 2005b, chapter 7, para 8).

xix. For low volume high priced drugs government to enter into arrangements with manufacturers and procurement to be done through government health system (Government of India 2005b, chapter 7, para 9.1).

xx. Complete exemption of anti AIDS/HIV drugs from excise duty, octroi and other levies with instruction to manufacturers to charge lower profit (Government of India 2005, chapter 7, para 9.2).

xxi. Central government to procure drugs from PSU's through normal tendering process and to have a system of common pricing and supply committee for all central government pharma PSU's (Government of India 2005b, chapter 7, para 10).

xxii. Medicines to be given free of cost to BPL families through all government hospitals (Government of India 2005b, chapter 7, para 11).

xxiii. Reduction of excise duty on all pharmaceutical products and to enhance exemption limit for small scale units from Rs. One crore to Rs. Five crores (Government of India 2005b, chapter 7, para 12).

xxiv. Liberal fiscal regime for domestic R&D to be provided through depreciation on investment made in land, dedicated research facilities, expenditure for

regulatory approvals, filings of patents abroad etc. (Government of India 2005b, chapter 7, para 13). Such benefits to be provided for a longer tenure.

xxv. Increase in the corpus of the Pharmaceutical Research and Development Support Fund which at the time of this report was Rs. 150 crores (Government of India 2005b, chapter 7, para 13.1).

xxvi. Creation of a fund for providing interest subsidy of 5 to 6% on borrowings to small scale pharma units in addition to any assistance currently available (Government of India 2005b, chapter 7, para 14).

xxvii. Educate people through alternative drug formulation available through publicity literature, booklets, dedicated newsletters, creation of dedicated agency etc. (Government of India 2005b, chapter 7, para 15).

xxviii. Cases pertaining to overcharging which is involved in protracted litigation to be brought before Settlement Commission created by the Government for decide the recoverable amount after summary hearing of both sides and to partly utilise such amounts for public awareness program and for operating and strengthening the price monitoring mechanism of NPPA (Government of India 2005b, chapter 7, para 16).

3.3.4. 2005 Report of the Technical Expert Group on Patent Law Issues

The Government of India appointed this Committee[63] comprised of Dr. R.A. Mashelkar (Chairman), Goverdhan Mehta (Member), Moolchand Sharma (Member), N.R. Madhava Menon (Member) and Asis Datta (Member). The terms of reference of this *2005 Technical Expert Group on Patent Law* Issues ("TEG") were the following:

a) whether it would be TRIPS compatible to limit the grant of patent for pharmaceutical substance to new chemical entity (NCE's) or to new medical entity (NME's) involving one or more inventive steps; and

b) whether it would be TRIPS compatible to exclude micro-organisms from patenting.

[63] Set up by Ministry of Commerce & Industry, Department of Industrial Policy & Promotion *vide* O. M. No. 12/14/2005-IPR-III dated April 5, 2005

The TEG held that granting patents only to NCE's or NME's could contravene the mandate under Article 27 of the TRIPS to grant patents to all inventions. They concluded that Article 7 and 8 which provided for social and economic welfare or development could not be used to derogate from the mandate under Article 27 (Government of India 2005a: para 5.6). They also held that new form of a known substance would not be patentable unless it differs significantly in terms of property on efficacy (Government of India 2005a: para 5.8). The TEG observed that restricting patentability to NCE'S would result in most of the pharmaceutical patents in India being owned by MNC's (Government of India 2005a: para 5.11).

On patenting of microorganisms, the TEG held that under Article 27.3 of the TRIPS, microorganisms are different from plants and animals and that while naturally occurring microorganisms do not qualify for patenting, microorganisms involving human intervention and utility are patentable under the TRIPS where they meet the patentability criteria (Government of India 2005a: para 5.23).

3.3.5. 2009 Report of TEG

In its revised report submitted in March 2009, the TEG reiterated on point a) that it may be deemed TRIPS incompatible if patents were to be restricted only to new chemical entities in India. The TEG concluded as below:

> 4.1 Article 27 of TRIPS, which deals explicitly with the issue of patentability, inter alia, states that 'Member States may not exclude any field of technology from patentability as a whole and they may not discriminate as to the fields of technology, the place of innovation' etc. Reading this obligation in the light of the overall purpose of the Agreement, it appears that linking the grant of patents for pharmaceutical substances only to a new chemical entity or to a new medical entity may prima facie amount to 'excluding a field of technology' even when they satisfy the basic requirements of patentability'. In such a situation, TEG concludes that it is possible to hold the provision as being not TRIPS Compatible (Government of India 2009, para 4.1).

In arriving at this conclusion, the TEG examined various provisions of the TRIPS Agreement and also the various provisions which provide the flexibilities under the TRIPS Agreement, but concluded that the objectives etc. cannot override the specific provisions of the TRIPS Agreement which specifically states that no class of inventions may be barred etc.

Further, allowing patenting with regard to only new chemical entities were not deemed advisable by the TEG as many of the Indian pharmaceutical companies did not have sufficient research and development capabilities. In addition, the practice worldwide also seemed to allow patenting of variations of new uses of the same drug or minor variations of the same. The TEG noted that restricting patentability to NCEs or NMEs could have legal and scientific ramifications in India as drug discovery in India is still finding it feet and that only few Indian companies were being successful in building pipeline of new molecules and that these molecules are in the early stages of evolution and their success is still awaited in the marketplace. Therefore the TEG considered that restricting patentability to NCEs would mean that most pharmaceutical patents would be owned by MNCs (See Government of India 2009, para 5.33).

Submissions from the Indian pharmaceutical industry to the TEG also supported this position. Ranbaxy stated that restricting patentability to NCEs may appear to be an attractive solution in the short-term to companies focusing on reverse engineering, but that this will not benefit hundreds of scientists working in public & private research and development centres, who are beginning on the arduous task of new drug discovery research.[64]

The TEG noted that incremental innovations were the norm rather than exception. The TEG concluded that it may not be advisable to restrict patents only to New Chemical entities and the method to prevent evergreening of patents would be through vigilance by the Indian Patent Office while processing the patent applications.

The report stated as below:

> 4.3. Every effort must be made to prevent the practice of 'ever greening' often used by some of the pharma companies to unreasonably extend the life of the patent by making claims based sometimes on 'trivial' changes to the original patented product. The Indian patent office has the full authority under law and practice to determine what is patentable and what would constitute only a trivial change with no significant additional improvements or inventive steps involving benefits. Such authority should be used to prevent 'evergreening', rather than to introduce an arguable concept in the light of 4.1 and 4.2 above

[64] Ranbaxy's submission, Annexure III to Government of India 2009a: 23

> of "statutory exclusion" of incremental innovations from the scope of patentability (Government of India 2009, para 4.3).

The TEG observed that the process of innovation occurs continuously and that incremental improvements based on existing knowledge and products is the norm than the exception in the process of innovation and that entirely new chemical structure with new mechanisms of action are a rarity. In such context the TEG recommended that incremental innovation involving new forms, analogs etc. which have significantly better safety and efficacy standards need to be encouraged and that the patent office should be vigilant to set high standards of judging such innovations so that the efforts of evergreening are prevented. (Government of India 2009, para 5.32)

On microorganisms, the TEG concluded that Article 27.3 of the TRIPS Agreement does not permit such exclusion and that excluding micro-organisms *per se* from patent protection in India would be violative of TRIPS Agreement (Government of India 2009, para 5.45). However, the TEG recommended that strict guidelines need to be formulated for examination of the patent applications involving micro-organisms from the point of view of substantial human intervention and utility.

4. Mechanisms under Indian law to Ensure Accessibility and Affordability to Medicines

India has various pieces of legislation such as the 1970 *Patents Act*, 1897 *Epidemic Diseases Act* etc. which have bearing on public health. The 1970 *Patents Act* is examined in detail below. The 1897 *Epidemic Diseases Act* empowers the government to take such step as is required through temporary regulations to prevent outbreak of disease where the ordinary provisions of law are insufficient for the purpose (See section 2 of the 1897 *Epidemic Diseases Act*).

4.1. National Pharmaceutical Pricing Authority

Government reports reveal that the expenditure on drugs in India constitutes 40 to 80 percent of the total cost of treatment of disease in India and expenditure on healthcare is second most common cause for rural indebtedness (See Govt. of India 2010c:6, para 3). The government in India has tried to address the issue of medicinal pricing

through forming the National Pharmaceutical Pricing Authority ("NPPA") etc. which would regulate the medicinal prices of essential drugs. There are instances when the NPPA has stepped in and regulated the medicinal prices. For example in January 2005 the NPPA regulated the prices of 99 formulations, after considering NPPA norms of Conversion cost, Packing Charges, Packing material cost and process loss (*Chronicle Pharmabiz* 2005d: 10).

The NPPA does the work of price fixation of certain medicines and is also entrusted with the task of updating the list of drugs under price control each year on the basis of established criteria/guidelines.[65] The NPPA utilises the provisions of the Drug Price Control Order 1995 ("DPCO 1995") promulgated by the Government of India in the exercise of the powers conferred by section 3 of the Essential Commodities Act (See *Secretary, Ministry of Chemicals and Fertilizers, Govt. of India*, AIR 2003 SC 3078: 3081).

Similarly, even among the developed countries, Canada has a Patented Medicines Price Review Board to ensure prices of patented medicines charged by the patentees are not excessive. And this body is quite effective in controlling prices and reporting the pricing trends in pharmaceutical industry to the parliament on a regular basis (*Chronicle Pharmabiz* 2005e: 8).

However, certain studies suggest that when drugs are brought under price control, the pharmaceutical industry does not find it lucrative and therefore either discontinue its production or create deviations (Padmashree Sampath, Gehl 2005: 61). Also, a 2010 Parliamentary Committee report has suggested that the NPPA is controlling only the prices of about 50 drugs only while about 354 molecules are mentioned in the National List of Essential Medicines (Govt. of India 2010c: 9, para 1). The NPPA in 1979 was controlling the prices of about 347 medicines.

4.2. 1940 *Drugs and Cosmetics Act*

The 1940 *Drugs and Cosmetics Act* defines 'drug' as below:

[65] See paragraph 11 of the Drug Policy document issued by the Government of India on September 15th, 1994

(b) "drug" includes—

(i) all medicines for internal or external use of human beings or animals and all substances intended to be used for or in the diagnosis, treatment, mitigation or prevention of any disease or disorder in human beings or animals, including preparations applied on human body for the purpose of repelling insects like mosquitoes;

(*ii*) such substances (other than food) intended to affect the structure or any function of the human body or intended to be used for the destruction of vermin or insects which cause disease in human beings or animals, as may be specified from time to time by the Central Government by notification in the Official Gazette;]

(iii) all substances intended for use as components of a drug including empty gelatin capsules; and

(iv) such devices intended for internal or external use in the diagnosis, treatment, mitigation or prevention of disease or disorder in human beings or animals, as may be specified from time to time by the Central Government by notification in the Official Gazette, after consultation with the Board;

Therefore the definition of the term 'drug' is very broad and can include even devices as may be specified by the Central Government. Section 26 B of the 1940 *Drugs and Cosmetics Act* as amended in 2008 provide that if the Central Government is satisfied that a drug is essential to meet the requirements of an emergency arising from epidemics or natural calamities, then in public interest the Government may regulate or restrict the manufacture, sale or distribution of the drug.

4.3. 1995 *Drug Price Control Order*

'Drug' as defined in the 1940 *Drugs and Cosmetics Act* is an essential commodity. As per the DPCO 1995, drug is defined as including (Clause 2 of DPCO 1995):

> All medicines for internal or external use of human beings or animals and all substances intended to be used for, or in the diagnosis treatment, mitigation, or prevention of any disease or disorder in human beings or animals, including preparations applied on human body for the purpose of repelling insects like mosquitoes;
>
> Such substances, intended to affect the structure or any function of the human or animal body or intended to be used for the destruction of vermin or insects which cause disease inhuman beings or animal, as may be specified from time to time by the government by notification in the official Gazette; and

As per the DPCO, formulation is defined as (Clause 2 of DPCO 1995):

'Formulation' means a medicines processed out of, or containing without the use of any one or more bulk drug or drugs with or pharmaceutical aids, for internal or external use for or in the diagnosis, treatment, mitigation or prevention of disease in human beings or and, but shall not include:

- Any medicines included in any bonafide Ayurvedic (including Sidha) or Unani (Tibb) systems of medicines.
- Any medicines included in the Homeopathic system of medicines; and
- Any substance to which the provision of the 1940 *Drugs and Cosmetics Act* (23 of 1940) do not apply.

The DPCO 1995 states that the Government may from time to time by order fix the retail price of a Scheduled formulation in accordance with the provisions therein (Clause 8.1 of DPCO 1995) and that the retail price of a formulation once fixed by the Government under the DPCO may not be increased by any manufacturer without the prior approval of the Government (Clause 8.3 of DPCO 1995). Also, the DPCO states that fixing of the ceiling price shall be keeping in view the cost or efficient or both of the major manufacturers of such formulations and such price shall operate as the ceiling price for all such packs including those sold under generic names for every manufacturer of such formulations (Clause 9.1 of DPCO 1995).

The DPCO 1995 also provides that the Government may, if it considers necessary to do so in public interest, after calling for such information by order, fix or revise the retail price of any formulation including a non-Scheduled formulation (Clause 10, DPCO 1995). It further provides that the government may if it considers necessary to do so in public interest, buy order include any bulk drug in the First Schedules and fix or revise the prices of such a bulk drug and formulations containing such bulk drug (Clause 10, DPCO 1995). Even where the manufacturer or importer of a bulk drug fails to provide the information as required within the time frame specified, the Government may fix the price in respect of such formulation on the basis of the information as may be available with it (Clause 11 of DPCO 1995).

4.4. 2013 *Drug (Prices Control) Order*

In the 2013 *Drug (Prices Control) Order* by the Ministry of Chemicals and Fertilizers dated May 15, 2013 ("DPCO 2013") the power of the government to fix the price has been detailed. Section 2(j) of the said 2013 DPCO defines generic version of a medicine as a formulation sold in pharmacopeial name of name of the active

pharmaceutical ingredient contained in the formulation without any brand name. Various definition such as active pharmaceutical ingredients or bulk drug, generic version of a medicine, new drug etc. is provided in the DPCO 2013.

'Active pharmaceutical ingredients or bulk drug' is defined as any pharmaceutical, chemical, biological or plant product including its salts, esters, isomers, analogues and derivatives, confirming to the standards specified in the Drugs and Cosmetics ACT, 1940 and which is used as such or as an ingredient in any formulation (Section 2(b) of DPCO 2013).

'Generic version of a medicine' is defined as a formulation sold in pharmacopeial name or the name of the active pharmaceutical ingredient contained in the formulation, without any brand name (Section 2(j) of DPCO 2013).

'New drug' for the purpose of the 2013 DPCO is defined as a formulation launched by an existing manufacturer of a drug of specified dosages and strengths as listed in the NLEM by combining the drug with another drug either listed or not listed in the NLEM or a formulation launched by changing the strengths or dosages or both of the same drug of specified dosages and strengths as listed in the NLEM (Section 2(u) of DPCO 2013).

Section 3 of the 2013 DPCO is very important from the perspective of public health. It provides for increased production/sale formulation and to call for information etc. It provides that the Government in order to achieve adequate availability and to regulate the distribution of drugs may in case of emergency or urgency or for non-commercial use in public interest, direct the manufacturer of a pharmaceutical ingredient or bulk drug formulation to increase the production of such ingredient or formulation to sell the same to institutions, hospitals or agencies as required. Also, the Government may require such manufacturer to furnish all the required information within such time as fixed by the Government.

The retail price of a new drug available in the domestic market shall be fixed by the Government on the principles of "Pharmaeconomics" of the new drug, on the

recommendation of the Standing Committee of experts as detailed in the DPCO 2013 (Section 5 of the 2013 DPCO).

Where the average price to the retailer of a scheduled formulation arrived at as per the formula laid down on paragraph 4(1) does not have the effect of reduction on average price with respect to the prices to the retailer of the schedule formulation and there are less than five manufacturers for that formulation having one percent or more market share the ceiling price shall be calculated through the formula laid down therein (Section 6 of the DPCO 2013). In the event other strengths or dosage formats of the scheduled formulation is not available in the schedule but there are other schedules formulations in the same sub therapeutic category then Ceiling price shall be calculated in the formula laid down in section 6 (ii) (See Section 6 (ii) of the 2013 DPCO). Paragraph 6(iii) provides that in case other strengths or dosage forms of the scheduled formulation are not available in the schedule and there is no sub therapeutic category under consideration then the ceiling price shall be calculated as per the formula provided therein.

While fixing the ceiling price of scheduled formulations and retail prices of new drugs, the margin allowed to the retailer is sixteen percent (Section 7 of the 2013 DPCO). Section 19 of the DPCO provides for the inherent power of the Government to fix the ceiling of the drug price. It reads:

> Notwithstanding anything contained in this order, the Government may, in case of extra-ordinary circumstances, if it considers necessary to do so in public interest, fix the ceiling price or retail price of any Drug for such period, as it may deem fit and where the ceiling price or retail price of the drug is already fixed and notified, the Government may allow an increase or decrease in the ceiling price or the retail price, as the case may be, irrespective of annual wholesale price index for that year.

Further section 26 of the 2013 DPCO provides that 'no person shall sell any formulation to any consumer at a price exceeding the price specified in the current price list or price indicated on the label of the container or pack thereof, whichever is less.' However 2013 DPCO also makes clear that the provisions of this order shall not apply to:

a) a manufacturer producing a new drug patented under the India Patent Act, 1970 and not produced elsewhere, if developed through indigenous research

and development, for a period of five years from the date of commencement of its commercial production in the country (emphasis added).

b) a manufacturer producing a new drug in the country by a new process developed through indigenous Research and Development patented under the *1970 Patents Act* for a period of five years from the date of the commencement of its commercial production in the country (emphasis added).
c) a manufacturer producing a new drug involving a new delivery system developed through indigenous Research and Development for a period of five years from the date of its market approval in India (emphasis added).

One of the reports note that the price of the drugs on the NLEM rose by only 15% while those out of price control rose 137%. Therefore the NLEM is definitely useful to the cause of the right to health.

4.5. Actions by State Governments

Even outside the NPPA state governments has tried to ensure price control, for e.g. the Governments of Tamil Nadu, Kerala, Rajasthan and Bihar have sought to ensure disbursement of free medicines to patients seeking health care in public health facilities (Govt. of India 2011: 26). Tamil Nadu, the pioneer in this measure, set up an autonomous corporation in the public sector called the Tamil Nadu Medical Services Corporation which directly procures drugs from manufacturers though bidding process. The TNMSC in turn supplies the medicines to the public health facilities through a passbook system under which about 260 drugs in the essential drug list and 192 specialty drugs for secondary and tertiary care. At a budget of Rs. 29 per person amounting to Rs. 210 crore for a population of 7.2 crore alongside the medicines supplied by the Central Government Tamil Nadu was able to supply free medicines to all(Govt. of India 2011: 26). The following is the comparative table on prices which could be realised in Tamil Nadu (source Govt. of India 2011: 29) by effective tendering process for the population.

Table 9: Comparative Table on Prices through Tamil Nadu Medical Services Corporation

Generic Name of Drug	Unit	Chittorgarh Tender Rate (Rs.)	MRP Printed on pack/strip (Rs.)	TNMSC Prices 2010-11 (Rs)* (5)
Albendazole Tab IP 400 mg	10 tablets	11.00	250.00	4.62
Alprazolam Tab IP 0.5 mg	10 tablets	1.40	14.00	0.45
Arteether 2 ml Inj	1 injection	9.39	99.00	9.71 for 80 mg per vial
Amylodipine Tab 5 mg	10 tablets	2.50	22.00	0.42 for 10 tabs of 2.5 mg
Cetrizine 10 mg	10 tablets	1.20	35.00	0.50
Ceftazidime 1000 mg	1 injection	52.00	370.00	8.77 for 250 mg injection
Atorvastatin Tab 20 mg	10 tablets	18.10	170.00	2.30 for 10 tabs of 10 mg
Diclofenac Tab IP 50 mg	10 tablets	2.20	25.00	0.63
Diazepam Tab IP 5 mg	10 tablets	1.90	29.40	0.47
Amikacin 500 mg	1 injection	6.95	70.00	6.78

The Planning Commission has recommended implementing this Tamil Nadu model in the whole of the country (Govt. of India 2011: 26). At the Tamil Nadu prices the Planning Commission estimated that the cost for all of India would be only 5735 crores in a year including additional requirement for the very poor 20% patients (Govt. of India 2011: 27).

The Government of Haryana also took steps to regulate the pricing of medicines in the beginning of year 2005 (*Chronicle Pharmabiz* (Mumbai) 2005b: 8). The state government of Haryana came out with an *Essential Medicines Policy* for improving the access to high quality essential medicines in the state. The EMP is intended at enabling optimal; use of limited resources, having an effective check on common

diseases and making available quality medicines at low cost (*Chronicle Pharmabiz* (2005g): 1). The distinctive feature of the policy is its thrust towards the promotion of generic medicines. Also, the government prepared a list of essential medicines in the context of prevailing disease profile and health scenario of the state and took steps in consultation with stated drug trade sector to announce a uniform price rate for 254 commonly used generic drugs was one of the major steps in this direction.

Further, the Government of Haryana issued the *Purchase Policy and Management of Drugs, Medical Consumables, Surgicals and Sutures* (*Chronicle Pharmabiz* 2005g: 1) which notes that medicines are part of our lives and that they save lives, promote health and prevent epidemics and diseases. It also notes that access to essential medicines is closely linked to health system performance. Through this policy, in order to facilitate better access to medicines the government proposed to decentralize the procurement system to the district level to ensure transparent and uninterrupted supply of drugs and medicines.

4.6. The National List of Essential Medicines

The NLEM 2011 was prepared in June 2011 after a period of 8 years. The earlier NLEM list was prepared in 2003. 47 drugs were deleted from the 2003 list and 30 were added. The NLEM 2011 has 348 medicines listed while the NLEM 2003 had 354 medicines listed (See Sinha Kounteya 2011).

This list of essential medicines are those that satisfy the priority healthcare needs of majority of the population which addresses the disease burden of the nation and the commonly used medicines at primary, secondary and tertiary healthcare levels. The NLEM 2011 states that it has been prepared after several rounds of wide consultations with experts of different disciplines from different parts of the country and from various organizations. The Government aims that medicines in NLEM should be available at affordable costs and with assured quality. The primary purpose of NLEM is to promote rational use of medicines considering the three important aspects i.e. cost, safety and efficacy (See National List of Essential Medicines of India 2011). The NLEM 2011 names the Government of India, Ministry of Health & Family Welfare (MOHFW) as the agency mandated to ensure the quality healthcare system by assuring availability of safe and efficacious medicines for its population. Furthermore

the NLEM 2011 promotes prescription by generic names. Healthcare delivery institutions, health insurance bodies, standards setting institutions for medicines, medicine price control bodies, health economists and other healthcare stakeholders will be immensely benefitted in framing their policies.

The Government of India has also announced certain schemes such 'Jan Aushadhi' under which government will procure the generic medicines in bulk and thereafter distribute these medicines at reduced prices (Sharma, Usha 2012). However, as per certain reports the scheme of the Central Government to provide the medicines on the NLEM free of cost has been discarded in April 2015 (See Natarajan, Rema 2015). This is a retrograde measure as some reports that every year about 39 million people in India are pushed to great financial hardships on account of expenses incurred for healthcare treatment.

4.7. Provisions in *1970 Patents Act*

A study of the *1970 Patents Act* after the *Patents Second (Amendment) Act 2002* and the Patents (Amendment) Act, 2005 came into force has revealed some provisions that are intended to safeguard public health interests.

4.7.1. Compulsory Licenses

Provided certain conditions such that the patented inventions are not worked on a commercial scale in the territory of India without undue delay and to the fullest extent reasonably practicable the government may issue compulsory license to any interested person who makes an application to the Controller for grant of the compulsory license on the patent.[66]

Section 83 of the *1970 Patents Act* lays down the general principles applicable to the working of the patents. It provides that in the context of working of the patents, consideration is to be had of the fact that patents are to encourage inventions and to

[66] Sections 89 of the *1970 Patents Act* states:

> The powers of the Controller upon an application made under section 84 shall be exercised with a view to securing the following general purposes, that is to say,-
> (a) that patented inventions are worked on a commercial scale in the territory of India without undue delay and to the fullest extent that is reasonably practicable;
> (b) that the interests of any person for the time being working or developing an invention in the territory of India under the protection of a patent are not unfairly prejudiced.

secure that inventions are worked in India on a commercial scale and to the fullest extent that is reasonably practical and without undue delay; and that patents are not granted merely to enable patentees to enjoy a monopoly over the patented article (See section 83(a) and (b) of the *1970 Patents Act*). The provision states that the protection and enforcement of the patent rights contribute to the promotion of technological innovation and to the transfer and dissemination of technology to the mutual advantage of the producer and users of technological knowledge in a manner conducive to social and economic welfare and to a balance of rights and obligations (See section 83(c) of the *1970 Patents Act*).

Consideration has to be had of the fact that:

a) patents granted do not impede protection of public health and nutrition and that patents should act as instrument to promote public interest specifically in sectors of vital importance for social economic and technological development of India (See section 83(d) of the *1970 Patents Act*).
b) patents granted do not in any way prohibit the Central Government from taking measures to protect public health (See section 83(e) of the *1970 Patents Act*).
c) the patent right is not abused by the patentee or the person deriving title or interest on the patent from the patentee and the patentee or the person deriving title or interest on the patent from the patentee is not to resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology (See section 83(f) of the *1970 Patents Act*).
d) patents are granted to make the benefit of the patented invention available at reasonably affordable prices to the public (See section 83(g) of the *1970 Patents Act*).

The Government has the right to grant compulsory licenses on the patent matter to some other person or entity where the objectives of granting the patent are not met by the patent holder.

The general purpose for issuing compulsory license is to ensure that the patented inventions are work on a commercial scale in the territory of India without undue delay and to the fullest extent reasonably practical and that the interests of any person

working on or developing an invention in India under the protection of a patent is not unfairly prejudiced (See section 89 of the *1970 Patents Act*).

Section 84 to 94 of the *1970 Patents Act* deals with issue of compulsory licenses.

The legislation provides that at any time after the expiration of three years from the date of the grant of a patent any person interested may make an application to the Controller for the grant of compulsory license on the patents on any the grounds namely, that the reasonable requirements of the public with respect to the patented invention has not been satisfied, that the patented invention is not available to the public at a reasonably affordable price or, that the patent is not worked in the territory of India (See section 83(1) of the *1970 Patents Act*). If the Controller is satisfied that the above grounds exist he may grant the license upon such terms as he deems fit (See section 83(4) of the *1970 Patents Act*).

In considering the application that is so made, the Controller is to take into account the nature of the invention, the time that elapsed since the sealing of the patent and the measures already taken by the patentee or any licensee to make full use of the invention; the ability of the applicant to work the invention to the public advantage; the capacity of the applicant to undertake the risk in providing capital and working of the invention, if the application is granted and also whether the applicant has made the efforts to obtain the license from the patentee on reasonable terms and conditions and whether such efforts have been successful within a reasonable period of time as the Controller deems fit (See section 83(6) of the *1970 Patents Act*). However the requirement whether the applicant has made reasonable efforts to obtain the license shall not apply in the context of a national emergency or other circumstances of extreme urgency or in the case of a public non-commercial use or when it is established that anti-competitive practices have been adopted by the patentee (See section 83(6) (iv) of the *1970 Patents Act*).

The legislation provides that the reasonable requirements of the public shall to be deemed to be satisfied if due to the refusal of the patentee to grant license on reasonable terms, if an existing trade or industry or the development thereof is prejudiced, establishment of any new trade or industry in India or the trade and

industry of any person or class of persons trading or manufacturing in India is prejudiced (See section 83(7) (a) (i) of the *1970 Patents Act*).

If due to the refusal of the patentee to grant license on reasonable terms,

- the demand for the patented article has not been met with to an adequate extent or in reasonable terms (See section 83(7) (a) (ii) of the *1970 Patents Act*).
- a market for export of the patented article manufactured in India is not being supplied or developed or the establishment or development of commercial activities in India is prejudiced (See section 83(7) (a) (iii) & (iv) of the *1970 Patents Act*).

Also, the reasonable requirements of the public shall not be deemed to be satisfied if by reason of the conditions imposed by the patentee upon the grant of licensee under the patent or upon the purchase, hire or use of the patented article or process, the manufacture, use or sale of the materials not protected by the patent, or the establishment, or development of any trade or industry in India is prejudiced (See section 83(7) (b) of the *1970 Patents Act*).

Similarly, if the patentee imposes condition under the license to provide exclusive grant back, prevention to the challenges to the validity of patent, or coercive package licensing the reasonable requirement of the public shall not be deemed to be satisfied (See section 83(7) (c) of the *1970 Patents Act*).

If the patented invention is not being worked in the territory of India on a commercial scale to an adequate extent or is not being so worked to the fullest extent that is reasonably practical the reasonable requirement of the public shall not be deemed to be satisfied (See section 83(7) (d) of the *1970 Patents Act*).

Further, if the working of the patented invention in India on a commercial scale is being prevented or hindered by the import of the patented article from abroad by the patentee or the person clang under him, by persons directly or indirectly purchasing from him or other persons against whom the patentee is not taking or has not taken

proceeding for infringement, the reasonable requirement of the public shall not be deemed to be satisfied (See section 83(7) (e) of the *1970 Patents Act*).

While granting a compulsory license, the Controller is to secure that the royalty or other remuneration reserved for the patentee is reasonable having regard to the nature of the invention, the expenditure incurred by the patentee in making or developing the invention, in obtaining the patent and other relevant factors (See section 90 (i) of the *1970 Patents Act*). Also, the Controller is to secure that the patented invention is worked to the fullest extent with reasonable profit by the person to whom the license granted, that the patented articles are made available to the public at reasonably affordable prices, that the license is non-exclusive and non-assignable by the patentee, that the license is for the balance term of the patent unless a shorter term is consistent with public interest, that the license is granted predominantly for supply in the Indian market and the licensee may export if the condition as further prescribed in the legislation is met with, that in case the license is granted to remedy an anti-competitive practice as determined by judicial or administrative process that the licensee shall be permitted to export the product if need be (See section 90 (ii) to (ix) of the *1970 Patents Act*).

4.7.2. Revocation of Patents after Issue of Compulsory License

The legislation provides that where a compulsory license has been granted, the central government or any person interested may after the expiration of two years from the date of the grant of the compulsory license apply to the Controller for revoking the patent on the ground that the patented invention has not been worked in India or that the reasonable requirements of the public with respect to the patented invention has not been satisfied or that the patented invention is not available to the public at a reasonably affordable price (See section 85(1) of the *1970 Patents Act*). If the Controller is satisfied that any of these grounds are not being met with he may issue an order revoking the patent (See section 85(3) of the *1970 Patents Act).*

4.7.3. Compulsory License in the Context of National Emergency, Extreme Emergency or for Public Non Commercial Use

In circumstances of national emergency, extreme urgency or public non-commercial use, the central government may permit grant of compulsory license and the

Controller shall on application made by any person interest in the grant of the license grant the license on such terms and condition as he deems fit (See section 92(1) of the *1970 Patents Act*). While granting such license, the Controller shall seek to secure that the articles manufactured under the patent shall be made available to the public at the lowest prices consistent with the patentee deriving reasonable advantage from their patent rights (See section 92(1) (i) of the *1970 Patents Act)*. In case of situations of national emergency, extreme urgency or public on commercial use, including public health crises relating to AIDS, HIV, malaria or other epidemics the Controller shall not be required to provide an opportunity for opposition to the patentee or any other person (See section 92(1) (ii) of the *1970 Patents Act*).

4.7.4. Compulsory License for Export

The *1970 Patents Act* provides that compulsory license shall be available for manufacture and export of the patented pharmaceutical products to any country having insufficient or manufacturing capacity in the pharmaceutical sector for the concerned product in order to address public health problems, solely for the manufacture and export of the concerned pharmaceutical product to such country on such terms and conditions as specified by the Controller of Patents. In order to do so, compulsory license should have been granted by such country or such country should have allowed importation of pharmaceutical products from India (See section 92 A(1) of the *1970 Patents Act*).

4.7.5. Use of Compulsory Licensing Provision in India

As discussed in detail in the case laws above, in March 2012 India ordered compulsory licensing for the first time post implementation of the TRIPS Agreement. Bayer was ordered to license its drug Nexaver or Sorefenib to Natco Pharma an Indian company in exchange for a royalty of 6 per cent of the net sales (See Vikas Bajaj and Andrew Pollack 2012). Under this order the drug which is used for the treatment of kidney cancer and liver cancer is to be sold at Rs. 8800/- which is about 3 percent of the sale price of Rs. 2,80,486/- which was being charged by Bayer for the drug in India (See Vikas Bajaj and Andrew Pollack 2012).

Earlier, Cipla had tried to introduce a generic version of this drug in India at a cost of Rs.28,000/- per pack which was subjected to an IP infringement suit in India by Bayer (Gopakumar, K.M. 2012: 26-28).

It is clear that such compulsory licensing initiatives from the government will be required for ensuring affordable drug availability in India. In May 2012, Cipla announced reduction of the price of an anti-cancer drug by as much as 75% (See Rajagopal, Divya 2012). It is quite likely that this drug price reduction is in response to the compulsory licensing granted to Natco.

4.7.6. Working of Compulsory Licenses

G Nair, Gopakumar et. al (2014a: 209-217) note that while compulsory licensing provisions in the amended 1970 *Patents Act* is to be understood as specifically relating to affordable access to essential and lifesaving medicines, the required results have not been achieved and that India may need to have a relook at the flexibilities under the TRIPS and Doha to wriggle out of the stranglehold of endless adjournments without cause of action and irrational injunction against imaginary infringements and validly granted compulsory licenses (G Nair, Gopakumar et. al 2014a: 209). He observes that, 'inspite of the provisions for grant of compulsory licenses under sections 84, 92, 92A and use for purpose of government permission under section 100 and 101, most of the Indian companies are reluctant to file for compulsory licenses in view of apprehension of protracted litigations' (G Nair, Gopakumar et. al 2014a: 211). Many a time a strategy of not rejecting a voluntary license application and having continued correspondence without leading to closure of negotiations is adopted by attorneys on behalf of international overseas patentees (G Nair, Gopakumar et. al 2014a: 211). Further, larger Indian companies being natural allies for joint venture and voluntary licenses have opted not to apply for compulsory license (G Nair, Gopakumar et. al 2014a: 212). Also, in the Indian scenario there are large number of adjournments on procedural issues extending over 4 to 5 years, without substantive hearing with the result that these protracted litigations tire out the generic companies and prevent them in future from applying for regulatory approvals under section 107(a) during validity of pharma patents (G Nair, Gopakumar et. al 2014a: 214). He notes that past and recent examples of compulsory licenses clearly

indicate strong reluctance on the part of authorities for grant of compulsory licenses (G Nair, Gopakumar et. al 2014a: 215).

This being the outcome inspite of the presence of compulsory licensing provision in India, India needs to take steps to effectively address the bureaucratic issues and legal interventions in connection with the issue of compulsory licenses.

4.7.7. Use of the Invention for the Purposes of the Government

Section 99-103 of the *1970 Patents Act* deals with use of the invention for the purposes of the Government.

The legislation provides that notwithstanding anything contained in the *1970 Patents Act*, at any time after an application for a patent has been filed or a patent has been granted, the Central Government may use the invention for the purposes of the Government in accordance with the detailed provision of the *1970 Patents Act*(See section 100(1) of the *1970 Patents Act*). An invention is said to be used for the purposes of the government of it is used, exercised or vended for the purposes of the Central government, state government or a government undertaking.

Also, where an invention has before the priority date of the relevant claim of the complete specification been recorded in a document or tested or tried on behalf of the government of a Government undertaking, any such use of the invention by the central government or any person authorized in writing by it for the purposes of the government may be made free of any royalty or other remuneration to the patentee (Section 100(2) of the *1970 Patents Act)*. This exception shall not apply if such recording, testing etc. happens in consequence of the communication of the invention directly or indirectly by the patentee or the person from whom he derives title.

If the invention has not been tried, tested or recorded by the government beforehand, use by the government after the grant of the patent or in consequence of the communication, such use shall be upon the terms as agreed upon between the Government and the patentee, either before or after the use (Section 100(3) of the *1970 Patents Act*).

The right to make, use, exercise and vend an invention under this proviso shall include the right to sell, on a non-commercial basis the goods made in the exercise of that right, and the purchaser of the goods so sold or the person claiming through him shall have the power to deal with the goods as if the Central Government were the patentee of the invention (Section 100(6) of the *1970 Patents Act).*

Section 47 of the *1970 Patents Act* also deals with government use. It states that the grant of a patent shall be subject to the condition that any machine or apparatus or other article in respect of which the patent is granted or any article made by using a process in respect of which the patent is granted, may be imported or made by or on behalf of the government for its own use (Section 47 (1) of the *1970 Patents Act).* Also, grant of a patent shall be subject to the condition that any process in respect of which the patent is granted may be used by or on behalf of the government for the purpose of its own use (Section 47 (2) of the *1970 Patents Act).* Further, grant of a patent shall be subject to the condition that in the case of a patent in respect of any medicines or drug, the medicines or drug may be imported by the government for the purpose of its own use or for distribution in any dispensary, hospital or other medical institution maintained by or on behalf of the government or any other dispensary, hospital or other medical institution which the central government may specify having regard to the public service that such dispensary, hospital or medical institution renders (Section 47 (4) of the *1970 Patents Act*).

Section 146 of the Patent Act, 1970 provides for power of the Controller to call for information from patentees on the working of the patent and to provide a statement on the extent to which the patented invention has been worked on a commercial scale in India. Also, Rule 131 prescribes filing of information about the working of the patents in prescribed form, every calendar year as to the extent to which the patented invention has been worked on commercial scale in India (G Nair, Gopakumar et. al 2014b: 9). G Nair, Gopakumar et. al (2014b: 9-10) note that section 146 is in line with Article 31 of the TRIPS providing for 'Other Use Without Authorisation of the Right Holder' and also Article 5A of the Paris Convention which provides that:

> Each Country of the Union shall have the right to take legislative measures providing for grant of compulsory licenses to prevent the abuses which might result from the exercise of the exclusive rights conferred by the patent, for example, failure to work.

4.7.8. Opposition

Under the amended legislation, there are provisions for pre grant and post grant opposition for against grant of patents (See section 25 of the *1970 Patents Act)*. The grounds for pre grant opposition can be that (See section 25(1) of the *1970 Patents Act*):

a) the applicant for the patent or the person through whom he claims wrongfully obtained the invention or any part thereof from him or from any person under or through him he claims
b) the invention as claimed had been published before the priority date of the claim in any specification filed in pursuance of an application for a patent made in India on or after January 01, 1912 or in India or elsewhere in any other document
c) the invention as claimed is claimed in a claim of complete specification published on or after the priority date of the applicant's claim and filed in pursuance of an application for a patent in India, being a claim of which the priority date is earlier than that of the applicant's claim
d) the invention as claimed was publicly known or publicly used in India before the priority date of the claim
e) the invention as claimed is obvious and does not involve any inventive step
f) the subject of the claim is not an invention within the meaning of the Act
g) the specification does not sufficiently and clearly describe the invention or the method by which it is to be performed
h) the applicant has furnished information in which any material particular was false to his knowledge
i) the application was not made within twelve months from the date of the first application for the invention in a convention country by the applicant or the persons through whom he derives title
j) that the complete specification does not disclose or wrongfully discloses the source or geographical origin of the biological material used for the invention
k) that the invention is anticipated having regard to the knowledge, oral or otherwise as available with any local or indigenous community in India or elsewhere.

Similar grounds exist for post grant opposition as well (See section 25(2) of the *1970 Patents Act*).

4.8. Parallel Imports

Parallel imports is yet another methodology available for the reduction of medicinal pricing. It acts as price levellers and helps to prevent monopolistic practices (Jain, Sneha, 2009: 15). However the *1970 Patents Act* does not allow parallel importing. The *1970 Patents Act* provides a patentee the exclusive right in case of a product, to prevent third parties who do not have his consent from the act of making, using, offering for sale, selling or importing for those purposes that product in India (Section 48(a) of the *1970 Patents Act*). In the case of a process, the *1970 Patents Act* provides the patentee the exclusive right to prevent third parties who do not have his consent from the act of suing that process and from the act of using, offering for sale, selling or importing for those purpose the product directly obtained by the process in India (Section 48(b) of the *1970 Patents Act).*

4.9. 2007 *Intellectual Property Rights (Imported Goods) Enforcement Rule*

India has enacted I*ntellectual Property Rights (Imported Goods) Enforcement Rule 2007* vide Notification no. 47/2007- Cus (N.T.) dated May 8, 2007 to deal with parallel imports. *Samsung Electronics Company* Ltd. & Anr. v. *G. Choudhary & Anr.* (2006 (33) PTC 425 (Del)) and *Cisco Technologies* v. *Shrikanth* (2005 (31) PTC 538 (Del)) are relevant case in points.

Under this notification "goods infringing IPRs" is defined as 'goods which are made, reproduced, put into circulation or otherwise used in breach of the IP laws in India or outside India and without the consent of the right holder or a person duly authorised to do so by the right holder' (Section 2(a) of Notification No. 47/2007). The notification provides that a right holder may give notice in writing to the Commissioner of Customs or any Customs Officer authorised in this behalf by the Commissioner, at the port of import of goods infringing IPRs in accordance with the procedures and under the conditions set out in the Rules, requesting for suspension of clearance of goods suspected to be infringing IP right (Section 3(1) of Notification No. 47/2007). In furtherance thereof where the Deputy Commissioner or Assistant Commissioner of Customs as the case may be, may based on notice by the right

holder has reason to believe that the imported goods are suspected to be goods infringing IPRs, he shall suspend the clearance of goods (Section 7(1)(a) of Notification No. 47/2007). Where the clearance of goods has been suspended, customs may on its own initiative seek from the right holder any information or assistance, including technical expertise and facilities for the purpose of determining whether the suspect goods are counterfeit or otherwise infringing IPRs (Section 7(5) of Notification No. 47/2007).

Where the goods detained or seized have upon determination found to have infringed IPRs and has been confiscated under section 11(d) of the Customs Act, 1962 and no legal proceeding s are pending in relation to such determination, the Deputy Commissioner or Assistant Commissioner of Customs as the case may be, shall destroy the goods under official supervision or dispose them outside normal channels of commerce after obtaining 'no objection' or concurrence of the right holder or his authorised representative (Section 11(1) of Notification No. 47/2007). Also, there shall not be any re-exportation of the goods infringing IPRs in an unaltered state (Section 11(2) of Notification No. 47/2007).

4.10. Excise duty on Drugs

Also, in its notification dated January 8, 2005 the finance ministry announced excise duty on drugs and medicines on the value determined after deducting an abatement of 35 per cent from the declared MRP printed on the pack (See *Chronicle Pharmabiz* 2005f: 8). One of the reasons for the government to introduce such duty is the huge difference between MRP and the actual manufacturing costs of generic drugs. By assessing excise duty on MRP it was intended that pharmaceutical companies bring down unreasonable MRP of generics. In case of price controlled brands, manufacturer's margin (MEPE) is fixed at 100 per cent on the declared ex-factory cost by NPPA. However, in the case of branded producers which are outside price control, manufacturers' margins are not fixed and MRP is usually quite high and the move was intended to address such high prices.

Various international guidelines such as International Guidelines on HIV/AIDS and Human Rights 2006 recommend doing away with such government levies.[67]

4.11. Competition for Price Control

Studies suggest that competition need not reduce the prices of the medicines as the very nature of medicines – therapy – override price concerns (Cuts International Jaipur 2006: 27). In developed economies the cost of the medicines are borne by the government or by insurance companies and therefore the consumers are disconnected at an immediate level from the medicinal pricing, though in some cases negotiation on the prices does take place between the government and the pharma companies before the pharma companies are given the rights to market a product within its jurisdiction. Also, the consumers (the patients) are not the decision makers in therapy in the medical field and tend to go by the advice from the doctors and when there is a nexus between the doctors and pharma companies the most cost effective medicines does not get prescribed many a time (Cuts International Jaipur 2006: 28).

Also, there can be instances of cartelization between competitors which may keep the medicinal prices high.

4.11.1 Cartels

According to one study, cartelization in the vitamin sector in the 1990s in India resulted in over charging to the tune of a total amount of USD 25 million (Cuts International Jaipur 2006: 51). The study suggests that there could be other such instances which are yet undiscovered. In the United States multiple instances of cartelization was detected. For example, Mylan, a generic drug maker was charged of price fixing to the effect that it suppliers hiked the cost of the medicines to as much as

[67] See UNAIDS (2006), *International Guidelines on HIV/AIDS and Human Rights 2006 Consolidated Version*, (©Joint United Nations Programme on HIV/AIDS), para 29. It states:
29. Access to HIV-related information, goods and services is affected by a range of social, economic, cultural, political and legal factors. States should review and, where necessary, amend or adopt laws, policies, programmes and plans to realize universal and equal access to medicines, diagnostics and related technologies, taking these factors into account. As one example, duties, customs laws and value-added taxes may hinder access to medicines, diagnostics and related technologies at affordable prices. Such laws should be revised so as to maximize access. States should ensure that national laws, policies, programmes and plans affecting access to HIV-related goods, services or information are consistent with international human rights norms, principles and standards. States should consider the experience and expertise of other States, and consult with people living with HIV, non-governmental organizations, and domestic and international health organizations with relevant expertise.

3000 per cent. In India, many of the multinational pharmaceutical companies are present, such as AstraZeneca, Bayer, GlaxoSmithKline, Pfizer and Bristol-Myers who have been accused of deceptive sales practices in various jurisdictions. Cartelization through cross licensing is another practice adopted by the multinational drug companies which affects fair and free competition (Cuts International Jaipur 2006: 51-52).

Huge trade margins provided to retailers is another reason for medicinal prices to increase. For example, according to statistics reported in one study (Cuts International Jaipur 2006: 59), while Cipla sells its painkiller Nicip to the retail dealer at Rs. 2 a strip, the retailer sells it to the customer at Rs. 25 at a profit of 1,150 percent. Similarly, erstwhile Ranbaxy's anti-allergic Stanhist costs retailers Rs. 1.80 a strip, which was sold to the customer at Rs. 26. The study suggests that such huge trade margins are usually provided to generic medicines than to branded medicines to provide incentive to the retailer to effective compete with the branded medicines. The matter was studied by the Ministry of Chemicals and Fertilizers and the NPPA (Cuts International Jaipur 2006: 59).[68]

The following chart by NPPA on 2004 (Source: NPPA, as cited in (2004), Financial Times, 27/07/2004) figures gives further conclusive data in the matter of massive trade margins to pharmacists with the profit margin being borne by the end consumer.

Table 10: Trade Margins to Pharmacists

Name of the Manufacturer and the Medicine	**Printed Price on the Strip in INR**	**Purchase Price of Retailers in INR**
Ranbaxy Stannist	26	1.80
Cadila Healthcare Ceticad	26	1.60
Lyka Labs Lycet	25	1.44
Wockhardt Setride	25.2	1.70

[68] Cuts International Jaipur, 2006: 59, states:

> The cases of at least three drugs –Nimesulide (for fever and pain), Omeprazole (antacid) and Cetrizine (anti-allergic) have come to the notice of the Ministry of Chemicals and Fertilizers. The government is now trying to rectify the situation. A meeting with NPPA was followed by a survey by the Drug Controller who discovered that the consumer was being overcharged for these three formulations

Cipla Cetcip	27.5	2.00
Ranbaxy Pyrestat-	100.25	1.50
Lupin Lupisulide	24	1.94
Welcure Drugs Omejel Caps	33	4.50
Wockhardt Merizole	20.39	6.48

A strong competition law may help to address many of the unfair trade practices. Most of the countries have such legislation in place including the United States, EC and Japan. India has also recently overhauled its legislation on the matter. The Monopolies and Restrictive Trade Practice Act in India was replaced with the *Competition Act* in 2009.

4.11.2. 2002 *Competition Act*

The 2002 *Competition Act* in India states that no enterprise or association of enterprises or person or association of persons shall enter into any agreement in respect of production, supply, distribution, storage, acquisition or control of goods or provision of services, which causes or is likely to cause an appreciable adverse effect on competition within India and that Any agreement entered into in contravention of these p provisions shall be void (See section 3(1) and (2) of the *2002 Competition Act*).

It further states that any agreement between enterprises or associations of enterprises or persons or associations of persons or between any person and enterprise or practice carried on, or decision taken by, any association of enterprises or association of persons, including cartels, engaged in identical or similar trade of goods or provision of services, which—

(a) directly or indirectly determines purchase or sale prices;

(b) limits or controls production, supply, markets, technical development, investment or provision of services;

(c) shares the market or source of production or provision of services by way of allocation of geographical area of market, or type of goods or services, or number of customers in the market or any other similar way;

(d) directly or indirectly results in bid rigging or collusive bidding,

shall be presumed to have an appreciable adverse effect on competition (See section 3(3) of the 2002 *Competition Act*):

However, the above limitations will not restrict the right of any person to restrain any infringement of, or to impose reasonable conditions, as may be necessary for protecting any of his rights which have been or may be conferred upon him under the various IP laws in India which are the 1957 Copyright Act, the 1970 *Patents Act*, the 1958 Trade and Merchandise Marks Act, the 1999 Trade Marks Act, the 1999 Geographical Indications of Goods (Registration and Protection) Act, the 2000 Designs Act or the 2000 Semi-conductor Integrated Circuits Layout-Design Act. Also, the limitations will not apply to the extent the agreement relates exclusively to the production, supply, distribution or control of goods or provision of services for export.

The Act further states that no enterprise or group shall abuse its dominant position and that there shall be an abuse of dominant position if an enterprise or group directly or indirectly imposes unfair or discriminatory condition in purchase or sale of goods or service or price in purchase or sale (including predatory price) of goods or service (See section 4 of the 2002 *Competition Act*). Discriminatory condition or price adopted to meet competition shall not come under such restriction.

Under the Act, no person or enterprise is to enter into a combination which causes or is likely to cause an appreciable adverse effect on competition within the relevant market in India and such a combination shall be void (See section 6(1) of the 2002 *Competition Act*).

Combinations such as acquisitions, mergers, amalgamations to which the restriction shall apply need to meet certain monetary criteria (See section 5 of the 2002 *Competition Act*,). For example, in the case of acquisitions in India, the acquirer or the joint value of the acquirer and the enterprise which is being acquired should have asset value of more than rupees one thousand crores or turnover of more than 3000 crores. In the case of acquisitions in India or outside India, asset value of more than five hundred million US dollars including at least 500 crores in India or turnover of

more than fifteen hundred million US dollars including at least rupees fifteen hundred crores in India.

In the context of the group to which the enterprise would belong after acquisition, such group would have in India asset value of more than four thousand crores or turnover of more than twelve thousand crores. In India or outside India asset value of more than two billion US dollar including at least 500 crores in India or turnover of more than six billion US dollar including at least rupees five hundred crores in India.

The punishments prescribed under the Act are monetary penalties.

Two cases which need attention here are *Director General (I&R)* v. *Stangen Pharmaceutical Ltd.* (2005 CTJ 82 (MRTP) and also *Director General (I & R)* v. *Jagson Pal Pharma Ltd*. (2002 CTJ 151 (MRTP)). In *Stangen Pharmaceuticals*, the Director General (Investigation & Research) brought to the attention of the MRTP Commission that the pricing of certain drugs manufactured by Stangen Pharmaceutical was unreasonable and unjustified and that the unreasonable increase on prices of drugs imposed unjustified costs on consumers. However in the Commissions' opinion the DG failed to establish that such a trade practice had the effect of preventing, distorting or restricting competition in the market. In Jagson Pal Pharma Ltd. also it was held that excessive pricing or pricing pattern having no relationship with the cost of input was not anti-competitive if such a trade practice does not have the effect of preventing, distorting or restricting competition in the market. It was also held that increasing prices of drugs per se is not an anti-competitive practice (Cuts International Jaipur 2006: 73).

According to the CUTS study, while the 2002 *Competition Act* in India maintains this position, this position could be reviewed in the light of the nature of the pharmaceutical industry where the consumers are not free to choose the lowest priced drugs. (Cuts International Jaipur 2006: 73). The CUTS study also suggests that there is enough justification to empower the competition authority to grant compulsory license or take any other action in case of abuse of IPRs (Cuts International Jaipur 2006: 74).

Proper use of competition law will definitely help to regulate abuse of dominant position by the multinational pharmaceutical companies. A perusal of the judgements of the Competition Commission brings out that in most of the cases the Commission has ordered investigations by the Director General. That in itself is a strong reason for the multinational pharma companies to be careful in its operations in India.

4.12. Pooling Initiatives

4.12.1. Indian Open Source Drug Discovery Initiative

The OSSD is an open innovation platform (www.ossd.net) where ongoing projects and research results are reported on a web resource and there are more than 5300 partners registered from more than 150 countries (See *MDG Gap Task Force Report 2012* 2012: 72). Also more than 1500 registered participants from 31 different countries are working on more than 100 projects posted online. In 2011 OSSD announced that they were in discussions with two pharmaceutical manufacturers for the start of clinical trials for two molecules for the production of effective and inexpensive medicines for treatment of tuberculosis (*MDG Gap Task Force Report 2012* 2012: 72).

4.12.2. Medicines Patent Pool

In this context it is useful to discuss 'Medicines Patent Pool' suggested by *Medecins San Frontieres* which is to enable patents held by different entities related to manufacture, distribution and sale of HIV/AIDS anti retrovirals and other diseases that affect the developing world be brought together to facilitate the manufacture of those medicines (Barpujari, Indrani, 2010: 351). This is required as the patent holders are not manufacturing these medicines or the medicines are not affordable for the people of the developing world (Barpujari, Indrani 2010: 351). The report recommends that provisions of competition law should be exercised where the large number of patents by a company affects the prices of medicines in an unreasonable manner.

A report published by a set of NGO's suggests that there is a basic lacuna in India on the manner of drug policy making as the same is done by the Department of chemicals and Pharmaceutical with little inputs from the Ministry of Health (See Sengupta, Amit, Joseph, Reji K., Modi, Shilpa, and Syam, Nirmalya: 57). The report

also brings out that in India 85% of the drug sales are through retail sales while in developed countries retail sales are very limited. The report recommends that India should have a stringent price control mechanism in place and that in the absence of a strong price control mechanism markets do not stabilize prices (See Sengupta, Amit, Joseph, Reji K., Modi, Shilpa, and Syam, Nirmalya: 57). The report:

- notes that there are no alternatives to instituting price controls in India and that this is substantiated by the experience of several countries.
- recommends that all essential medicines should be brought under price control in India and that since companies tend to shift away from price controlled drugs complex set of measures are required to be implemented to counter this (Sengupta, Amit, Joseph, Reji K., Modi, Shilpa, and Syam, Nirmalya: 58).
- notes that the current scenario where list of price controlled drugs is not regularly reviewed is not proper and that such list should be regularly reviewed (Sengupta, Amit, Joseph, Reji K., Modi, Shilpa, and Syam, Nirmalya: 59)

Other recommendations in the report include tax reduction on drugs, weeding out of irrational drugs/combinations from the market, governmental measures aimed at medical profession with standard treatment guidelines for common illnesses to rationalize drug use, revision of curriculum of medical professional to include economic related to drug use, requiring cost data from manufacturers to prevent mark up of more than 150% on a voluntary basis, ensuring that the notified prices or generic drugs is not more than the average price for their manufacture, strengthening the NPPA, change in law to provide for compounding of offences under the DPCO than to have it dealt with under the Essential Commodities Act so that officials are not deterred from prosecuting, formation of a national drug authority with participation from Ministry of Health and the Department of Chemicals, revival of public sector units involved in drug manufacturing to prevent high prices from private sector and also to deal with gaps where private companies stop manufacture due to price control etc., bulk drugs purchasing by various state governments to reduce the cost of purchases etc. (Sengupta, Amit, Joseph, Reji K., Modi, Shilpa, and Syam, Nirmalya: 59).

Internationally, there are instances of negative patent pools as well. These patent pools that are formed by corporates through intercompany agreements with roadmap on license fees, distribution of license fees etc. may also impact medicinal pricing where these patents pools are used to define and establish technical standards (Jinjin Wang, Xiabao Peng, Wei Song, Xuehe Zhang, Xiaoyan Song and Yuan Yao, 2013: 514)[69]. Such technical standards and patent pools has widely impacted the DVD industry. For example since April 2002 DVD enterprises in China pay US $ 13.8 to DVD 6C Union, US $ 5 to DVD 4C Union and US % 1-1.5 to Thomson (Jinjin Wang, Xiabao Peng, Wei Song, Xuehe Zhang, Xiaoyan Song and Yuan Yao, 2013: 514). Using their technical standards, countries such as United States, Canada, France, Japan, Korea etc. conducted series of patent litigations against China which significantly impacted Chinese industries on DVD, TV, battery, turbine blades, digital cameras, CD's etc. Jinjin Wang, Xiabao Peng, Wei Song, Xuehe Zhang, Xiaoyan Song and Yuan Yao, 2013: 513). It is important that such negative patent pools or technical standards do not evolve in the pharma field and threaten the medicinal production and pricing.

4.13. Policy Documents

India has various policy documents on the topic of IPR, health rights etc. The following is a perusal of such documents.

4.13.1. 2002 *Pharmaceutical Policy*

The government of India formulated the *2002 Pharmaceutical Policy* with the intent to spell out the policy of the Government with regard to the pharma sector. The *2002 Pharmaceutical Policy* was to replace the Drug Policy 1986, as modified in 1994. Under this policy the function of the Government was sought to be changed from a controlling regime to a monitoring regime with ultimate control over price control reserved by the Government of India if there is abnormal behaviour in the price of drugs and pharmaceuticals.

[69] Patent pools are formal or informal organisations that unites patents of different patent holders and grants unified license (Jinjin Wang, Xiabao Peng, Wei Song, Xuehe Zhang, Xiaoyan Song and Yuan Yao, 2013: 512)

The main objectives of the *2002 Pharmaceutical Policy* (See section 5 of the 2002 *Pharmaceutical Policy*) are mentioned as below:

a. Ensuring abundant availability at reasonable prices within the country of good quality essential pharmaceuticals of mass consumption.
b. Strengthening the indigenous capability for cost effective quality production and exports of pharmaceuticals by reducing barriers to trade in the pharmaceutical sector.
c. Strengthening the system of quality control over drug and pharmaceutical production and distribution to make quality an essential attribute of the Indian pharmaceutical industry and promoting rational use of pharmaceuticals.
d. Encouraging R&D in the pharmaceutical sector in a manner compatible with the country's needs and with particular focus on diseases endemic or relevant to India by creating an environment conducive to channelising a higher level of investment into R&D in pharmaceuticals in India.
e. Creating an incentive framework for the pharmaceutical industry which promotes new investment into pharmaceutical industry and encourages the introduction of new technologies and new drugs.

The position adopted by the *2002 Pharmaceutical Policy* is that the government shall reduce the span of price control over drugs and pharmaceuticals and at the same time retain the power to intervene in the interest of the weaker sections of the society where the medicinal prices increase abnormally (See section 11 of the 2002 *Pharmaceutical Policy*). The *2002 Pharmaceutical Policy* suggests certain measures to encourage the pharma industry in India. It provides (See section 12 (VI) (f) of the 2002 *Pharmaceutical Policy*) that:

> (i) A manufacturer producing a new drug patented under the 1970 Patents Act, and not produced elsewhere, if developed through indigenous R&D, would be eligible for exemption from price control in respect of that drug for a period of 15 years from the date of the commencement of its commercial production in the country.
>
> (ii) A manufacturer producing a drug in the country by a process developed through indigenous R&D and patented under the 1970 Patents Act, would be eligible for exemption from price control in respect of that drug till the expiry of the patent from the date of the commencement of its commercial production in the country by the new patented process.

(iii) A formulation involving a new delivery system developed through indigenous R&D and patented under the 1970 Patents Act, for process patent for formulation involving new delivery system would be eligible for exemption from price control in favour of the patent holder formulator from the date of the commencement of its commercial production in the country till the expiry of the patent.

This *2002 Pharmaceutical Policy* was challenged before the High Court of Karnataka as unreasonable and arbitrary and that the same is framed like a business policy and that this policy if implemented will take away lifesaving and essential drugs from price control under the Drug (Prices Control) Order, 1995 as the yardstick adopted under this policy is the sales figure for a particular drug than the volume of sales. The Karnataka High Court agreed with this prayer raised by the petitioners and held the concerned policy to be arbitrary and unreasonable and violative of the provisions of the 1995 *Essential Commodities Act*. The Government of India was directed not to implement the *2002 Pharmaceutical Policy* until a list of essential and lifesaving drugs is prepared and the prices of the same are brought under price control.

The decision of the Karnataka High Court was over ruled in the Supreme Court.

4.13.2. 2011 *National Health Research Policy*, Government of India

India has formulated the National Health Research Policy through Department of Health Research, Ministry of Health & Family Welfare to facilitate systematic generation of knowledge that can be used to promote, restore, maintain and/or protect the health of individual and pollutions. The policy states that health is a fundamental right of all people (National Health Research Policy 2011: 14).

The policy identifies that there is weakness in the publicly funded health structures and research infrastructure and also that as of 2007, 96% of the research publications in India emanate from 9 medical colleges in spite of the fact that the country had almost 300 medical colleges (National Health Research Policy 2011: 4). The policy recognizes that a clearly defined Health Research Policy with well-defined vision, mission, strategy and deliverables is the basis for maximizing return on investment and that special attention is to be devoted to attend to the health problems of socially underprivileged groups and difficult to access geographical areas ((National Health Research Policy 2011: 5). In nutshell, this policy calls for the establishment of a

National Health Research System and a National Health Research Management Forum and also to operationalise an action programme for achievement of better health of the population (National Health Research Policy 2011: 6).

4.13.3. 2014 *Draft National IPR Policy*

Government of India has come out with a draft National IPR Policy which:

a) states that in future international negotiations India will give precedence to its national development polices and avoid TRIPS plus provisions and that the flexibilities under the international instruments will be judiciously used (Draft National IPR Policy 2014: 2).
b) notes that IP will be an integral part of India overall development policy (Draft National IPR Policy 2014: 2).
c) self congratulates India and notes that India statutory framework as robust, effective and balanced and that it is in consonance with development priorities while being in conformity with India's international obligations (Draft National IPR Policy 2014: 3).
d) notes that India has adopted a balanced approach to patent law (Draft National IPR Policy 2014: 4).
e) notes as its vision for an India where IP led growth in creativity and innovation is encouraged for the benefit of all, where IPRs promote advancement in science and technology, arts and culture, traditional knowledge and biodiversity resources, and where knowledge is the main driver for development and knowledge owned is transformed into knowledge shared (Draft National IPR Policy 2014: 5).
f) rightly notes that knowledge in India was viewed as something that is created and put in public domain and that monetisation of knowledge was not the norm in India. The policy further notes that this does not fit in with the global regime and that there is need to propagate the value of transforming IP into assets (Draft National IPR Policy 2014:6).
g) adopts the view that one of the results of enhanced IP creation will be to raise India's position in the global indices of innovation and competitiveness (Draft National IPR Policy 2014:9).
h) calls for accession by India in some multilateral treaties which are in India's interest and also to become signatory to those treaties which India has defacto

implemented so that India can become party to the decision making process (Draft National IPR Policy 2014:12).

5. Case Laws

5.1. The Right to Health

The courts in India have emphasised on the protecting the right to health of the citizen through several judgements. In *Bandhua Mukti Morcha* v. *Union of India and Ors* (1984 AIR 802), the Supreme Court of India held as below:

> It is the fundamental right of every one in this country, assured under the interpretation given to Article 21 by this Court in Francis Mullen's Case, to live with human dignity, free from exploitation. This right to live with human dignity enshrined in Art. 21 derives its life breath from the Directive Principles of State Policy and particularly clauses. (e) and (f) of Art. 39 and Arts. 41 and 42 and at the least, therefore, it must include protection of the health and strength of the workers, men and women, and of the tender age of children against abuse, opportunities and facilities for children to develop in a healthy manner and in conditions of freedom and dignity, educational facilities, just as humane conditions of work and maternity relief. These are the minimum requirements which must exist in order to enable a person to live with human dignity, and no State - neither the Central Government - has the right to take any action which will deprive a person of the enjoyment of these basic essentials

This observation was reiterated in subsequent decisions of the Supreme Court as well such as in *Vincent Panikulamgara* vs. *Union of India and Others*[70]. In *Vincent Panikulamgara* vs. *Union of India and Others* it was held:

[70] See *Vincent Panikulamgara vs. Union of India and Others*, (1987) 2 Supreme Court Cases 165, 173-174, Supreme Court, Ranganath Misra and M.M.Dutt, JJ. Held:

> A healthy body is the very foundation for all human activities. That is why the adage "Sariramadyam Khaludharma Sadhanam", In a welfare State, therefore, it is the obligation of the State to ensure the creation and the sustaining of conditions congenial to good health. This Court in *Band- hua Mukti Morcha v. Union of India*, [1984] 3 SCC 161 aptly observed:- "It is the fundamental right of everyone in this country, assured under the interpretation given to Article 21 by this Court in *Francis Mullin's case*--[1981] 1 SCC 608--to live with human dignity, free from exploitation. This right to live with human dignity enshrined in Article 21 derives its life breath from the Directive Principles of State Policy and particularly clauses (e) and (f) of Article 39and Articles 41 and 42 and at least, therefore, it must include protection of the health and strength of the workers, men and women, and of the tender age of children against abuse, opportunities and facilities for children to develop in a healthy manner and in conditions of freedom and dignity, educational facilities, just and humane conditions of work and maternity relief. These are the minimum requirements which must exist in order to enable a person to live with human dignity and no State-neither the Central Government nor any Sate Government-has the right to take any action which will deprive a person of the enjoyment of these basic essentials.
>
> The article has laid stress on improvement of public health and prohibition of drugs injurious to health as one of the primary duties of the States.

> In a series of pronouncements during the recent years this Court has culled out from the provisions of Part IV of the Constitution these several obligations of the State and called upon it to effectuate them in order that the resultant pictured by the Constitution Fathers may become a reality. As pointed out by us, maintenance and improvement of public health have to rank high as these are indispensable to the very physical existence of the community and on the betterment of these depends the building of the society of which the Constitution makers envisaged. Attending to public health, in our opinion, therefore, is of high priority-perhaps the one at the top.

While reviewing the validity of the *Pharmaceutical Policy* 2002, the Karnataka high court in *Lt Col (Retd) K. S. Gopinath and Another* vs. *Union of India through its Secretary and Others* (WP 21618 of 2002) held that health is a fundamental human right and that the Constitution of India directs the State to regard the improvement of public health as among its primary duties.

5.2. 2008 *Indian Network for People living with HIV/AIDS* v. *Union of India* - Madras High Court

In this matter *Indian Network for People living with HIV/AIDS* v. *Union of India* (MANU/TN/1217/2008) before the Madras High Court, the petitioners were registered society under Tamil Nadu Societies Registration Act, 1975 and were proving support to people living with HIV/AIDS. The 4th respondent F. Hoffman –La Roche, was a pharmaceutical company which was allocated patent relating to Valganiciclovir which was a drug used to treat CMC retinitis. The tablet was priced at Rs.1040/- as per the maximum retail price and thus patients have to spend approximately Rs. 2,74,560/- for treatment course of an induction therapy for 21 days and maintenance therapy for three months. Patient who receive organ transplants have to spend approximately Rs. 1,87,200/0 for a treatment course staring within 10 days of transplant to 100th day post-transplant period (*Indian Network for People living with HIV/AIDS,* para 44).

> ….
> In a series of pronouncements during the recent years this Court has culled out from the provisions of Part IV of the Constitution these several obligations of the State and called upon it to effectuate them in order that the resultant pictured by the Constitution Fathers may become a reality. As pointed out by us, maintenance and improvement of public health have to rank high as these are indispensable to the very physical existence of the community and on the betterment of these depends the building of the society of which the Constitution makers envisaged. Attending to public health, in our opinion, therefore, is of high priority-perhaps the one at the top.

When the 4th respondent had filed the patent application before the Controller of Patents, the petitioner had filed a pre grant opposition that all inventions relating to the products that were disclosed prior to 1995 were in public domain and that any patent application in respect of an invention which was in public domain prior to 1995 must be rejected in the ground that the subject matter lacks novelty (*Indian Network for People living with HIV/AIDS,* para 3). However, the 3rd respondent the Controller of Patents took decision to grant patent in favour of the 4th respondent though the objection filed by the petitioners were not disposed off till then. Section 25(1) which required a haring to be provided to the petitioners was not provided. In response to the legal notice issued by the petitioners the 3rd respondent advised that they could file a post grant application under section 25(2) of the Patent Act, 1970.

The petitioners approached the High Court and the issue that was considered by the High Court was whether by denying the petitioners their statutory right of hearing under section 25(1) (k) of the Act , the Controller could have rejected the petitioners objection to the grant of patent at pre-grant stage and a whether the paten which has been granted is valid in the eyes of law (*Indian Network for People living with HIV/AIDS,* para 11). The 4th respondent argued that mere denial of hearing even though statutorily provided, the resultant decision does not become bad unless the person who have been denied such hearing proves that he has suffered a prejudice and that in this case the petitioners did not suffer any prejudice (*Indian Network for People living with HIV/AIDS,* para 19).

The High Court allowed the petition and the grant of patent was set aside (*Indian Network for People living with HIV/AIDS,* para 68).

5.3. 2011 *Natco Pharma* vs. *Bayer Corporation* - Controller of Patents

In this case *Natco Pharma* vs. *Bayer Corporation* (Compulsory License Application 1 of 2011, Decision of the Controller of Patents) filed before the Controller of Patents Natco Pharma sought compulsory license from Bayer Corporation in the matter of 'Sorafenib tosylate' which is a compound covered by Patent No. 215758 and sold under the brand name NEXAVER by the Patentee Bayer Corporation and which was sold for the treatment of advanced stages of kidney and lung cancer. This was a life

extending drug which in the case of kidney cancer extended life of the patient by 4-5 years and in the case of liver of cancer extended the life of the patient by 6-8 months (Compulsory License Application 1 of 2011, para 5). The drug had to be taken throughout the lifetime of the patient and the cost of therapy was Rs. 2,80,428/- and Rs.33,65,136/- per year (Compulsory License Application 1 of 2011, para 5). From the worldwide sales in various countries in three years preceding to this 2011 compulsory license application, the applicant had raked up 2454 million whereas the sales in India did not exceed USD 32-40 million. As per the data made available by the Applicant in its submissions, the following were the sales figures of the drug between 2006 and 2010.

	2006	**2007**	**2008**	**2009**	**2010**
Sales per year (worldwide)	$165m	$371.7m	$677.8m	$843.5m	$934m
Sales in India	Nil	Nil	Nil	16 crores	unknown

From the above figures the applicant Natco Pharma argued that the Patent was clearly neglectful of India in its attempt to make the medicines available in India. While the patentee had developed and launched the products in various parts of the world and reported sales since 2006 and despite the patent application filed in India in 2000, the patentee did not launch the product in India until 2009. From 2008 when the patent was granted till 2001, the patentee did not fulfill the demand in the Indian market (Compulsory License Application 1 of 2011, para 10(c) and (d)).

After going through the figures the Controller held that Patentee had made available the drug to 2% of the eligible patients where the annual requirement as estimated for the number of 8842 patients per year would have been 70000 boxes (Compulsory License Application 1 of 2011: 22).

The patentee argued that a large amount of money is spent on failed projects and that the same comes to about 75% of the total R&D cost and that the marketed product must pay not only for its own R&D but also for the cost of underlying failed R&D.

Also, that the R&D of a product does not stop with the launch of the drug in the market, but continues with considerable investments. In the case of Sorafenib, the Patentee submitted that it was working on its potential for treatment of other cancers such as breast cancer, thyroid cancer and non-small cell lung cancer (Compulsory License Application 1 of 2011: 28). They submitted that in 2010 the Patentee had spent €1.8 billion or 16% of its net sales into R&D while in 2007, the cumulative R&D spent of the patentee was €8 billion.

The patentee also argued that:

- the term 'reasonable' should be interpreted to mean reasonable to the patentee as well. If not, the same word reasonable would not have been present in the *1970 Patents Act* (Compulsory License Application 1 of 2011: 30).
- cost of R&D and the cost of manufacture both have to be taken into account to determine 'reasonable affordable price'(Compulsory License Application 1 of 2011: 30).
- 'public' denotes different sections of the public – rich class, middle class and poor class and that a blanket compulsory license cannot be granted giving the drug to all section of the public at the same price (Compulsory License Application 1 of 2011: 30).
- the cost of treatment can become affordable by way of insurance cover and that affordability has to be judged from the cost to be incurred on insurance cover.
- The quantities required in India do not economically justify setting up a manufacturing facility within India and that with a view to achieving the economies of scale the Patentee has made a strategic decision to consolidate both chemical API synthesis and pharmaceutical bulk production of the product covered by the subject patent within its manufacturing facilities in Germany (Compulsory License Application 1 of 2011: 39).

<u>Decision</u>

The Controller after considering the various arguments raised by the Patentee held:

- that it stands to common logic that a patented article like the drug in this case was not bought by the public due to only one reason, i.e. its price was not

reasonably affordable to them. Hence, I conclude beyond doubt that the patented invention was not available to the public at a reasonably affordable price and that section 84(1)(b) of the *1970 Patents Act* is invoked in this case. Consequently, a compulsory license be issued to the Applicant under Section 84 of the Act (Compulsory License Application 1 of 2011: 36).

- that by not manufacturing the medicine In India, that the Patentee has failed to satisfy the requirements of the *1970 Patents Act* and that section 84(1) of the *Patents Act* is attracted, and therefore compulsory license be issued to the Applicant (Compulsory License Application 1 of 2011: 45).

This was a significant decision in terms of ensuring the availability of drugs at affordable prices in India. Surprisingly, there are authors who have downplayed the contribution of this significant decision, such as the piece by Liu, Jodi (2015) in which the author has tried to argue that this decision has made India vulnerable to a challenge before the WTO as the decision mentioned that local working of the patent may sometimes to be necessary to meet the 'working' requirements under section 84 of the *Patents Act*, 1970 (Liu, Jodi 2015: 326). The author failed to note that lower court decisions or decisions by tribunals do not have the status of law under Indian law.

5.4. 2012 *Bayer Corporation* vs. *Union of India* - High Court of Bombay

On losing the afore discussed matter before the Controller of Patents, Bayer Corporation brought the matter before the High Court of Bombay as well **(**OA/35/2012/PT/MUM **)**.

The facts as brought before the High Court was that Bayer Corporation had been granted patent in March 2008 for the drug Sorafenib Tosylate which was sold under the name Nexavar. This was a palliative drug for patients suffering from Renal Cell Carcinoma and Hepato Cellular- Carcinoma. Natco Pharma Limited applied for compulsory license of this drug which was sold at a cost of Rs.2,80,428/- in a month while Natco Pharma was ready to manufacture and sell the same at Rs.10,000/- per month. The letters sent in this regard by Natco Pharma to Bayer Corporation had been rejected by Bayer Corporation. Interestingly Bayer Corporation had filed infringement

suit against CIPLA in the Delhi High Court as CIPLA was manufacturing and selling this drug at a price of Rs. 30,000/- per month since 2010. This matter was pending before the Delhi High Court in which the Delhi High Court had asked CIPLA to maintain records of the sales it had been carrying out but did not injunct CIPLA from the sales of this drug.

Bayer Corporation raised various arguments including that:

a) That Natco did not make serious efforts to obtain voluntary license from the petitioner before making the application for compulsory license
b) That the reasonable requirement of the public was met by the petitioner
c) affordable price should be fixed taking into account various factors including R&D costs, marketing costs etc. and that socio-economic conditions are not the only factors
d) CIPLA's presence must be used to determine whether the reasonable requirement of the public has been met and whether the patented invention is being made available to the public at a reasonably affordable price.
e) If CIPLA has effectively met the entire demand for the drug, there should not be a grant to another entity.

The Court considered various provisions of the *1970 Patents Act* such as Section 83 (General Principles Applicable to the Working of Patented Inventions), 84 (Compulsory License), 86 (Power of the Controller to adjourn applications for compulsory license etc. in certain cases), 89 (General Purpose for granting compulsory licenses), 90 (terms and conditions of compulsory licenses) etc. The Court also went through the history of patent law and noted as below:

> The object of the patent law is to encourage scientific research, new technology and industrial progress. … Patent law encourages research and invention by guaranteeing to the holder of the patents an exclusive right to prevent all others from manufacturing, using and /or selling invented goods i.e. patented product for a particular number of ears to the exclusion of all others. In consideration for the above rights, an inventor has to make available/disclose his knowledge of the invention. This disclosure would allow the other members of the society to the exploit the same after the prescribed number of years. Thus, an inherent objective in the grant of patent is the obligation of the patent holder to utilise the invention to meet the needs of the society. The invented product is not to be kept in the attic but is to be available to Society for use and also to form the basis for further research and development. All of which would lead to betterment of human existence on

> planet earth while contributing to improvement of technological advancement. It is in the above context that Sir Isac Newton has said "I have been able to see further than others is because I stood on the shoulders of giants"…

However, after hearing both the parties, the Delhi High Court refused to interfere with the order from the IPAB.

5.5. 2012 *Hoffman-La Roche Ltd.* vs. *Cipla Ltd.*, Delhi High Court

There have been decisions by the Indian Courts which have not totally favoured the cause of access to medicines one of them being *F. Hoffman-La Roche Ltd., Switzerland and OSI Pharmaceuticals, Inc., New York* vs. *Cipla Ltd., Mumbai Central, Mumbai* (MANU/DE/4182/2012) decided by Justice Manmohan Singh, of the Delhi High Court.

In this case F. Hoffman –La Roche Ltd. along with OSI Pharmaceuticals Inc., filed a case in respect of a small drug molecule termed as Human Epidermal Growth Factor Type-I/Epidermal Growth Factor Receptor (HER/EFGR) inhibitor popularly known as 'Erlotinib' over Pfizer Products Inc. and OSI Pharmaceuticals Inc., has a joint patent. This drug was a mentioned as a major breakthrough in the treatment of cancer and used to destroy some type of cancer dells while casing little harm to normal human cells. The tablet formulation of Erlotinib sold by the plaintiffs under the trademark name 'Tarceva' is approved by the US Food & Drug Administration in the year 2004 and thereafter by the European Union in the year 2005.

Also, the Controller General of Patents, Trademarks and Designs New Delhi granted patent No. 196774 dated February 23, 207 in favour and F. Hoffman –La Roche Ltd. along with OSI Pharmaceuticals Inc. Also, F. Hoffman –La Roche Ltd. along with OSI Pharmaceuticals Inc. entered into a Development Collaboration and Licensing Agreement where under F. Hoffman –La Roche Ltd. had the license to use, sell and offer for sale the licensed products including Erlotinib. The plaintiffs' were actively engaged in the manufacture, marketing and sale of the drug in various countries including India (*F. Hoffman-La Roche Ltd.,* MANU/DE/4182/2012, para.6).

The case of the plaintiffs against Cipla Ltd. was that Cipla Ltd. was involved in various actions of violations of IPRs of the plaintiffs which the plaintiffs noticed from

various news reports in print as well as electronic media (*F. Hoffman-La Roche Ltd.*, MANU/DE/4182/2012, para.6).

The plaintiffs alleged that section 48 of the *1970 Patents Act* provides exclusive rights of the patentee of a products or a process to prevent any third parties from non-consensual usage of the product or the process and that the assignment of the patents by way of a license etc. has to be compulsorily by way of an instrument in writing covering all the terms and conditions (*F. Hoffman-La Roche Ltd.*, MANU/DE/4182/2012, para.7). The plaintiff's held that the drug Tarceva (Erlotinib) has been developed after a long and substantial research and that the invention be protected and no other person other than an authorised person be allowed to cop the same.

The defendants submitted that:

a) the patent of the plaintiffs has been granted under suspicious circumstances,
b) the patent in question is liable to be revoked as it sought to only improve from the existing prior art as Quinazoline compounds have been known to inhibit growth and have been used in anti-cancer treatment, is available in the market for treatment of various cancers and that it is a derivative of a known compound and hence not patentable under section 3(d) of the Indian Patent Act.
c) That the plaintiff's when they filed a subsequent patents before the United States Patent Office have admitted to short comings in the patent in issue
d) That there is no inventive step in the patent and that the plaintiff engaged in Bio-Isusterim which makes the patent obvious
e) That in the area of life saving drugs no injunction be granted as it is in the public interest of general public and patients suffering from diseases.

However, the court held that Cipla Ltd. had failed to discharge the burden of non-obviousness. The Court further noted that as per the provisions of the 1970 *Patents Act* there is nothing which is indicative of the fact that any stricter approach of to be followed while testing the patents relating to the chemical compounds due to any reason whatsoever (*F. Hoffman-La Roche Ltd.*, MANU/DE/4182/2012, para.43).

The Court did not agree with the position of Cipla Ltd. that there is no inventive step and that the defendants are not able to establish the three requirements as to the material facts leading up to obviousness in the chemical compounds. The Court concluded that no ground of obviousness or lack of inventive step under Section 64(1) (f) of the *Patents Act* is made out. (*F. Hoffman-La Roche Ltd.,* MANU/DE/4182/2012, para.109).

The Court also held that the plaintiff's have not led any positive evidence to establish that the polymorphic versions are always the same as that of the underlying compound and that it has not established on record that how may polymorphic versions are available of the compound and if there are then whether all are same in nature, characteristics and properties in all respects to the parent compound (*F. Hoffman-La Roche Ltd*., MANU/DE/4182/2012, para.218).

The Court also rejected the position of the plaintiff that the defendant has not made any reference to the polymorphic version of the compound anywhere on the product and therefore that the Court should hold the onus of establishment of the infringement to be proved. The Court noted that the claim of the plaintiffs is based on the right of the plaintiffs in the patent of a chemical compound and that their infringement has to be established by corresponding chemical analysis of the defendant's product and not by comparison of the labels etc.. The plaintiff had not led any evidence to counterclaim the defendant's assertion that the Polymorph B version corresponds to the Tarceva product (*F. Hoffman-La Roche Ltd.*, MANU/DE/4182/2012, para.262). The Court also noted that even if there is material on record which suggest that the defendant is making generic version of the Tarceva Product even then the same nowhere establishes infringement (*F. Hoffman-La Roche Ltd.*, MANU/DE/4182/2012, para.263).

5.6. 2012 *Roche Products (India) Pvt. Ltd.* vs. *Drugs Controller General of India and Others* - Delhi High Court

Interestingly Justice Manmohan Singh of the Delhi High Court who was the same judge as in *F. Hoffman-La Roche Ltd.*, (MANU/DE/4182/2012) had passed in this case an *exparte order* against Drugs Controller General of India and Others (CS(OS) No.355/2014 before the Delhi High Court). At the injunction stage the petitioner

Roche sought ex parte interim order restraining the defendants from launching, introducing, selling, marketing and/or distributing the drug CANMAb and HERTRAZ or any other biosimilar version of Trastuzumab in the Indian market until the disposal of the suit and also sought injunction restraining the defendants from relying upon or otherwise referring to HERCEPTIN, HERCOLIN or BICELTIS or any data relating to Trastuzumab marketed as HERCEPTIN, HERCOLIN or BICELTIS; including data relating to manufacturing process, safety, efficacy and sales in any press releases. Also, that the defendant drugs CANMAb and HERTRAZ is not to claim any similarity with HERCEPTIN, HERCOLIN or BICELTIS. While the single judge (Justice Manmohan Singh) court did not pass any order against the launch of the medicines for the reason that the drug could not be launched without the required approvals, it did pass the order stating that till the next date of hearing the defendants are restrained from relying upon or referring to HERCEPTIN, HERCOLIN or BICELTIS or any data relating to Trastuzumab or from claiming any similarity with HERCEPTIN, HERCOLIN or BICELTIS.

5.7. 2013 *Novartis A.G.* vs. *Union of India* - Supreme Court

In the recent decision of the Supreme Court in *Novartis A.G. v. Union of India & Ors* (Civil Appeal Nos. 2706-2716 of 2013) decided by Justice Aftab Alam and J. Ranjana Praksh Desai, the patentability of a derivative compound in pharmacological preparations came in question. The patent if granted would have made the medicines extremely expensive and unaffordable to the Indian population.

As per the facts of this case, *Jurg Zimmerman* invented a number of derivatives of N-phenyl-2-pyrimidine-amine one of which is CGP 57148 later named as Imatinib by the World Health Organisation. These derivatives have valuable anti-tumour properties and can be used for the preparation of pharmaceutical compositions as anti tumuoral drugs or drugs against atherosclerosis. The N-phenyl-2-pyrimidine-amine including Imatinib were submitted for US patent on April 28, 1994 and patent was granted on May 28, 1996 in US. Also, European patents were received for the Zimmerman compounds i.e. N-phenyl-2-pyrimidine-amine derivatives (*Novartis A.G.* 2013, para 5).

Natco Pharma Ltd. filed application for patent for Imatinib Mesylate in beta crystalline for at Chennai Patent office in July 1998. In the application it was stated that the invented product has i) more beneficial flow properties, better thermodynamic stability and lower hygroscopicity than alpha crystal form of Imatinb Mesylate. Also, it was claimed that these properties made the invented product new as it stores better and is easier to process. The law of patent in India underwent significant changes after the filing of the patent application but Natco Pharma Ltd. continued to reinforce the patent claim. Before the application for patent was taken up, Natco Pharma Ltd. made application for grant of Exclusive Marketing Rights as per the law applicable at such time (*Novartis A.G.* 2013, para 8).

In December 2005, the Assistant Controller of Patents passed its decision after hearing all parties and rejected Natco Pharma Ltd. s application for grant of patent. The Assistant Controller held that the invention claimed by Natco Pharma Ltd. was anticipated by prior publication i.e. the Zimmermman patent; that the invention claimed by Natco Pharma Ltd. was obvious to a person skilled in the art in view of the disclosure provided in the Zimmermman patent specifications, that the patentability of the alleged invention was disallowed by section 3(d) of the Act and that the Swiss priority date was wrongly claimed as the priority date for application in India and hence the alleged invention was also anticipated by the specification made in the application submitted in Switzerland. Natco Pharma Ltd. challenged the matter before the Chennai High Court which were transferred to the Intellectual Property Appellate Board (*Novartis A.G.* 2013, para 14).

The IPAB reversed the findings of the Assistant Controller on the issues of anticipation and obviousness and held that Natco Pharma Ltd.'s invention satisfied the tests of novelty and non – obviousness and that in view of amended section 133 Natco Pharma Ltd. was fully entitled to get July 18, 1997 the date on which the patent application was made in Switzerland as the priority date for the application in India. The IPAB held that the patentability of the subject product was hit by section 3(d) of the Act and held as below (*Novartis A.G.* 2013, para 17):

> Since India is having a requirement of higher standard of inventive step by introducing the amended section 3(d) of the Act, what is patentable in other countries will not be patentable in India. As we see, the object of amended

> section 3(d) of the Act is nothing but a requirement of higher standard of inventive step in law particularly for drug/pharmaceutical substances.

The IPAB also noted that the high pricing of the drug while exclusive marketing rights were enjoyed by Natco Pharma Ltd. would create havoc in the lives of poor people and their families affected with the cancer for which this drug is effective. The IPAB further noted that this will have disastrous effect on the society as well and that considering all the circumstances of the appeal before the IPAB, that Natco Pharma Ltd.'s alleged invention will not be worthy of a reward of any product patent . It also noted that the possible disastrous consequences of such patent grant will attract the provisions of section 3(b) of the Act which prohibits grant of patent on inventions, exploitation of which would create public disorder among other things (*Novartis A.G.* 2013, para 19).

On appeal before the Supreme Court, the Court held that in the face of the details adduced, Imatinib Mesylate cannot be sad to be a new product. The Court held that the same has come through an invention that has a feature that involves technical advance over existing knowledge and that would make the invention not obvious to a person skilled in the art. The Court concluded that Imatinib Mesyalte is all that there is in Zimmerman patent and that it is a known substance from the Zimmerman patent (*Novartis A.G.* 2013, para 131).

While this decision was cheered by many, interestingly, there have also been writings from the west which have sought to downplay the contribution of decisions favouring public health by the tribunal and courts, such as the piece by Liu, Jodi (2015) in which the author has tried to argue that this decision has made India vulnerable to a challenge before the WTO as the decision mentioned that local working of the patent may sometimes to be necessary to meet the 'working' requirements under section 84 of the *Patents Act*, 1970 (Liu, Jodi 2015: 326). This of course, is a wrong view as the decision of a court in a case on its merits cannot be held to be contrary to WTO.

5.8. 2013 *Union of India and Anr.* vs. *Swiss Garnier Life Sciences and Ors.*- Supreme Court

In this case *Union of India and Anr.* vs. *Swiss Garnier Life Sciences and Ors.* (MANU/SC/0664/2013) decided by (Judges G.S Singhvi and Sudhansu Jyoti Mukhopadhaya JJ.), writ petitions were filed before the Supreme Court challenging the price fixation notifications dated April 30, 209 and November 17, 2009 wherein the Government had fixed the process of 'Doxofylline formulations' in the exercise of the power conferred under paras 9 and 11 of the Drugs (Price Control) Order 1995. The High Court had set aside the notifications and held that Doxyfylline is not a bulk drug within the meaning under para 2(a) of the DPCO 1995 (*Swiss Garnier Life Sciences and Ors.* MANU/SC/0664/2013, para 2).

On May 14, 2008 there was newspaper report regarding the sale of 'Doxofylline formulations' as part of tactics to replace less profitable price controlled products 'Theophylline'. The more profitable 'Doxofylline' was being offered as a more profitable alternative to Theophylline. By various orders in 2006 the National Pharmaceutical Pricing Authority had closed the loopholes to sell Theophylline products at high profit margins. In such scenario it was alleged that various pharmaceutical companies were scouting for similar molecules outside the price control systems irrespective of whether they are similar, better or even worse (*Swiss Garnier Life Sciences*, MANU/SC/0664/2013, para 3).

The NPPA had written to all Doxofylline formulation manufacturers asking them why Doxofylline should not be classified as derivative of Theophylline. No information was provided by the manufacturers/formulators and Industry Associations inspite of lapse of time and repeated reminders (*Swiss Garnier Life Sciences*, MANU/SC/0664/2013, para 4).

The technical committee of the NPPA considered the matters and sought expert opinion from the Indian Institute of Science (IISc) on whether Doxofylline is a derivative of Theophylline and IISc informed NPPA that Doxofylline is in fact a derivative of the drug Theophylline. Thereupon it was decided by the NPPA to fix the price of Doxofylline and NPPA required all manufacturers of the drug Doxofylline to provide details of the purchase price of the bulk drug Doxofylline. Though the DPCO

paras 4 and 5 required the manufacturers to provide such information none of the manufacturers complied with the provisions. Thereupon the NPPA considered the price of Doxofylline as per the terms of para 11 of the DPCO and fixed the prices of the Doxofylline (*Swiss Garnier Life Sciences*, MANU/SC/0664/2013, para 6).

This was challenged by the manufacturers and industry associations before the NPPA for review and thereafter before the High Court which ruled in favour of the manufacturers and industry associations.

The apex court after hearing the matter decided in favour of the NPPA and held that "the government is empowered to fix the ceiling price of a scheduled formulation an and that in their view Doxofylline is a scheduled formulation as defined under para 2(v) of the DPCO and held that the Government is very well within its jurisdiction to fix the price of Doxofylline formulation.

5.9. 2013 *BDR Pharmaceuticals International Pvt. Ltd.* vs. *Bristol Myers Squibb Company* - Controller of Patents

In this case *BDR Pharmaceuticals International Pvt. Ltd.* vs. *Bristol Myers Squibb Company* (CLA No. 1 of 2013) BDR Pharma made the application for compulsory license of DASATINIB which is a suitable chemotherapeutic option for treatment of Chronic Myeloid Leukemia and the said drug has orphan drug status in USA, Europe and Switzerland. The price of each tablet sold by the patentee is Rs. 2761/- which works out to Rs. 1,65,680/- per month for 60 tablets and Rs. 19,88,160/- per year per patient (*BDR Pharmaceuticals International Pvt. Ltd.*, para 2). BDR Pharma proposed to sell the tablet at Rs. 135/- per tables working out to Rs. 8100/- in a month (*BDR Pharmaceuticals International Pvt. Ltd.*, para 3). BDR Pharma submitted that an infringement suit with respect to the said patent was filed by the patentee against BDR Pharma before the High Court of Delhi as BDR Pharma had filed an application before the Drug Controller General in India for obtaining approval to market DASATINIB in India.

BDR Pharma highlighted that more than 6 years had lapsed since the grant of the patent and the patentee still import the drug into India (*BDR Pharmaceuticals International Pvt. Ltd.*, para 7).

Upon raising request with the patentee for voluntary license, the patentee had replied seeking various details form BDR Pharma, which BDR Pharma did not revert to. The application for compulsory license was filed after a year of receiving reply from the patentee (*BDR Pharmaceuticals International Pvt. Ltd.,* para 8). BDR Pharma maintained that by not specifically replying to the request for voluntary license, and by continuing to correspond for more information, the patentee can keep the request for voluntary license in abeyance and that this is unfair exploitation of section 84(6) (iv) (*BDR Pharmaceuticals International Pvt. Ltd.,* para 11).

Inspite of the clear high pricing of the drug the Controller of Patents focused on the technicalities of procedure and held that BDR Pharma has not entered into any detailed discussions with the patentee after its letter seeking approval for voluntary license is a deliberate choice to invoke the provisions of compulsory license without taking the required steps under law and that the same cannot be condoned. The Controller decided that BDR Pharma did not follow the scheme of law and procedure mandated by law and that BDR Pharma failed to make out a prima facie case for making an order for compulsory license and that the application for compulsory license is rejected (*BDR Pharmaceuticals International Pvt. Ltd.,* para 30).

The Controller in the order even observed that mutual deliberations between BDR Pharma and patentee cannot succeed if they happen under constant shadow of pending application for compulsory license and that if they do succeed such success would be attributable to the shadow which would amount to coercion of the patentee which is not as per the scheme of law (*BDR Pharmaceuticals International Pvt. Ltd.,* para 25(1))

Thus the adjudicating authority failed to appreciate the pressing need of the population for affordable medicines and instead focused on the technicalities of law. This decision is a clear violation of the right to health and it is surprising that our own bureaucracy has failed to appreciate the need of the public, especially in a case where the costing of the patented product has been exorbitantly high.

5.10. *2013 Merck Sharp & Dohme Corporation & Anr.* vs. *Glenmark Pharmaceuticals Ltd.* - Delhi High Court

In this case *Merck Sharp & Dohme Corporation & Anr*. vs. *Glenmark Pharmaceuticals Ltd.*, CS(OS) 586/2013 the plaintiff Merck sought to restrain the defendant Glenmark from making, using, selling, distributing, advertising, exporting or offering for sale or dealing in Sitagliptin Phosphate Monohydrate or any other salt of Sitagliptin in any form, alone or in combination with one or more drugs, as it claimed infringement of the patent of the plaintiffs by the defendant. While the single judge of the Delhi High Court ruled in favour of the defendant, the division bench of the Delhi High Court on appeal ruled in favour of the plaintiffs. The case is interesting as it reflects an evolution of patent jurisprudence in India, with the defendant claiming that the plaintiff's patent was invalid as the suit patent a 'Markush structure' which covers billions of compounds. This claim of the defendant was not granted by the court.

5.11. Table on Litigation

Table 11: Litigation on Access to Medicines- India

	Litigation and Judge	Forum and Citation	Drug
1	*Indian Network for People living with HIV/AIDS* v. *Union of India* (Judges A.K.Ganguly, C.J and Fakkir Mohammed Ibrahim Kalifulla)	Madras High Court MANU/TN/1217/2008)	Patent relating to Valganiciclovir which was a drug used to treat CMC retinitis. The drug was priced at Rs.1040/- per tablet.
2	*Natco Pharma* vs. *Bayer Corporation* (Decision of the Controller of Patents)	Controller of Patents, Compulsory License Application 1 of 2011	Natco Pharma sought compulsory license from Bayer Corporation in the matter of 'Sorafenib tosylate'. The drug had to be taken throughout the lifetime of the patient and the cost of therapy was Rs.2,80,428/- and Rs.33,65,136/- per year.
3	*Bayer Corporation* v. *Union of* India	High Court of Bombay (OA/35/2012/PT/MUM)	Drug Sorafenb Tosylate which was sold under the name Nexavar. It was sold at a cost of Rs.2,80,428/- in a

			month while Natco Pharma was ready to manufacture and sell the same at Rs.10,000/- per month
4	*Hoffman-La Roche Ltd., Switzerland and OSI Pharmaceuticals, Inc., New York* vs. *Cipla Ltd.* (Justice Manmohan Singh)	Delhi High Court, MANU/DE/4182/2012	Human Epidermal Growth Factor Type-I/Epidermal Growth Factor Receptor (HER/EFGR) inhibitor popularly known as 'Erlotinib'
5	*Roche Products (India) Pvt. Ltd.* vs. *Drugs Controller General of India and Others*	Delhi High Court, CS(OS) No.355/2014	CANMAb and HERTRAZ or any other biosimilar version of Trastuzumab
6	*Natco Pharma Ltd.* v. *Union of India* (Justice Aftab Alam and J. Ranjana Praksh Desai)	Supreme Court, Civil Appeal Nos. 2706-2716 of 2013	number of derivatives of N-phenyl-2-pyrimidine-amine one of which is CGP 57148 later named as Imatinib by the WHO
7	*Union of India and Anr.* vs. *Swiss Garnier Life Sciences and Ors.* (Judges G.S Singhvi and Sudhansu Jyoti Mukhopadhaya JJ.)	Supreme Court, MANU/SC/0664/2013	Doxofylline formulations
8	*BDR Pharmaceuticals International Pvt. Ltd.* vs. *Bristol Myers Squibb Company* (Chaitanya Prasad, Controller of Patents, Designs and Trademarks, Mumbai)	CLA No.1 of 2013	Drug 'DASATINIB' for treatment of Chronic Myeloid Leukemia. Each tablet sold by the patentee is Rs. 2761/- which works out to Rs. 19,88,160/- per year per patient (para 2). The applicant proposed to sell the tablet at Rs. 135/- per tablet working out to Rs. 8100/- in a month.
9	*Merck Sharp & Dohme Corporation & Anr.* vs. *Glenmark Pharmaceuticals Ltd.*	Delhi High Court, CS(OS) 586/2013	Permanent injunction was passed against Glenmark in the matter of Sitagliptin Phosphate Monohydrate or any other salt of Sitagliptin in any form

In sum, as some note, where there are public health considerations, courts should abstain from granting injunctions against generic versions produced. In the Indian context while there have been some good decisions favouring public health such as the judgement of the Supreme Court in *Natco Pharma* v. *Union of India*, while there have also been some decisions which have not adequately focused on the right to health, but have rather focused on trade interests such as the decision of the Delhi High Court in *F.Hoffman Roche Ltd.* (MANU/de/4182/2012, para.109).

6. Food Safety

Food Safety in India is dealt with under the 2006 *Food Safety and Standards Act*. Considering that this is a legislation that has impact on the right to health, the same has been briefly outlined as below. The said legislation sets up a food authority to regulate and monitor the manufacture, processing, distribution, same and import of food with intent to ensure safe and wholesome food (Section 16(1) of 2006 *Food Safety and Standards Act*). The said Act set up a Food Authority which prescribe the standards and guidelines in relation to articles of foods and does the following (Section 16(2) of 2006 *Food Safety and Standards Act*) among other heads:

a) specify the appropriate system to enforce various standards notified under the Food Act.
b) limit the use of food additive, contaminants, pesticide residues, antibiotics etc.
c) Mechanisms and guidelines of accreditation of certification bodies engaged in the certification of food safety management systems
d) quality control of any article of food imported into India
e) guidelines for accreditation of laboratories etc,
f) method of sampling, analysis, exchange of information etc.
g) food labelling standards

The Food Act prescribes that the Central Government, State Government and the Food Authority shall be guided by various principles in the implementation of the provisions of the Act namely (Section 18(1) of 2006 *Food Safety and Standards Act*):

a) Endeavour to achieve an appropriate level of protection of human life and health and protect consumers, interest including fair practices in the all kinds of food trade.

b) Carrying out risk management including taking into account the result of the risk assessment which are relevant to achieve the general objective of the regulations.
c) Where on the basis of assessment of available information, possibility of harmful effects on health is identified by scientific uncertainty persists, provisional risk management, measures as required to ensure appropriate level of health protection may be adopted pending further scientific information for more comprehensive risk assessment.
d) Measures to be adopted need to proportionate and not more trade restrictive than is required to achieve the appropriate level of health protection with due regard to be taken to the technical and economic feasibility and other factors regarded as reasonable and proper
e) The measures adopted to be reviewed within reasonable period of time depending of the nature of the risk to like or health identified and the type of information need to clarify the scientific uncertainty
f) Where there are reasonable grounds to suspect that the food may present a risk for human health the Food Authority to take appropriate steps to inform the public about the nature of risk to the health
g) Where any food part of a batch fails to comply with the food safety requirement, till the contrary is proved all the foods in such batch shall be deemed to fail to comply with such requirement.

While framing the regulations, standards etc. the Food Authority is to take into account the prevalent practices and conditions, international standards and practices where international standards or practices exists or is in the process of being formulated unless such consideration would not be an effective or appropriate means for securing the objectives or where it would result in a level of protection which is not appropriate in the country (Section 18(2) of 2006 *Food Safety and Standards Act*).

The Food Authority is to undertake risk assessment based on available scientific evidence in an independent, objective and transparent manner and is to ensure open and transparent public consultation (Section 18(2) of 2006 *Food Safety and Standards Act*).

Under this legislation no article of food shall contain any food additive or processing aid unless it is in accordance with the provisions of the Act and regulations there under (Section 19 of 2006 *Food Safety and Standards Act*). Also, no article of food shall contain any contaminant, naturally occurring substances or toxins or hormone or heavy metals in excess of the quantities specified by the regulations (Section 20 and Section 21 of 2006 *Food and Safety and Standards Act*). Also, no article of food shall contain insecticides or pesticides residues, veterinary drugs residues, antibiotic residues, solvent residues, pharmacological active substances and micro biological counts in excess of such tolerance limits as may be specified by the regulations (Section 21 of 2006 *Food and Safety and Standards Act*).

Further, no person shall manufacture, distribute, sell or expose for sale or dispatch or deliver to any agent or broker for the purpose of sale, any packaged food products which are not marked and labelled in the manner as specified by regulations (Section 23(1) of 2006 *Food Safety and Standards Act*). Also, the labels are not to contain nay statement, claim, design or device which is false or misleading in any particular concerning the food products contained in the package, or concerning the quantity or nutritive value implying medicinal or therapeutic claims or in relation to the place of origin of such food products.

This comprehensive legislation covering various aspects of food safety is a welcome step. However, inspite of about 9 years since this legislation and 4 years since the various regulations there under, there is no significant impact which the public has witnessed from the formation of this authority.

Chapter Summation

While the linkage between the right to health and the WTO regime is on many fronts including technical details which impact exports, import restrictions etc., the foremost issue addressed in this chapter is access to medicines at affordable prices. On the matter of access to medicines, there are many provisions in Indian law which can provide relief in case there is an issue of affordability and accessibility of medicines. At the Indian governmental level, there have been various initiatives to deal with the issue, some of which are as below:

i. The *1970 Patents Act* has provisions such as compulsory licensing to ensure that patented inventions are worked on a commercial scale in India, revocation of patent, compulsory license in the context of national emergency, extreme emergency, public non-commercial use, for export etc., government use, pre grant and post grant opposition etc. which can all be effectively used to ensure the affordability and accessibility of medicines.

ii. The 2013 DPCO has wide reaching provisions which enable price control. Also, it provides for increased production, calling for information etc.

iii. Under the *2002 Competition Act* anti-competitive practices can be dealt with especially where there are high monetary transactions. For e.g. if the patents are not being utilized or is not being worked in an affordable manner, these can be treated as anti-competitive practices and remedies administered.

iv. The creation and functioning of bodies such as the NPPA facilitates control over the prices of medicines.

v. Various policy documents such as the 2012 *National Pharmaceutical Pricing Policy*, 2011 *National Health Research Policy* etc. have been formulated by the Government of India.

vi. Various governmental committees were constituted such as 2007 *Satwant Committee on Data Protection*, 2005-06 *Standing Committee on Chemicals and Fertilisers* where data protection requirements under the TRIPS Agreement was explored, 2005 *Task Force from Department of Chemicals and Fertilisers* which explored options other than price control to make life saving drugs available at reasonable prices and also laid down the principle of price regulation, 2005 *Technical Expert Group on Patent Law Issues* which explored the issue of whether it is TRIPS compatible to limit the grant of patent for pharmaceutical substance to new chemical/medical entity with one or more inventive steps, whether it would be TRIPS compatible to exclude micro-organisms from patenting etc., all highlight that there has been some effort by the Government of India to understand and explore ways to deal with the issue of medicinal pricing.

vii. State governments have also come out with measures to distribute generic and essential medicines free of cost such as in Tamil Nadu, Kerala etc.

viii. Some states have also adopted policy documents such as the 2005 *Essential Medicines Policy in Haryana*.

ix. Government of India has come out with the National List of Essential Medicines identifying the critical medicines as needed by the population.

x. Measures such as excise duty reduction have been adopted by the Government of India.

xi. 2006 *Food Safety and Standards Act* and Rules and regulations there under to deal with the food standards, though the impact from the authority created under this law is yet to be felt in India.

xii. The Essential Commodities Act etc. provides for ensuring supply of the medicines in India.

Therefore on the regulatory front India has taken some steps to deal with the exorbitant pricing etc. due to the implementation of the TRIPS regime in India, food safety issues etc. Initiatives such as Medicines Patents Pool, Indian Open Source Drug Discovery Initiative, NLEM in India also aim to deal with the issue of medicinal pricing in relation to patents.

On the ground, as evident from the above study in many cases, the cost of medicines are kept exceptionally high by the pharmaceutical companies. For example, the cost of the drug Sorafenb Tosylate which is a palliative drug for patients suffering from Renal Cell Carcinoma and Hepato Cellular- Carcinoma, the patent holder was selling at the cost of Rs. 2,80,428/- per month, which the patent infringer CIPLA was selling at Rs. 30,000 per month and which the applicant for compulsory licensing Natco Pharma offered to sell for Rs. 10,000/- per month. This means that the profits that are reaped by the pharmaceutical companies are at indecent and immoral levels whatever be the argument they raise for keeping such costs of the medicines including research and development and marketing costs. The pharmaceutical company in the litigation on such pricing even argued erroneously that:

- CIPLA's presence must be used to determine whether the reasonable requirement of the public has been met and whether the patented invention is being made available to the public at a reasonably affordable price.
- If CIPLA has effectively met the entire demand for the drug, there should not be a grant to another entity.

- Reasonably affordable price should be fixed taking into account various factors including R&D costs, marketing costs etc. and that socio-economic conditions are not the only factors

Such ground level reality has resulted in opinions such as that there is legal, policy and institutional deficit in the implementation of TRIPS flexibilities in India (Gopakumar, K.M in Selvaraj, Sakthivel et. al 2014: 141). Therefore, it becomes all the more important to bridle the pharma companies and to strengthen the Indian law and institutions, irrespective of the threat of no more investment in diseases affecting the developing economies etc. Studies have already revealed that the investment to deal with diseases in the developing world have been minimal.

In India, as always has been the case, there is gap in the implementation of these measures, in ensuring availability of medicines at reasonable and affordable prices to the population. Government hospitals, dispensaries etc. normally experience shortage or absence of medicines, medical facilities and medical staff. Also, the March 2015 decision of the Government of India to do away with the central scheme for free provision of the drugs and diagnostics on the NLEM is discouraging. In fact, the scheme was initiated in 2012 after studies revealed that 67% of people's expenditure on healthcare is for drugs. The Government of India has passed on this responsibility to the state governments and decided that if a state starts free drug scheme and fulfils the condition of putting in place a quality assurance system, prescription audits and so on, it will be given 5% of its National Health mission allocation as incentive (Natarajan, Rema 2015).

In the retail sector, medicines in India display an upward trend in pricing which may also have to do with the inflation in the country. As a result purchase from the retail sector and treatment of diseases from the private sector entail significant burden on the common citizen. Therefore in addition to the regulatory controls India need to have in place good governance to deal with general inflation, availability of medicines in government sector, facilitating good treatment at government facilities etc.

It is welcome that some state governments like Kerala etc. have set up a list of essential medicines at the state level which are provided free of cost by such state

governments. The willingness in the government servants to bring into proper action the provisions of the law is also indispensable to ensure proper health of the people in the country. As discussed above in the chapter, Tamil Nadu procures medicines in bulk through a tender process at prices less than MRP and then makes them available in public heath institutions while Rajasthan facilitates distribution of medicines though Government run dispensaries at reasonable costs.

Certain areas such as prices of medicinal devices such as 'stents' to be inserted in the heart case of heart blockages etc. are broadly unregulated even though the stent is notified as 'drug' under the 1940 *Drugs and Cosmetics Act*. Such lacuna exposes the population to a serious risk of non-access and the proposals to set up a regulatory authority to deal with this segment need to be immediately implemented.

Imposition of any taxes, duties etc. on sale of medicines should be done away with and the manufacturers and retailer should be paying income tax only, instead of charging excise duty, sales tax etc. on the sale of medicines in India. Since the government has been unable to make significant steps, make sufficient budgetary allocation for improvement of health facility in the country, the least it can do is to reduce the tax burden on the citizen when they purchase medicines or avails treatment.

There have been multiple case laws as well some of which advance the cause of affordable access to medicines in India. Some of these decisions have been in favour of steps which reduce the costs of the medicines such as the decision in *Bayer Corporation* vs. *Natco Pharma*. However, some decisions in India such as the *exparte* decision granted by Justice Manmohan Singh in *F. Hoffman-La Roche Ltd., Switzerland and OSI Pharmaceuticals, Inc., New York* vs. *Cipla Ltd., Mumbai Central, Mumbai* (MANU/DE/4182/2012) and in *Roche Products (India) Pvt. Ltd.* vs. *Drugs Controller General of India and Others* (CS(OS) No.355/2014 before the Delhi High Court) has been unmindful of the actual impact of such decision on the lives of many people. There is important need to sensitise the judiciary as well as the government to act on an even footing when it comes to medicinal pricing and health issues.

CHAPTER 5
TRIPS AGREEMENT AND PRACTICES FROM DIFFERENT COUNTRIES

1. Introduction

In 1986 at the start of the Uruguay Round countries were free to determine the duration of patents and that about 50 countries did not grant patent protection for pharmaceutical products at all, while some excluded pharmaceutical processes (See UNAIDS, WHO and UNDP: 2). With the TRIPS Agreement coming into force the patents laws of many of developing countries had to be amended. The repertoire of obligations under the TRIPS and TRIPS plus obligations is not only on patenting front, but also in other areas such as data protection.

The ever expanding nature of TRIPS and TRIPS plus obligations are detrimental to the interests of the developing countries. Interestingly, the problem of lack of access to medicines is faced not just by developing countries but developed countries as well. The reason for such shortage will be different in the context of developed countries. Greater global demand, consolidation of generic production at a few sites and changes in the regulatory standards requiring upgrade of manufacturing plants are some of the suggested reasons for shortage of certain medicine categories such as injectable generic medicines in the United States (See Gray, Andy and Manasse Jr., Henri R. 2012).

The impact of any increase in medicinal prices is more pronounced in developing countries. In developing countries, the citizens bear the majority of the health related costs. For example, a study on health care financing in Ghana reveals that as per the data available in 2005-06, 48% of the total health care financing is by out of pocket insurance (James Akazili, John Gyapong and Diane McIntyre 2011: 18). The rest is by taxes and national health insurance.

African countries, most countries in the APAC region, many Latin American countries all have large concentrations of people who are below the poverty line. A 2007 study by the *United Nations Economic and Social Commission for Asia and the Pacific* noted that the Asia Pacific region has the largest number of people without

access to essential medicines and that of the 1.7 billion people worldwide who are without access to essential medicines, 60 per cent of them are in the Asia Pacific region (E/ESCAP/63/4, 28 February 2007, para 52). The study further noted that in 2007 the Asia Pacific region had three fifths of the world's population but its share in the world pharmaceutical market is 18.1 percent of which Japan contributes 11.4 per cent and the rest of the region 6.6 per cent. The study noted the APAC region as a net importer of the pharmaceuticals and that the concentration of investment and capacity for drug research and development in high income countries has resulted in the neglect of tropical diseases and that very few drugs meant for tropical diseases have been discovered in the last 30 years (E/ESCAP/63/4, 28 February 2007, para 52). For example only one new drug came to the market in the last 50 years for treatment of tuberculosis which killed around 1.5 million people worldwide in 2013 (Quigley, Fran 2014).

In such background, it is useful to survey the legal steps adopted by various nations to address the concern of access to medicines, be it patent related or production capacity related. A perusal of domestic law provisions become important as it helps to identify how the jurisprudence at the international level is translating to the level of the individual.

2. Developing Countries

On an indicative basis, the domestic legal provisions of ten developing countries namely South Africa, Namibia, Kenya, Uganda, Egypt, Thailand, Argentina, Cambodia, Columbia and Ecuador are done below.

2.1. South Africa

South Africa has made suitable amendments to the Medicines and Related Substances Control Act of 1965 to ensure supply of affordable medicines. Under section 15(c) of the 1965 *Medicines and Related Substances Act*, the Government may prescribe conditions for the supply of affordable medicines. Also, notwithstanding the rights granted under the 1978 *Patents Act* in South Africa, the government may determine that the rights with regard to any medicine under a patent granted shall not extend to acts in respect of such medicine which has been put into the market by the owner of the medicines or with or her consent. Also, the government may prescribe the

conditions under which the medicine which is identical in composition and quality standard as that of another medicine registered in South Africa but which is imported by another person other than the holder of the registration certificate of the medicine and which originates from any site of manufacture of the original manufacturer may be imported. Under section 16 of the 1965 *Medicines and Related Substances Act* the Medicines Control Council has the right to cancel the registration of any medicine if it determines that any person to whom the registration has been granted has failed to comply with any condition subject to which any medicines has been registered or, is of the opinion that any medicine does not comply with prescribed requirement or is of the opinion that it is in public interest that any medicine shall be available to the public.

Under section 22 F of the 1965 *Medicines and Related Substances Act* pharmacists are required to inform all members of the public who visit his or her pharmacy which a prescription for dispensing the benefits of substitution of branded medicine with interchangeable multi source medicine. Such pharmacist shall also dispense an interchangeable multisource medicine instead of the medicine prescribed by the medical practitioner, dentist etc. unless expressly forbidden by the patient from doing so. However, a pharmacist shall not sell such interchangeable multisource medicine if the person prescribing the medicine has written in his/her own hand that on the prescription, 'no substitution' next to the item prescribed or, if the retail price of the multi-source interchangeable medicine is higher than the price of the medicine prescribed.

Also, under section 22 G of the 1965 *Medicines and Related Substances Act* , the Government maintain price control over the medicines by the constituting a pricing committee which is to make recommendation in making regulations on the introduction of a transparent pricing system for all medicines and Schedules substances sold in South Africa and on an appropriate dispensing fee to be charged by a pharmacist or medical practitioner, dentist, practitioner, nurse or other person registered under the 1974 *Health Professions Act*. The transparent pricing system shall include a single exit price which is to be published and such price is the only price at which manufacturers shall sell medicines and Scheduled substances to any

person other than the State. The dispensing fee to be collected by the pharmacist is not to exceed the exit price which is published.

Thus South Africa seems to have an effective mechanism to effect price control over the medicines.

In 2002 complaints were filed against the multinational pharma companies GlaxoSmith Kline and Boehringer Ingelheim before the South African Competition Commission alleging that the companies engaged in anticompetitive practices through excessive pricing of their patented products zidovudine, lamivudine, and nevirpaine the South African Competition Commission agreed with this position and held that these companies had engaged in excessive pricing and had denied generic competitors with an essential facility i.e. license to manufacture there medicines. Considering the impact of these finding by the Competition Commission, these companies agreed to provide license for the patents to generic producers at a royalty not exceeding 5% of the sale price of the generic versions (UNDP 2010: 44).

Similarly in 2007, another compliant was brought against the multinational Merck Sharp and Dohme (MSD) for refusing to license its patent on the ARV efavirenz on reasonable terms which also was settled by MSD through agreement to grant multiple licenses of its patent on efavirenz to generic producers and also to export their products to 10 other African nations along with a waiver of the royalty (UNDP 2010: 44).

2.2 Namibia

2.2.1. 2003 *Medicines and Related Substances Control Act*

The Republic of Namibia passed the 2003 *Medicines and Related Substances Control Act* (hereinafter "2003 Namibian Act") which deals with various aspects of the control of marketing and sale of medicines drugs in Namibia.

The 2003 Namibian Act defines 'essential medicines' as the medicines listed in the prevailing Namibian Essential Drugs Lists as published by the Ministry in Namibia responsible for health. The 2003 Namibian Act further defines 'public need and

interest' as the health care needs and interest of the greater Namibian community in respect of availability and equitable access to health care services (clause 1(1)).

The 2003 Namibian Act requires the government to classify the medicines as Schedule 1, 2 3, 4 and 5 medicines and a person may not sell a medicine or a schedules substance except in accordance with the prescribed conditions. Also, the person may not manufacture, pack or sell medicines or scheduled substances unless the person has the license, complies with the specified conditions etc as prescribed therein (Clause 29(3) (a) and (b)).

Further, the 2003 Namibian Act provides that a pharmacist must inform all members of the public who visits his/her pharmacy with the prescription, the benefits of substituting the prescribed medicine with an interchangeable multisource medicine and may dispense with such interchangeable multi-source medicines instead of the medicine of prescription (Clause 30(1) (a) and (b)).

However a pharmacist may not dispense such an interchangeable multi source medicine where the person who has issued the prescription has written on the prescription the words 'no substitution' (Clause 30(3) (a)). Where the patient expressly objects to such substitution (Clause 30(3) (b)), if the retail price of such interchangeable medicines is higher than that of the medicines specified on the prescription (Clause 30(3) (c)) or if the product is declared as not substitutable by the Council (Clause 30(3) (d)).

Clause 31(1) of the 2003 Namibian Act empowers the Council to issue a license authorising the applicant to acquire, possess, prescribe, use in respect of or sell to his or her patients medicines as specified in Schedule 1 and 3 where the council is satisfied that granting such license is in public need and interest.

Further, the Council may issue license authorising the pharmacist to prescribe, sell Schedule 2 and 3 medicines subject to such conditions as determined by the Council where the Council is satisfied that such license is in public need ad interest and where

the pharmacist has the required competence to prescribe those schedules medicines (Clause 32(2)).

Also, the Council can issue license to a medical practitioner, dentist or veterinarian authorising such person to sell medicines listed in Schedule 1, 2 3 or 3 to the patients of such persons where the Council is satisfied that such license is in public need and interest and that such person has the competence to dispense such scheduled medicines (Clause 32(3)). In addition the 2003 Namibian Act also permits the Council to issue permits to a person not being a pharmacist authorising such person to manufacture or pack and sell medicines or a scheduled substance subject to such conditions as mentioned in the permit (Clause 32(4)).

The Council is to issue license to a permit holding the permit as issued by the Minister to manufacture or pack and sell a medicines or a scheduled substance (Clause 32(5) (a)). Also, the Council may issue a license to a pharmacist on application, authorising him or her to manufacture or pack and sell medicines or scheduled substance subject to such condition as determined by the Council (Clause 32(5) (b)).

Also the Council may issue a license authorising the applicant who can sell a medicine or scheduled substance under the 2003 Namibian Act to import or export medicines or schedules substance subject to such conditions as determined by the Council (Clause 32(5) (c)).

2.3. Kenya

In Kenya a significant step which enhanced the right to health was the promulgation of the new Constitution on August 27, 2010, which has made the right to health justiciable for all citizens vide Article 43(1) and for all children vide Article 53(1) c (See Malache, Allan and Day, Emma Ely, 2014: 98). Under the previous Constitution, the right to health was sought to be enforced by linking it to right to life which was more difficult to enforce. In addition there are some legislation which specifically dealt with access to medicines and are discussed below.

2.3.1. 2001 *Industrial Property Act in Kenya*

The 2001 *Industrial Property Act in Kenya* provided that the patents rights under the Act shall be limited by provisions on compulsory license based on grounds such as

public interest, interdependence of patents and provisions with regard to the right of the State to exploit patented inventions.[71]

The Act provides that where in public interest and in particular in the context of health etc. where it is determined by the government that the manner of exploitation of a patent by an owner of the patent is not competitive, the government may upon application to him and after consultation with Kenya Industrial Property Institute and the owner of the patent, order that such invention shall be exploited by a Government Ministry, Department, agency or other person as the Government may designate, subject to payment of adequate compensation to the owner of the patent in accordance with the provisions section 80 of the 2001 *Industrial Property Act* (Section 80 (1) (b) (1A)).

Also, the Minister may authorise the importation, manufacture or supply, or authorise the utilization of any molecule or substance by any individual, corporation or society as named in the order without notice to the patent holder or any other notifiable party, such order to remain in force until revoked in writing and after giving six months prior notice of such intention to revoke to the party named in the order (Section 80 (1) (b) (1A)). Such order shall not require any payment of compensation to the owner of the patent or license holder or any other party so interested (Section 80 (1) (b) (1B)).

Also, the Government may authorise the utilization of any process for the manufacture, sale or supply of any molecule or substance whatsoever by any individual, corporation or society named in the order, such order to remain in force until six month prior to the communication of the intention to revoke such authorisation to such party (Section 80 (1) (b) (1C)).

The requirement to seek a contractual license to manufacture does not apply in the context of national emergency or extreme national urgency (Section 80 (2)).

[71] Section 58 (5) of 2001 *Industrial Property Act*, Kenya:

> The rights under the patent shall be limited by the provisions on compulsory licences for reasons of public interest or based on interdependence of patents and by the provisions on State exploitation of patented inventions.

Where an order under section 80 is made, the Managing Director is required to fix the amount of compensation to be paid to the owner of the patent, such compensation to be equitable in view of the circumstances of the case and the economic value of the patent (Section 80 (5)).

The exploitation under section 80 should be primarily for the supply of the market in Kenya (Section 80 (9)).

This legislation was crucial in making essential medicines available to large number of people in Kenya as it permitted parallel imports i.e. import of non-counterfeit drugs from other countries without the permission of the patent holder (Malache, Allan and Day, Emma Ely, 2014 : 97).

2.3.2. 2006 *HIV and AIDS Prevention and Control Act*

The 2006 *HIV and AIDS Prevention and Control Act* in Kenya require the government to take the necessary steps to ensure access to essential healthcare services and essential medicines at affordable prices by persons with HIV or AIDS or those exposed to the risk of HIV infection.[72]

2.3.3. 2008 *Anti Counterfeit Act*

Kenya also enacted the 2008 *Anti Counterfeit Act* (Act No. 13 of 2008) to deal with counterfeiting. However, this 2008 Anti Counterfeit Act impinged on the right to life of the Kenyan citizens as the Act potentially criminalized the manufacture, import, export and possession or sale of generic medicines in Kenya (UNDP 2010: 47) without the permission of the patent holder. In Kenya close to 1.6 million people suffer from HIV/AIDS and generic drugs are widely used for treatment of such diseases in Kenya (See (2012) "UNAIDS Welcomes Kenya High Court Judgment on Anti-Counterfeit Law"). The Act in section 2(d) stated that counterfeiting meant taking certain actions without the authority of the owner of the IP right in Kenya or elsewhere in respected of the protected goods (Malache, Allan and Day, Emma Ely,

[72] See clause 19 (2) of 2006 *HIV and AIDS Prevention and Control Act in* Kenya, Act 14 of 2006

> **19.** (2) The Government shall, to the maximum of its available resources, take the steps necessary to ensure the access to essential healthcare services, including the access to essential medicines at affordable prices by persons with HIV or AIDS and those exposed to the risk of HIV infection.

2014 : 99). As generic medicines were not excluded from this definition parallel imports of generic medicines became illegal under this 2008 *Anti Counterfeit Act* and therefore the provisions of the said legislation was challenged before the High Court of Kenya.

2.3.4. 2008 Decision of the High Court at Kenya

The 2008 Anti Counterfeit Act was challenged before the High Court of Kenya at Nairobi by three HIV patients stating that their right to life is affected. In April 2012, the High Court of Kenya held that the 2008 *Anti Counterfeit Act* failed to clearly distinguish between counterfeit drugs and generic medicines and that this could hinder access to life saving medicines (UNAIDS 2012). The High Court of Kenya required then Kenya's Parliament to review the Act and to remove ambiguities that could result in arbitrary seizures of generic medicines under the pretext of fighting counterfeit drugs (UNAIDS 2012).

The United Nation Special Rapporteur for health was joined as an interested party to the case and he submitted that the definition of 'counterfeiting' conflated generic medicines with medicines produced in violation of private IPRs and that this is likely to have a serious adverse impact on the availability, affordability and accessibility of low cost, high-quality medicines (Petition Number 409 of 2009, High Court of Kenya at Nairobi, Republic of Kenya, para 35). The Rapporteur also submitted that this would lead to a situation here medicines that are genuine and which has regulatory approval may be seized on the ground that the same is counterfeit and that medicines destined for importation to Kenya may be seized on the ground of possible infringement of the Act upon delivery of the shipment significant delays of the shipments for inspection and legal clarification, seizures by customs officials and police officers who are not trained to distinguish between counterfeit and generic drugs, all of which could lead to an increase in the price of the ARV's (Petition Number 409 of 2009, High Court of Kenya at Nairobi, Republic of Kenya, para 36).

The Court agreed that the definition of counterfeit in section 2 of the Act is likely to be read as including generic medication (Petition Number 409 of 2009, High Court of Kenya at Nairobi, Republic of Kenya, para 78).

The Court finally concluded as below:

> 87. In view of the matters above, I find that Sections 2, 32 and 34 of the Anti Counterfeit Act threaten to violate the right to life of the petitioners as protected by Article 26(1), the right to human dignity as guaranteed under Article 28 and the right to the highest attainable standard of health guaranteed under Article 43(1) and grant the declaration sought as follows:
>
> (a) The fundamental right to life, human dignity and health as protected and envisaged by Articles 26(1), 28 and 43(1) of the Constitution encompasses access to affordable and essential drugs and medicines including generic drugs and medicines
>
> (b) In so far as the Anti Counterfeit Act, 2008 severely limits or threatens to limit access to affordable and essential drugs and medicines including generic medicines for HIV and AIDS, it infringes on the petitioners' right to life, human dignity and health guaranteed under Articles 26(1), 28 and 43(1) of the Constitution.
>
> (c) Enforcement of the Anti Counterfeit Act, 2008 in so far as it affects access to affordable and essential drugs and medication particularly generic drugs is a breach of the petitioners' right to life, human dignity and health guaranteed under the Constitution
>
> 88. It is incumbent on the state to reconsider the provisions of section 2 of the Anti-Counterfeit Act alongside its constitutional obligation to ensure that its citizens have access to the highest attainable standard of health and make appropriate amendments to ensure that the rights of petitioners and others dependent on generic medicines are not put in jeopardy.

In its reasoning on the judgment, the Court held that the Anti-Counterfeit Act has prioritised enforcement of IPRs in dealing with the problems of counterfeit medicines and has not taken an approach focused on the quality and standards which would achieve the protection of the public from substandard medicines (Petition Number 409 of 2009, High Court of Kenya at Nairobi, Republic of Kenya, para 83). The Court noted that protection of consumers may have been only a collateral issue in the minds of the drafters of the Act (Petition Number 409 of 2009, para 83). Also, the court held that any legislation which would render the costs of essential drugs unaffordable to citizens would be a violation of the state's obligation under the Constitution (Petition Number 409 of 2009, High Court of Kenya at Nairobi, Republic of Kenya, para 66).

This was a good decision which substantially bolstered the case of the right to health in Kenya. Beyond that it also resulted in changes to be made to the provisions of the

Anti-Counterfeit Bill, 2010 which was before the Ugandan Parliament (Malache, Allan and Day, Emma Ely, 2014 : 101).

2.4. Uganda

Uganda has a 2002 *National Drug Policy* in which it sets out that the private sector should be encouraged in drug procurement, for example, in procurement of essential drugs by generic name and that local manufacturers should produce essential drugs at competitive prices. It also notes that procurement agencies should source locally available essential drugs so as to support the local drug industry (See section 3.7 and 3.8 of 2002 *Uganda National Drug Policy*). It also notes as a goal to:

i. ensure the provision of high quality dispensing services in both public and private sectors and to institute generic substitution as a means of improving the access and affordability of drugs (Section 4.3of 2002 *Uganda National Drug Policy*).
ii. to ensure the availability of the required quantities of essential drugs at affordable prices and to ensure the availability of sufficient funds to maintain regular and adequate supply of essential drugs (Section 5.1 of 2002 *Uganda National Drug Policy*).
iii. equity of access to essential drugs by ensuring their affordability to the country and the population (Section 5.1 of 2002 *Uganda National Drug Policy*).

For, this, the Policy has as its strategy to design, establishment and maintenance of a system to monitor the word market, local retail, wholesale and cists prices of essential drugs, ensure dissemination of such prices to both supplier and consumer and to ensure that the prices for procurement of drugs at the public sector do not exceed such indicator prices. The policy further prescribes active promotion of the concepts and practice of generic prescribing and generic substitution towards minimizing drug costs (See section 5 of 2002 *Uganda National Drug Policy*).

Though the Uganda National Drug Policy was of 2002, a report by UNCTAD – ICTSD in 2009 stated that the country's poor health care infrastructure, weak management of funds, shortage of funds to National Drug Authority has all contributed to the lack of access by large parts of the pollution to treatments for

various diseases such as HIV/AIDS, malaria, tuberculosis etc. (UNCTAD-ICTSD 2009: ix). Also, the report noted that 80 percent of drugs procured by the government in 2009 was imported and that the costs of such imports have been rising sharply from $ 3 million in 2004/2005 to $ 54 million in 2007/2008 (UNCTAD-ICTSD 2009: ix). The said 2009 report noted various defects in the Ugandan laws and its non-conformities with the various TRIPS requirements. The report made the concluding recommendation that to bring increased domestic capabilities, countries such as Uganda should rely on a robust public domain (i.e. the area beyond the private rights created through the IP laws) than rely on broad exclusive rights (UNCTAD-ICTSD 2009: 37). The report summed up that where the public domain is well developed, the local innovator would have better access to information and even where such innovator is driven out of the market the competitive environment would benefit all the consumers.

2.5. Egypt

The 2002 IPR law in Egypt provides that where the competent Minister determines that the exploitation of the patent will benefit public non-commercial interest including preservation of national security, health, environment and food safety, cases of emergency or circumstances of extreme urgency, then a non-voluntary license to counter the conditions may be granted without prior negotiations with the patent owner or after certain period of negotiations offering reasonable condition to procure the consent of such patent owner (See section 23(1) of the 2002 *Law on Protection of Intellectual Property Rights in Egypt*).

Also, the law provides that when the quantity of the patented medicines made available does not adequately address national needs due to their poor quality or if they are offered at a prohibitive price or if the patents is on the medicines addressing critical cases, incurable or endemic disease or products used in the prevention of these diseases, or where the invention is related to medicines, their manufacturing process, raw material necessary for the preparation or the process of manufacturing those materials, then the Minister of Health may notify decision granting non-voluntary licenses (Section 23(2) of the 2002 *Law on Protection of Intellectual Property Rights in Egypt*).

If the owner of the patent fails to exploit the invention in Egypt either by himself or through his consent, or of the patent has not been sufficiently exploited after the lapse of three years since the date of application or three years since the grant of the patent or if the patent owner suspends the exploitation of the patent for more than one year without sufficient reason, in all such case non-voluntary license may be given by the Government for the exploitation of the patents through the manufacturing of the patented product or the patent process in Egypt (Section 23(4) of the 2002 *Law on Protection of Intellectual Property Rights in Egypt*).

Where the patent owner abuses or exercises the rights conferred in a manner contrary to fair completion such as fixing exorbitant prices of the patented products or preferential treatment of agent with regard to price and sales conditions, failure to supply the local market with the patented product or supplying it under prohibitive terms, stopping the production of the patented item or its production in a disproportionate manner, undertaking acts or practices which have adverse effect on free competition exercising the patent rights in a manner adversely affecting transfer of technology etc. then non-voluntary license may be granted by the government without recourse to negotiation or expiry of time lines (Section 23(5) of the 2002 *Law on Protection of Intellectual Property Rights in Egypt*).

Also, where the exploitation of an invention by a legitimate patent holder requires the use of another invention which has concrete technical advance and technical and economic significance to the other, a non-voluntary license is to be granted for the exploitation of the other invention with same rights to the underlying patent holder (Section 23(6) of the 2002 *Law on Protection of Intellectual Property Rights in Egypt*).

Further the law also provides that the rights conferred by a patent shall lapse and the matter shall fall into public domain where the invention is not exploited in Egypt within two years flowing the grant of a non-voluntary license upon request by an interested party, where there is an abuse of the rights by the patent owner and the non-voluntary license is not sufficient to remedy that abuse (Section 26 (5) and (6) of the 2002 *Law on Protection of Intellectual Property Rights in Egypt*).

2.6. Thailand

Thailand as a country had introduced product patent protection in 1992 i.e. 13 years ahead of the required implementation period for prescribed under TRIPS for product patents (Yamabhai, Inthira and Smith, Richard D 2015: 90).

In 2006-2007 period Thai government issued compulsory licensing on the drug Plavix which is used for heart disease which drug was patented by Sanofi, Aventis and Bristol Meyer Squibb and also for Efavirenz which drug was used for AIDS treatment and which was owned by Merck. Under such compulsory licensing of Efavirenz during the five year contract period at one percent royalty to Merck, the drug was to be manufactured in Thailand at fifty percent of its cost resulting is savings of about US $ 28 million (Yang, Deli 2012:76).

Also, in 2008, the Ministry of Public Health issued compulsory licenses for four anti-cancer medicines – Letrozole, Docetaxel, Erlotinib an Imanitinib (Yamabhai, Inthira and Smith, Richard D, 2015: 89). Also, civil society groups in Thailand successfully challenged the patent granted by the Thai patent office on the drug ARV didanosine (UNDP 2010: 23). Compulsory licensing in Thailand reduced the cost of second live ARV's by 90% and represented a saving of US$ 3.2 billion (UNDP 2010:.27, f.n.86).

Similarly, when compulsory license was issued for the drug clopidogrel used for heart medication, the cost of each tablet came down from US $ 2.00 to US $ 0.028 which represented a saving of 98%. One of the reasons for such low price of the drug clopidogrel was because about 41 separate brands of clopidogrel was competing in the Indian market as the said drug was not under patent protection in India, the patent application having been filed in 1987 (Yale Law School (n.d.). The study noted that when five or more competitors enter a market then price of the product reduces dramatically (Yale Law School (n.d.): 13).

Such issue of compulsory licenses in Thailand has created much furore among the patent holders as well as the countries from which they were based. The move to compulsory license found support among the nongovernmental organisations which noted that such issue of compulsory licenses would benefit many people and also establish precedence for other countries to issue compulsory license for social welfare

(Yang, Deli 2012:79). The issue resulted in Thailand being included by the United States in the Special 301 Priority watch List and the issue was brought to a temporary halt only after the WHO promised commitment to technical and policy support on the use of compulsory licenses at its 193 member annual meeting in May 2007 (Yang, Deli 2012:79).

Thailand also has enacted other laws to protect traditional Thai medicines which would contribute to the health and wellbeing of its citizens. Important provisions of the concerned legislation are as below:

2.6.1. 1999 *Act on Protection and Promotion of Traditional Thai Medicinal Intelligence*

Thailand enacted the *Act on Protection and Promotion of Traditional Thai Medicinal Intelligence* in 1999 which seeks to protect and promote traditional Thai medicinal intelligence. Traditional Thai medicine is defined in the Act as medical procedures concerned with the examination, diagnosis, therapy, treatment or prevention of promotion and rehabilitation of the health of humans, animals, obstetrics, traditional Thai massage and invention of medical devices based on knowledge or text that has been passed on from generation to generation (See section 3 of 1999 *Act on Protection and Promotion of Traditional Thai Medicinal Intelligence*).

This law states that IP right on traditional Thai medicines shall not be transferred to others except where it is passed on from generation to generation (Section 35 of *Act on Protection and Promotion of Traditional Thai Medicinal Intelligence*). The law categorizes traditional Thai medicinal IPRs as (Section 16 of 1999 *Act on Protection and Promotion of Traditional Thai Medicinal Intelligence*):

i. national formula of traditional Thai drugs or the national text on traditional Thai medicine
ii. General formula of traditional Thai drugs or general traditional Thai medicine document
iii. personal formula of traditional Thai drugs or personal text on traditional Thai medicine.

IP protection on traditional Thai medicine is prohibited where the registrar is of the opinion that (Section 22 of 1999 *Act on Protection and Promotion of Traditional Thai Medicinal Intelligence*):

- the drug formula belongs to the national formula on traditional Thai drugs, or national text on traditional Thai medicine or is a general formula on traditional Thai drug or general text of traditional Thai medicine or,
- The drug formula is a personal formula on traditional Thai drug that has been developed on non-medicinal basis like extracts of plants, animals or microorganisms that have not been obtained from the natural extracts or the transformation that is not considered rough transformation.

However, personal formula of traditional Thai drugs or personal text on traditional Thai medicine may be registered for IP protection. However, the right to register the personal formula of traditional Thai drugs is limited to (Section 20 of *1999 Act on Protection and Promotion of Traditional Thai Medicinal Intelligence*):

i. inventor of the formula on traditional Thai drugs or text of traditional Thai medicines
ii. improver or developer of formula on traditional Thai drugs or text of traditional Thai medicine
iii. inheritor of the formula on traditional Thai drugs or text on traditional Thai medicine.

The right granted under the said law is valid for the lifetime of the bearer of the registration and shall extend for another 50 years from the time the owner of the registration has deceased (Section 33 of 1999 *Act on Protection and Promotion of Traditional Thai Medicinal Intelligence*). At the end of such period the government shall specify the formula on traditional Thai drug or text on traditional Thai medicine as general formula on traditional Thai drug or general text of traditional Thai medicine (Section 33 of 1999 *Act on Protection and Promotion of Traditional Thai Medicinal Intelligence*).

Barring any act for the benefit of studies, finding, research test according to government regulation or preparation of specific drugs according to prescription of

holders of registration certificate on traditional Thai medicine or production of drugs for house hold use or production of drugs by state hospitals for government or state agencies for use in state hospitals; the right holder alone has the right to produce, research, distribute, and improve or develop the formula of the traditional Thai drug or IPRs of traditional Thai medicines from the registered text on traditional Thai medicine (Section 34 of 1999 *Act on Protection and Promotion of Traditional Thai Medicinal Intelligence*).

This law permits persons with nationality from other nations to seek registration of IP protection on local traditional medicine in their country under this Act provided they agree to permit persons with Thai nationality to have the protection of IPRs on traditional Thai medicine (Section 43 of 1999 *Act on Protection and Promotion of Traditional Thai Medicinal Intelligence*).

2.7. Cambodia

The Cambodian law on patent i.e. the 2002 *Law on the Patents, Utility Model Certificates and Industrial Designs* provide that the inventions the commercial exploitation of which would be contrary to public order or morality or would not protect human, animal or plant life or health (See Article 9 of 2002 Law on the Patents, Utility Model Certificates and Industrial Designs, Cambodia). The law further provides that the Minister may decide that without the consent of the owner of the patent allow a Government agency or a third person to exploit the invention where so required by public interest especially national security, health etc. or where the judicial body determines that the manner of exploitation by the owner of the patent is anticompetitive. In such cases the exploitation is to be limited to the purpose for which it was authorised and subject to payment of an adequate remuneration to the said owner (Article 47 of the 2002 Law).

The Law also provides that pharmaceutical products mentioned in the law shall be excluded from patent protection till January 01, 2016 in accordance with the Doha

Declaration.[73] Also article 4 of the said law provides that pharmaceutical products as provided in article 136 shall be excluded from patent protection.

2.8. Argentina

In Argentina there is a procedure to be followed to register medicinal products with Medicines, Food and Medical Technology National Administration (ANMAT). Only local entities authorised by ANMAT can manufacture, market, import, export and distribute medicinal products. In case a foreign company wants to manufacture in Argentina it must incorporate a local company or enter into a commercial relationship with a local laboratory (See Vogelius Emelia N., Eppens Hugo J, Rosti Millan Florencia, and Andres Ana 2012: 3).

Argentinean Patent law No. 24.481 provides for limited exceptions to the rights conferred by a patent. Article 41 of the Argentinean Patent law provide that the National Institute of Industrial Property may at the reasoned request of a competent authority introduce limited exceptions to the rights conferred by a patent and that such exceptions shall not unjustifiable prejudice the exploitation of the patent or do unjustified harm to the legitimate interest of the owner and due account should be taken of the legitimate interests of third parties.

Article 45 of the Argentinean Patent law provides that the National executive may for reason of health emergency or national security grant the exploitation right under a patent the scope of duration of which is to be limited to the purposes of the grant.

The law also provides that where three years has elapsed since the grant of a patent or four years since the filing of the application of the invention has not been exploited then except in situation of force majeure and where no genuine or effective preparations has been made for the exploitation of the patents then an application may be filed for use of the invention without seeking permission from the patent holder, Thereafter the National Institute of Industrial Property may inform the patent owner of the no fulfillment of the provisions and allow the use of the patent without such authorization. Also, after hearing both the Parties the National Institute of Industrial

[73] Article 136 of the 2002 *Law on the Patents, Utility Model Certificates and Industrial Designs*, Cambodia

Property shall set reasonable remuneration to be charged by the owner of the patent with due consideration to the economic value of the authorization and also the average rate of the royalties that is payable in the sector.

2.9. Columbia

Columbia has a National Medicines Pricing Commission which fixes the reference prices for all medicines commercialised in Columbia. This is done at least once a year and for this it takes into account the average price in the domestic market for a group of homogenous pharmaceutical products, which means products with identical composition, doses and formulas. If there are less than three homogenous products in the market then the Columbian National Medicines Pricing Commission establishes an international reference price by comparing the price for the same product in at least three of the eight selected countries on the region namely Argentina, Brazil, Chile, Ecuador, Mexico, Panama, Peru and Uruguay as well from the countries in the Organisation for Economic Co-operation and Development countries. The price which is lowest in any of these countries is fixed as the minimum retail price for Columbia (WHO, WIPO and WTO 2013: 158).

One of the scenarios addressed by Columbia for ensuring price control and availability was with regard to the medicine lopinavir and ritonavir provided to AIDS patients. While the Columbian Ministry of Health rejected a 2008 application for compulsory licensing on the ground of lack of public interest the medicines was listed in National Essential Medicines List and its supply to patients by insurers were made mandatory as well as the price of the medicines was fixed at US$ 1067 for public sector and 1591 for private sector resulting in a reduction of 54 percent and 68 percent per person per year (WHO, WIPO and WTO 2013: 158).

2.10. Ecuador

In Ecuador, compulsory licensing of the ARV combination lopinavir/ritonavir marked under the name ‘Kaletra’ which was owned by Abbot Laboratories from United States, to Eskegroup the local distributor of the Indian generic pharmaceutical company Cipla, facilitated cheaper availability of the medicine in Ecuador. The license was valid till November 2014 (UNDP 2010: 32). While the patented version of the drug cost about USD 1000 per person per year, the compulsory licensing was slated to reduce the cost of the drug to about USD 500 per person per year (People’s

Health Movement 2010). The pricing methodology that was adopted was the Tiered Royalty Method in which the royalty is based not on the price of the generic product but on the price of the patented product in the high income country. Such method is considered to be more sustainable for middle/high income countries as the same provides for higher royalties in middle and high income countries with low disease burdens and lowest royalties for countries that have the lowest incomes and the highest rate of disease burden (People's Health Movement 2010).

3. Developed Countries

The legal provisions in two developed nations Canada and the United States are reviewed below.

3.1. Canada

In Canada the legislative provisions as well as the jurisprudence seem to be advanced in a manner favouring public health, as evident from the following discussions.

The concept of patents as explained by the Supreme Court in Canada is that the patent system is based on a bargain that the inventor is granted exclusive rights in a new and useful invention for a limited in exchange for the disclosure of the details of the invention so that the society can benefit. A patent, as the court held is not an accolade or civic award for ingenuity but is a method by which inventive solutions to practical problems are coaxed into the public domain by promise of limited monopoly for a limited time (*Teva Canada* v. *Pfizer Canada Inc.* 2012: 639). In this case Pfizer in its patent specifications for the drug Viagra did not provide adequate details of the active components which provided efficacy to the drug and instead chose to mask it with many other ingredients. The applicant in this proceeding Teva Pharmaceutical Industries, alleged that Pfizer's patent was invalid for obviousness, lack of utility and insufficient disclosure (*Teva Canada* v. *Pfizer Canada Inc.* 2012: 630). The Supreme Court held that Pfizer's patent was not valid as sufficient disclosure of the specification had not been done by Pfizer. The Court noted that the disclosure in the specification would not have enabled the public to make the same successful use of the invention as the inventor could (*Teva Canada* v. *Pfizer Canada Inc.* 2012: 652). The Court held that the patent held by Pfizer was not valid and dismissed Pfizer's

challenge to the generic version of the drug produced by Teva Pharmaceutical Industries.

3.1.1 1985 *Patents Act* in Canada

The prices of patented medicines are under price control in Canada from 1987. The Patented Medicines Review Board (hereinafter "PMPRB") is a quasi judicial body in Canada which ensures that the prices of medicines from the manufacturers of patented medicines are not excessive (*Health Canada* (n.d.). PMPRB is accountable to the Parliament through the Minister of Health.

3.1.1.1. Provisions to Control Excessive Pricing of Medicines:

The 1985 *Patents Act* in Canada (hereinafter "Canada *Patents Act*") has provisions to control excessive pricing of medicines. It:

- provides that when the PMPRB finds that a patentee of an invention pertaining to a medicines is selling the medicine in any market in Canada at a price which in the PMPRB's opinion is excessive the PMPRB may direct the patentee to cause the maximum price at which the patentee is selling the medicine in that market to be reduced to such level as the PMPRB considers to be not excessive (See Section 83(1) of the Canada *Patents Act*).
- provides that where the PMPRB finds that a patentee of an invention pertaining to a medicines has sold the medicine in any market in Canada at a price that in the PMPRB's opinion is excessive, the PMPRB may direct the patentee to reduce the price at which the patentee sells the medicine in any market in Canada to such extent and for such period as specified in the order and/or reduce the price at which the patentee sells another medicine to which the patented invention of the patentee pertains in any market in Canada to such extent and for such period as specified in the order and/or pay to the government an amount specified in the order. Such acts shall be to offset the amount of the excess revenues estimated to have been derived by the patentee form the sale of the medicine at an excessive price (See Section 83(2) of the Canada *Patents Act*).

In the case of a former patentee of an invention pertaining to a medicine, if in the opinion of the PMPRB, the patentee had sold the medicine in any market in Canada at a price which in the PMPRB's opinion was excessive, the PMPRB may direct the former patentee to reduce the price at which the former patentee sells a medicine to which a patented invention of the former patentee pertain in any market in Canada to such extent and period as specified in the order or to pay the government an amount specified in the order (See section 83(3) of the 1985 Canada *Patents Act*). Such acts shall be to offset the amount of the excess revenues estimated to have been derived by the former patentee from the sale of the medicine at an excessive price.

- In lieu of the actions stated above, the PMPRB also retains the power to direct the patentee or the former patentee to do one or more things stated above, to offset up to twice the amount of the excess revenues estimated by it to have been derived by the patentee or the former patentee from the sale of the medicine at an excessive price (See section 83(4) of the Canada *Patents Act).*
- In order to determine whether the being is being sold at an excessive price in any market in Canada, the PMPRB considers the price at which the medicine was sold in the relevant market, the price at which other medicines in the same therapeutic class have been sold in the relevant market, the price at which the medicine and other medicines have been sold in countries other than Canada, the changes in the Consumer Price Index and such other factors as may be specified in any regulations made for this purpose (See section 85(1) of the Canada *Patents Act).* Where the PMPRB is unable to determine whether the medicine is being or has been sold at an excessive price in any market in Canada, the PMPRB is to take into consideration the cost of making and marketing the medicines and such as factors which are specified in the relevant regulations or are relevant in the circumstances, in the opinion of the PMPRB (See section 85(2) of the Canada *Patents Act).* In order to determine whether the medicine is being sold at an excessive price, the PMBRB is not to take into consideration the research costs other than the Canadian portion of the world costs related to the research that led to the invention pertaining to that medicine or to the development and commercialisation of that invention. The proportion of the ratio of the sales by the patentee in Canada to that of the

total world sales is also to be considered (See section 85(3) of the Canada *Patents Act).*

3.1.1.2. Provisions for Developing and Least Developed Countries:

The Canada Patent Act has elaborate provisions providing for permission to manufacture patented medicines for international humanitarian purposes to address public health problems affecting developing and least developed countries especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics. This was made possible through the 2004 *Jean Chretien Pledge to Africa* which is an amendment to the Patent Act and the Food and Drugs Act in Canada. Some of the relevant provisions from such amended 1985 Canada *Patents Act* are as below. It:

a) provides that the Governor in Council may on recommendation of the named Ministers amend Schedule 1 by adding the name of the patented product that may be used to address public health problems afflicting many developing and least developed country members, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics by adding a dosage form, a strength and a route of administration and by removing any entry listed in it (See section 21.03(1)(a) of the Canada *Patents Act).*
b) provides that that the Governor in Council may on recommendation of the named Ministers amend Schedule 2 by adding the name of any country recognized by the United Nation as a least developed country; if it is a WTO member provided the TRIPS Council with a notice stating that the country intends to import in accordance with the General Council Decision pharmaceutical products; and if it is not a WTO member provided the Government of Canada with a notice in writing through diplomatic channels that the Country intends to import pharmaceutical products as defined in paragraph 1(a) of the General Council decision and if it agrees that those products will not be used for commercial purposes and that it undertakes to adopt the measures referred in Article 4 of the decision (See section 21.03(1)(b) of the Canada *Patents Act).*
c) On the recommendation of the named ministers, Schedule 3 of the 1985 Canada *Patents Act* can be amended to add the name of any WTO Member not listed in Schedule 2 that has provided the TRIPS Council with a notice in writing that the WTO member intends to import in accordance with the

General Council decision, pharmaceutical products (See section 21.03(1)(c) of the 1985 Canada *Patents Act).*

d) On the recommendation of the named ministers Schedule 4 of the 1985 Canada *Patents Act* can be amended by adding the name of any WTO Member not listed in Schedule 2 or 3 that has provided the TRIPS Council with a notice in writing stating that the WTO member intends to import in accordance with the General Council decision, pharmaceutical products. In the case of any country which is not a WTO member but is named on the Organization of Economic Co-operation and Developments list of countries that are eligible for development assistance a notice in writing needs to be provided through the diplomatic channels (See section 21.03 (1)(d) of the Canada *Patents Act).* Such notice should state that such country is faced with a national emergency or other circumstances of extreme urgency, specify the name of the pharmaceutical product and it's quantity as needed by the country to deal with the emergency, state that it has no or insufficient pharmaceutical capacity to manufacture the product and state that it agrees that the product will not be used for commercial purposes and that it undertakes to adopt the measure referred in Article 4 of the general Council decision (See section 21.03 (1)(d) of the Canada *Patents Act).*

e) Section 21.04 provides for any person based on authorization from the Commissioner on application to make, construct and use a patented invention solely for the purpose directly related to the manufacture of the pharmaceutical product and to sell it for export to a country or WTO member' listed in Schedule 2 to 4. The application is to set out the name of the pharmaceutical product to be manufactured and sold for export under the authorization, the prescribed information in respect of the version of the pharmaceutical product to be manufactured and sold for export under the authorization, the maximum quantity of the pharmaceutical product to be manufactured and sold under the authorization, the name of the patentee of the invention and them number as recorded in the Patent office of the patent issued in respect of that invention, the name of the country or the member to which the pharmaceutical product is to be exported, the name of the governmental person or entity, or the person or entity permitted by the

government of the importing country to which the product is to be sold and any other information as may be prescribed.

3.1.1.3. Conditions for the Authorization of the Use of the Patented Invention

The legislation prescribes several conditions for the authorization of the use of the patented invention such as:

a) that the applicant has complied with the prescribed conditions, that the Minister of Health has notified the Commissioner that the version of the pharmaceutical product that is named in the application meets the requirements under the Food and Drugs Act including the requirement pertaining to labelling, packaging etc that identify the product as having been manufactured in Canada as permitted by the General Council decision, in form a manner that distinguishes it from the version of the pharmaceutical product sold in Canada by the patentee or with the consent of the patentee (See section 21.03 (3) of the *Canada Patents Act).*

b) the applicant is to provide the Commissioner with a solemn declaration that at least thirty days before the filing of the application, the applicant had sought from the patentee or patentee a license to manufacture and sell the pharmaceutical product for export to the country or the WTO member named in the application on reasonable terms and that such efforts have not been successful and that the applicant has provided the patentee or the patentees as the case may be, a written request for license with all material information (See section 21.03 (3) (c) of the *Canada Patents Act).*

c) the applicant is to provide the Commissioner with a certified copy of the notice in writing that the WTO member has provided to the TRIPS Council the name of the pharmaceutical product and the quantity of that product as needed by the WTO member and a solemn declaration that the product to which the application related is the product specified in the notice and that the product is not patented in the WTO member or that the WTO Member has provided to the TRIPS Council a notice that such WTO member in accordance with Article 31 of the TRIPS Agreement and the provisions of the General

Council decision granted or intends to grant a compulsory license pertaining to the product (See section 21.03 (3) (d) of the *Canada Patents Act)*.

Similar details need to be provided for various classes of applicants like country listed in Schedule 2 that is not a WTO member, a WTO Member listed in schedule 3, WTO member listed in schedule 4 etc.

d) that the quantity of the product authorized to be manufactured by the authorization should not be lesser than what is set out in the application for authorization and the quantity set out in the notice referred in any of subparagraphs 21.04(3)(*d*)(i) to (v) (See section 21.05 (1) of the 1985 Canada *Patents Act*).

e) that before exporting a product manufactured under the authorization the holder of the authorization must establish a website which discloses the name of the product, the name of the country or the WTO member to which it is exported, the quantity that is authorized to be manufactured and sold for export, distinguishing features of the product, its label and packaging, information identifying every known party handling the product while in transit from Canada to the country or WTO member to which it is exported (See section 21.06 (1) of the Canada *Patents Act)*. This website is to be maintained by the holder during the entire period for which the authorization is valid (See section 21.06 (2) of the *Canada Patents Act)*.

f) Before each shipment of any quantity the holder of the authorization is to provide the patentee or patentees, country or WTO member named in the authorization, the person or entity that purchased the product to which the authorization related with a notice specifying the quantity to be exported as well as every known party that will be handling the product while in transit from Canada to the country or WTO member to which it is exported (See section 21.07 of the *Canada Patents Act)*. The holder of the authorization is to provide the patentee or each of the patentees as the case may be, royalty as prescribed under the regulations formed under the 1985 Canada *Patents Act (*See section 21.08 (1) of the Canada *Patents Act)*.

3.1.1.4. Involvement of the Federal Court

The legislation authorises the Federal Court to make an order on the application of the patentee or one of the patentees an enhanced amount as royalty over what is provided by the regulations if it is satisfied that the royalty otherwise required to be paid is not adequate remuneration. In making such determination the federal court is to take into consideration the humanitarian and non-commercial reasons underlying the issuance of the authorization and the economic value of the invention or invention to the country or WTO member (See section 21.08 (7) of the Canada *Patents Act).*

The authorization granted is valid for two years (Section 21.09 of the Canada *Patents Act*) and is nonexclusive (Section 21.10 of the 1985 Canada *Patents Act*) and non-transferable, other than in the case of the sale or assignment of the corporation or enterprise, or part of the corporation or enterprise to which such authorization is granted (Section 21.11 of the *Canada Patents Act).* The authorization may be renewed once on application where the applicant to whom authorization was initially granted certifies that the quantities of the pharmaceutical product to be exported were not exported before the authorization ceases to be valid (Section 21.12 of the *Canada Patents Act).*

The Act also has provisions dealing with the termination on the authorization which could be the earliest of: a) the expiry of the period of authorization b) when notice is provided by the Commissioner that the government is of the opinion that the requirements of the Food and Drugs Act are not being met with c) the date on which the last of the authorized pharmaceutical product is exported d) thirty days from the date on which the name of the pharmaceutical product or the name of the country or WTO member to which the pharmaceutical product is to be exported is removed from the relevant schedules of the 1985 Canada *Patents Act* (Section 21.13 of the 1985 Canada *Patents Act*).

There are also provisions which enable the patentee to approach the Federal Court and to get an order terminating the authorization on grounds such as that the information provided by the holder of the authorization to the Commissioner is inaccurate, that the holder of the authorization has failed to establish the website as required or has failed to disclose the information as required in the website, that the holder of the

authorization has failed to pay the royalty as required, that the product exported to the WTO Member as authorized has been re-exported, that the product was exported to a WTO Member other than the one named in the authorization, that the product was exported in a quantity greater than that authorized, when the product is exported to a non WTO member that the country has allowed the product to be utilized for commercial purposes etc. (Section 21.14 of the 1985 Canada *Patents Act*).

Further of the average price of the product to be manufactured under an authorization is equal to or greater than 25 percent of the average price in Canada for the equivalent product sold by or with the consent of the patentee, the patentee may apply to the Federal Court that the essence of the agreement under which the product is to be sold is commercial in nature (Section 21.17 of the *Canada Patents Act*). The Federal Court is to take a decision on the matter by taking into account the need of the holder of the authorization to make reasonable return sufficient to sustain continued participation in humanitarian initiatives, the ordinary levels of profitability in Canada of commercial agreement involving pharmaceutical products, international trends in prices as reported by the United Nations for the supply of such products for humanitarian purposes (Section 21.17(2) of the *Canada Patents Act*).

3.1.2. *Eli Lilly and Company* vs. *Government of Canada*

Eli Lilly and Company vs. *Government of Canada* (UNCT/1/2) is a significant case in which the pharmaceutical company Eli Lilly has taken the Government of Canada to arbitration under the North American Free Trade Agreement. In this proceeding Eli Lilly and Company attempts to relitigate two Federal Court Proceedings in Canada with regard to patents on atomoxetine and olanzapine which were invalidated under Canadian law (See Counter memorial of Government of Canada: 1, para 1). Repeatedly Eli Lilly and Company sought patents on atomoxetine and olanzapine on various uses thus attempting to evergreen its patents rights. Canada submitted that the patent filing practice of Eli Lilly and Company had the effect of diminishing rather than increasing competition by discouraging competing research (Counter memorial of Government of Canada: 4, para 9).

In fact, it can be seen that Eli Lilly has litigated in various matters in the Canadian courts on similar issues where it had sought through various means to prevent generic

manufactures from producing the patented product. In *Eli Lilly Canada Inc.* vs. *Apotex Inc.* (2009 FCA 97) Eli Lilly sought to prohibit the Minister of Health from issuing Notice of Compliance to Apotex Inc. in the matter of the drug containing an active ingredient raloxifene for use in the treatment and prevention of osteoporosis until after the expiration of the Canadian patent held by Eli Lilly. The Federal Court declined the application on the ground that Eli Lilly's patented invention was based on a prediction. The Federal Appeal Court also held that the invention was based on a prediction (2009 FCA 97: 5, para 10).

3.2 United States

In United States as well, there are various case laws and pieces of legislation which deal with patents and medicinal pricing. Pieces of legislation such as the 1983 *Orphan Drug Act*, 1944 *Public Health Services Act* has provisions intended to address concerns about lack of pharmaceuticals to treat are diseases and conditions. The latest legislation in this sector is the 2010 *Patient Protection and Affordable Care Act* introduced by the Obama administration and is popularly known as 'Obama care'.

Compulsory license as a provision is used in the United States as well, for e.g. compulsory license was issued on IP surrounding the RX delivery system' in drug-eluting stents (Khor, Martin et al. 2014: 24). In the judicial front also, there has been significant decisions, for e.g., in 2013 Myriad Gene patent case before the United States Supreme Court (*Association for Molecular Pathology v. Myriad Genetics, Inc.*) Myriad sought to claim monopoly on the method of detecting inherited breast cancer and ovarian cancer genes BRCA 1 and BRCA 2. The United States Supreme Court in a unanimous decision held that a naturally occurring DNA segment is a product of nature and not patent eligible because it has been isolated (See Brinckerhoff, Courtenay C. 2013).

However, the fact remains that the United States is among the most unregulated markets on medicinal pricing and also has the highest drug prices in the world (Quigley, Fran 2015).

3.2.1. 1938 Federal Food, Drug and Cosmetic Act

The Federal Food, Drug and Cosmetic Act (hereinafter "FDCA"), regulates drug approval etc. in the United States and also has certain provisions which facilitate the right to health. Under the FDCA no person is to introduce or deliver for introduction into interstate commerce any new drug unless an approval is received with respect to application filed under Section 505 of the FDCA. Also, the Secretary under the FDCA may withdraw approval of application with respect to any drug where:

a) the clinical or other experience or tests of scientific data shows that the drug is unsafe for use under the conditions of use upon which the application was approved.
b) There is new evidence of clinical experience not contained in such application which shows that the drug is not shown to be safe for use under the conditions of use upon the basis of which the application was approved.
c) On the basis of new information available with him together with the evidence that is available shows that there is a lack of substantial evidence that the drug will have the effect it purports or is represented to have
d) The patent information prescribed was not filed within 30 days after the receipt of the written notice from the Secretary specifying failure to file such information
e) The application contains any untrue statement or material fact

For example, the Secretary may make grants to enter into contracts with public and private entities and individuals to assist in defraying the costs in the context of rare diseases and conditions for (Sec 528 of Feral Food, Drug and Cosmetic Act):

- qualified clinical expenses incurred in connection with the development of drugs
- developing medical devices
- developing medical foods

Rare 'disease or condition' under the Federal Food, Drug and Cosmetic Act is defined same as that under the 1983 *Orphan Drug Act* i.e. in the case of a drug, any disease or conditions which affects less than 200,000 person in the United States or affects more than 200,000 persons in the United States for which there is no reasonable expectation

that the cost of developing and making available in the United States will be recovered from sales in the United States for such a drug. In the case of a medical device or medical food, the frequency of the disease or condition that same has to be so infrequent that there is no reasonable expectation that such medical devices or food for the condition will be developed without the assistance under this provision. Under section 526 of Feral Food, Drug and Cosmetic Act the manufacturer or sponsor of the drug may request the Secretary to designate a drug as a drug for rare disease or condition.

3.2.2. 1944 *Public Health Services Act*

The 1944 *Public Health Services Act* in the United States notes that an Orphan Products Board is established in the Department of Health and Human Services for the development of drugs and devices for rare diseases or condition. The function of the board is to promote the development of drugs and devices for rare diseases or conditions and to co-ordinate among federal, public and private agencies in carrying out the respective functions relating to the development of such articles for diseases or conditions (Sec 227 of Public Health Services Act).

The Board is required to seek business entities and others to undertake sponsorship of drugs for rare diseases or conditions and to reorganize the efforts of public and private entities and individuals in seeking the development of drugs for rare dieses or conditions (Sec 227(c) (6) and (7) of Public Health Services Act).

3.2.1.1983 *Orphan Drug Act*

The 1983 *Orphan Drug Act* provided incentives to drug manufacturers to develop drugs to treat rare diseases and conditions. Incentives for developing drugs to cater to such rare diseases include marketing exclusivity for drug sponsors for 7 years, tax incentives, research grants etc. these drugs were referred to as Orphan drugs because prior to the Act, not many companies were willing develop products to treat such rare diseases because of the lack of financial incentives required to develop products for small patient populations. To qualify as an orphan drug such disease of rare condition should have a) affected less than 200,000 person in the United States b) affect more than 200,000 persons but there is no reasonable expectation that the cost of developing and making available the drug for such disease in United States will be

recovered from the sale of such drug in the United States (M. Angeles Villarreal 2001).

The 1983 *Orphan Drug Act* provides that a sponsor may request orphan drug designation for a previously unapproved drug or apply for orphan drugs status for an already marketed drug. Also, for an already approved orphan drug, the sponsor can obtain orphan drug designation if it can present the case that its drugs is clinically superior to the first drug (Sec. 316.20 (b) of Code of Federal Regulations).

3.2.4. 2010 *Patient Protection and Affordable Care Act*

This is a nearly 1000 page legislation and brings changes in various laws related to health care in the US. The following are some of the important features of the said legislation:

a) prohibits all insurance plans from establishing lifetime or unreasonable limits on dollar value benefits (Sec 2711).
b) prohibits all plans from rescinding coverage except for fraud or misrepresentation (Sec 2712).
c) prohibits employers providing health coverage from limiting eligibility of coverage on the basis of wages or salaries of such full time employee (Sec 2716).
d) require health insurance companies from reporting publicly the percentage of total premium revenue expended on clinical services and quality than administrative costs. Required insurance companies to refund each enrollee the amount by which premium revenue expended by the health insure for non-claim costs exceeded 20 per cent in the group market and 25 per cent in the individual market. This refund was to be done by Dec 31, 2013 (Sec 2718).
e) makes it mandatory for all individuals in the United States to maintain insurance coverage failing which there is penalty of US $95 in 2014, $350 in 2015, $750 in 2016 and so on (Sec 5000A).
f) Employers with more than 200 employees to automatically enrol new full time employees in coverage with proper notice and opportunity for such employee to opt out of any coverage the individual or employee was automatically enrolled in (Sec 1511).

g) Authorises States to buy adult vaccines under Centers for Disease Control and Prevention ("CDC") contracts which will enable savings ranging from 23-69 per cent to the private sector cost (Sec 4204).
h) Imposes annual flat fee of $2.3 billion on pharmaceutical manufacturing sector beginning 2010 except on those companies with sales of branded pharmaceuticals of $ 5 million or less (Sec 9008).
i) Imposes annual flat fee of $2 billion on the medical device manufacturing sector beginning 2010. This will not apply to companies with sales of medical devices in the US of $ 5 million or less (Sec 9009).
j) Imposes annual flat fee of $6.7 billion on the health insurance sector beginning 2010. This will not apply to companies whose net premiums written are $ 25 million or less or whose fees from administration of employer self-insured plans are $ 5 million or less (Sec 9010).

While many of the provisions such as non-discrimination on the basis of wages and salaries etc. are laudable, the impact of the imposition of flat fee of billions of dollars on the pharmaceutical, devices and health insurance sector need to be investigated, as the companies are likely to pass on such cost to the end consumers.

Chapter Summation

From an examination of the domestic law provisions of the various countries above, it is clear that countries including developed countries have adopted various mechanisms to deal with the pricing and access issues of medicines. Some of the key mechanisms which have been identified from the above study to deal with high prices are as below:

a) Compulsory Licensing: Many countries seem to have adopted the route of compulsory licensing to deal with the issue of high medicinal pricing, or lack of availability of patented medicines in the context of public health. For example, in 2007 Brazil issued compulsory license to manufacture a version of the antiretroviral drug efavirenz from Merck locally. In 2008, Thailand permitted compulsory licensing of Novartis's drug letrozole for treatment of breast cancer, drug docetaxel from Sanofi Aventis for treatment of breast and lung cancer and drug erlotinib from Roche for treatment of lung, pancreatic

and ovarian cancer (University of Pennsylvania 2012). Also, in 2006 and 2007 Thailand has issued compulsory license for two drugs for treatment of AIDS and for treatment of hypertension (University of Pennsylvania 2012). The analysis of the legal provisions in Kenya, Namibia, Egypt etc. as above, reveal the existence of compulsory licensing provisions. The flexibilities such compulsory license which is present in the TRIPS Agreement is not a new invention. In fact, the UK Statutes of Monopolies of 1624 required that patent grants should not be mischievous to the state or hurt trade. Non-working of patents is a ground for compulsory license as per section 22of the Patents Act, 1883 in UK. Internationally, both the Paris Convention of 1883 in Article 5 requires working of patents to prevent abuses and added compulsory licensing of patents through the revision in 1925 (Yang, Deli 2012:77).

However issue of compulsory licenses has resulted in much furore among the patent holders and the developed nations as the nature of global business has made the compulsory license not a business of one nation alone (Yang, Deli 2012:79). To meet with the requirements of justice and reasonableness organisations responsible for issue of compulsory license should allow the parties to negotiate a term of compensation rather than impose royalty free or minimal royalty compulsory licenses (Yang, Deli 2012:80). Issue of compulsory license has resulted in significant increase in R&D by the firms against which compulsory license was issued and this may be due to the intense pressure on these firms to continue innovating to beat competition (Yang, Deli 2012:79). Yang, Deli (2012) recommends having in place an international system to co-ordinate the granting of compulsory licensing in cross border situations to ensure consistency, and also fairness to the stakeholders (Yang, Deli 2012:81).

b) Governmental Support: For achieving better and proper coverage for the population there is need for more allotment of funds for health care as a whole. Provisions such as ‘orphan drug’ status in the United States are examples of the active involvement and steps taken by national governments to improve the discovery and manufacture of medicines for even neglected diseases. Developing nations which have the wherewithal for medicine

preparation should be actively involved in the development of such medicines which benefit their population.

c) Interchangeable Medicines: In countries such as South Africa as discussed above, innovative mechanisms exists. For example pharmacists are required to inform all members of the public who visit the pharmacy with a prescription, of the benefits of branded medicines with interchangeable medicine. Further, the pharmacist is required to dispense an interchangeable multisource medicine instead of the medicine prescribed by the medical practitioner, dentist etc. unless expressly forbidden by the patient from doing so. Also, price control is in vogue through the Government maintaining price control over the medicines by constituting a pricing committee which is to make recommendation on the introduction of a transparent pricing system for all medicines sold in South Africa.

d) Restrictions on Patenting: The 1999 Act on Protection and Promotion of Traditional Thai Medicinal Intelligence states that IP right on traditional Thai medicines shall not be transferred to others except where it is passed on from generation to generation (Section 35 of 1999 *Act on Protection and Promotion of Traditional Thai Medicinal Intelligence*). This 1999 Act notes that IP protection is prohibited where the drug formula belongs to national formal non-traditional Thai drugs or national text on traditional Thai medicines or is a general formula on traditional Thai drug or general text of traditional Thai medicine, or the drug formula is a personal formula on traditional Thai drugs that has been developed on non-medicinal basis.

e) Price Control: Another mechanism adopted by various States is to have price control. Even developed countries utilise this provision. For e.g. the provisions of Canadian law as analysed above bring out the existence of such price control mechanism in Canada. Similarly developing countries such as Columbia, India, South Africa all have established bodies, which look into price control of the medicines as per the needs of the population.

f) Insurance Coverage: Developed countries facilitate insurance coverage for its people as can be seen from the 2010 Patient Protection and Affordable Care Act in the United States. The said Act requires insurance coverage to be non-discriminatory and not to be based on wages and salaries. Tax cuts are provided to both employers and individuals to ensure that insurance schemes are popular.

The above study also brings out that even developed countries have concern on the medicinal pricing and has evolved mechanisms to deal with excessive pricing of medicines by patent holders and even former patent holders. Elaborate provisions were seen in the 1985 Canada *Patents Act* that if the PMPRB finds that a patentee of an invention pertaining to a medicines or a medicine itself, is selling the medicines in any market in Canada at a price which is excessive, then the PMPRB may direct the patentee to cause the maximum price to be reduced to such level as the PMPRB considers to be not excessive. Similar provisions apply to a former patentee who has sold the medicines in any market in Canada at a price which is excessive.

Such measures as above to make available medicines at affordable pricing has increased access to medicines in such countries. A 2013 WHO study reveals that about 9 million people in low and middle income countries were receiving anti-retroviral therapy by the end of 2011. This is a 20 fold increase from 2003 (WHO 2013). Therefore effective use of the various provisions such as compulsory licensing, price control etc. can help with the control of the prices of medicines. For this nations need to have the resources to adequately understand and utilize the various provisions available to control medicinal pricing. Further, provisions such as those in the 1985 Canada *Patents Act* which permit manufacture medicines for international humanitarian purposes to address the public health problems of developing and least developed country members especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics is also heartening.

In India also, many of these measures are implemented such as compulsory licensing, price controls on medicines in NLEM etc. However, measures such as requirement on the pharmacist to dispense an interchangeable multisource medicine instead of the medicine prescribed by the medical practitioner, dentist etc. unless expressly

forbidden by the patient, can be implemented in India as well, with necessary safety guidelines in place, as unscrupulous pharmacists may use the opportunity to sell spurious and wrong medicines. Improved medical insurance coverage must be pursued by all developing nations including India.

Broadly, after going through the provisions in the countries above, it can be said that India is better than in some countries in certain matters, for e.g. in the matter in data protection, there is no codified law that is enacted. In India, courts have addressed data protection issues through common law principles based on equity and contract. Remedy for breach of trade secrets/ confidential information has been also through Section 27 of the Contract Act and the Specific Relief Act, 1963 (Verma, S.K.2013: 29).

CHAPTER 6

THE RIGHT TO HEALTH AND GATT 1994, SPS, TBT AND GATS

1. INTRODUCTION

The SPS, TBT and GATS Agreement, all deal with health standards and the measures adopted under these agreements can impact the health of the ordinary citizens. For example, the food products which are imported can impact the health of the citizen. Trade issues like import of cigarettes etc. or the movement of health personnel or services across boundaries can all impact the right to health of the citizen. Many a time, the health standard requirements may be tailored to stifle imports into the country so as to protect the domestic industry. When health standards are formulated with this intention then they come under the head of Non-Tariff Barriers (hereinafter "NTB's") to international trade. NTB's include those standards and regulations, testing requirements, border procedures etc. intended to bring down the quantum of imports into a country under the pretext of protection of public health, environment etc. Trade barriers can either be tariff barriers, that is levy of ordinary customs duties with binding commitments undertaken by the concerned country in accordance with Article II of GATT or non-tariff barriers, that is any trade barriers other than the tariff barriers (Saqib, Mohammed and Taneja, Nisha 2005: 4). As Marceau, Gabrielle & Trachtman, Joel P., (2014: 432) note, NTB's can be expected to increase in the light of the expanding globalization and multilayered efforts to engage in global governance.

Countries are very sensitive to the issue of using health standards as NTB's, because this interface between health and trade has the potential to significantly bring down the quantum of their exports and thus seriously affect their foreign exchange earnings, which they cannot afford. While such impact of the NTB's to limit a country's export potential is significant, the theme of the study here is limited to NTB's which affect the pharmaceutical industry. Where NTB's affect exports from the pharmaceutical industry the same may in turn affect the availability of the medicines at the cheapest price to the people of such countries. This is when restrictions are placed on the pharma product on technical or other grounds.

The WTO regime attempts to address the issue of health standards through the SPS and the TBT Agreement. Motaal, Doaa Abdel (2004:855) notes that the first instrument dealing with product regulations was the Tokyo Round Agreement on Technical Barriers to Trade which explicitly introduced the concept of science into international trade. In the Uruguay Round this instrument was broken down into two separate agreements, the TBT Agreement and the SPS Agreement (Motaal, Doaa Abdel (2004: 855).

The SPS agreement attempts to do away with arbitrary and trade restrictive sanitary and phytosanitary measures[74], and to put in place international standards for products as per the scientific standards recommended by *Codex Alimentarius Commission*[75], the *International Office on Epizootics*, under *International Plant Protection Convention* etc., after due deliberations by scientists from various nations in the scientific committees of these international organisations. The TBT Agreement deals with packaging norms and does not mention any international standardising body by name. It covers everything from a light bulb to an airplane and therefore the span of international scientific bodies involved would be much more (Motaal, Doaa Abdel 2004: 857).

The ambit of the SPS and the TBT Agreements are different. Although the SPS Agreement, TBT Agreement and the GATT share the same goal, they provide norms with subtle variations (Marceau, Gabrielle & Trachtman, Joel P., 2014: 432). Under the SPS Agreement measures may be imposed on the basis of scientific information to the extent necessary to protect life or health. Under the TBT Agreement, technical regulations may be introduced to meet a variety of legitimate objectives such as national security, protection of human health, environment, prevention of deceptive

[74] Section 1of Annex A to the SPS Agreement defines sanitary or phytosanitray measure as any measure applied to protect animal or plant life or health within the territory of a Member against the risks arising from the entry, establishment or spread of pests, disease or disease carrying organisms or from additives, contaminants, toxins or disease causing organisms in foods, beverages or feedstuffs or disease carried by animals, plants or products thereof. Sanitary or phytosanitray measures include all relevant laws, decrees, regulations, requirements and procedures including end product criteria, processes and production methods, testing, inspections, certification and approval procedures, quarantine treatments associated with the with the transport of animals or plants or with materials necessary for their survival during transport, relevant statistical methods, sampling procedures, methods of risk assessment, packaging and labeling requirements directly related to food safety.

[75] Formed in 1963 by the Food and Agricultural Organisation of the United Nations and the World Health Organisation.

practices etc. While standard setting on the measures that can be adopted by individual nations is done through these agreements, these agreements may substantially tie down the ability of individual nations to take measures to protect the health of the citizens based on its own assessment. The SPS Agreement can be considered a carve out from the TBT Agreement, as the SPS Agreement covers all measures that countries take to ensure the safety of food, beverages and of animal feedstuff and to protect their territory against spread of pests and diseases, all other product requirements would fall under the TBT Agreement (Motaal, Doaa Abdel 2004:856). Due to the broader coverage of the TBT agreement, science is only one of the many justifications that countries can provide in defence of a regulation (Motaal, Doaa Abdel 2004:856). The SPS Agreement differs from the TBT in that the SPS focuses on the need to ground SPS measures in scientific principles and sufficient science (Motaal, Doaa Abdel 2004:859).

The World Trade Report 2014 notes that the SPS and the TBT Agreements provide more detail on the exception available to WTO members to enact measures to achieve an appropriate level of protection or to protect human health or safety, animal plant life or health or the environment (WTO 2014: 194). However, it needs to be investigated whether the SPS and the TBT Agreements advance the cause of the right to health.

The case laws that have come about are of particular interest in this context. Some of the case laws explored in this chapter are *Australia- Measures Affecting Importation of Salmon* (WT/DS18/AB/R of 20 October 1998), *European Communities - Measures Affecting Asbestos and Products Containing Asbestos* (WT/DS135/AB/R of 12 March 2001), *Argentina – Measures affecting the Import of Pharmaceutical Products* (WT/DS233/1 of 30 May 2001), *Canada – Continued Suspension of Obligations in the EC – Hormones Dispute* (WT/DS321/R of 21 March 2008) etc. In all ten decisions under the DSU pertaining to SPS, four pertaining to TBT and one pertaining to GATT 1994 is explored in this chapter.

The Panel reports and the appellate body reports have much significance under the current WTO systems as the process involved currently is that the sanctions etc. in the context of noncompliance can be blocked only if there is consensus among all the

Members states not to adopt a Panel or an AB report. This is popularly referred to as 'reverse consensus' and is different from the previous WTO regime where the requirement was to have consensus among all the Member States not to adopt a report[76](WHO and WTO Secretariat 2002: 53, para 87). Further, as Hsu (2006: 526) notes, WTO case law could form a body of specialised international rules within the wider universe of public international law as a matter of custom. Hsu (2006: 528) even argues that in addition to being subsidiary means for determining rule of law under Article 38(1)(d) of the International Court of Justice, there is also case to argue that WTO DSU interpretations are potential source of customary international law. Therefore a perusal of the WTO case law becomes important.

Of the various decisions discussed in this chapter, the AB decision in *European Communities - Measures Affecting Asbestos and Products Containing Asbestos* (WT/DS135/AB/R of 12 March 2001, para. 172) is particularly significant as it recognized human health as being "important in the highest degree." However not all AB and Panel reports have taken a pro human rights perspective in its decisions as can be seen from the discussion in this chapter.

The GATS obligations impact access to health, albeit in an indirect manner. While GATS does not require a withdrawal of the state from the provision of essentials services, the logic of liberalisation does not favour equitable provision of services especially health and the legal requirements of GATS threaten the effective state involvement in the provision of health (Mabika, Aulline H and London, Leslie 2007a: 16).

This chapter examines the impact of the SPS, TBT and GATS Agreements of the WTO on the right to health.

2. SPS Agreement

2.1 Overview

The Agreement seeks to improve the human and animal health and phytosanitary condition in all Members and reaffirms that Members should not be prevented from

[76] The previous regime could not effectively implement Panel reports as the losing party could block unfavourable decisions(WHO and WTO Secretariat, 2002: 53, para 87)

adopting and enforcing necessary measures to protect human, animal, or plant life and health. However such measures are not be arbitrary or unjustifiable discrimination or a disguised restriction on international trade ((Preamble to the SPS Agreement).The SPS Agreement applies to all sanitary and phytosanitary measures which directly or indirectly may affect international trade and the measures are required to be developed in accordance with the provision of the SPS Agreement (Article 1 of the SPS Agreement). The Agreement seeks to establish a multilateral frame work of rules to guide the development, adoption and enforcement of sanitary and phytosanitary measures (Preamble to the SPS Agreement).

The SPS Agreement elaborates on Article XX (b) of the GATT Agreement which deals with the use of sanitary and phytosanitary measures (Preamble to the SPS Agreement). Sanitary and phytosanitary measure is defined in Annex A, Article 1 of the SPS Agreement as any measure applied to:

a) protect animal or plant life or health within the territory of the Member from risks arising from the entry, establishment or spread of pests, diseases, disease carrying organisms or disease causing organisms.
b) protect human or animal life or health within the territory of the Member from risks arising from additives, contaminants, toxins or disease causing organisms in foods, beverages or feedstuffs
c) protect human life or health within the territory of the Member from risks arising from diseases carried by animals, plants or products thereof, or from the entry, establishment or spread of pests; or
d) prevent or limit other damage within the territory of the Member from the entry, establishment or spread of pests.

Articles 2, 3 and 4 as discussed below are the provisions on non-discrimination, harmonization and equivalence under SPS Agreement.

Under Article 2.1 of the SPS Agreement Members have the right to take sanitary and phytosanitary measures necessary for the protection of human, animal or plant life or health to the extent that such provisions are not inconsistent with the provisions of the SPS Agreement. The measures shall be applied only to the extent necessary to protect

human, animal or plant life or health and the same is to be based on scientific evidence (Article 2(2) of SPS Agreement). The measures are not to be maintained without stuffiest scientific evidence except as provided in Article 5(7) which deal with scenarios where the scientific evidence is insufficient (Article 2(2) of SPS Agreement). Where the scientific evidence is insufficient the Member may take provisional sanitary or phytosanitary measures on the basis of available pertinent information (Article 5(7) of SPS Agreement). Such information could be those from relevant international organisations as well as measures applied by other Members. The Member applying the measure is required to obtain additional information necessary for objective assessment of risk and review the sanitary or phytosanitary measure accordingly within reasonable period of time (Article 5(7) of SPS Agreement).

2.1.1.Non discrimination

In Article 2(2) the key requirement of non-discrimination is mentioned. It requires that the sanitary or phytosanitary measure shall not arbitrarily or unjustifiably discriminate between Members where identical or similar conditions prevail and that sanitary or phytosanitary measure is not to applied in manner constituting a disguised retraction to international trade. The conforming sanitary or phytosanitary measures are presumed to be complaint with Article XX(b) of GATT 1994 (Article 2(4) of SPS Agreement). Similarly those sanitary and phytosanitary measures which conform to international standards, guidelines and recommendations are deemed to be necessary to protect human, animal or plant life or health and presumed to be compliant with relevant provisions of the GATT 1994 (See Article 3(2)of the SPS Agreement).

The SPS Agreement permits the members to introduce and maintain sanitary or phytosanitary measures which result in a higher level of sanitary or phytosanitary protection than those based on relevant international standards, guidelines or recommendations if there is scientific justification for such measures (See Article 3(3) of the SPS Agreement).

2.1.2. Harmonisation

Harmonisation means establishment, recognition and application of common sanitary and phytosanitary measures by different Members (Article 2 of Annex A of SPS

Agreement). Article 3 deals with another key principle of harmonization as required by the SPS Agreement. Under this Article, in order to achieve harmonisation of sanitary or phytosanitary measures as much as possible, Members are to base their sanitary or phytosanitary measures in international standards, guidelines, recommendation etc. where they exist (Article 3(1) of SPS Agreement). However, Member may introduce sanitary or phytosanitary measures which result in higher level of sanitary or phytosanitary protection than those achieved by measures based on international standards where there is scientific justification or also where the Member determines such higher measure to be appropriate based on risk assessment and determination of appropriate level of sanitary or phytosanitary protection under article 5 (Article 3(3) of SPS Agreement). However, such measures are not to be inconsistent with any other provision of the SPS Agreement.

The Committee on Sanitary and Phytosanitary measures is to coordinate the efforts with international organisations for harmonisation. Members are encouraged to participate in full within the limits of their resources in the relevant international organizations and their subsidiary bodies such as the Codex Alimentraius Commission, the International Office on Epizootics and the international and regional organizations operating within the framework of International Plant Protection Convention in order to promote these organisations and to facilitate period review of the relevant standards, guidelines and recommendations (See Article 3(4)of the SPS Agreement).

2.1.3. Equivalence

Members are to accept the sanitary or phytosanitary measures of other Members as equivalent even where such measures are different from such Members measures or those used by other members in trading the same product where the exporting Member objectively demonstrates that the measure meets the importing members appropriate level of sanitary or phytosanitary protection (Article 4(1) of SPS Agreement). For this, reasonable access is to be given by the exporting Member to the importing Member for inspection, testing and other relevant procedures (Article 4(1) of SPS Agreement).

2.1.4. Risk Assessment

Members are required to ensure that their sanitary and phytosanitary measures are based on an assessment as appropriate in the circumstances of the risks to human, animal or plant life or health and after taking into considerations the risk assessment techniques developed by the relevant international organizations (See Article 5(1) of the SPS Agreement). In assessing the risks Members are to take into account available scientific evidence, relevant processes and production methods etc (See Article 5(2) of the SPS Agreement).

While determining the measures to be applied the member are also to take into account relevant economic factors such as potential damage in terms of loss of production or sales in the event of the spread of a pest or disease, the cost of control and eradication in the territory of the importing Member and the alternative approaches to limit the risks (See Article 5(3) of the SPS Agreement).

Members are to avoid arbitrary or unjustifiable distinctions in the levels of protection and also make sure that the measures do not result in discrimination or a disguised restriction on international trade (See Article 5(5) of the SPS Agreement). The measures are not to be more trade restrictive than required to achieve the appropriate level of sanitary or phytosanitary protection and should take into account technical and economic feasibility (See Article 5(6) of the SPS Agreement).

Where the scientific evidence is insufficient, members may provisionally adopt the measures on the basis of the available pertinent information such as that from relevant international organizations as well as such measures as applied by other members. The members should seek to obtain additional information necessary for an objective assessment of the risk and should review the sanitary or phytosanitary measure within a reasonable period of time (See Article 5(7) of the SPS Agreement).

In case the measures are deemed to be constraining or as ones having potential to constrain its exports and that the measures is not based on relevant international standards etc. such members may ask for an explanation of the reason for such

measure and the same shall be provided by the member maintaining such measure (See Article 5(8) of the SPS Agreement).

The SPS Agreement embraces and states that members are to take into account the special needs of developing country members and least developed country members (See Article 10(1) of the SPS Agreement). The Agreement provides that where phased introduction is possible longer time frame for compliance should be accorded to products of interest to developing country members (See Article 10(2) of the SPS Agreement). The Agreement also provides for the Committee to grant time limited exceptions in whole or in part from the obligations under this Agreement in order to ensure compliance by developing country members (See Article 10(3) of the SPS Agreement).[77]

As Marceau, Gabrielle & Trachtman, Joel P., (2014: 417) note, the scope of the SPS Agreement is limited to sanitary and phytosanitary measures that may affect international trade. The SPS Agreement**:**

a) recognizes that members should not be prevented from 'adopting and enforcing measures necessary to protect human, animal or plant life or health' to the extent such measures do not constitute an arbitrary or unjustifiable discrimination between Members where the same conditions prevail and that such measures should not be a disguised restriction to international trade (Preamble to the SPS Agreement).

[77] **Article 10.Special and Differential Treatment**

1. In the preparation and application of sanitary or phytosanitary measures, Members shall take into account of the special needs of developing country Members, and in particular of the least-developed country Members. (emphasis added)

2. Where the appropriate level of sanitary or phytosanitary protection allows scope for the phased introduction of new sanitary or phytosanitary measures, longer time-frames for compliance should be accorded on products of interest to developing country Members so as to maintain opportunities for their exports. (emphasis added)

3. With a view to ensuring that developing country Members are able to comply with the provisions of this Agreement, the Committee is enabled to grant to such countries, upon request, specified, time-limited exceptions whole or in part from obligations under this Agreement, taking into account their financial, trade and development needs. (emphasis added)

4. Members should encourage and facilitate the active participation of developing country Members in the relevant international organizations. (emphasis added)

b) seeks to establish a ‘multilateral framework of rules and disciplines to guide the development, adoption and enforcement of sanitary and phytosanitary measures in order to minimize their negative effects on trade’ (Preamble to the SPS Agreement).
c) recognises the role of international standards, guidelines and recommendations in preventing such disguised trade barriers and seeks to promote the use of harmonized sanitary and phytosanitary measures between Members based on ‘standards, guidelines and recommendations developed by relevant international organizations such as Codex Alimentarius Commission, the International Office of Epizootics, and the relevant international and regional organizations operating within the framework of the International Plant Protection Convention without requiring members to change their appropriate level of protection of human, animal or plant life or health’ (Preamble to the SPS Agreement).
d) recognises that developing country members ‘may encounter special difficulties in complying with sanitary and phytosanitary measures of the importing members’ and as a result lose access to markets and that the developing country members may also face difficulties in the ‘formulation and application of sanitary and phytosanitary measures in their own territories’.
e) requires all sanitary and phytosanitary measures which directly or indirectly affect international trade to be developed and applied in accordance with the provisions of the SPS Agreement (See Article 1of the SPS Agreement).
f) recognises the right of the Members to take sanitary and phytosanitary measures to the extent such measures are not consistent with the provisions of this Agreement (See Article 2(1)of the SPS Agreement).
g) requires the Members to ensure that sanitary and phytosanitary measure are applied only to the extent necessary to protect human, animal or plant life and health and is based on scientific principles. Such measures are not to be maintained without sufficient scientific evidence (See Article 2(2) of the SPS Agreement).
h) specifies that sanitary and phytosanitary measure are not applied in a manner which constitute a disguised restriction on international trade and members are required to ensure that sanitary and phytosanitary measures do no arbitrarily or unjustifiably discriminate between members where identical and similar

conditions prevail including between their own territory and that of other members (See Article 2(3) of the SPS Agreement).

Examples of SPS measures include certification to the effect that animals and animal products comes from disease-free areas, inspection to be done on products for detection of any microbiological contaminants, specific steps to be taken for ensuring that the products are free of disease agents, defining allowable levels of pesticide residues in food etc. (WHO and WTO Secretariat 2002: 36, para 37). As noted in the 2002 WTO WHO Report, in the context of increase in export of processed foods, the SPS Agreement brings in measures to protect human life and health from risks caused by additives, contaminants, toxins, veterinary drugs, pesticide residues, disease organisms in foods or beverages (WTO WHO Report 2002: 13-14, para 13).

The Codex Alimentraius Commission has performed work on areas such as the risk analysis of the foods derived from biotechnology, labelling of allergens in food/food ingredient wherein it has sought to provide necessary framework on the safety aspect of genetically modified foods (WHO and WTO Secretariat 2002: 70, para 122). When countries adopt food safety standards that are not more stringent than codex standards and have mechanisms to monitor the compliance among the food producers and exports on these standards, such food safety standards are considered to be consistent with SPS provisions (WHO and WTO Secretariat 2002: 65, para 111).

As opined by some, it is in the best interest of the exporters to have guidelines creating transparent and predictable procedures and that they should encourage the development of such procedures and 'play an active role in their formation to ensure that obtaining recognition from trading partners is as expedient and predictable as possible, while still ensuring the necessary degree of safety' (Laura J.Loppacher, William A.Kerr and Richard R.Barichello 2007: 678).

As summed up in a study by the Indian Council for Research on International Economic Relations (Saqib, Mohammed and Taneja, Nisha 2005: 4), the SPS Agreement gives members the right to take sanitary and phytosanitary measures necessary for the protection of human, animal or plant life or health, provided:

a) such measures are not inconsistent with the provisions of the Agreement;

b) they are applied only to the extent necessary;
c) they are based on scientific principles and are not maintained without sufficient
d) scientific evidence;
e) they do not arbitrarily or unjustifiably discriminate between Members where identical or
f) similar conditions prevail including between their own territory and that of other Members, and
g) they are not applied in a manner which would constitute a restriction on international trade.

The report brought out by WHO and WTO Secretariats note that the SPS Agreement aims to recognize the sovereign right of member states to determine the level of protection they deem appropriate and also to ensure that the sanitary or phytosanitary requirement does not represent an unnecessary, scientifically unjustifiable or disguised restriction on international trade. While members are encouraged to use international standards and recommendations where they exist, member may adopt SPS measures which result in higher levels of health protection or health measures for which internationals standards do not exist, to the extent they are scientifically justified (WHO and WTO Secretariat 2002: 35, para 35). Therefore, scientific justification is critical under the SPS Agreement.

3. WTO Case Law

3.1. 2007 Brazil – Measures Affecting Imports of Retreated Tyres

Article 40 of Potaria No. 14 of the Secretariat of Foreign Trade of the Brazilian Ministry of Development, Industry and Foreign Trade reads as below:

> Article 40: An import license will not be granted for retreaded tyres and used tyres, whether as a consumer product or feedstock, classified under NCM code 4012.11,00, 4012.12.00, 4012.13.00 and 4012.19.00, originating and proceeding from Mercusur Member states under the Economic Complementation Agreement No.18

In *Brazil – Measures Affecting Imports of Retreated Tyres* (WT/DS332/AB/R of 3 December 2007), the European Communities alleged that:

- Brazil's prohibition on the importation of retreaded tyres by virtue of Article 40 of Potaria No. 14 of the Secretariat of Foreign Trade of the Brazilian Ministry of Development, Industry and Foreign Trade dated November 17, 2004 was inconsistent with Article XI:1 of GATT 1994[78]
- Brazil's imposition of fines on the importation of retreaded tyres and on marketing, transportation, storage, keeping or warehousing of imported retreaded tyres were inconsistent with Article XI:1 or alternatively Article III:4 of GATT 1994[79].

Further:

- The EC made claims under Article III:4 of GATT 1994 in respect of certain state measures prohibiting the marketing and/or imposing disposal obligations on importers of/imported retreaded tyres
- The EC challenged the exemption from import prohibition on retreaded tyres and associated fines provided by Brazil to retreaded tyres originating in MERCUSUR countries

Brazil in its response did not contest the prohibitions or state measures or the exemptions, but instead submitted that the measures were justified under Article XX(b)[80] of GATT 1994 and also maintained that the exemptions to imports of

[78] Article IX: 1 of GATT 1994 states:

> 1. No prohibitions or restrictions other than duties, taxes or other charges, whether made effective through quotas, import or export licences or other measures, shall be instituted or maintained by any contracting party on the importation of any product of the territory of any other contracting party or on the exportation or sale for export of any product destined for the territory of any other contracting party.

[79] Article III: 4 of GATT 1994 states:

> 4. The products of the territory of any contracting party imported into the territory of any other contracting party shall be accorded treatment no less favourable than that accorded to like products of national origin in respect of all laws, regulations and requirements affecting their internal sale, offering for sale, purchase, transportation, distribution or use. The provisions of this paragraph shall not prevent the application of differential internal transportation charges which are based exclusively on the economic operation of the means of transport and not on the nationality of the product.

[80] Article XX of GATT 1994 states: General Exceptions

> Subject to the requirement that such measures are not applied in a manner which would constitute a means of arbitrary or unjustifiable discrimination between countries where the same conditions prevail, or a disguised restriction on international trade, nothing in this Agreement shall be construed to prevent the adoption or enforcement by any contracting party of measures:
>
> (*a*) necessary to protect public morals;
>
> (*b*) necessary to protect human, animal or plant life or health;
>
> …

remoulded tyres to MERCUSUR countries were justified under Articles XX(d) and XXIV of GATT 1994.

The Panel report dated June 12, 2007 found that:

a) the import prohibition on retreaded tyres was inconsistent with Article XI:1 and not justified under Article X(b)
b) the importation of used tyres under court injunctions resulted in import prohibition on retreaded tyres being applied by Brazil in manner constituting a means of unjustifiable discrimination between the countries where the same conditions prevail and a disguised restriction on international trade.
c) The fines associated with the import prohibition on retreaded tyres were inconsistent with Article XI:1 and not justified under paragraph (b) or (d) of Article XX of GATT 1994
d) the state law restrictions on the marketing of imported retreaded tyres and associated disposal obligations were inconsistent with Article III:4 and not justified under Article XX(b) of GATT 1994

The Panel turned to the alternatives to improve management of waste tyres and in the analysis of the schemes, the Panel noted that Brazil's chosen level of protection is the reduction of risks associated with waste tyre accumulation to the maximum extent possible. The Panel examined the methods of disposal methods identified by the European Communities such as land filling, stock piling, incineration of waste tyres in cement kilns and similar facilities and material recycling.

On land filling the Panel found that land filling of waste tyres may pose the very risks Brazil seeks to reduce through the Import Ban and cannot constitute a reasonably available alternative and also the land filling of waste tyres poses problems such as instability of sites which affect future land reclamation, long term leaching of toxic substances, risk of tyre fires and mosquito borne diseases (WT/DS332/AB/R of 3 December 2007, para 165).

On stock piling the Panel observed that by this method waste tyres were not disposed and that controlled stock piling designed to prevent the risk of fires and pests and may still pose considerable risk to human health and environment and that the same does

not constitute an alternative to import ban (WT/DS332/AB/R of 3 December 2007, para 164). On incineration the Panel held that there was sufficient evidence that there are health risks in the incineration of waste tyres though the risks could be significantly reduced through strict emission standards. Further, the most upto date technology that can control toxic emissions was not necessarily readily available due to financial reasons (WT/DS332/AB/R of 3 December 2007, para 165). The Panel concluded that the material recycling applications are not entirely safe and that even if they are completely harmless they would not be able to dispose of the quantity of waste tyres sufficient to achieve Brazil's desired level of protection due to the prohibitive costs and that therefore it would not constitute a reasonably available alternative (WT/DS332/AB/R of 3 December 2007, para 166).

The Panel recommended that the DSB request Brazil to being those measures into conformity with the obligations under GATT 1994.

The decision was appealed by the EC on certain issues of law, Brazil filed appellee's submission. Argentina, Australia, Japan, Korea, the Separate Customs Territory of Taiwan, Penghu, Kinmen, and Matsu filed third participant's submission and China, Cuba, Guatemala, Mexico, Thailand and Paraguay notified intention to appear as third participant in the oral hearing. Several nongovernmental organisations filed amicus curie brief.

3.1.1. The AB Decision

The AB held that:

a) the Panel could have adopted a more holistic approach by examining two elements of Article 40 that relate to retreaded tyres and could have analysed whether the import ban in combination with the Mercusur exemption violated Article XI:1 and whether the combined measure, or the resulting partial import ban, could be considered 'necessary'.
b) that Brazil had adopted variety of measures which were challenged or discussed before the Panel which are not directly in appeal but which the AB considered to be useful to identify (WT/DS332/AB/R of 3 December 2007, para 128).

c) that the participants did not dispute that it is within the authority of a WTO member to set the public health or environmental objectives it seeks to achieve and to adopt the level of protection it wants to obtain through the measure or the policy it chooses to adopt (WT/DS332/AB/R of 3 December 2007, para 140).

d) that Article X(b) of GATT 1994 refers to measures 'necessary to protect human, animal or plant life or health' and that the term necessary is mentioned not only in Article X(b) of GATT 1994 but also in Article XX(a) and XX(d) of GATT 1994 (WT/DS332/AB/R of 3 December 2007, para 141). Also, the AB noted that in *Korea- Various Measures on Beef*, the AB underscored that the word 'necessary' is not limited to that which is indispensable and noted the relevant portions from the decision as below:

> Measures which are indispensable or of absolute necessity or inevitable to secure compliance certainly fulfil the requirements of Article XX(d). But other measures, to, may fall within the ambit of this exception. As used in Article XX(d), the term 'necessary' refers, in our view, to a range of degrees of necessity, At one end of this continuum lies 'necessary" understood as "indispensable"; at the other end, it is "necessary" taken to mean as "making a contribution to". We consider that a "necessary" measure is, in this continuum, located significantly closer to the pole of "indispensable" than to the opposite pole of simply "making a contribution to".

The AB noted from *Korea- various Measures on Beef* that 'necessary" within the meaning of Article XX(d) involves weighing and balancing in every case of a series of factors. These include a) contribution made by the compliance measure to the enforcement of the law or regulation at issue, b) the importance of the common interests or values protected by that law or regulation and c) the accompanying impact of the law or regulation on imports or exports.The AB further:

a) noted that the Panel examined the impact of the replacement of imported tyres with new tyres on the reduction of waste, sought to determine whether imported retreaded tyres would be replaced with domestically retreaded tyres and considered whether the reduction in the number of tyres would contribute to a reduction of the risks to human, animal and plant life and health (WT/DS332/AB/R of 3 December 2007, para 148).

b) held that it cannot be held that an import ban or another trade restrictive measure, the contribution of which is not immediately observable cannot be

justified under Article XX(b). Certain complex public health or environmental problems may be tackled only with a comprehensive policy comprising a multiplicity of interacting measures and that in short term it may prove difficult to isolate the contribution to public health or environmental objectives of a specific measure from those attributable to the other measures which are part of the same comprehensive policy (WT/DS332/AB/R of 3 December 2007, para 151).

c) noted that the results obtained from certain actions such as those pertaining to climate change, preventive actions to reduce incidence of diseases etc. may manifest only after a period of time and can be evaluated with the benefit of time

d) noted that to justify a ban, the Panel must be satisfied that it brings about a material contributions to achieve its objective and that such a demonstration can be made by resorting to evidence or date pertaining to the past or present that establish that such measure makes a material contributions to the public health or environmental objectives pursued.

e) noted that the import ban must be viewed in the broader context of the comprehensive strategy designed and implemented to deal with waste tyres and that this strategy includes not only the import ban on used tyres but also the collection and disposal scheme adopted by the CONAMA Resolution 258/1999 under which it is mandatory for manufacturers and importers to provide for safe disposal of waste tyres in specified proportions (WT/DS332/AB/R of 3 December 2007, para 154). The Panel observed that the said resolution encourages Brazilian retreaders to retread more domestic used tyres by exempting domestic retreaders from disposal obligations to the extent they process tyres consumed within Brazil. The Panel noted that the 'two mutually enforcing pillars of Brazil's overall strategy – the import ban and the import ban on used tyres imply that the demand for retreaded tyres in Brazil must be met by domestic retreaders and that these retreaders can in principle use only domestic used tyres for raw material.

f) noted that tyres new or retreaded are essential for modern transportation and that at the end of their useful life they turn into waste which carries risks for public health and environment and the governments may legitimately take actions to minimize the adverse effects of waste tyres, adopt preventive

measures aimed to reduce the accumulation of waste tyres and also contemplate remedial measures for the management and disposal of waste tyres, all of which have their own risks or need for resources, advanced technologies, know how etc. Therefore the capacity of a country to implement remedial measures that are particularly costly, or which require advanced technologies may be relevant to the assessment of whether such measures are reasonably available alternatives to a preventive measure (WT/DS332/AB/R of 3 December 2007, para 171).

g) concluded that the 'Import Ban appears to us as one of the key elements of the comprehensive strategy designed by Brazil to deal with waste tyres, along with import ban on used tyres and the collection and disposal scheme established by CONAMA Resolution 258/1999, as amended in 2002'(WT/DS332/AB/R of 3 December 2007, para 155).

h) agreed with the Panel's reasoning that fewer waste tyres will be generated with the import ban in place and that Brazil has developed and implemented a comprehensive strategy to deal with waste tyres and that the Import Ban is a key element to the strategy which is likely to bring material contribution to the achievement of the objective of reducing exposure to risks arising from the accumulation of waste tyres (WT/DS332/AB/R of 3 December 2007, para 155).

In the determination of a measure as 'necessary' the AB noted that (WT/DS332/AB/R of 3 December 2007, para 156):

a) in order to determine whether a measure is "necessary" within the meaning of Article XX(b) of GATT 1994, a panel must assess all the relevant factors, particularly the extent of contribution to the achievement of a measure's objective and its trade restrictiveness, in the light of the importance of the interests or value at stake.

b) If this analysis yields a preliminary conclusion that the measure is necessary, this result must be confirmed by comparing the measure with its possible alternatives, which may be less trade restrictive while providing an equivalent contribution to the achievement of the objective pursued. It rests upon the complaining Member to identify possible alternatives to the measure at issue that the responding Member could have taken.

c) As the AB indicated in US-Gambling, while the responding Member must show that a measure is necessary, it does not have to "show, in the first instance, that there are no reasonably available alternatives to achieve its objectives.
d) In order to qualify as an alternative, a measure proposed by the complaining Member must be not only less trade restrictive than the measure at issue, but should also preserve for the responding Member its right to achieve its desired level of protection with respect to the objective pursued.
e) If the complaining Member has put forward a possible alternative, the responding Member may seek to show that the proposed measure does not allow it to achieve the level of protection it has chosen and, therefore is not a genuine alternative. The responding Member may also seek to demonstrate that the proposed alternative is not, in fact, "reasonably available".
f) If the responding Member demonstrates that the measure proposed by the complaining Member is not a genuine alternative or is not "reasonably available", taking into account the interests or values being pursued and the responding Member's level of protection, it follows that the measure at issue is necessary.

The AB held that:

- the Panel did not breach its duty under Article 11 of the DSU and upheld that the import ban can be considered necessary to protect human, animal or plant life or health (WT/DS332/AB/R of 3 December 2007, para 212).
- the Panel's conclusion that MERCOSUR exemption has not resulted in a disguised restriction on international trade was based on interpretation which is not upheld by the AB and therefore the Panel's findings that the MERCOSUR exemption has not been shown to result in import ban being held in a manner that would constitute a disguised restriction on international trade cannot be maintained (WT/DS332/AB/R of 3 December 2007, para 239).

In sum, the AB concluded as below:

a) upheld the Panel decision that the import ban can be considered to be necessary within the meaning of Article XX(b) an is thus provisionally justified under that provision.

b) held that the Panel did not breach its duty under Article 11 of the DSU to make an objective assessment of the facts
c) reversed the Panel finding that the MERCOSUR exemption would result in the import ban being applied in a manner that constitutes unjustifiable discrimination and a disguised restriction on international trade only to the extent that it would result in volumes of retreaded tyres that would significantly undermine the achievement of the objective of the import ban.
d) held that the MERCOSUR exemption resulted in the import ban being applied in a manner that constitutes arbitrary or unjustifiable discrimination within the meaning of the chapeau of Article XX
e) held that the imports of used tyres under court injunctions have resulted in the import ban being applied in a manner that constitutes arbitrary or unjustifiable discrimination within the meaning of chapeau of Article XX

The AB recommended that the DSB request Brazil to bring its measure found in the Panel report and as modified by the AB report to be inconsistent with GATT 1994. Thus this has been an important decision where public health objectives were highlighted and the measure upheld on the basis of such consideration at least at the AB stage. That the Panel did not appreciate the public health requirements in the same manner as the AB gives us the perspective that the dispute resolution forum is inherently a trade forum where public health considerations may not receive its due.

3.2. SPS related WTO Case law

3.2.1. 1996 *United States - Standards for Reformulated and Conventional Gasoline*

The United States appealed from the Panel Report in *United States – Standards for Reformulated and Conventional Gasoline* (WT/DS2/R of 29 January 1996). The dispute related to the implementation by the United States of Clean Air Act 1990 (CAA) to control toxic and other pollution causes by the combustion of gasoline manufactured or imported into the United States. Under the CAA the sale of conventional gasoline in non-attainment areas was prohibited and the same gasoline in the non-attainment areas was to be reformulated.

In order to prevent dumping of the pollutants from the reformulated gasoline into conventional gasoline, the CAA required that conventional gasoline sold by domestic refiners, blenders and importers in the United States should remain clean at the 1990 baseline levels (WT/DS2/R of 29 January 1996, para 2).

Domestic refiners which were in operation for at least six months in 1990 was to establish an individual baseline representing the quality of the gasoline produced by that refiner in 1990. Under method 1, the domestic refiners were to use the quality data and volume records of its 1990 gasoline. If such data was not available, the domestic refiner was to use its 1990 gasoline blend stock quality data and 1990 blendstock production records. In case this method 2 was also not available, then the domestic refiner was to establish the individual 1990 baseline on the basis of post 1990 gasoline blendstock and/or gasoline quality data modelled in the light of refinery changes to show 1990 gasoline composition. However, the second and third method was not made available to importers and blenders. Instead, if data as per method 1 was not available, they were to use the statutory baseline established by the Environment protection Agency (WT/DS2/R of 29 January 1996, para 3.1). The rule did not provide for foreign refiner individual baselines. The EPA's proposal of 1994 providing for limited use by importers of individual baselines established for foreign refineries did not come into force as the United States Congress enacted legislation in September 1994 denying the funding necessary for such implementation (WT/DS2/R of 29 January 1996, para 3.1).

The Panel (see WT/DS2/AB/R of 29 April 1996: 7) had:

- held that the baseline establishment methods contained in the concerned US legislation could not be justified under paragraphs (b), (d) and (g) of Article XX of General Agreement.
- recommended that the DSU request the United States to brings its Gasoline Rule in conformity with the obligations under the General Agreement.

The Panel made a principal finding that imported and domestic gasoline was 'like products' and since imported gasoline was prevented from benefiting from, the favourable domestic condition made available to domestic gasoline, imported gasoline

was treated less favourably than domestic gasoline (WT/DS2/AB/R of 29 April 1996:7).

The AB held that the Panel erred in its conclusion that baseline establishment rules in Part 80 of Title 40 of the Code of Federal Regulations did not fall within the terms of Article XX(g) of the GATT 1994. However the AB held that the baseline establishment rules contained in Part 80 of *Title 40 of the Code of Federal Regulations* fail to meet the requirements of Article XX of GATT 1994 and accordingly are not justified under Article XX of GATT 1994 (WT/DS2/AB/R of 29 April 1996: 27).

3.2.2. 1998 *Australia- Measures Affecting Importation of Salmon*

In *Australia- Measures Affecting Importation of Salmon* (WT/DS18/AB/R of 20 October 1998), a complaint was raised by Canada against the prohibition imposed by Australia on the importation of fresh, chilled or frozen salmon from Canada under Australia's Quarantine Proclamation 86A (hereinafter "QP86A"). Before the promulgation of QP86A, Australia did not impose restriction on the import of Salmonid products. However, under QP86A, Australia prohibited the import of dead fish of the sub order Salmonidae or any part of such fish in any form unless prior to such import the fish or parts of fish have not been subjected to such treatment that in the opinion of the Director of Quarantine is likely to prevent the introduction of infectious or contagious disease, or disease or pest affecting person, animals or plants (WT/DS18/AB/R of 20 October 1998, para 1). The Panel held that Australia:

- by maintaining a sanitary measure which is not based on a risk assessment has acted inconsistently with the requirements under Article 5.1 and on that ground has also acted inconsistently with Article 2.2 of the SPS Agreement
- by adopting arbitrary or unjustifiable distinctions in the levels of sanitary protection it considers to be appropriate in different situations which resulted in discrimination or disguised restriction on international trade has acted inconsistently with Article 5.5 of the SPS Agreement and
- by maintaining a sanitary measure which is more trade restrictive than required to achieve the appropriate level of protection has acted inconsistently

with Article 5.6 of the SPS Agreement (WT/DS18/AB/R of 20 October 1998, para 3).

The AB:

- noted that in a proper risk assessment, the Member must evaluate the likelihood or probability of the entry, establishment or spread of the disease and the associated biological and economic consequence as well as likelihood (probability) of the entry, establishment or spread of the disease according to which the SPS measure will be applied (See WT/DS18/AB/R of 20 October 1998, para 123).
- upheld the Panel finding that by maintaining a measure as it applies to ocean caught salmon, Australia has acted inconsistently with the obligations under Article 5.5 and 2.3 of the SPS Agreement. In other words, Australia by maintaining import prohibition on all Canadian salmon had acted inconsistently with Article 5.5 and 2.3 of the SPS Agreement (WT/DS18/AB/R of 20 October 1998, para 279 and para 240).
- found that Australia that by maintaining SPS measure at issue with regard to other Canadian salmon acted inconsistently with Article 5.5 of the SPS Agreement (WT/DS18/AB/R of 20 October 1998, para 279).
- reversed the Panel's finding that the measure at issue as it applies to ocean caught salmon is not based on a risk assessment in accordance with Article 5.1 because the Panel made this finding on the wrong premise that the heat treatment requirement rather than import prohibition is the SPS measure at issue (WT/DS18/AB/R of 20 October 1998, para 279).
- required Australia to bring its measure to the extent found inconsistent into conformity with the SPS Agreement (WT/DS18/AB/R of 20 October 1998, para 279).

The AB in the course of its judgement noted that in order to establish the violation of Article 5.6 of the SPS Agreement, there are three elements, namely (WT/DS18/AB/R of 20 October 1998, para 194):

a) there is another SPS measure which is reasonably available taking into account technical and economic feasibility

b) such other measure achieves the member's appropriate level of sanitary and phytosanitary protection
c) such other measure is significantly less trade restrictive than the SPS measure contested.

If any of these tests are not fulfilled then the measure will be inconsistent with Article 5.6.

The AB also noted that the determination of the appropriate level of protection will precede the establishment of an SPS measure and that it is the appropriate level of protection which will determine the SPS measure to be maintained and not vice versa (See WT/DS18/AB/R of 20 October 1998, paras 201 and 203).

3.2.3. 2000 *Australia – Measures Affecting Importation of Salmon*

In *Australia – Measures Affecting Importation of Salmon - Recourse to Article 21.5 by Canada* (WT/DS18/RW of 18 February 2000), Australia had imposed import restrictions on fresh chilled and frozen salmon from Canada since 1975 with the objective to prevent introduction of exotic disease agents into Australia which may natively impact health of the fish in Australia (WT/DS18/RW, 18 February 2000, para 2.1). Australian law AQPM 1999/51 required that fish should be eviscerated, should not be derived from a population slaughtered as official disease control measure, should not be juvenile salmonids or reproductively mature adults/spawners, should be processed within the premises of competent authority, the heads and gills to removed and internal and external surfaces thoroughly washed, to be derived from a population for which there is documented systems of official health monitoring and surveillance, exports to Australia to be accompanied by official certification confirming that the exported fish meets Australia's import conditions etc (WT/DS18/RW, 18 February 2000, para 2.19).

Canada raised the contention that Australia has not taken the measures to comply with recommendations and rulings of DSB and that the new polices announced by Australia in 1999 are inconsistent with several provisions of the SPS Agreement and that it cannot be reasonably said that Australia has implemented the measures to comply with the direction of the DSB (WT/DS18/RW, 18 February 2000, para 3.1). Australia maintained that the measures are based on risk assessment which forms part

of the Import Risk Analysis (IRA) on non-viable salmonids, other non-viable marine fin fish, live ornamental finfish etc (WT/DS18/RW, 18 February 2000, para 4.1). Australia maintained that the measures should be seen as least trade restrictive approach to risk management and that crude comparisons between products on the basis of the conditions attached to different products are not based on scientific merit (WT/DS18/RW, 18 February 2000, para 4.6). Australia submitted that the transparent process and techniques together with the scientific and analytical vigour has resulted in least trade restrictive measures (WT/DS18/RW, 18 February 2000, para 4.11).

Canada maintained that the Australian measures are at odds with sound science and internally accepted good practice and that Australia has imposed extremely stringent and excessive restrictions in the place of the complete ban which ban was brought before the DSB earlier (WT/DS18/RW, 18 February 2000, para 4.15). Canada highlighted that Australia imposed no similar legislative restrictions on the domestic movements of the non-viable fin fish for human consumption despite insisting that such controls are required on the imported products (WT/DS18/RW, 18 February 2000, para 4.16). Canada maintained that the effect of the Australian policy was to protect the Australian salmon aquaculture industry against imports and at the same time leaving other Australian fisheries and aquaculture interest free to import and trade the products they required such as bait, feed fish and live ornamental fish (WT/DS18/RW, 18 February 2000, para 4.17).

The Australian policy permitted fresh chilled or frozen Canadian salmon to be imported in three ways namely a) product in consumer ready form b) product for processing c) products which meet equivalent approached to managing risk and quarantine prohibition on fresh chilled or frozen salmon was removed (WT/DS18/RW, 18 February 2000, para 4.63). The Import Risk Analysis (IRA) conducted by Australia in 1999 identified certain diseases in salmon of Canadian origin and considered certain mechanisms for risk management towards Australia's appropriate level of protection (WT/DS18/RW, 18 February 2000, para 4.62).

Canada maintained that the measures were arbitrary or unjustifiable distinctions in the levels of protection which resulted in disguised restriction on international trade and that the measures are contrary to Article 5.1 (WT/DS18/RW, 18 February 2000, para

4.68 and 4.83). Canada maintained that the two elements of obligations under Article 5.1 of the SPS Agreement i.e. that there must be a proper risk assessment or risk assessments on which it relies and that the measure must be based on such risk assessments (WT/DS18/RW, 18 February 2000, para 4.84).

In the third party submissions made by the EC, they submitted that Canada could not fault Australia risk assessment and that Canada has not fulfilled its burden to prove that there was no rational relationship between Australian measures and the scientific basis of its risk assessment (WT/DS18/RW, 18 February 2000, para 5.7). The EC maintained that setting such level of protection was an autonomous right or prerogative and that the chosen level of measures conveyed the necessity of such measures and not otherwise (WT/DS18/RW, 18 February 2000, para 5.8).

In the third party submissions by the United States, it submitted that there was no scientific basis for such restriction on trade and that the July 1999 regulations could not be based on a risk analysis which was completed only in November 1999 (WT/DS18/RW, 18 February 2000, para 5.26).

The Panel:

a) however held that the 1999 IRA met the required level of objectivity (WT/DS18/RW, 18 February 2000, para 7.52) and that the Article 5.7 of the SPS Agreement allowed Members to take provisional sanitary measures when relevant scientific measures is insufficient or pending search for additional information necessary for objective assessment of risk (WT/DS18/RW, 18 February 2000, para 7.49).

b) held that the level of objectivity to be achieved in a risk assessment must be such that one can have reasonable confidence on the evaluation made with particular emphasis on the levels of risk assigned (*Australia – Measures Affecting Importation of Salmon - Recourse to Article 21.5 by Canada* WT/DS18/RW, 18 February 2000, para 7.51).

c) recalled that *OIE International Aquatic Animal Health Code on Import Risk Analysis* states that the 'principal aim of the import risk analysis is to provide the importing countries with an objective and defensible method of assessing the disease risks associated with the importation of aquatic animals (WT/DS18/RW, 18 February 2000, para 7.50).

d) held that the 1999 IRA meets the requirements of risk assessment as required under Article 5.1 and paragraph 4 of Annex A and that the publication of 1999 IRA after the date the new sanitary measures were taken does not preclude the measures from being based on the IRA and that the consumer ready requirement of AQPM 1999/51 and 1999/69 are not based on risk assessment and are contrary to Article 5.1 (WT/DS18/RW, 18 February 2000, para 7.84).

e) held that to the extent Australia maintained sanitary measures in the case of consumer ready requirements, Australia has acted inconsistently with the general obligation in Article 2.2 which is to ensure that any sanitary measure is applied only to the extent necessary to protect human, animal or plant life or health and that the same is based on scientific principle and is not maintained without sufficient scientific evidence (WT/DS18/RW, 18 February 2000, para 7.85).

f) concluded that the Canada has not convinced the Panel that the differential treatment accorded to salmonids and pilchards is arbitrary or unjustifiable (WT/DS18/RW, 18 February 2000, para 7.101).

g) noted that three elements were required for the violation of the concerned provision namely, that the measure discriminates between the territories of Members other than the Member imposing the measure or between the territory of the member imposing the measure and that of another member, the discrimination is arbitrary or unjustifiable and that identical or similar conditions prevail in the territory of the Members concerned (WT/DS18/RW, 18 February 2000, para 7.111).

h) held that it is not convinced that 'identical or similar conditions' prevailing in both Canada and Australia and that there is substantial difference in disease

status between Canada and Australia (WT/DS18/RW, 18 February 2000, para 7.113).

i) concluded that the Tasmanian measure of November 24, 1999 imposed a much stricter trade regime than what is required under the 1999 IRA (WT/DS18/RW, 18 February 2000, para 7.161) and that the Tasmanian measures is not based on risk assessment and that the same is inconsistent with Articles 5.1 and 2.2 of the SPS Agreement (WT/DS18/RW, 18 February 2000, para 7.163).

j) held that the delay in the implementation of several measures such as absence of measures from 06 July 1999 to 20 October 1999 in respect of Canadian fresh chilled or frozen salmon and from July 06, 1999 to December 01, 1999 in respect of Canadian fresh chilled or frozen salmon and from July 06, 1999 till the date of the Panel report for live ornamental finfish was noncompliance with the SPS Agreement (WT/DS18/RW, 18 February 2000, para 8.1(i)). Also by maintaining that salmon product which is only consumer ready can be imported into Australia and released from quarantine, since such measures are not based on risk assessment, is contrary to Article 5.1 of the SPS Agreement and therefore also with Article 2.2 of the SPS Agreement (WT/DS18/RW, 18 February 2000, para 8.1(ii)).

k) concluded that by requiring that only consumer ready salmon product can be imported into Australia and released from quarantine Australia is maintaining sanitary measures that are more trade restrictive than what is required to achieve Australia's appropriate level of protection and that the same is contrary to Article 5.6 of the SPS Agreement (WT/DS18/RW, 18 February 2000, para 8.1 (v)).

l) held that Tasmanian measure is not based on risk assessment and that the same is without sufficient scientific evidence and therefore such Tasmanian measures are inconsistent with the obligations under Article 5.1 and 2.2 of the SPS Agreement (WT/DS18/RW, 18 February 2000, para 8.1 (vii)).

m) concluded that Australia has not acted inconsistently with its obligations under Articles 5.5, 2.3 and under paragraph 1(c) of Annex C or Article 8 of the SPS Agreement (WT/DS18/RW, 18 February 2000, para 8.1).

n) recommended that the parties should resume efforts to reach a mutually acceptable solution consistent with the SPS agreement and also requested the DSB to request Australia to bring its measures in conformity with the obligations under the DSU and the SPS Agreement (WT/DS18/RW, 18 February 2000, para 8.1 (iii) (iv) and (vi)).

3.2.4. 1998 *EC Measures Concerning Meat and Meat Products (Hormones)*

In *EC Measures Concerning Meat and Meat Products (Hormones)*, WTO Document WT/DS26/AB/R, WT/DS48/AB/R of 16 Jan 1998), United States and Canada raised complaint against the EC relating to the prohibition of import of meat and meat products from cattle to which either natural hormones oestradiol – 17, or progesterone or testosterone or synthetic hormones trenbolone acetate, zeranol or melengestrol acetate is administered for growth promotion purpose. These prohibitions was set in a series of EC Directives enacted before January 01, 1995 and were Council Directive 81/602/EEC of 31 July 1981, Council Directive 88/146/EEC of 7 March 1988 and Council Directive 88/299/EEC of 17 May 1988 (WT/DS26/AB/R, WT/DS48/AB/R of 16 Jan 1998, para 2).

In the EC submissions it raised the position that the precautionary principle is a general customary rule of international law or at least a general principle of law and that it applies not only in the management of a risk but also in its assessment and that the Panel had erred in stating that the application of precautionary principle would not override the explicit working of Article 5.1 and 5.2 of the SPS Agreement (WT/DS26/AB/R, WT/DS48/AB/R of 16 Jan 1998, para 16).

The Panel held as below:

a) by maintaining sanitary measures that are not based on international standards and without justification under article 3.3 of the SPS Agreement, the EC had acted inconsistently with articles 5.5 and 3.1 of the SPS Agreement (Panel Report, *EC – Hormones (US)*, para. 9.1; Panel Report, *EC – Hormones (Canada)*, para. 9.1. Cited

from para 3 of the *Canada – Continued Suspension of Obligations in the EC – Hormones Dispute*, WT/DS321/AB/R of 16 October 2008).

b) The US Panel Report and the Canada Panel report reached the conclusion that the EC by maintaining sanitary measures which are not based on risk assessment had acted inconsistently with the requirements contained in Article 5.1 of the SPS Agreement

On appeal, the AB had held that the scientific studies submitted by the EC were general studies which does show the existence of general risk of cancer, but that those studies do not focus on or address the risk at stake in the dispute and therefore that no risk assessment which reasonably supported or warranted the import prohibition was furnished to the Panel and that the EC's import ban under Directive 96/22/EC was not based on risk assessment under Article 5.1 of the SPS Agreement (See AB Report, *EC – Hormones*, para. 200; and *Canada – Continued Suspension of Obligations in the EC – Hormones Dispute*, WT/DS321/AB/R of 16 October 2008, para 5). Also, the AB agreed with finding of the Panels that the precautionary principle will not over ride Article 5.1 and 5.2 of the SPS agreement and that the precautionary principle was incorporated into Article 5.7 of the SPS Agreement (WT/DS321/AB/R of 16 October 2008, para 5).

The AB concurred with the finding of the panel and noted that precautionary principle at least outside the field of international environmental law, still await authoritative formulation and the AB concurred with the finding of the Panel that precautionary principle does not override the provisions of Article 5.1 and 5.2 of the SPS Agreement (WT/DS26/AB/R, WT/DS48/AB/R of 16 Jan 1998, para 123 and 125).

The AB held that Article 3.1 cannot be read as requiring Members to harmonize their SPS measures with international standards or to vest such international standards, guidelines and recommendations as having obligatory force and effect. The AB held that it cannot be assumed that the sovereign states intended to assume upon themselves the more onerous obligation by mandating conformity or compliance with such standards, guidelines or recommendation and to sustain such an assumption would warrant a far reaching interpretation of treaty language which is far more

specific and compelling than that found in Article 3 of the SPS Agreement (WT/DS26/AB/R, WT/DS48/AB/R of 16 Jan 1998, para 165).

The EC by adopting arbitrary or unjustifiable distinction in the level of sanitary protection it considers to be appropriate in different situations result in discrimination or disguised restriction on international trade and had acted inconsistently with Article 5.5 of the SPS Agreement and the EC by maintaining sanitary measures which are not based on existing international standards without justification under Article 3.3 of the SPS Agreement had acted inconsistently with the requirements of Article 3.1 of the SPS Agreement (WT/DS26/AB/R, WT/DS48/AB/R of 16 Jan 1998, para 6).

The DSB adopted the Panel and the AB Reports and recommended the EC to bring its measures in conformity with the SPS Agreement (WT/DS321/AB/R of 16 October 2008, para 5). While the time period for implementation of the Panel and the AB reports was fixed at 15 months through arbitration, the EC had intimated the DSB that in the light of the fresh scientific evidence that was available with EC, the EC was not in a position to lift the ban at the end of the 15 month period (See WT/DS321/AB/R of 16 October 2008, para 6). Thereupon the US and Canada received authorisation from the DSB to suspend various concessions and other obligations to EC.

3.2.5. 2008 *Canada - EC- Hormones Dispute*

The EC Hormones Panel Reports[81] arose from the Directive 2003/74/EC on 22 September 2003 (hereinafter "2003 EC Directive") adopted by the EC based on the scientific opinions drawn in 1999, 2000 and 2002. The 2003 EC Directive amended Directive 96/22/EC adopted earlier by EC and provided for permanent prohibition on the importation of meat and meat products from animals treated with oestradiol - 17 β for growth promotion purposes.

More scientific evidence had been made available to the SCVPH which in May 2000 reviewed its 1999 Opinion and declined to alter the conclusions therein. In April 2002, a second review of the 1999 Opinion was issued by the SCVPH which again stood by the 1999 Opinion (WT/DS321/AB/R of 16 October 2008, para 10).

[81] AB Report, WT/DS26/AB/R, WT/DS48/AB/R; the Panel Report, WT/DS26/R/USA; and the Panel Report, WT/DS48/R/CAN (hereinafter "EC Hormones Panel Reports")

The 2003 EC Directive also provided for a provisional ban on meat and meat products from cattle treated with progesterone, testosterone, zeranol, trenbolone acetate and MGA for growth promoting purposes. The *Scientific Committee on Veterinary Measures relating to Public Health* (the "SCVPH") of the EC had assessed that "recent evidence suggests that oestradiol-17β has to be considered a complete carcinogen, as it exerts both tumour initiating and tumour promoting effects and that data currently available do not make it possible to give a quantitative estimate of the risk." (WT/DS321/AB/R of 16 October 2008: 207, para 493).

The EC considered the Opinions to be risk assessments which sufficiently justified the import prohibitions under the SPS Agreement. The EC submitted that the suspensions of concessions by US and Canada no longer justified as in its view it had implemented the DSB's decisions in the Panel reports. The US and Canada did not share this view and refused to suspend the concessions and obligations (WT/DS321/AB/R of 16 October 2008, para 12).

The matter was brought before the DSB by EC and the Panel formed on the matters held that:

a) the Opinions do not satisfy the definition of risk assessment as laid down in Annex 4 and that as the Opinions do not satisfy the requirement for being risk assessment as appropriate, the measures cannot be deemed to be risk assessment within the meaning of Article 5.1. Accordingly, the Panel held that the EC measure on oestradiol-17β is not compatible with Article 5.1of the SPS Agreement (*Canada – Continued Suspension of Obligations in the EC – Hormones Dispute*, WT/DS321/AB/R of 16 October 2008, para 18 and Panel Report, *US – Continued Suspension*, para. 7.579; Panel Report, *Canada – Continued Suspension*, para. 7.549).

b) as it is not established that the EC has removed the measures found to be inconsistent with the relevant SPS provisions, that the EC did not demonstrate a breach of article 22.8 of the DSU (*Canada – Continued Suspension of Obligations in the EC – Hormones Dispute*, WT/DS321/AB/R of 16 October

2008, para 21 and Panel Report, *US – Continued Suspension*, para. 7.847; Panel Report, *Canada – Continued Suspension*, para. 7.832).

c) by redressing violation of obligations without abiding by the rules and procedures of the DSU, the US and Canada have breached article 23.1 of the DSU and that by making a determination under article 23. 2(a) without having recourse to dispute settlement under the rules and procurers of the DSU the US and Canada have breached article 23.2 (a) of the DSU (WT/DS321/AB/R of 16 October 2008, para 24).

d) by maintaining sanitary measures that are not based on a risk assessment, the EC had acted inconsistently with Article 5.1 of the SPS Agreement and that by adopting arbitrary and unjustifiable distinctions in the levels of sanitary protection the EC actions resulted in discrimination or disguised restriction on international trade and the EC had thereby acted inconsistently with article 5.5 of the SPS Agreement. The Panel relied on the reasoning of the Panel in *Japan – Apples* and held that Article 5.1 of the SPS Agreement does not require compliance with risk assessment techniques developed by international organisations in so far as such techniques are taken into account by the risk assessor which was done by the EC while preparing the SCVPH opinions (WT/DS321/AB/R of 16 October 2008: 211-12, para 503). While EC did not absolutely comply with the CODEX and JECFA risk assessment guidelines they were aware of the same while preparing the SCVPH Opinions.

e) With regard to satisfaction of 'risk assessment' as contained in paragraph 4 of Annex A of the SPS Agreement, the Panel relied in the reasoning of the AB in *EC-Hormones* and *Australia –Salmon* and stated that risk assessment in paragraph 4 of Annex A required WTO members to (WT/DS321/AB/R of 16 October 2008: 212, para 505):

- identify the additives, contaminants , toxins or disease causing organisms in food, beverages or feed stuffs
- identify any possible adverse effect on human or animal health

- evaluate the potential for that adverse effect to arise from the presence of the identified additives, contaminants, toxins or disease causing organism in food, beverages or feedstuffs.

f) On such risk assessment, the Panel decided that:

i) SCVPH Opinions met the 'first and second requirements of the definition of risk assessment as they sufficiently identified both the contaminant (oestradiol-17β) and the food at issue (meat and meat products) as well as the possible adverse effects on human or animal health (neurobiological, developmental, reproductive, and immunological effects, and immunotoxicity, genotoxicity and carcinogenicity)' (WT/DS321/AB/R of 16 October 2008: 213, para 506).

ii) that the EC 'failed to evaluate specifically the third requirement i.e. the possibility that the identified adverse effects came into being, originated or resulted from the presence of residues of the presence of residues of oestradiol-17β in meat or meat products as a result of the administration of that hormone to cattle for growth-promoting purposes' (WT/DS321/AB/R of 16 October 2008: 213, para 506).

iii) that the SCVPH Opinions do not constitute a risk assessment as they do not satisfy the definition of risk assessment contained in Annex A(4) second sentence and that the scientific evidence referred to in the opinions do not support the conclusion therein. The Panel concluded that 'the permanent ban on meat and meat products treated with oestradiol-17β for growth promoting purposes is not a measure' based on 'risk assessment within the meaning of Article 5.1 of the SPS Agreement' and that the EC's implementing measure on oestradiol-17β is not compatible with Article 5.2 of the SPS Agreement (WT/DS321/AB/R of 16 October 2008: 215, para 511).

iv) that the SCVPH Opinions do not constitute a risk assessment because the Opinions do not satisfy the definition of risk assessment as stated in Annex A(4) because the scientific evidence referred to in the Opinion do not support the conclusions there and that therefore the permanent ban of meat and meat

products treated with oestradiol - 17β is not a measure based in risk assessment within the meaning of Article 5.1 of the SPS Agreement and that the EC's measure on oestradiol-17β is not compatible with Article 5.1 of the SPS Agreement (WT/DS321/AB/R of 16 October 2008, para 511).

3.2.5.1. The Appeal

The EC, United States and Canada appealed on certain issues of law and legal interpretations from the Panel Report in *United States- Continued Suspension of Obligations in the EC-Hormones Dispute* (WT/DS320/R of 21 March 2008) and the Panel report in *Canada – Continued Suspension of Obligations in the EC-Hormones Dispute* (WT/DS321/R of 21 March 2008). These Panel Reports considered the complaints by the EC regarding suspension of concessions by the US and Canada against the EC because of the EC's alleged failure to comply with the recommendations and rulings of the DSB stemming from the adoption of the DSB of *EC Hormones Panel Reports* i.e. AB Report, WT/DS26/AB/R, WT/DS48/AB/R; the Panel Report, WT/DS26/R/USA; and the Panel Report, WT/DS48/R/CAN (WT/DS321/AB/R, 16 October 2008: 1, para 1) and the decisions as mentioned in the previous paragraph was arrived at.

In appeal i.e. *Canada – Continued Suspension of Obligations in the EC – Hormones Dispute* (WT/DS321/R of 21 March 2008), the AB considered whether the SCVPH Opinions constituted a risk assessment within the meaning of Article 5.1 of the SPS Agreement and examined whether the SCVPH opinions satisfied the following (See WT/DS321/AB/R of 16 October 2008: 211, para 502):

a) took into account the risk assessment techniques of relevant international organisations
b) took into account the factors listed in Article 5.2 of the SPS Agreement
c) satisfied the definition of risk assessment contained in Annex A, paragraph 4 of the SPS Agreement
d) whether the conclusions in the SCVPH Opinions are supported by scientific evidence

3.2.5.2. EC Submissions

The EC:

a) asserted that the Panel erred in finding that the EC acted inconsistently with Article 5.1 by failing to evaluate the risks arising from residues of oestradiol -17β in meat from cattle treated with the said hormone for growth promotion.EH highlighted that new evidence suggested that oestradiol -17β acted as a complete carcinogen exerting tumour initiating and promoting effects (WT/DS321/AB/R of 16 October 2008, para 72).

b) submitted that the Panel should have adopted a 'reasonableness' approach as is usually followed by domestic courts and international tribunals. EC further submitted that as per the interpretation of the AB, members are entitled to rely on divergent opinions in adopting their risk assessment and that a Panel reviewing a member's SPS measure should seek to determine whether there is any scientific basis for such measure and respect the right of the members to set their level of SPS protection. Also, EC submitted that the Panel should not substitute its scientific judgment to that of the member taking the measure particularly where the available scientific opinion is providing alternative and competing explanations (WT/DS321/AB/R of 16 October 2008, para 75).

c) submitted that the Panel had engaged in picking and choosing between conflicting and contradictory scientific opinions of experts, in an arbitrary manner and that it had imposed its choice on the EC between the different scientific alternatives the EC maintained that the Panel failed to take onto account the diverging views upon a genuine controversy among the experts (WT/DS321/AB/R of 16 October 2008, para 76). EC highlighted that the Panel failed to take into account the evidence related to the risk on human health from multiple exogenous and endogenous sources though it was raised several times in the written submissions and comments by the EC and discussed extensively in the meeting of the Panel with the experts (WT/DS321/AB/R of 16 October 2008, para 77).

d) submitted that majority of the experts advising the Panel had agreed that there was sufficient scientific evidence in support of the conclusion of EC that

oestradiol-17β is actually or potentially carcinogenic and that the Panel had side stepped such crucial evidence and held that the EC had not provided the analysis of potential harmful effects arising from the consumption of meat or meat products containing the residues of oestradiol-17β (WT/DS321/AB/R of 16 October 2008, para 78).

e) submitted that there was no conclusive evidence on whether there can be a safe threshold in relation to the use of oestradiol-17β and that to determine so would require test on human beings which would be unethical and impossible and hat by ignoring the totality of the evidence, the EC had acted inconsistently with Article 11 of the DSU (WT/DS321/AB/R of 16 October 2008, para 78).

f) further submitted that no country had conducted the kind of specificity test as required by the Panel and that the EC cannot be found to be in violation of the SPS agreement for failing to meet such test and that the Panel had ignored that three of the experts advising the Panel has confirmed the potential of the adverse effect as submitted by the EC (WT/DS321/AB/R of 16 October 2008, para 79).

g) submitted that the scientific evidence on the five hormones was not insufficient within the meaning of article 5.7 of the SPS Agreement and submitted that the AB may reverse the finding of the Panel (WT/DS321/AB/R of 16 October 2008, para 81). The EC maintained that Article 3.3 of the SPS Agreement allows the members to adopt a higher level of protection than the international standard (WT/DS321/AB/R of 16 October 2008, para 83). The EC also highlighted that the Panel had ignored evidence demonstrating that progesterone and testosterone are carcinogenic to humans and that the international agency for research on cancer had also concluded so and that the provisional ban imposed by EC on the meat containing the residues of these hormones was therefore justified (WT/DS321/AB/R of 16 October 2008, para 90).

h) submitted that the Directive 2003/74/EC is based on a comprehensive risk assessment consistent with the requirements under Article 5.1 of the SPS agreement and that therefore the permanent ban is consistent with requirements under article 5.1 of the SPS Agreement. The EC also submitted that the provisional ban is based on the available pertinent information and is therefore consistent with article 5.7 of the SPS Agreement (WT/DS321/AB/R of 16 October 2008, para 326).

i) submitted that the fact that majority of the scientific experts consulted by the Panel held a particular view does not form the proper basis for determining whether a WTO Member's risk assessment complied with the requirement under Article 5.1 and Annex A of the SPS Agreement (WT/DS321/AB/R of 16 October 2008, para 602).

3.2.5.3. Submission by the US

The United States:

a) submitted that the EC had failed to remove the measures inconsistent with the WTO obligations as pointed out in the Panel reports and that it had simply switched Directive 96/22/EC with Directive 2003/74/EC and that the EC had failed to remove the inconsistent measure (WT/DS321/AB/R of 16 October 2008, para 109).

b) submitted that the Panel was correct in its finding that the ban on meat and meat products treated with oestradiol- 17β was not based on risk assessment as provided in Article 5.1 of the SPS Agreement and that the EC appeal be dismissed (WT/DS321/AB/R of 16 October 2008, para 123).

c) submitted that the core of the EC argument was that the EC considered that it is justified in banning oestradiol because misuse and abuse in the administration of oestradiol 17β may happen one day, but that the Panel had correctly held that the additional risks arising from the use and misuse of the hormone would be relevant only if EC successfully demonstrated that a specific risk arose from the consumption of meat treated with oestradiol 17β (WT/DS321/AB/R of 16 October 2008, para 124).

d) argued that contrary to what is argued by EC, the specificity test would not require demonstration of the actual effects on humans and that it is possible to perform tests on laboratory animals and to extrapolate the results to human beings (WT/DS321/AB/R of 16 October 2008, para 125).

e) maintained that statement from one expert divorced from the rest of the evidentiary record is not sufficient to demonstrate that EC has evaluated the specific risk arising from residues of oestradiol-17β in meat (WT/DS321/AB/R of 16 October 2008, para 125).

f) submitted that the reasonableness approach submitted by the EC should only apply to measure adopted by governments or specialised agencies in highly complex and technical matters and is not supported in the context of the SPS Agreement and that the Panel acted within its bounds of discretion by attributing different weight and significance to different pieces of evidence than that attributed by the EC (WT/DS321/AB/R of 16 October 2008, para 139).

3.2.5.4. Submission by Canada

Canada:

a) submitted that the EC did not provide evidence demonstrating that it had evaluated the misuse and abuse in the administration of oestradiol-17β as a specific risk in relation to consumption of meat form cattle treated with this hormone for growth purposes (WT/DS321/AB/R of 16 October 2008, para 168).

b) agreed with the finding of the Panel that as EC had not specifically assed the risk arising from consumption of meat containing hormone residues the impact of whether the concentrations of residues of oestradiol-17β resulting from abuse or misuse need not be addressed (WT/DS321/AB/R of 16 October 2008, para 168).

c) agreed with the Panel's approach taking the Codex approach to risk assessment as a general reference (WT/DS321/AB/R of 16 October 2008, para 168).

d) maintained that EC was not absolved from conducting a quantitative assessment of the risk simply because the SCVPH Opinions indicated that oestradiol – 17 is genotoxic and stated that the evidence from the SCVPH Opinions relates to oestradiol-17β *in vitro* and not whether oestradiol-17β is genotoxic *in vivo*.

e) drew the attention to the AB's finding in EC-Hormones decision that the evidences considered should be sufficiently specific to the substance at issue to warrant an SPS measure (WT/DS321/AB/R of 16 October 2008, para 170).

f) highlighted that certain experts maintained that the EC did not have sufficient evidence to support the assertion of the specific risk and to justify the SPS measure (WT/DS321/AB/R of 16 October 2008, para 170).

g) asserted that the EC's risk assessment did not contain quantitative or qualitative evidence of the genotoxic potential of oestradiol-17β in vivo and that the CE failed to substantiate its assertion that no threshold could be identified for the safe consumption of oestradiol-17β (WT/DS321/AB/R of 16 October 2008, para 171).

h) submitted that the Panel was entitled to accord more weight to the view of those experts it found credible and persuasive and that as per the decision of the AB on Brazil- Retreaded Tyres (See WT/DS321/AB/R of 16 October 2008, para. 61 quoting AB Report, *Brazil – Retreaded Tyres*, para. 185), the Panel was entitled to consider all the evidence presented to it and assess its credibility and ensure that its factual findings have proper basis in this evidence (WT/DS321/AB/R of 16 October 2008, para 173).

i) maintained that rather than picking and choosing between the opinions of experts as alleged by EC, that the Panel had performed an objective assessment of the evidence before it in conformity with the requirements in article 11 of the DSU (WT/DS321/AB/R of 16 October 2008, para 174).

3.2.5.5. Third Party Submission - Australia

Australia in its third party submissions asserted that the Panel failed to take into account article 3.3 of the SPS Agreement which permitted members to take SPS measures that resulted in higher level of protection than that achieved to measures based on international standards (WT/DS321/AB/R of 16 October 2008, para 231) and that it agreed with the EC position that the Panel erred in the standard of review under Article 5.1. Australia submitted that the standard of review applicable under Article 5.1 required the Panel to accord considerable defence to the Member's risk assessment and that the Panel should have focused on whether the risk assessment from EC represented an objective and credible view from a qualified source (WT/DS321/AB/R of 16 October 2008: 219, para 520). Australia also submitted that when a wide range of measures were possible to address a particular risk, members retained the discretion to select the most appropriate measure after considering the relevant circumstances and the appropriate level of protection (WT/DS321/AB/R of 16 October 2008, para 231). Australia maintained that Panels are to make considerable deference to the decision making powers of members where the scientific evidence supported more than one credible interpretation (WT/DS321/AB/R of 16 October 2008, para 230). Australia further submitted that while international standards may be relevant in interpreting the provisions of the SPS Agreement they should not be elevated to binding treaty obligations (WT/DS321/AB/R of 16 October 2008, para 231).

3.2.5.6. Third Party Submission - New Zealand

New Zealand submitted that the Panel had correctly interpreted that the Directive 2003/74/EC was not based on a proper risk assessment within the meaning of article 5.1 and that the Panel findings were sufficiently supported by relevant scientific evidence. New Zealand also noted that article 2.2 of the SPS Agreement required that SPS measures must be based on scientific principles and not maintained without

sufficient scientific evidence (WT/DS321/AB/R of 16 October 2008, para 252 and 521).

3.2.5.7. Determination by the AB

The issues addressed by the AB included:

i. whether the Panel failed to respect the principle of due process and in selecting and relaying upon the advice of two experts who were not independent and impartial as required by the rules of conduct and whether the Panel erred in its determination with regard to the import ban on meat from cattle treated with oestradiol-17β for growth promotion purposes.

ii. whether the Panel had adopted a narrow interpretation of risk assessment and failed to take into account the evidence on misuse and abuse in the administration of hormones and also failed to make an objective assessment of the matter before it as required by Article 11 of the DSU (WT/DS321/AB/R of 16 October 2008, para 262).

iii. whether the Panel had incorrectly determined that the scientific evidence was insufficient and incorrectly determined that where international standards exist for a substance, a critical mass of new evidence is required to render the relevant scientific evidence insufficient (WT/DS321/AB/R of 16 October 2008, para 262).

The AB:

a) noted that in order to comply with DSB's recommendations the EC had to remove the import ban or ensure that the import ban had proper justification under the SPS agreement; and that the replacement of Directive 96/22/EC with Directive 2003/74/EC is insufficient (WT/DS321/AB/R of 16 October 2008, para 320). Also, AB held that the mere existence of an implementing measure in good faith and its notification to the DSB does not require Canada and US to cease the application of suspension of concessions (WT/DS321/AB/R of 16 October 2008, para 318).

b) held that due process protection applies to the process of selecting experts and to the Panel's consultations with experts and continues throughout the proceedings and that the appointment of the experts who are not independent or impartial will compromise the ability of the Panel to act as an independent adjudicator (WT/DS321/AB/R of 16 October 2008, para 436). The Panel noted that the standard to be applied by the Panels while selecting experts is whether there is an objective basis to conclude whether the expert's independence or impartiality is likely to be affected or whether there are justifiable doubts about the expert's independence or impartiality (WT/DS321/AB/R of 16 October 2008, para 454). While the AB noted that it did not consider that the Panel exceeded its authority in dismissing the objections raised by the EC to the statement of certain experts relied on by the Panel (WT/DS321/AB/R of 16 October 2008, para 455), the AB held that the consultation with certain specific experts compromised the ability of the Panel to act as an independent adjudicator and that the Panel therefore cannot be held to have made an objective assessment of the matter as required by Article 11 of the DSU (WT/DS321/AB/R of 16 October 2008, para 401).

c) with regard to SPS measures, the AB held that it is the prerogative of a WTO member to determine the level of protection it deems appropriate. Also, the AB reiterated the already stated position in AB Report, *Australia – Salmon*, para. 200. that the appropriate level of protection determines the SPS measure rather than the level of protection determining the SPS measure (WT/DS321/AB/R of 16 October 2008, para 523). The AB further held that under Article 5.7 of the SPS Agreement, the WTO members are allowed to take SPS measures on provisional basis where the relevant scientific evidence is insufficient to perform risk assessment, provided certain conditions are fulfilled (WT/DS321/AB/R of 16 October 2008, para 524).

d) held that the AB in EC Hormones case has cautioned against taking a too narrow approach to risk assessment and that the risk to be evaluated in a risk assessment under Article 5.1 is not only a risk under strictly controlled conditions, but risk as it actually exists in human societies, the actual potential for adverse effects on human health in the real world (WT/DS321/AB/R of 16

October 2008, para 527 quoted from See AB Report, *EC – Hormones*, para. 187).

e) concluded that the SPS Agreement recognizes the right of the WTO members to take necessary measures to protect human, animal or plant life or health and that the right to take the protective measure must be exercised consistently with the obligations that are set forth in the agreement and to ensure that such measure are properly justified (WT/DS321/AB/R of 16 October 2008, para 522).

f) held that the WTO member may adopt an SPS measure based on divergent or minority views as long as the views are from qualified and respected sources. The Panel elaborated that the scientific basis on which the SPS measures is based need not reflect the majority view within the scientific community, but should have the necessary scientific and methodological rigour to be considered reputable science. Such scientific evidence should be objective and coherent and the Panel should review whether the conclusions drawn by the member has sufficient support in the scientific evidence relied on and thereafter assess whether the results of the risk assessment sufficiently warrant the SPS measure (WT/DS321/AB/R of 16 October 2008, para 591)

g) reiterated that the SPS measure need not reflect the majority view of the scientific community but should come from qualified and respected source (WT/DS321/AB/R of 16 October 2008, para 591).

h) held that the Panel erred in its interpretation of Article 5.1 on the risk of misuse and abuse in the administration of hormones to cattle for growth promotion and also held that the Panel misallocated the burden of proof and failed to conduct an objective assessment of the fat as to whether the EC met the requirements of article 5.1 of the SPS Agreement (WT/DS321/AB/R of 16 October 2008, para 617).

i) also held that the EC's rights to due process were infringed by the Panel when it inappropriately relied on the testimonies on certain experts while

determining whether the risk assessment by EC on oestradiol-17β is consistent with Article 5.1 of the SPS Agreement (WT/DS321/AB/R of 16 October 2008, para 618).

j) reversed the finding of the Panel that the EC did not satisfy the requirements stated in Article 5.1 Annex A, paragraph 4 of the SPS Agreement and also the Panel's finding that Directive 2003/74/EC was not based on proper risk assessment within the meaning of article 5.1 of the SPS Agreement (WT/DS321/AB/R of 16 October 2008, para 619). The AB reversed the finding of the Panel that the implementing measure of EC on oestradiol-17β is not compatible with Article 5.1 of the SPS Agreement (WT/DS321/AB/R of 16 October 2008, para 619).

k) noted that in the EC-Hormones case, the ban imposed by the EC on meat and meat products from cattle treated with six hormones namely oestradiol – 17 β, testosterone, progesterone, trenbolone acetate, zeranol and MGA was held to be inconsistent with the requirements in 5.1 of the SPS Agreement as the scientific studies submitted by EC was not sufficiently specific to the case. Instead they were general studies which showed the existence of general risk of cancer and did not focus on the particular kind of the risk at stake. For this reason the AB held that risk assessment was not reasonably supported or warranted by the import prohibition (WT/DS321/AB/R of 16 October 2008, para 487).

l) SCVPH Opinion 1999: On the *SCVPH Opinion 1999 - Assessment of Potential Risks to Human Health from Hormone Residues in Bovine Meat and Meat Products*, the AB noted that it brought out that 17β- oestradiol has genotoxic potential and that oestrogens are DNA reactive and mutagenic (WT/DS321/AB/R of 16 October 2008, para 489). It also brought out 17 β oestradiol can even when administered at very low doses can modulate growth of children of both sexes and decrease the height. It also brought out that the said hormone can exert deleterious effects on the fertility in men and women and that at relatively high doses the said hormone produces a number of adverse effects on the human immunity system, while the finds were

insufficient to determine whether the ingestion of meat or meat products containing the said hormone could adversely affect the immune effects of the consumers. However, in sum it held that a risk to the consumer has been identified with different levels of the six hormones in question and that oestradiol-17β has to be considered as a complete carcinogen. Also, for all the six hormones endocrine, developmental, immunological, neurobiological, immunotoxic, genetoxic and carcinogenic effects could be envisaged (WT/DS321/AB/R of 16 October 2008, para 490).

m) SCVPH Opinion 2000: On the SCVPH Opinion 2000, the AB noted that the Panel held that the 2000 Opinion concluded that the recent scientific information did not provide convincing data and arguments for the revision of the conclusions drawn in the 1999 Opinion. Also, the 2002 second review of the 1999 Opinion held that the data from 17 scientific studies and recent scientific literature confirmed that the validity of the 1999 Opinion as reviewed in 2000 and that no amendments to that Opinion are justified (WT/DS321/AB/R of 16 October 2008, para 491). The 2002 Opinion further highlighted some of the other risks from these hormone and the consumption of the meat derived from animals treated with hormones in question (WT/DS321/AB/R of 16 October 2008, para 492).

n) held that Article 5.1 requires that the SPS measures must be based on risk assessment i.e. the results of the risk assessment must sufficiently warrant/reasonably support the SPS measure at stake. Therefore there must be rational relationship between the SPS measure and the risk assessment (WT/DS321/AB/R of 16 October 2008, para 528).

o) noted that the risk assessment need not come to the single conclusion that coincides with the scientific conclusion or view implicit in the SPS measure and that the risk assessment need not embody the only view of the majority of the scientific community. The AB observed that responsible and representative governments may act in good faith on the basis of a divergent opinion coming from qualified and respected sources and that an approach based on a divergent opinion from a qualified and respected source does not

signal the absence of a reasonable relationship between the SPS measure and the risk assessment (WT/DS321/AB/R of 16 October 2008, para 529).

p) decided that risk assessment need not be based on the risk assessment by the same WTO member but that it can be based on the risk assessment from a relevant international organisation or by another WTO Member. The risk assessment can be quantitative or qualitative in nature and that the risk must be an ascertainable risk and that the risk assessment must have the requisite degree of specificity and that the assessment must be sufficiently specific in terms of the harm concerned and the precise agent which may cause the harm (WT/DS321/AB/R of 16 October 2008, para 530).

q) noted that there may be cases where the WTO member chooses to set a higher level of protection that what is based on an SPS measure based on an international standard of protection. However, the AB held that such chosen level protection must not affect the objective nature of the risk assessment which must in essence remain as a process where possible adverse effects are evaluated using scientific methods (WT/DS321/AB/R of 16 October 2008, para 534).

r) held that Codex draws a distinction between 'risk assessment and risk management' and that it defined risk management as the process of weighting policy alternatives including considering risk assessment and other factors relevant for health protection of consumers and for the promotion of fair trade practices (WT/DS321/AB/R of 16 October 2008, para 535). The AB also held that in EC-hormones case, the AB noted that the SPS agreement does not refer to the concept of risk management (WT/DS321/AB/R of 16 October 2008, para 535 and see also WT/DS26/AB/R of 16 January 1998, para 181).

s) Noted that risk arising from abuse or misuse in the administration of hormones can properly be considered as part of risk assessment and where a WTO member has taken such risk into account, they must be considered by the Panel reviewing the Members assessment and that any suggestion that such

risks cannot form part of risk assessment would constitute legal error (WT/DS321/AB/R of 16 October 2008, para 545).

t) noted that there were inputs from scientific experts consulted by the Panel that risks arising from residues of oestradiol - 17β were likely to increase where good veterinary practices are not followed and that abuse or misuse in the administration of the oestradiol - 17β has bearing on particular risk being assessed by the EC and that the Panel prematurely decided that the EC failed to valuate specifically the possible adverse effects of residues of oestradiol - 17β in meat (WT/DS321/AB/R of 16 October 2008, para 547).

u) decided that the Panel failed to address the evidence on abuse or misuse and that at least two scientific Opinions i.e. the 1999 and the 2002 Opinions, consulted by the Panel recognised that the misuse or abuse in the administration of hormones could give rise to adverse effects which evidence the Panel should have engaged with. It further held that by summarily dismissing the evidence on the issue or the abuse in the administration of hormones and consequent conclusions on the SCVPH Opinions by the Panel, the Panel incorrectly applied Article 5.1 of the SPS Agreement and the definition of 'risk assessment' in the Annex of the SPS Agreement (WT/DS321/AB/R of 16 October 2008, para 553).

v) decided that the Panel erred in its interpretation and application of Article 5.1 of the SPS Agreement in relation to the risk and abuse in the administration of hormones to cattle for growth promoting purposes (WT/DS321/AB/R of 16 October 2008, para 555).

w) decided that it did not agree with the submission of EC that the Panel required testing in humans to determine the risks associated with the consumption of meat from cattle treated with oestradiol - 17β (WT/DS321/AB/R of 16 October 2008, para 563) and also held that Panel's reference to potential occurrence of adverse health effects could be held to be consistent with the definition of risk assessment as provided in paragraph 4 of Annex A of the SPS Agreement (WT/DS321/AB/R of 16 October 2008, para 564). The AB

further held that the Panel erred in the allocation of burden of proof in its assessment of the consistency of the Directive 2003/74/EC with Article 5.1 of the SPS Agreement (WT/DS321/AB/R of 16 October 2008, para 584).

x) noted that it is the task of the WTO Member to perform the risk assessment and that the Panel's task is to review the risk assessment i.e. to determine whether that risk assessment is supported by coherent reasoning and respectable scientific evidence. If the Panel goes beyond this role and substitutes its own risk assessment the Panel goes beyond its mandate and would exceed its function under Article 11 of the DSU (WT/DS321/AB/R of 16 October 2008, para 590).

y) did not agree with the Panel approach in determining the correctness of the EC's risk assessment and held that the Panels' role should be limited and consisted of identifying the scientific basis and evidence relied upon in risk assessment, in verifying whether the scientific evidence comes from respected and qualified sources and in determining whether the reasoning articulated by the EC on the basis of the scientific evidence of its objective and coherent (WT/DS321/AB/R of 16 October 2008, para 597).

z) held that the Panel's focus should have been the evidence relied on by the EC in its risk assessment and that the Panel has not given any reason why it did not consider the evidence evaluated by the EC to be important (WT/DS321/AB/R of 16 October 2008, para 610).

aa) held that the Panel did not apply the proper standard of review and that the Panel exceeded its authority in the assessment of the testimony of the scientific experts and that it is not in the authority of the Panel to become a trier of facts (WT/DS321/AB/R of 16 October 2008, para 615).

The AB's conclusion was that the Panel failed to conduct an objective assessment of the facts as required by Article 11 of the DSU in determining whether the EC's risk assessment satisfied the requirement of Article 5.1 and Annex A of the SPS Agreement (WT/DS321/AB/R of 16 October 2008, para 616). The AB while it did

not uphold the Panel report in its key findings also did not give additional relief to the EC, than reversing the Panel Report on its negative findings.

3.2.6. 2009 *European Communities - Poultry - United States*

In *European Communities – Certain Measures Affecting Poultry Meat and Poultry Meat Products from the United States* (WT/DS389/4 of 16 January 2009), the United States in raised request for consultation with the European Communities with regard to certain EC measures affecting poultry and poultry meat products from the United States. The EC prohibited import of poultry treated with substances other than water, unless such other substance is approved by EC. The poultry from US is processed with chemicals designed to reduce the amount of microbes in the meat. Since EC has not approved any such substance this measures effectively prohibited the shipment of all poultry from US to the EC. Also, the EC maintained the measures that poultry meat should not have undergone any treatment other than cold treatment.

The United States requested the EC to approve four types of pathogen reduction treatments (PRT's) with regard to the poultry intended for export to the EC, namely acidified sodium chloride, trisodium phosphate, peroxyacids and chlorine dioxide. However, the EC rejected the request for such usage after six years of delay. Such ban was inspite of the fact that scientific reports from various EC agencies did not find any scientific basis for the banning of the PRT'S. The conclusion in many of the reports was that the importation and consumption of the poultry processed with such PRT'S did not pose a risk for human health. The proposal from the EC to the EC Standing Committee on the Food Chain and Animal Health in 2008 to approve the imports of the poultry treated with such PRT's was rejected by the SCoFCAH in June 20087.

The US approached the DSB with the allegation that the EC measures appear to be inconsistent with the SPS Agreement [(Articles 2.2, 5.1, 5.2., 7 and 8) and Annexes B(1), B(5) And C(1), the Agriculture Agreement (Article 4.2)], GATT 1994 (articles III: 4, X:1, XI:1 and TBT Agreement Article 2,1).

Australia which has similar trade interest in using PRT's also joined as a party to this dispute (WT/DS389/2).

3.2.7. 2014 *Indonesia - Chicken Meat and Chicken Products*

In *Indonesia - Measures Concerning the Importation of Chicken Meat and Chicken Products* (WT/DS484/1 of 23 October 2014), the WTO decision making process is being used by developing countries as well. For example in the recent dispute *Indonesia – Measures Concerning The Importation Of Chicken Meat And Chicken Products*, (WT/DS484/1) Brazil raised request for consultations against Indonesia as Brazil raised the concern that certain Indonesian measures with regard to shipping and quarantine on importation of chicken meat and chicken products are 'unnecessarily constraining and discriminatory against the exports' and that they 'are not based on relevant international standards, guidelines or expectations'. Also some other regulations were alleged to be constraining the exports of chicken and chicken products. Brazil alleged that importation of chicken meat and chicken products from Brazil is subject to approval by multiple agencies and acquisition of multiple licenses. The non –automatic import licensing regime was alleged to be unjustifiably restricting trade. The administration of such non-automatic licensing regime was alleged to be inconsistent and unpredictable.

The matter is pending consultations now.

3.2.8. 2014 *Russian Federation - European Union*

In *Russian Federation – Measures on the Importation of Live Pigs, Pork and other Pig Products from the European Union* (WT/DS475/1 of 14 April 2014), the facts were that following two cases of African Swine Fever (ASF) in the south eastern part of Lithuania on 24 Jan 2014, Russia stopped accepting certain of the products at issue from the entire EU as of 27 Jan 2014. Two more cases of ASF in wild boar was reported in the eastern region of Poland on 17 and 19 Feb 2014. The emergency measures adopted by Russia comprised of temporary restriction on import of live pigs and their genetic material, pork products (which were not heat treated to at least 72 degree Centigrade for at least 3 minutes), including products from slaughter of wild boar, horn hoofed and leather, intestinal materials, bristles, feed for pigs, hunting trophies, previously used equipment for maintenance, transportation, slaughter cutting of pigs.

However when Ukraine notified cases of ASF in wild boar in Luhansk region close to Russian border, Russia restricted the import of live pigs and pork products for this region only. This decision was issued few days before the cases of ASF in Lithuania. Also, Russia accepted lifting certain import restrictions against Belarus inspite of that ASF had been identified and notified in two regions of Belarus since June 2013.

EU brought the matter before the WTO and alleged that Russia:

a) has not ensured and does not ensure that the measures are applied only to the extent necessary to protect human or animal life or health and that it does not appear necessary for Russia to restrict imports from non-affected areas of EU with respect to the products at issue.
b) has imposed measures which does not appear to be based on or confirm to the relevant international standards, guidelines or recommendation as provided in Article 3.1 and 3.2 of the SOS Agreement.
c) has not ensured that the measures are based on an assessment of the risks to human or animal life or health taking into account risk assessment techniques developed by international organisations as required under Article 5.1 of the SPS Agreement.
d) has failed to comply with the requirement of Article 5.7 of the SPS Agreement, that the measures appear to be not provisional and that Russia does with not appear to have proceeded on the basis of available pertinent information
e) has imposed measures which did not appear to be ‘based or conform to the relevant international standards, guidelines or recommendations as provided in Article 3.1 and 3.2 of the SPS Agreement
f) has imposed measures that are not consistent with Article 3.3 of the SPS Agreement as there is no scientific justification for departing form relevant standards, guidelines etc.
g) has imposed measures which are not based on assessment of the risks to human, animal life or health taking into account the risk assessment techniques developed by international organisations as required by Article 5.1
h) is relying on Article 5.7 of the SPS Agreement, Russia has failed to comply with the requirements of Article 5.7 of the SPS Agreement of the as it appears to proceed on the basis of insufficient scientific evidence, that the measures

are not provisional, that while Russia has received information for objective assessment it has not reviewed the sanitary measure accordingly.

i) in assessing the sanitary characteristics of the affected area, has failed to take into account the existence of eradication and control programs implemented in accordance with the international standards laid down by the OIE and appropriate criteria or guidelines developed by international organisations and has not met with the requirements of Article 6.1 of the SPS Agreement.

j) failed to take into account all relevant economic factors referred in Article 5.3 of the SPS Agreement including relative cost effectiveness of the alternate approaches

k) has failed to take into account the objective of minimizing trade effects as required by Article 5.4 of the SPS Agreement.

l) is applying the measures in manner that constitutes a disguised restriction on international trade and the measures do not ensure that they do not arbitrarily and unjustifiably discriminate between Members where identical and similar conditions prevail, and fails to meet with the obligations under 2.3 and 5.5. of the SPS Agreement.

Panel Report is expected by February 2016.

3.2.9. 2015 *Korea- Radionuclides*

In *Korea- Import Bans, and Testing and Certification Requirements for Radionuclides* (WT/DS495/1 of 1 June 2015), request for consultation were raised by Japan against Korea following certain Korean measures as below.

Following the accident at the Fukishima Daiichi nuclear power plant subsequent to the great East Japan earthquake of March 11, 2011, Korea adopted series of measures which ban import of certain food products from around 13 Japanese prefectures and in the event radionuclide's including cesium 134 or 137 or iodine 131 are detected in certain food products from Japan to impose additional testing and certification requirements regarding the presence of other radionuclide's. Thereafter Korea extended the scope of import ban to all fishery products caught or landed in 8 Japanese prefectures and extended the additional testing and certification requirements regarding the presence of radionuclide's other than cesium and iodine

131 to all food products from Japan that are not subject to import bans Also, Japan alleged that Korea failed to publish these measures.

Japan raised concern about the lack of transparency of the Korean measures and Japan maintained that it has reason to believe that Korea's SPS measures have the potential to and do constrain export from Japan and that these are not based on relevant international standards, guidelines or recommendations. Japan maintained that while Korea did not respond to Japan's repeated offers to hold meetings at the level of each side's technical experts, Korea finally sent a group of technical experts and representatives of consumers association to Japan and that the reports of the joint inspections sowed that the levels of radionuclide's in fishery products are significantly below applicable Japanese and Korean thresholds and that there are no more trace amounts of radionuclide's in the ocean water.

The matter is pending the outcome of the consultations.

3.2.10. 2015 *United States - Argentina*

In *United States - Measures Affecting the Importation of Animals, Meat and other Animal Products from Argentina* (WT/DS447/R of 24 July 2015), Argentina raised the issue that for over ten years United States maintained prohibition of fresh bovine meat (chilled or frozen) from Argentina as contained in the provisional and final regulations of the Animal and Plant Inspection Service without any scientific justification. Argentina stated that though Argentina is recognised as a food and mouth disease free zone by the WHO United States has maintained such prohibition. Argentina highlighted that the failure of the United States to recognize Argentina territory as FMD – free zone without vaccination lacked scientific justification and that even on the basis of the level of sanitary protection determined by the United States, the prohibition entailed a greater degree of trade restriction than is necessary to achieve the level of protection. Argentina also maintained that the United States is guilty of undue delays in the procedures under the Code of Federal Regulations regarding the recognition of the animal health status of a region or the approval of exports of animals or animal products from such region (See WT/DS447/1 of 10 March 2014).

The Panel held among other things that (See WT/DS447/R of 24 July 2015, para 8):

a) the United States did not undertake and complete the procedure to review Argentina's request for imports of chilled or frozen beef from Northern Argentina and has therefore acted inconsistently with Articles 8 and Annex C(1)(A) of the SPS Agreement.
b) that United States did not undertake and complete the procedure to review Argentina's request for recognition of Patagonia as FMD free region without undue delay and has therefore acted inconsistently with Articles 8 and Annex C(1)(A) of the SPS Agreement.
c) that United States did not seek to obtain additional information not reviewed its measures within reasonable time and that therefore such measures do not fall within the scope of Article 5.7 of the SPS Agreement.
d) that scientific evidence required review or new risk assessment which United States did not complete as of the date of establishment of the Panel and therefore that the measures are not based on risk assessment as required by Article 5.1 of the SPS Agreement.
e) that since Article 5 was violated by United States consequently the measures were also inconsistent with Article 2.2

that certain claims from Argentina were outside the terms of reference. Argentina's claim that United States breached Article 6.1, 6.2 etc. were not upheld by the Panel.

Summation- SPS

The presence of the large number of disputes before the DSB shows that nations are using the WTO mechanism to resolve their trade disputes. The analysis of the various Panel decisions brings out that the SPS Agreement and the WTO decisions has required the national measures are based on sound scientific principles and should not be without the tests of discrimination between producers within the territory and outside or between places where 'identical and similar conditions' exist. The SPS requirements as such cannot be deemed to be a violation of the right to heath of the people of such countries which has imposed such restrictions.

By now, the DSB under the WTO has rendered several decisions on the issue pertaining to WTO and health. In many of the decisions it has pointed out that the measures adopted by nations are not in accordance with the requirements under the

SPS Agreement. In the *Canada – Continued Suspension of All Obligations in the EC-Hormones Dispute* (WT/DS321/R) it was held by the Panel that the permanent ban on meat is not a measure based on risk assessment within the meaning of Article 5.1 of the SPS Agreement and that the implementation of EC on oestradiol -17β is not compatible with Article 5.2 of the SPS Agreement, which was reversed by the AB. In *Australia – Measures Affecting Importation of Salmon – Recourse to Article 21.5 by Canada* (WT/DS18/RW of 18 February 2000), the DSB held that on certain matters i.e. sanitary measures in the case of consumer ready requirements, Australia's measure violated the provisions of the SPS Agreement and Australia was required to do away with some of the restrictive measures under QP 86 A. The Panel held that such measure by Australia are not based on risk assessment and is contrary to Article 5.2 of the SPS Agreement and also Article 2.2 of the SPS agreement. It was held that the Tasmanian measure is not based on risk assessment and that the same is without sufficient scientific evidence and that the Tasmanian measures are not consistent with Article 5.1 and 2.2, of the SPS Agreement. In the *United States - Standards for Reformulated and Conventional Gasoline* (WT/DS2/R) it was held that the baseline establishment methods contained in the concerned US legislation could not be justified under paragraphs (b), (d) and (g) of Article XX of General Agreement.

The presence of such elaborate mechanisms to look into the basis behind measures by various countries can both be a reason of concern as well as a reason of respite. As with any dispute settlement process engagement into such proceeding can be consuming for the parties involved, especially for the weaker party. On the other hand, the presence of the guidelines under the SPS Agreement may rather enable proper measures to be adopted by nations than have haphazard measures and also advance the cause of health jurisprudence by facilitating measures based on scientific basis.

From the survey of the decisions it is seen that findings have been against the stronger country as well for example the decision in *United States - Standards for Reformulated and Conventional Gasoline* (WT/DS2/R). It is noticed that developing countries are also making use of the dispute resolution process for example the recent dispute *Indonesia - Measures Concerning the Importation of Chicken Meat and Chicken Products* (WT/DS484/1). While this is useful it is a significant concern how

sovereign right of nations is currently ring fenced. For example, if tomorrow, India decides to ban import of any food product that it determines to be containing harmful ingredients to the public, the same will have to be justified on the grounds of the strict scientific principles and standards.

If this is the new world order to deal with such issues, then nations – both developing and least developed will have to come out with mechanisms to deal with such scenarios. For example, alignments such as the South Centre can be entered into in the context of the SPS Agreement as well.

4. TBT Agreement

4.1. Overview

As Marceau, Gabrielle & Trachtman, Joel P., (2014: 420) note, the TBT Agreement covers all technical regulations other than those that are sanitary and phytosanitary measures as defend in the SPS Agreement. Where the SPS Agreement applies by its terms, the TBT Agreement would not be applicable and vice versa as well. Aspects or components of a specific measure could be covered by the SPS Agreement while others would be covered by TBT/GATT (Marceau, Gabrielle & Trachtman, Joel P., (2014: 421).

The TBT Agreement under the WTO follows the old TBT Agreement i.e. the Standards Code which came into force in 1980. The Standards Code was a plurilateteral Agreement to which 46 countries adhered to whereas the current TBT Agreement contains much more stringent obligations than under the Standards Code (WHO and WTO 2002: 32, para 26).

The TBT Agreement recognizes the importance of international standards and conformity assessment systems in improving efficiency of production and facilitating the conduct of international trade and seeks to encourage the development of such international standards and conformity assessment systems (Preamble to TBT Agreement). The Decision of the Committee on Principles for the Development of International Standards, Guides and Recommendations calls upon the international standardising bodies to observe certain principles in their work such as transparency,

openness, impartiality, consensus, effectiveness, relevance and coherence. International standardising bodies that meet the required criteria are considered 'international' within the meaning of the TBT Agreement (WHO and WTO 2002: 34, para 33).

The TBT Agreement seeks to ensure that technical regulations and standards, including packaging, marking and labelling requirements and procedures for assessment of conformity with technical regulations and standards do not create unnecessary obstacles to international trade (Preamble to TBT Agreement). The Agreement recognizes that countries should be able to take measures necessary to ensure the quality of its exports or for the protection of human, animal or plant life or health, environment or to prevent deceptive practices at levels it considers appropriate. However these measures should not be applied in a manner constituting arbitrary or unjustifiable discrimination between countries where same conditions prevail. The measures should not be a disguised restriction to trade and should be in conformity with the provisions of the TBT Agreement (Preamble to TBT Agreement). The TBT Agreement notes that developing countries may encounter difficulties in the formulation and application of technical regulations and standards and procedures for assessment of conformity with technical regulations and standards and seeks to assist them in their endeavours in this regard (Preamble to TBT Agreement).

The TBT Agreement requires members to ensure that in respect of technical regulations, products imported from the territory of any members should be accorded treatment no less favourable than that accorded to like products of national origin and like products originating in any other country (Article 2.1 of TBT Agreement). Further Members are required to ensure that their technical regulations are not prepared, adopted or applied with a view to or to create unnecessary obstacles to international trade. Such technical regulations should not be more trade restrictive than necessary to fulfil a legitimate objective such as national security requirements, prevention of deceptive practices, protection of human health, safety, animal or plant life or health or environment. In assessing the risks available scientific and technical information, related processing technology or intended end-uses of products are to be considered (Article 2.2 of TBT Agreement).

If requested, Members are to assist other members especially developing country members and grant them technical assistance on mutually agreed terms and conditions for the establishment of national standardizing bodies and participation in international standardization bodies and encourage their national standardizing bodies to do likewise (Article 11.2 of TBT Agreement).

The TBT agreement requires special and differential treatment to be provided to developing country members and the members are to take into account the special developmental, financial and trade needs to developing country members in the implementation of the TBT Agreement (Article 12.1 and 12.2 of the TBT Agreement). In the preparation and application of technical regulations, standards and conformity assessment procedures, Members are to take into account the special development, financial and trade needs of developing country members with a view to ensure that such technical regulations, standards and conformity procedures do not constitute unnecessary obstacles to exports from developing country members (Article 12.3 of the TBT Agreement). The TBT Agreement further notes that developing country members should not be expected to use international standards as a basis for their technical regulations or standards, including test methods which are not appropriate to their development, financial and trade needs, as developing country members adopt certain technical regulations, standards or conformity assessment procedures aimed at preserving the indigenous technology and production methods compatible with their development needs (Article 12.4 of the TBT Agreement).

The international standardizing bodies and conformity assessments systems are to be organized and operated in a way which facilitates active and representative participation of relevant bodies in all Members (Article 12.5 of the TBT Agreement). Reasonable measures are to be taken to ensure that international standardizing bodies upon the request of developing country members examine the possibility of and if practical prepare international standards concerning products of special interest to developing country Members (Article 12.6 of the TBT Agreement).

Members are to provide technical assistance to developing country members and to ensure that the preparation and application of technical regulations, standards and conformity assessment procedures do not create unnecessary obstacles to the

expansion and diversification of exports from developing country members (Article 12.7 of the TBT Agreement). During consultations the developed countries are to bear in mind the special difficulties experienced by developing country members in formulating and implementing standards, technical regulations and conformity assessment procedures and take into account the special needs of the developing country members in the form of financing, trade and development (Article 12.8 of the TBT Agreement).

The TBT Agreement recognizes that developing country members may face special problems such as institutional and infrastructural problems in the preparation and applications of the technical regulations, standards and conformity assessment procedures and that the special development and trade needs of developing country members may hinder their ability to discharge their obligations under the TBT Agreement. Accordingly, the Committee on Technical Barriers to Trade (hereinafter "TBT Committee") is enabled to grant upon request specified, time limited exceptions in whole or in part from obligations under the TBT agreement (Article 12.8 of the TBT Agreement). The TBT Committee is to examine periodically the special and differential treatment as granted to developing country members at national and international levels (Article 12.10 of the TBT Agreement).

Scientific justification under the TBT Agreement is a must only for those product regulations that claim to be based on science (Motaal, Doaa Abdel 2004: 857)

4.2. Pharma Industry Exports from India

In the pharmaceutical industry gelatin is used to make the shells of hard and soft capsules for medicines as it is highly digestible and serves as a natural protective coating for medication. Since gelatin is derived from animal hide, in the case of export to countries such as Indonesia, Malaysia, Thailand etc. the exporters are required to procure Halal certificate from the Ministry of Health, Government of India stating that the gelatin is derived from Halal animal (Saqib, Mohammed and Taneja, Nisha 2005: 28-29). In the case of export of bulk drugs to Vietnam exporters are required to be registered with the Government of Vietnam and registration is done by importers who ask for confidential information such as information on manufacturing

process, raw material mixture etc. which Indian exporters are uncomfortable in supplying (Saqib, Mohammed and Taneja, Nisha 2005: 33).

In the case of pharmaceuticals, exports to Thailand require a bio-equivalence study which takes about 6- 12 months to obtain the report and costs between Rs. 5-10 lakhs. This is inspite of that there are various laboratories in India that conduct the tests such as the National Accreditation Board for Testing and Calibration whose certificate is accepted by over 57 countries. Certain studies note that this requirement makes exports to Thailand almost impossible (Saqib, Mohammed and Taneja, Nisha 2005: 34-35).

In the case of certain pharmaceutical formulations, exports from India to Vietnam are required to have a tamper proof seal i.e. Alu Alu packaging which results in additional costs for Indian exporters (Saqib, Mohammed and Taneja, Nisha 2005: 37).

In all the above scenarios the principles of harmonisation as advocated under the SPS and TBT Agreements would help countries such as India.

4.3. TBT related WTO Case law

4.3.1. 1998 *European Communities - Asbestos*

In *European Communities – Measures Affecting Asbestos and Products Containing Asbestos* (WT/DS135/1 of 3 June 1998), Canada requested consultations with EC over the measures taken by France to prohibit asbestos and products containing asbestos. Canada raised the request under article XXII of GATT 1994, Article 11 of the SPS Agreement and Article 14 of the TBT Agreement. The French law prohibited the manufacture, processing, import, placing in the domestic market, possession or sale, offering, sale and transfer on any ground all varieties of asbestos fibres and any product containing asbestos fibres. Canada alleged that the French law infringed Articles 2, 3 and 5 of the SPS Agreement, Article 2 of the TBT Agreement, Article III, XI and XXIII of GATT 1994.

The relevant provisions of the French law Decree No. 96-1133 are as below (Article I):

"I. – For the purpose of protecting workers, […] the manufacture, processing, sale, import, placing on the domestic market and transfer under any title whatsoever of all varieties of asbestos fibres shall be prohibited, regardless of whether these substances have been incorporated into materials, products or devices.

II. – For the purpose of protecting consumers, […] the manufacture, import, domestic marketing, exportation, possession for sale, offer, sale and transfer under any title whatsoever of all varieties of asbestos fibres or product containing asbestos fibres shall be prohibited […]."

The ban imposed by Canada was to become total by January 01, 2002. Canada's challenge was on the ban of chrysotile fibre and the products containing it. Before the ban was imposed, France was importing about 20,000 to 40,000 tonnes of chrysotile type of asbestos from Canada each year which had fallen to almost zero after the imposition of the ban (WT/DS135/R of 18 September 2000, para 3.8).

Canada:

a) submitted that unlike amphibole fibres which was the most hazardous category, chrysotile fibres could be used without incurring any detectable risk and that chrysotile fibres are encapsulated in an inert matrix and are found in a limited number of products which do not pose any risk to any business, general public or the environment (WT/DS135/R of 18 September 2000, para 3.9), that the ban imposed by France was a political reaction to the anti asbestos propaganda which was imposing pressure on the French Government, than based on any sound scientific reasoning (WT/DS135/R of 18 September 2000, para 3.10) and that the United States Environment Protection Agency had in 1989 prohibited asbestos under public pressure and had in 1992 reversed its decision and acknowledged that modern products containing chrysotile in an inert matrix such as cement or resin do not pose any detectable risk.

b) submitted the right of the WTO members to take measures to protect public health must be exercised in compliance with the obligations under the various WTO agreements and that France was not entitled to make a total ban on

asbestos without making the distinction between the various types of asbestos (WT/DS135/R of 18 September 2000, para 3.12), that the total ban is irrational and disproportionate and that the scientific data with France does not justify such as radical step (WT/DS135/R of 18 September 2000, para 3.12), that the total ban was an excessive measure and submitted that other measures which were less restrictive and compatible with the various WTO obligations should have been availed by France (WT/DS135/R of 18 September 2000, para 3.12). Canada submitted that in the light of the available data there is no justification for the prohibition or reduction of the manufacturing or use of modern asbestos products (WT/DS135/R of 18 September 2000, para 3.58).

c) also submitted to the WTO Panel that more than 4000 Canadian jobs depend directly or indirectly on the chrysotile industry (WT/DS135/R of 18 September 2000, para 3.20), that by using new technology and proper work practices the harmful effects of chrysotile can be greatly reduced and that such controlled use has been implemented in a number of countries (WT/DS135/R of 18 September 2000, para 3.55) and that uncontrolled use of certain types of asbestos and certain work processes were responsible for the unacceptable emissions which resulted in health problems (WT/DS135/R of 18 September 2000, para 3.55).

d) further submitted that the French Decree is incompatible with Article 2.2 of the TBT Agreement and that the effects of the French Decree are more trade restrictive than necessary and that alternative solutions which are less prejudicial was available, such as controlled use (WT/DS135/R of 18 September 2000, para 3.284).

e) submitted that the INSERM report on which the which the French Decree was based does not stand up to scientific criticism and that the INSERM report is based on hypothetical data without factual basis, that the INSERM report was based on the data arising from exposure to amphiboles or mixed fibres than chrysotile fibers, that the report is based on exposures in the 1960'S which work practices were banned in France in the 1970's, that the report does not address the key issue of the ban i.e. exposure to chrysotile fibers, and that the

INSERM report did not recommend banning high density chrysotile fibers (WT/DS135/R of 18 September 2000, para's 3.286 and 3.332).

f) maintained that alternative solutions such as controlled use was available to protect human health and that the practice of controlled use is based on recognized scientific principles and on international consensus and that the total ban on asbestos is most trade restrictive measure from an international stand point which led to the complete closure of the domestic market for these products (WT/DS135/R of 18 September 2000, para 3.288), that the measures based on controlled use that existed in France at the time of announcement of the ban made it possible to fulfill the objective of protecting public health without creating unnecessary obstacles to trade and that the excessive effects of the ban is the result of the political desire of the French Government to respond in a spectacular fashion to the public pressure mounting on the issue (WT/DS135/R of 18 September 2000, para 3.289).

g) maintained that the French Decree is not compatible with Article 2.2 of the TBT Agreement as it does not fulfill the objective of protecting the health of workers and consumers as is pursued by the French Government, that the ban does not do anything more than controlled use which is already in place to protect health, that chrysotile fibers does not pose detectable risk for public health and that the French Decree is an excessive measure and that less trade restrictive alternative such as controlled use is already in place (WT/DS135/R of 18 September 2000, para 3.289).

j) submitted that the preamble to the TBT Agreement cannot be used to justify noncompliance with Article 2.2 and that the preamble outlines the rights and obligations under a treaty and does not confer any rights or obligations. Canada maintained that the measures must form an unjustifiable discrimination between countries where the same conditions prevail nor be a disguised restriction to trade and that the measures should comply with article 2.2 of the TBT Agreement (WT/DS135/R of 18 September 2000, para 3.310).

h) submitted that it was mentioned by the AB in *Japan – Measures affecting Agricultural Products* that the preamble and Articles 3.3 and 5.7 of the SPS Agreement refer to the precautionary principle and also that the precautionary principle cannot be used to justify a violation of any of the obligations under the SPS agreement and that this is applicable even in the context of the TBT Agreement (WT/DS135/R of 18 September 2000, para 3.310). Canada also submitted that precautionary principle cannot be invoke to attain zero risk (WT/DS135/R of 18 September 2000, para 3.310).

EC, in its submissions:

a) highlighted that asbestos caused three kinds of diseases (WT/DS135/R of 18 September 2000, para 3.66). The first being mesothelioma, which is a pleural cancer caused by the inhalation of asbestos. In this disease liquid forms between lung and thoracic cavity causing pain and breathlessness. This cancer results from occasional low intensity exposure to asbestos and there is no curative treatment for this disease. As per the figures made available by EC about 750 people died in France in 1996 because of mesothelioma. The second disease resulting from asbestos is lung cancer caused by inhalation of asbestos. Only certain forms of such cancer can be treated. The third disease is asbestosis, a form of pulmonary fibrosis which results from the accumulation of asbestos fibres in the lungs. Inflammatory reactions are caused by the presence of asbestos fibre in the pulmonary alveoli and also results in a scarring process (*European Communities – Measures Affecting Asbestos and Products Containing Asbestos*, WT/DS135/R of 18 September 2000, para 3.66). The fibrous thickening of the thin alveolar wall prevents circulation of oxygen. The disease can either stabilize or becomes progressively worse ending in the patient's death from respiratory difficulties. There is no curative treatment available. As per the submission made by EC, asbestosis result from high level of occupational exposure and there were about 150 cases of asbestosis in a year in France.

b) highlighted that there is international awareness on the harmful effect of asbestos and that both WHO and the ILO had highlighted the harmful effects of asbestos. ILO in its Convention No. 162 had recommended replacement of

asbestos by less harmful materials or technologies and the WHO since 1977 recognized the carcinogenic effects of asbestos and had in 1996 and 1998 again called for the replacement of chrysotile variety of asbestos with harmless substitutes (WT/DS135/R of 18 September 2000, para 3.69).

c) brought to the attention of the Panel that several of the European nations had introduced ban on asbestos much earlier. Iceland introduced ban in 1983 on all types of asbestos with some limited exceptions, since 1989 Switzerland had in principle prohibited the use of asbestos with limited exceptions such as lack of a identified asbestos free substitute or that use of alternative components is impossible, since 1983 New Zealand had banned the use of all types of asbestos (chrysotile, crocidolite, tremolite, actinolite, anthophyllite and amosite) in the construction of new buildings, which law was further strengthened in 1999 and that since January 1999 Czech Republic neither imported or processed any form of asbestos (WT/DS135/R of 18 September 2000, para 3.31).

d) further pointed out that since 1972 Denmark had introduced a ban on applying asbestos by spraying process and on using it for insulation and that in 1986 Denmark has placed a total ban on asbestos with limited exceptions till 1993, that in 1972 United Kingdom banned the import of crocidolite (blue asbestos), in 1975 Sweden banned the marketing and use of crocidolite and in 1986 introduced a total ban on asbestos with few exceptions, in 1991 Netherlands introduced a total ban on asbestos with limited exceptions till 1997, in 1990 Austria banned the use of chrysotile asbestos with limited exceptions, in 1990 Germany imposed a total ban on asbestos with limited exceptions, in 1992 Finland and Italy imposed a total ban on asbestos with limited exceptions till 1993 and that in 1998 Belgium imposed a total ban on asbestos with limited exceptions (WT/DS135/R of 18 September 2000, para 3.32). France had imposed the ban on asbestos in 1996 with limited exceptions.

e) submitted that it was very easy to replace asbestos with a less dangerous product and that all asbestos cement can be replaced by products which show

no sign of being carcinogenic (WT/DS135/R of 18 September 2000, para 3.46).

f) submitted that once asbestos is used for the construction of the building, much work is required in forms like plumbing, heating, electrical work and also regular servicing and maintenance work which is carried out by people who are not aware of the material that they are working on. Also, France pointed out that scientists had noted an increase in cases of mesothelioma affecting personnel who are not working in the asbestos manufacturing industry and that this brought out the seriousness of the risk faced by workers and individuals at stages other than manufacturing and installation (WT/DS135/R of 18 September 2000, para 3.59). France further submitted that the demolition and removal of asbestos involves huge expenses in form of various technical measures to be adopted to protect the workers and that no safe use reduces the risk of using asbestos (WT/DS135/R of 18 September 2000, para 3.64).

Canada:

a) asserted that the French Decree is incompatible with Article 2.1 of the TBT agreement as the said decree subjected chrysotile fibre and chrysotile cement products imported from Canada to a less favourable treatment than like PVA, cellulose, glass fibre and like fibro cement products of French or foreign origin (WT/DS135/R of 18 September 2000, para 3.266), that the substitute fibers for the chrysotile fibers can be more harmful than chrysotile and that blind faith is placed in the substitute fibers for asbestos (WT/DS135/R of 18 September 2000, para 3.283).

b) submitted that in the context of Article XX(b), all GATT Panels have held that the it was not the necessity of the objective pursued by the measure concerned that should be examined, but whether or not it was necessary to submit the imported products to the measure concerned in order to achieve the chosen level of protection; for e.g. in United States- Section 337, Thailand-Cigarettes and United States- Gasoline Panel report (WT/DS135/R of 18 September 2000, para 3.253), that France was free to choose the level of protection it deemed appropriate in order to halt the spread of the risk linked with the use

of asbestos (WT/DS135/R of 18 September 2000, para 3.353) and that under the TBT agreement, the burden of proof to prove the inconsistency with the TBT Agreement lies with the party which invokes the specific provision of the Agreement to establish the inconsistency (WT/DS135/R of 18 September 2000, para 3.353).

c) refuted the submission from Canada that the ban on asbestos is trade restrictive and submitted that the prohibition of asbestos and asbestos containing products is the sole measure available to meet the objectives of protecting public health. EC further contended that the less trade restrictive measure of controlled use supported by Canada is insufficient to halt the spread of the risk lined to the exposure to asbestos and is ineffective in halting the spread of the risk to people who are occasionally or unwittingly exposed to the asbestos (WT/DS135/R of 18 September 2000, para 3.291), that in addition to the several thousand workers involved in production and processing of asbestos, in para-occupational and domestic context, several hundreds of thousands of people are exposed to asbestos and may even be subjected to highly unacceptable levels of exposure (WT/DS135/R of 18 September 2000, para 3.293).

d) maintained that safe use cannot halt the spread of the risks linked to the exposure of asbestos and that it is impossible to implement safe use with regard to hundreds of thousands of people who are exposed to asbestos daily in their course of activity such as construction industry or millions of do-it-yourself enthusiasts, with little supervision on the health impact (WT/DS135/R of 18 September 2000, para 3.295).

e) submitted that manufacturers can carry out technical tests on the substitute products and that of the manufacturers can demonstrate that there are no substitute products, they can submit application for waiver to continue to use asbestos (WT/DS135/R of 18 September 2000, para 3.296), that the modern use of asbestos such as encapsulation is not safe as a variety of operations such as cutting, sanding, crushing sawing etc. are applied to asbestos cement in the occupational, para occupational and domestic context, during which

operations large number of carcinogenic fibres are released in the form of dust (WT/DS135/R of 18 September 2000, para 3.297).

f) EC maintained that under the TBT Agreement the burden is on the complaining party to establish a violation and that the complaining member must demonstrate the availability of a consistent or less consistent alternative measure that can be employed to achieve the level of protection deemed necessary by the defending member and that Canada has not shown that the French measure is not necessary under Article 2.2 of the TBT Agreement (WT/DS135/R of 18 September 2000, para 3.321).

4.3.1.1. Panel Decision

The Panel:

a) held that the object and purpose of a treaty can be found in its preamble and that it is important to look into the preamble of the WTO Agreement as well as the TBT Agreement (WT/DS135/R of 18 September 2000, para 8.47). After considering the preamble, the Panel noted that the TBT Agreement aims to improve market access by encouraging the use of international standards while at the same time exercising control over the development and use of standards at the national level and that the reference in the preamble to packaging, marking and labelling confirms that the object and criteria of the Agreement is the marketing of the products (WT/DS135/R of 18 September 2000, para 8.48).

b) held that the Decree providing for the general prohibition on the marketing of asbestos and asbestos containing products does not constitute a technical regulation within the definition in Annex 1.1 of the TBT Agreement (WT/DS135/R of 18 September 2000, para 8.58), that the TBT Agreement does apply to the part of the Decree relating to the exception to the ban on the imports of asbestos and asbestos containing products as the said of the Decree constitutes a technical regulation within the meaning on Annex 1.1 of the TBT Agreement (WT/DS135/R of 18 September 2000, para 3(a) and (b)).

c) concluded that chrysotile fibres and PVA, cellulose and glass fibres are in some circumstances similar on properties, nature and quality and that these products have similar end uses, though they do not have the same chemical composition or structure and that chrysotile fibres and PVA, cellulose and glass fibres are like products within the meaning of Article III:4 of GATT 1994 (WT/DS135/R of 18 September 2000, para 8.126 and 8.144) and further, that since the Decree does not place an identical ban on PVA, cellulose and glass fibres and products containing these, the Decree treats the imported chrysotile fibres and the chrysotile-cement products less favourably than the substitutes (WT/DS135/R of 18 September 2000, para 8.155). On such basis, the Panel held that the provisions of the Decree relating to prohibiting of the marketing of chrysotile fibers and chrysotile cement products violate Article III: 4 of GATT 1994 (WT/DS135/R of 18 September 2000, para 8.158).

d) held that the French Decree was necessary to achieve the public health objective and did not constitute any arbitrary or unjustifiable discrimination. Since the Panel held that there is no arbitrary or unjustified discrimination, the Panel held it unnecessary to decide whether it is a disguised restriction on international trade (WT/DS135/R of 18 September 2000, para 8.237).

e) held that the evidence before it tend to show that the handling of chrysotile-cement products constitute health risk than the opposite and accordingly that the responsible decision maker for taking public health measures may reasonably conclude that the chrysotile-cement products posed a risk because of the risk involved in the working with such products (WT/DS135/R of 18 September 2000, para 8.193).

f) concluded that there is undeniable public health risk in relation to chrysotile contained in high-density chrysotile cement products and that the risk exist even at low or intermittent exposure levels and that it can affect a broad section of the population (WT/DS135/R of 18 September 2000, para 8.203).

g) further held that after examination of the design, architecture and revealing structure of the Decree it does not lead the Panel to conclude that the Decree

has protectionist objectives (WT/DS135/R of 18 September 2000, para 8.238), that while there is the possibility that measures such as those contained in the decree may have the effect of favouring domestic substitute product manufacturers, the same is a natural consequence of prohibiting a product and does not justify the conclusion that the measure has protectionist aim. Also, the Panel held that after examination of the information available with the Panel, it does not seem that the import ban benefitted the French substitute fibre industry to the detriment of third country producers to extent to consider the Decree as a disguised restriction on international trade (WT/DS135/R of 18 September 2000, para 8.239) and that the Decree satisfies the conditions of the introductory clause on Article XX (WT/DS135/R of 18 September 2000, para 8.240).

h) noted that a primafacie case was made by EC with regard to the existence of health risk in connection with the use of chrysotile which has not been rebutted by Canada and that EC has shown that the policy of prohibiting chrysotile asbestos fell within the range of polices designed to protect human life or health. The Panel noted that the comments from independent experts also confirm such risk. The Panel therefore upheld the French Policy of prohibiting chrysotile asbestos within the ground provided in Article XX(B) of GATT 1994 (WT/DS135/R of 18 September 2000, para 8.194) and concluded that there is undeniable public health risk in relation to the chrysotile contained in high-density chrysotile cement products.

i) observed that although controlled use has been applied in some countries such as United States, Canada, France etc. its efficacy is still to be demonstrated. The Panel therefore concluded that in view of the difficulty in the application of controlled use, the official may reasonably consider that controlled use did not provide the protection that was adequate in relation to policy objectives (WT/DS135/R of 18 September 2000, para 8.209).

j) concluded that the EC has shown that controlled use if neither effective not reasonably available at least in the building sector and for DIY enthusiasts and

the controlled use does not constitute a reasonable alternative to banning chrysotile (WT/DS135/R of 18 September 2000, para 8.217).

k) noted that situations falling under Article XX justify a stricter burden of proof being applied in the context of the party invoking XXIII (b) (WT/DS135/R of 18 September 2000, para 8.282).

l) noted that in the present case, Canada has not provided a detailed explanation of why it could not reasonably expect France to adopt measures restricting the use of any asbestos product 50 and 35 years respectively (WT/DS135/R of 18 September 2000, para 8.293), that since 1977 chrysotile has been classified by WHO as a category I carcinogen and that in 1986 the ILO Convention 162 required national legislators to make provisions wherever possible for the replacement of asbestos or of certain types of asbestos or of products containing asbestos or the use of alternate technology and that these form evidence to show that regulations restricting the use of asbestos could have been anticipated. The Panel also noted that in 1990 the EC had issued Directive No. 90/394/EEC providing for replacement of asbestos (WT/DS135/R of 18 September 2000, para 8.295), that countries at the same level of social and economic development had already banned the use of chrysotile asbestos by the end of Uruguay Round (WT/DS135/R of 18 September 2000, para 8.303). In conclusion the Panel noted that Canada had not established the existence of nullification or impairment of a benefit within the meaning of Article XXIII: 1 (b) of GATT 1994 as a result of the measure in question (WT/DS135/R of 18 September 2000, para 8.304).

m) noted the report of the AB in *Japan - Alcoholic Beverages* which laid down the principle for interpreting words like ‘like products’ in the various provisions of GATT 1947, which report stated that the interpretation of the term ‘like products’ should be examined on a case-by-case basis which would allow a fair assessment in each case of the different elements that would constitute a similar product and that the criteria for determining on a case by case whether a product is similar would include the products end use in a given market, consumers tastes and habits which vary from country to

country, the products properties, nature quality etc (WT/DS135/R of 18 September 2000, para 8.112).

n) concluded that the Decree applies to chrysotile and chrysotile cement products a treatment less favourable than that which it applies to PVA, cellulose and glass fibres and products containing them within the meaning of Article III: 4 (WT/DS135/R of 18 September 2000, para 8.157)

o) concluded that the provisions of the Decree prohibiting the marketing of chrysotile fibres and chrysotile cement products violate Article III: 4 of GATT 1994 (WT/DS135/R of 18 September 2000, para 8.158).

p) noted the decision of the Panel on *United States – Gasoline* (AB and Panel Report, adopted on 20 May 1996, WT/DS2/R, in particular para.6.24.) in which the term 'necessary' was examined and it was held therein that a contracting party cannot justify a measure inconsistent with a GATT provision where an alternative measure could reasonably be expected to be employed which is not inconsistent with the other GATT provisions, Also, where a measure consistent with other GATT provisions is not reasonably available, the contracting party is required to use that measure which is reasonably available to it and which has the least degree of inconsistency with other GATT provisions (*United States – Gasoline*, AB and Panel Report, adopted on 20 May 1996, WT/DS2/R, in particular para.6.24.).

q) noted that in *Thailand – Cigarettes case* (adopted on 7 November 1990, BISD 37S/200, para.75), the Panel held that the import restrictions imposed by Thailand could be considered necessary in accordance with Article XX(b) only where there were no alternative measures consistent with the GATT or less inconsistent measures which Thailand could be expected to employ to achieve its health policy measures (WT/DS135/R of 18 September 2000, para 3.317)

r) noted that the criterion of necessity under Article 2.2 of the TBT Agreement also is based on whether the measure is more restrictive than necessary to

fulfill a legitimate objective and that Article 2.2 of the TBT Agreement echoes the test of necessity under Article XX (b) of GATT i.e. whether a less restrictive measure could be employed to fulfill the Member's objective (WT/DS135/R of 18 September 2000, para 3.317).

s) observed that the Panel in *Thailand – Cigarettes* Case (BISD 37S/200, report adopted on 7 September 1990, para.75) held that under the necessity test in Article 2.2 of the TBT Agreement, a measure will be found inconsistent if a less trade restrictive means is available to reach the same policy objective and that even when the chosen end is legitimate, the measure must not be excessive or over- reaching means to achieve a legitimate end (WT/DS135/R of 18 September 2000, para 3.329).

Thus this decision from the Panel upheld the French Decree. The Panel decision was challenged before the AB, which decided on the matter as below.

4.3.1.2. The AB Decision

The AB while deciding the appeal made by both Canada and the EC made some significant observations such as that:

a) it is undisputed that WTO Members have the right to determine the level of protection of health that they consider appropriate in a given situation (WT/DS135/AB/R of 12 March 2001, para. 168).

b) France had determined and the a panel had accepted that level of protection chosen by France was to halt the spread of asbestos related health risks and that by prohibiting all form of amphibole asbestos and by severely restricting the use of chrysotile asbestos, the measure was intended to achieve such level of health protection (WT/DS135/AB/R of 12 March 2001, para. 168).

c) it seemed perfectly legitimate for a Member to seek the halt of the spread of a highly risky product while allowing the use of a less risky product (WT/DS135/AB/R of 12 March 2001, para. 168).

d) there is no requirement under Article XX (b) of the GATT 1994 to quantify as such the risk to human life or health and that a risk may be evaluated in

quantitative or qualitative terms (WT/DS135/AB/R of 12 March 2001, para. 167).

e) France could not be reasonably expected to use alternative measure if such measure would involve continuation of the very risk which Decree seeks to halt and that such alternative measure would prevent France from achieving its chosen level of health protection. The Panel had found that the efficacy of controlled use is particularly doubtful for the building and DIY (do it yourself) enthusiasts who are the most important users of such cement based product containing chrysotile asbestos (WT/DS135/AB/R of 12 March 2001, para. 174).

The AB at the end:

a) upheld the panels finding that the EC had demonstrated a prima facie case that there was no reasonably available alternative to the prohibition inherent in the Decree (WT/DS135/AB/R of 12 March 2001, para 174)

b) reversed the Panel's finding that the TBT Agreement does not apply to the part of the Decree relating to the ban on imports of asbestos and asbestos containing products because that part does not constitute a technical regulation within the meaning of Annex 1.1 to the TBT Agreement. Instead the AB held that the measure viewed an integrated whole constitutes a technical regulation under the TBT Agreement (WT/DS135/AB/R of 12 March 2001, para 192).

c) reversed the Panel's findings that it is not appropriate to take into consideration the health risks associated with chrysotile fibres in examining likeness under Article III: 4 of GATT 1994 with PCG fibres and cement based products containing chrysotile asbestos fibres (WT/DS135/AB/R of 12 March 2001, para 192).

d) reversed the Panel's finding that cement based products containing chrysotile asbestos fibres and cement based products containing PCG fibres are like products under Article III:4 of GATT 1994 and that Canada has not satisfied

its burden of proving that cement based products are like products under Article III:4 of GATT 1994 (WT/DS135/AB/R of 12 March 2001, para 192).

e) reversed the Panel's finding that the measure is inconsistent with Article III:4 of GATT 1994 (WT/DS135/AB/R of 12 March 2001, para 192)

f) upheld the Panel's finding that the measure at issue is necessary to protect human life or health within the meaning of Article XX(b) of GATT 1994 (WT/DS135/AB/R of 12 March 2001, para 192)

g) upheld the Panel's finding that the measure may give rise to a cause of action under Article XXIII (b) of GATT 1994 (WT/DS135/AB/R of 12 March 2001, para 192).

4.3.2. 2001 *Argentina - Pharmaceutical Products*

In *Argentina – Measures affecting the Import of Pharmaceutical Products* (WT/DS233/1 of 30 May 2001), India approached the DSB alleging that the Argentina's Law/Act No. 24.766 and Decree No. 150/92, constitute unnecessary obstacles to international trade and prevent Indian pharmaceuticals from entering into the Argentinean market thus discriminating against Indian drugs *vis-à-vis* like products of other countries and of Argentina. The said laws require that before entering the Argentinean market, all drugs and other pharmaceuticals must be registered with the National Administration of Drugs, Foodstuffs and Medical Technology under the Ministry/Department of Health of Argentina.

The Decree (text ordered by Decree 177/93) contains two Annexes listing countries. In respect of Annexe-I countries, pharmaceutical products are required to be manufactured in facilities approved by the relevant governmental bodies of these countries or by the Argentinean Ministry/Department of Health and meet the National Health Authority's manufacturing and quality control requirements. In respect of Annexe-II countries, manufacturing facilities for such countries are required to be inspected and approved by the Ministry/Department of Health of Argentina before export of these pharmaceutical products into Argentina. India did not figure in either of these two Annexes. Indian alleged that this discrimination has led to total lack of market access for Indian drugs and pharmaceutical products in Argentina and that the

above Law and Decree of Argentina are in violation of Article 5.1.1 of the Agreement on TBT and violates the fundamental MFN provisions under Articles I and III of GATT 1994. The Government of India submitted that the Argentinean Law No. 24.766 and Decree No. 150/92 have also violated obligations under Article 5.2 of the Agreement on TBT thus constituting unnecessary obstacles to international trade (See WT/DS233/1 of 30 May 2001).

The matter is pending consultations as on 13 September 2015.

4.3.3. 2005 *Dominican Republic - Sale of Cigarettes*

In *Dominican Republic – Measures Affecting the Importation and Internal Sale of Cigarettes* (WT/DS302/AB/R of 25 April 2005), Honduras asked for the request for consultations followed by the request for constitution of the Panel. The issues before the Panel included, among others that the Dominican Republic imposed a "transitional surcharge for economic stabilization" amounting to 2 per cent of the c.i.f value of the imported goods. Also, the Dominican Republic imposed a foreign exchange fee on all imports which at the time of the Panel report was 10 per cent of the value of the imports at the selling exchange rate for foreign currency. Pursuant to this the Dominican Republic required tax stamps to be affixed on all cigarette packets in the territory of Dominican Republic. In the case of domestically produced cigarettes the tax stamp could be affixed during the production process before the cellophane wrapping was done on each packet. However, for imported cigarettes, the tax stamp was to be affixed after the production process and the cellophane wrapping, in the presence of tax officials (WT/DS302/R of 26 November 2004, para 4.3). The Dominican Republic contended that this was to prevent the smuggling of the cigarettes into the Dominican market.

The Dominican Republic:

a) submitted that affixation of the stamp is a requirement which is 'necessary' to secure compliance with Dominican Tax Code and to prevent smuggling of cigarettes (WT/DS302/R of 26 November 2004, para 4.88). The Dominican Republic also pointed out that there is international consensus that tax stamps are necessary to prevent cigarette smuggling and submitted that The International Conference on Illicit Tobacco Trade has identified tax stamps as

a labelling method which will constrain the distribution of the contraband (WT/DS302/R of 26 November 2004, para 4.90).

b) further pointed out that the 2003 WHO Framework Convention on Tobacco Control (hereinafter "2003 WHO Framework Convention") had also stressed the importance of marking on cigarette packets (WT/DS302/R of 26 November 2004, para 4.91 and 4.94).

c) contended that while it permitted tax stamps for alcohol to be affixed abroad, there is risk of forgery of stamps, smuggling and evasion and that the stamp requirement is 'necessary' within the meaning of Article XX (d) of GATT (WT/DS302/R, 26 November 2004, para 4.90).

d) denied that there is any discrimination which is arbitrary or unjustifiable and that the measure to be applied is clearly laid down in the text of the applicable law and does not deny basic fairness or due process (WT/DS302/R of 26 November 2004, para 4.96).

e) denied that this is a disguised restriction on international trade and highlighted that the stamp requirement is not concealed or unannounced, nor arbitrary or unjustifiable (WT/DS302/R of 26 November 2004, para 4.98).

In response, the Honduras, noted that the documents pertaining to the International Conference on Illicit Tobacco Trade is not legally binding as it is the result of the work of nongovernmental organisations (WT/DS302/R of 26 November 2004, para 4.196). With regard to the 2003 WHO Framework Convention, Honduras submitted that the 2003 WHO Framework Convention has not entered into force and the number of parties required for the 2003 WHO Framework Convention to enter into force is 40, while only 16 of the 116 contracting parties have deposited the instruments of ratification (WT/DS302/R of 26 November 2004, para 4.196). It was further pointed out by Honduras that both Dominican Republic and Honduras are not signatories to the 2003 WHO Framework Convention and that the 2003 WHO Framework

Convention is not binding on the parties to the dispute.[82] In another portion of the report it is noted that Honduras maintained that the entry into force of the Convention is not a relevant factors in the Panel's assessment of the WTO consistency of the measures at issue (WT/DS302/R of 26 November 2004, para 4.370).

Dominican Republic expressed surprise at the response from Honduras to the 2003 WHO Framework Convention and outcome document of the International Conference on Illicit Tobacco Trade that the documents were not binding in law over the parties and submitted that the intent of the submission of these documents was to bring out the problem of smuggling of tobacco products as recognized worldwide (WT/DS302/R of 26 November 2004, para 4.314). The Dominican Republic highlighted that no cigarette packet, locally produced or imported can enter the market without affixation of the stamp and since the governmental authorities control the stamps that have been sold to each trader and importer they would know how many cigarette packets have entered the market (WT/DS302/R of 26 November 2004, para 4.315).

The Panel:

a) noted that the Dominican Republic has demonstrated that the since the introduction of the stamp requirement, it contributes to securing the desired level of enforcement of tax laws and that since the introduction of the stamp requirement there is practically no cigarette smuggling, while in the case of alcoholic beverages and matchboxes where stamp are permitted to be affixed before packing, outside the Dominican Republic, smuggling is a problem (WT/DS302/R of 26 November 2004, para 4.324).

b) pointed out that the growth rate of import of cigarettes from Honduras had reached 4800 percent during the first quarter of the said year compared to the same period, the previous year, which in shows that the stamp requirement has nil impact on the import of cigarettes (WT/DS302/R of 26 November 2004, para 4.324).

[82] *Dominican Republic – Measures Affecting the Importation and Internal Sale of Cigarettes*, WT/DS302/R, 26 November 2004, para 4.196. Elsewhere in the para 4.370 of the panel report, it is noted that Honduras signed the 2003 WHO Framework Convention on June 18, 2004

c) held that Honduras has presented a prima facie case that the tax stamp requirement imposes on the importers of the cigarettes burden of performing additional steps to those performed by domestic producers of the like products and that the Dominican Republic has not shown that the additional steps required to be undertaken by the importers are avoidable or are the result of the technology used by the importers (WT/DS302/R of 26 November 2004, para 7.186).

d) further held that form an aesthetic point of view, as submitted by Honduras, the tax stamp affixation process results in the imported cigarette packets having a less smooth presentation and that other conditions being equal, the consumer may prefer the domestic product which will be more aesthetically packaged as the tax stamps in the domestic products are affixed during the production process (WT/DS302/R of 26 November 2004, para 7.194).

e) held that the tax stamp requirement though it is applied to both domestic and imported cigarettes, it modifies the conditions of competition in the marketplace to the detriment of the imported cigarettes and that the tax stamp requirement imposes additional processes and costs on the imported cigarettes and that it leads to the imported cigarettes being presented in a less appealing manner to the customers (WT/DS302/R of 26 November 2004, para 7.196).

f) held that Dominican Republic could have chosen to apply the tax stamp requirement in a different manner vis-a-vis the imported products so as to ensure that the treatment accorded to the imported cigarettes is not defacto less favourable (WT/DS302/R of 26 November 2004, para 7.197).

g) concluded that the requirement imposed by the Dominican Republic that a tax stamp be affixed to all cigarette packets in its own territory and under the supervision of the local authorities accords less favourable treatment to imported cigarettes than that which is accorded to like domestic products and is inconsistent with Article III:4 of GATT 1994 (WT/DS302/R of 26 November 2004, para 7.198).

While the Panel noted that tax stamps are a useful mechanism to monitor collection of taxes and to avoid tax evasion and also noted the submission of the parties with regard to the International Conference on Illicit Tobacco Trade document as well the 2003 WHO Framework Convention, and that the relevant documents called for monitoring and collecting data on cross border trade in cigarettes, the Panel went on to observe that both parties had agreed that these documents are not legally binding (WT/DS302/R of 26 November 2004, para 7.216 and 217). The Panel's position was that even of it is admitted that tax stamps can be generally used to monitor tax collection, the specific stamp requirement in place in Dominican Republic which require that tax stamps must be affixed under the supervision of the Dominican tax authorities will still need to be justified. The Panel's view was that the tax stamp requirement only serves to guarantee that tobacco products that have legally entered into the Dominican Republic through proper customer procedures carry authentic stamps as a proof that appropriate tax has been paid (See WT/DS302/R of 26 November 2004, para 7.226). In the view of the Panel, more security features incorporated into the tax stamps to avoid forgery, police controls on the roads and at different commercial levels such as production, interdiction into the country, distribution and sale, may play a more important role to prevent the forgery of tax stamps and the smuggling of tobacco products., than the requirement that tax stamps be affixed in the territory of Dominican Republic and in front of the government personnel (See WT/DS302/R of 26 November 2004, para 7.226).

4.3.2.1. AB report

In the appeal from the Panel report, the Dominican Republic submitted that the link between cigarette smoking and public health is well established and that the tax stamp requirements aims to prevent the smuggling of the cigarettes and also helps to ensure the health and wellbeing of its citizens (WT/DS302/AB/R of 25 April 2005, para 10). The Dominican Republic submitted that the tax stamp requirement should be accepted as a necessary enforcement instrument because of the value and importance of the interest it protects (WT/DS302/AB/R of 25 April 2005, para 10).

Honduras contested the submission from the Dominican republic and submitted that the arguments regarding human health is dealt with under Article XX(b) and not

Article XX(d) and that arguments regarding the protection of human health were not made before the Panel and that there is no undisputed evidence upon which the assertion from Dominican Republic is based (WT/DS302/AB/R of 25 April 2005, para 21). Honduras also submitted that the thrust of the tax stamp requirement is fiscal in nature and not protection of human life or health (WT/DS302/AB/R of 25 April 2005, para 22).

In the context of challenge to a measure introduced as necessary to protect public health under Article XX(b) of GATT, the AB noted that in determining whether a suggested alternative measure is reasonably available, several factors must be taken into account other than the difficulty in implementation. The Panel noted that in the context of Article XX (b) the determination of whether a WTO consistent alternative measure is reasonably available is to be determined. Also, the importance of the interest or the values pursued is important and the more vital or important the common interest of values pursued, it will be easier to accept the necessary measures designed to achieve the end (WT/DS302/AB/R of 25 April 2005, para 68).

The AB did not agree to the submissions made by the Dominican Republic and upheld the findings by the Panel.

4.3.2.2. Criticism of the Panel Decision

While the Panel noted that the International Conference on Illicit Tobacco Trade document identified tax stamp as a practice available for the purpose of labelling, the Panel seems to have proceeded based on the premise that both the International Conference on Illicit Tobacco Trade document and the 2003 WHO Framework Convention are not legally binding documents (WT/DS302/R of 26 November 2004, para 7.216). The Panel went on to make its decision purely on the basis of the provisions of the GATT Agreement and the various Panel and AB reports. Thus in this decision while the impact of the trade measure on human health was considered, at the time of the decisions, the Panel went purely by trade principles than any consideration the concerned trade measure favoured protection of human health. Also, the Republic of Honduras failed to justify its position under Article XX(b) of the GATT Agreement. While it tried to do so during the AB proceedings, it was too late

to do so, as this was position was never raised during the Panel proceedings and its introduction at the appellate stage was strongly objected to by Honduras.

4.3.4. 2010 *Armenia - Cigarettes and Alcoholic Beverages - Ukraine*

In *Armenia – Measures Affecting the Importation and Internal Sale of Cigarettes and Alcoholic Beverages* **(**WT/DS411/1 of 22 July 2010), in the request for consultations document, Ukraine alleged that Armenia applies a tax of AMD 6500 per 1000 imported cigarettes while it imposes AMD 4500 per 1000 domestic cigarettes which Ukraine in its request for consultation document before the DSB call to 'like' in nature. Ukraine alleged that imposition of a lower rate of tax on the domestic products vis. a vis. directly competitive or substitutable products from Ukraine is a protection to the domestic production and that this is in violation of Article III: &2 and Article III: 4 first sentence of GATT 1994.

Panel creation was deferred in this matter. It is likely that Armenia would have raised protection of human health as a ground, if the matter had proceeded as a dispute.

Summation -TBT

Under the TBT Agreement there are provisions to differentially treat the developing countries. Various packaging norms can be used to protect and enhance the health levels of a population, but care needs to be exercised that there is no discrimination between the domestic and foreign suppliers. For developing countries like India, the principles of harmonization and equivalence are beneficial for exports to be made to other countries, for e.g., the case of pharma exports to be made to Thailand, Vietnam etc. which was discussed above in this chapter.

However, the analysis of various WTO case decisions in the domain does not give much strength to the aspiration that health issues will receive its due before the various Panels/AB, except for the *European Communities - Measures Affecting Asbestos and Asbestos-containing Products* case. For example, in the WTO case *Dominican Republic – measures Affecting the importation and Internal Sale of Cigarettes* that the tax stamp affixation was to be done on the finished product entering Dominican Republic vis-à-vis the tax stamp affixation on unfinished product locally being manufactured in Dominican Republic, and this impacting the aesthetic

appearance of a product, led to the Panel decision being adopted against the Dominican Republic on such tax stamp affixation. Also, while the Panel noted that the International Conference on Illicit Tobacco Trade document identified tax stamp as a practice available for the purpose of labelling, the Panel proceeded based on the premise that both the International Conference on Illicit Tobacco Trade document and the 2003 WHO Framework Convention are not legally binding documents (See *Dominican Republic – Measures Affecting the Importation and Internal Sale of Cigarettes*, WT/DS302/R of 26 November 2004, para 7.216). In this decision while the impact of the trade measure on human health was considered by the Panel at the time of the decisions, however, it went purely by provisions of the GATT Agreement and the various Panel and AB reports than any consideration the concerned trade measure favoured protection of human health. Here, the rationale for such decision was strict adherence to trade law provisions, while health issues were sidelined. While in this case health protection was raised as a ground in the AB proceedings, the AB refused to entertain this ground as the same was not raised during the Panel proceedings.

All these gives ground to have the view that the WTO cannot be a forum to rely on to protect health issues.

5. GATS AGREMENT

Among the various multilateral agreements under the WTO regime, the GATS has also raised legal concerns, the actual scale of issues arising from GATS has been lesser when compared to the scale of issues which has resulted from TRIPS, SPS etc. The major concern under the GATS in the context of this thesis has the deregulation and the privatisation of the health sector.

Paul Hunt, the Special Rapporteur on the *Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health* (UN Doc.A/HRC/7/11 of 31 January 2008) examined the various facets of the right to health and noted that liberalization of trade in health services can impact the right to health in many ways including effect of increased FDI on enjoyment of the right to health wherein there is insufficient regulation to protect enjoyment of the right to health. In an environment

of increased focus on commercial objectives the same may be at the expense of social objectives and those who cannot afford the commercial rates may not get quality health services (Hunt, Paul (2003), UN Doc.E/CN.4/2003/58 of 13 February 2003, para 88).

5.1. Overview

GATS, which is Annex 1B to the WTO Agreement,[83] is in the nature of a framework agreement establishing a framework within which liberalization commitments in the area of services are to be undertaken and implemented (Das, Bhagirath Lal 1999: 325. The GATS is the first set of multilaterally agreed and legally enforceable rules and disciplines ever negotiated over international trade in services. GATS has annexes dealing with the details of the regulatory mechanism for specific areas in trade in services, such as movement of natural persons supplying services under the agreement, air transport services, financial services, etc.

As stated in the preamble to GATS, the agreement seeks to establish a multilateral framework of principles and rules for trade in services with a view to the expansion of such trade under conditions of transparency and progressive liberalization and as a means to promote the economic growth of all trading partners and the development of developing countries. Trade in services expanded at around 5.5 percent at 2014 prices and at about 7 percent in the first quarter of 2014 compared with the same period for the previous year (UNCTAD 2014:6). Trade in services reached $4.7 trillion in 2013 representing about 20 per cent of the total global export of goods and services (UNCTAD 2014:6).

The agreement contains 29 articles, which contain the basic obligations of total coverage, national treatment, most favoured nation treatment, transparency, recognition, market access, progressive liberalisation etc. This is followed by annexes addressing special conditions relating to relevant sectors and national schedules of initial liberalisation commitments. GATS permit a positive list approach in which countries list their liberalisation commitments, but retain autonomy over other sectors (UNCTAD 2014: 84).The key principles under the GATS in detail are as follows:

[83] On WTO, *see* Jackson, John H. (2000), *The Jurisprudence of GATT and the WTO: Insights on Treaty Law and Economic Relations* (Cambridge: University Press).

5.1.1. Total Coverage

The scope of the agreement will cover service in any sector except services supplied in the exercise of governmental authority (Article III(b) of GATS). Therefore GATS covers trade in health services as well.

5.1.2. National Treatment

Article XVII[84] deals with national treatment. In the sectors recorded in its schedule, and subject to any conditions indicated there, each government is to treat foreign services and service suppliers no less favourably than its own like services and service suppliers. This is the national treatment obligation. A Member will be presumed to be bound by the obligation of unrestricted national treatment in a service sector mentioned in its schedule, except if conditions and qualifications have been inscribed by the Member in its schedule (Das, Bhagirath Lal 1999: 329).

5.1.3. Most Favoured Nation

Article II[85] speaks of Most Favoured Nation Treatment. This obligation does not permit a WTO Member to discriminate among other Members and accordingly, a Member who commits to open its market cannot close its market on a selective basis to service suppliers from selective WTO Members. Hence a government cannot discriminate between services or service suppliers of other Members, but must accord to services and service suppliers of all Members treatment no less favourable than that which it accords to like services and service providers of any other Members. However, governments may indicate specific Most Favoured Nation (hereinafter "MFN") exemptions in a separate list, which will be reviewed after five years, with a normal limitation of ten years on their duration. Paragraph 2(c) of GATS permits departure from MFN treatment for developing countries and allow them to enter into regional or global arrangements with other developing countries for mutual reduction

[84] Article XVII(1) of GATS states that, "in the sectors inscribed in its Schedule, and subject to any conditions and qualifications set out therein, each Member shall accord to services and service suppliers of any other Member, in respect of all measures affecting the supply of services, treatment no less favorable than that it accords to its own like services and service suppliers."

[85] Article II(1) of GATS states: "with respect to any measure covered by this Agreement, each Member shall accord immediately and unconditionally to services and service suppliers of any other Member treatment no less favourable than that it accords to like services and service suppliers of any other country."

or elimination of tariffs and non-tariff measures for products imported between these parties (WTO 2014: 197).

The difference between the national treatment principle and the most favoured nation treatment principle is that the former requires non-discrimination between a Member's own service suppliers and foreign service suppliers while the latter requires non-discrimination among the foreign service suppliers.

The impact of national treatment and MFN clauses would be in the context of supplies to be made to the health sector as maintained and funded by the government.

5.1.4. Transparency

Article III of GATS lays down the transparency requirements which include publication of all relevant laws and regulations. Since domestic regulations in the absence of tariffs provide the most significant means of influence or control over services trade, all such measures should be administered in a reasonable, objective and impartial manner. Governments are also required to establish the means for prompt review of administrative decisions relating to supply of services. This by itself may not negatively impact health services as transparency usually seeks to prevent malicious practices.

5.1.5. Recognition

Article VII states that for the purpose of the fulfillment of standards and criteria for the authorization, licensing or certification of service suppliers, a Member may recognise the education or experience obtained, requirements met or licenses or certifications granted in a particular country. Harmonization of requirements for the purpose of securing authorizations, licences or certifications of service suppliers is encouraged. Further, the development of internationally agreed criteria on the requirements for securing authorizations is sought.

This can be beneficial for developing nations as many a time the educational qualifications provided by institutions in developing nations are not recognised by institutions in the developed nations. A method of accreditation of the qualifications can held to do away with such problems.

5.1.6. International Payments and Transfers

By virtue of Article XI, current transactions relating to specific commitments under the Agreement are not to be restricted, except in the event of balance of payment difficulties. Restrictions imposed in the event of balance of payment difficulties will be limited, temporary and subject to conditions.

This can help institutions in developing nations which are under financial problems as random restrictions cannot be imposed.

5.1.7. Market Access

Article XVI[86] deals with market access. Here a Member has to select the sector in which it makes commitments. In the sectors selected by a Member for commitments, access has to be freely granted, unless the Member has qualified its commitments with any terms, limitations and conditions. The schedule of a Member list are those sectors where it will allow any particular service to be supplied in its territory by the service suppliers of another country (Das, Bhagirath Lal 1999: 327). This clause by itself may not impact the health sector in a negative manner. However, this clause can be used to pry open the sectors where transnational capital has interest.

The GATS provides that through future negotiations progressive liberalization is to take place at five-year intervals in order to reduce or eliminate the adverse effects of measures on trade in services, and to increase the general level of specific commitments undertaken by governments. (World Trade Centre 1995: 22)

5.2.GATS and Public Health

Commercialisation of the health sector can happen through the four modalities for provision of services that is mentioned in Article 1 of the GATS Agreement (See ESCAP (2007), E/ESCAP/63/4, 28 February 2007, para 56), namely:

[86] Article XVI(1) states that, "with respect to market access through the modes of supply identified in Article I, each Member shall accord services and service suppliers of any other Member treatment no less favourable than that provided for under the terms, limitations and conditions agreed and specified in its Schedule."

(a) Mode 1: Cross-border supply;
(b) Mode 2: Consumption abroad;
(c) Mode 3: Commercial presence;
(d) Mode 4: Movement of natural persons.

Under mode 1 there is cross border supply of services. With advances in the information technology sector there is increased usage of telemedicine and similar methods of treatment (See ESCAP (2007), E/ESCAP/63/4, 28 February 2007, para 57).

In the mode 2 mechanism, services will be delivered in the territory of one member to the consumer of another member. This is made possible by the travel of consumers to the member where the services are provided. India, Malayasia, Singapore etc. has made much advance in this sector (See ESCAP (2007), E/ESCAP/63/4, 28 February 2007, para 57). There are several factors which promotes the mode 2 method of supply of services in favour of developing countries. The non-converge of certain procedures by the national health insurances schemes, increased waiting period for surgical procedures under national health schemes, increasing popularity of cosmetic surgery, high quality and state of the art medical services by the health sector in developing countries, the large difference in costs between developed and developing countries for the same procedures are some of the reasons promoting travel of patients from developed countries to developing countries (See ESCAP (2007), E/ESCAP/63/4, 28 February 2007, para 59). This also facilitates increased tourism as well as reason for upgrading quality of medical care in developing countries, primarily in the private sector. (See ESCAP (2007), E/ESCAP/63/4, 28 February 2007, para 59).

Under Mode 3, presence could be through the establishment of hospitals, management of hospitals, health insurance etc. (See ESCAP (2007), E/ESCAP/63/4, 28 February 2007, para 58). Investments by the foreign firms i.e. FDI, in the health service providers in a country is a mode 3 measure which will have an impact on the various policy decisions of these service providers which in turn will impact the right to health (WHO and WTO 2002: 48-49, para 71). A 2002 study notes that certain

pharmaceutical firms have made investments in the health service providers in Latin America as a part of their strategy (WHO and WTO 2002: 48-49, para 71).

Mode 4 involves movement of natural persons. This in the context of the health sector would be through the migration of health workers from one country to another. Doctors, nurses and other health personnel from developing countries like India move in large numbers to the developed economies such as EU, USA etc. While this benefits the developing countries through the remittances by these personnel, it also results in the depletion of quality health personnel in developing countries.

In the context of health services, a grave threat from GATS is in the nature of brain drain – both internally to foreign institutions which establish operations in India and externally with increased movement of medical and related professional from India/developing nations to the developed nations.

As an ESCAP study notes that there is considerable increase in trade in health services over the recent years (See ESCAP (2007), E/ESCAP/63/4, 28 February 2007, para 56) and therefore the impact of the GATS on the right to health needs to be carefully monitored. Simon, Lestor, Bryan, Mercurio and Arwel, Dawies (2012: 666) note that GATS has become a fairly controversial part of the WTO and that concern has been raised that the continued push for trade liberalisation in certain sectors will lead to privatisation and regulation of the sectors that are government owned which may result in negative consequences for certain segments of the society. They state that the concern appear to have some legitimacy for two reasons. First, in that there are genuine debates that need to take place as to what are the appropriate policies to pursue in terms of privatisation and deregulation and with regard to balancing trade and non-trade concerns. Second is with regard to the necessity standard and the prudential carve out. However, they conclude that when the rules are uncertain it becomes difficult for the governments to know what they can do and cannot do and this create and atmosphere which leads itself to exaggeration on the effect of GATS on domestic policy making (Simon, Lestor, Bryan, Mercurio and Arwel, Dawies 2012: 667).

At the same time, certain reports noted that GATS may help to improve on health services. The 2002 WTO WHO Report notes that trade liberalization under the WTO can bring in hospitals financed by foreign investors which will help provide services that are not previously available. It also noted that the trade liberalization provisions will enable export of doctors, nurses etc. from countries which have sufficient facility for the same such as Cuba, India, Philippines etc. (WTO WHO Report 2002: 15, para 27). The 2002 WTO WHO Report also notes that such liberalization regimes can also negatively affect the health scenario in developing countries as there could be a brain drain of health professionals from developing countries to the developed countries creating shortages of health personnel in developing countries (WTO WHO Report 2002: 15, para 28).

Article XIV (b) of the GATS Agreement is relevant in this context. It provides that nothing in the Agreement shall prevent the adoption or enforcement of measures by any member which are necessary to protect human, animal or plant life or health subject to the requirement that such measures are not applied in a manner which constitute a means of arbitrary or unjustifiable discrimination between countries where like conditions prevail or a disguised restriction on trade in services. Similarly, members may also adopt suitable measures to protect public morals or to maintain public order (Article XIV (a) of the GATS Agreement). Further, under the GATS Members can choose the services which they are to open up for trade liberalization (WHO and WTO Secretariat 2002: 48-49, para 77).

However such protective mechanisms may not be enough as is evident from the following studies.

5.2.1. Zambia Study

According to a 2006 study by DFID Zambia is one of Africa's poorest countries – with about 7 million of the 10 million population living below the national poverty line of less than $0.93 a day, and very low health indicators including one in six children dying before five years, maternal mortality of 729 per 100,000 during 2001-2, life expectancy of 39.01 years (World Health Report 2005); 16% adult HIV infection rates and child hunger (24% child malnutrition from 1996-2000 to 28% during 2001-2) (See Mabika, Aulline H and London, Leslie 2007a: 4). The study

noted that the patent systems has worked well in industrialized countries where the burden of health care on the governments and the individuals is relatively low, but that in poor countries where the burden of health care is high the patent regime has failed to provide adequate response to prevalent diseases. The study noted that the pressure of liberalizing privatizing the health services under the GATS Agreement will lead to collapse of the health delivery systems in poor countries (Mabika, Aulline H and London, Leslie 2007a: 3). The study noted that by fully liberalising the health sector the government of Zambia may not be able to continue subsidising the public health sector and that if it does so it will be in violation of the national treatment clause under the GATS under which private sector health providers will also be required to be provided with government subsidy, which according to the study would be a clear abuse of the public funds (Mabika, Aulline H and London, Leslie 2007a: 5). The study noted that in the Zambian market a particular pharmaceutical product is not being supplied or developed and thereupon if another country was to grant a compulsory license such drugs may be exported to Zambia. However Zambia would have to incorporate the doctrine of exhaustion into its law so that such import does not violate the rights of the inventor in Zambia (Mabika, Aulline H and London, Leslie 2007a: 7)

5.2.2. Malawi Study

A similar study in the context of the African nation of Malawi brought out that Malawi liberalised its health sector by indicating 'none' in the schedules for market access and national treatment for professional services, meaning which Malawi did not place any restrictions on foreign suppliers in the domestic market and committed to provide, market access to other WTO member countries without restrictions (Mabika, Aulline H and London, Leslie 2007b: 4).

This is inspite of the fact that Malawi has limited pharmaceutical manufacturing base and is dependant significantly on imports from foreign based manufacturers. The health sector in Malawi remain underfunded (Mabika, Aulline H and London, Leslie 2007b: 3). The study noted that free trade is not a guarantee for national development. The study further noted that GATS agreement fails to differentiate between services that fall under its auspices and ones that fall under the government authority and consequently should not be subject to GATS. The study noted that governments under

the international law are required to provide primary health care and free primary education to its citizens which is under threat from GATS (Mabika, Aulline H and London, Leslie 2007b: 5).

The study noted that though it is claimed that the 'right to regulate' is protected under GATS still there is an unrealistic expectation on the foresight and capacity of least developed countries such as Malawi which may not know when to make the exceptions and impose limitations. Also, since the WTO agreements by its very nature seek to reassure the foreign investors that the regulatory environment in the country will not change, this makes it difficult to reverse decisions once taken (Mabika, Aulline H and London, Leslie 2007b: 5).

5.2.3. Concerns

Neoliberalism which is also known as market fundamentalism favours reduction of the role of the state in providing social services, calls for decrease in state budgets, tight limits on public health care expenditures, deregulations of markets to enable corporate to operate freely, imposition of user fees and transfer of social services from the state to the private sector (Chapman, Audrey (2014): 124). However, s study of the health sector in middle and poor income countries does not support the claim that private sector is more efficient, effective or accountable than the public sector. As a result of the neoliberal policies the share of the government in health expenditure fell precipitously, health workers were laid off, rural-urban divide increased, public health systems in many countries deteriorated and regional disparities in access to health care widened (Chapman, Audrey (2014): 124). After many years of low public expenditure on health facilities the public health facilities become very limited and of poor quality. Audrey Chapman further notes that in Brazil the expansion of the private health sector was subsidised by the State at the expense of investments in public sector health institutions Chapman, Audrey (2014): 125).

With the increased presence of foreign participants in the domestic heath care sector of developing countries, the already limited availability of health personnel such as doctors could be adversely affected as the foreign entities would absorb the practitioners with the expertise and skill set from the public health care facilities (May 2003, "The GATS Threat to Public Health: A Joint Submission to the World Health

Assembly": 2). The 2007 ESCAP study also reflect this position (ESCAP (2007), E/ESCAP/63/4, 28 February 2007 para 59). In the opinion of some this would amount to subsidy to the foreign entities and at the same time erode the national health care facilities (May 2003), "The GATS Threat to Public Health: A Joint Submission to the World Health Assembly": 2). The study points out that as of 2003, the EU, US and many other countries have maintained the position that they are not opening up health services under the GATS Agreement and that countries should not make GATS commitments in the health care sector (May 2003), "The GATS Threat to Public Health: A Joint Submission to the World Health Assembly": 4). The ESCAP study recommends that sufficient protective polices should be adopted by the governments to ensure that the modern facilities that come in through foreign investment are made available to the poor patients and that governments should adopt suitable retention policies for the health personnel by addressing issues such as labour and wage polices (ESCAP (2007), E/ESCAP/63/4, 28 February 2007 para 60). The study notes that regional co-operation is important in this context.

The civil society has raised concerns that under the GATS Agreement domestic regulations like the one in India which prohibit marketing of breast milk substitutes and foods for babies under the age of two years in order to support breast feeding could be challenged as unnecessary (May 2003, "The GATS Threat to Public Health: A Joint Submission to the World Health Assembly": 3). Also, commitments in the financial services sector such as health insurance may also have an impact on the right to health (WHO and WTO Secretariat 2002: 48-49, para 77). In this context it is relevant to note that the international human rights law is more or less agnostic to how health care is delivered or paid for and the focus under the international human rights law is that health care provision be as per the human right obligations (See Chapman, Audrey 2014: 125).

Drager, Nick and Fiddler, David P. (2004) noted that although experts acknowledge that GATS has not significantly affected trade in health related services, the potential for GATS to do so through the progressive liberalisation process is tremendous. Certain other studies noted that observers have expressed concern about the full reach of GATS regulations and have argued that GATS effectively covers regulations as well as domestic laws, guidelines, unwritten practices, subsidies and grants, licensing

standards etc. making it applicable to all regulations and measures by governments at all levels viz. central, state, provincial, local, municipal etc. (UNCTAD 2014: 84). Also, there is ambiguity as to which non-commercial governmental services are excluded from GATS most of the services delivery in the current times being a mix of public and private involvement (UNCTAD 2014: 84). Also, there are civil society concerns that the GATS requirement that regulations must be necessary in WTO terms could expose any domestic health policy to challenge at the WTO (May 2003 "The GATS Threat to Public Health: A Joint Submission to the World Health Assembly": 3).

Also, there is the case of contract research outsourcing under which clinical trials for new medicines are outsourced to developing countries where the laws are less stringent. As per some estimates about half of the clinical rails in the worlds are now contracted out to more than 1100 contract research organisations. As a result of the lax controls that India had on this sector, there was a scenario of HPV vaccination against cervical cancer done on about 23000 girls in India under Government project in Andhra Pradesh and Gujarat, which was sponsored by the Bill and Melinda Gates Foundation. The vaccines used for this project were developed by Merck (vaccine Gardasil) and GlaxoSmithKline (vaccine Cervarix). Proper consent was not obtained from the girls who took this vaccination and the project was finally suspended after the health activist and doctors raised concerns (Terwindt, Carolijn 2014: 86). The impact of the GATS Agreement on facilitating clinical trials for multinational pharmaceutical companies in India also needs consideration. Another such example was when Pfizer tested a new drug 'Trovan' against meningitis in 1996, on young children in Nigeria where half of the group of children were administered the already proven drug Ceftriaxone while the other half was administered Trovan. The children whose health did not improve with Trovan were not switched to the other drug and as a result six of the children died with brain damage (Terwindt, Carolijn 2014: 85).

In this context it is pertinent to note the contents of the 2000 General Comment No.14 which noted that States are duty bound to adopt legislation or other measures to ensure equal access to health care and that privatization of the health sector does not constitute a threat to the availability, accessibility, acceptability and quality of health facilities, goods and services and also that States are required to control the marketing

of medical equipment and medicines by third parties. (See United Nations (2000), Economic and Social Council, E/C.12/2000/4., para 35).

Summation- GATS

Explicit promotion of commercialisation of services have the capability to undermine the availability of health care to the citizen/ consumer to the extent that increasing reliance on the private sector for provision of health care leads to the reduction of the role of the government in providing health care if governments will withdraw/further scale down their already skeletal health services. On the other hand, it is also possible that this move will create the presence of leading health care facilities of the world available to the developing/least developed country population within their own territory and thereby contribute towards bettering the health care facilities within the nation, albeit for the affluent part of their population. If there is increased presence of medical facilities in India through remote presence or actual establishment of institutions in India, this will help with the availability of treatment facilities in India. The concern for the population will be the cost associated with use of these medical facilities. The government needs to take steps to control the spiralling costs for treatment as offered by these institutions.

In the context of the Indian society it is evident that the measures adopted by the government to provide for the health care of its citizens is abysmal. It is seen that hospitals and health care facilities which are functioning overflow with large number of patients which are beyond the capacity of such institution to cater to. At the same time there are a large number of government medical institutions which are not functioning or are under equipped. That there are many facilities which come up in the private sector for medical treatment should not be ground for the government to distance itself from offering the right facilities to the common population. Therefore any measure which makes the government distance itself from its obligation to provide the necessary care to its citizens cannot be advocated. The government offers abysmal conditions of treatment through the government institutions and has left the population at the mercy of the private sector which fleece the populations without any scruples. It needs to be stated that the Government has failed in governance when it adopts such stance. Any restrictions which are placed of realisation of health care of

its citizens cannot be the way forward even if it means that commercial gains of multinational companies are not protected.

6. Relevant Principles in WTO decisions

The study of the various decisions of the DSB and the AB is helpful in bringing to our attention some of the important principles which have been relied by the DSB and AB. Some of them are as below:

6.1. Preamble to be considered

In *European Communities – Measures Affecting Asbestos and Products Containing Asbestos* (WT/DS135/R of 18 September 2000), the appellate body of the WTO held that the object and purpose of a treaty can be found in its preamble and that it is relevant to look at not only the preamble of the WTO agreement but also the concerned Multilateral Trade Agreement as well, the TBT Agreement in the instant case.[87]

6.2. Good Faith

In EC- Sardines case, the AB of the WTO held that members of the WTO need to abide by their treaty obligations in good faith and that the principle of *pacta sunt servanda* as stated in Article 26 of the Vienna Convention requires that in dispute settlement every Member of the WTO must assume good faith of every other Member. (*Canada – Continued Suspension of Obligations in the EC – Hormones Dispute*, WT/DS321/AB/R of 16 October 2008, para 314).

6.3. Period of Countermeasures

In *Canada – Continued Suspension of Obligations in the EC – Hormones Dispute* (WT/DS321/AB/R of 16 October 2008), the AB held that the relevant provisions of international law as reflected in the Article on State responsibility supports the proposition that countermeasures may continue till such time the responsible State has

[87] See *European Communities – Measures Affecting Asbestos and Products Containing Asbestos*, WT/DS135/R, 18 September 2000, para 3.310 where it was held: [8.47.We note that the object and purpose of a treaty can also be found in its preamble.[87] Applying the practice of the Appellate Body in this respect[87], it is relevant to look not only at the preamble to the WTO Agreement but also at the preamble to the TBT Agreement itself, which provides certain indications.]

ceased the wrongful act by complying with its obligations (WT/DS321/AB/R of 16 October 2008: 213, para 382).

6.4. Like Products

The like products concept which is the highlighted in many environment related disputes states that national environment polices have to treat like products similarly i.e. products which are deemed alike whether they are from foreign suppliers or from domestic supplier need to be treated at par without discrimination (WHO and WTO Secretariat 2002: 79, para 146). For e.g. in *Dominican Republic – Measures Affecting the Importation and Internal Sale of Cigarettes* (WT/DS302/R of 26 November 2004), Honduras submitted that imported cigarettes and domestic cigarettes of all brands are like products and that both imported and domestic cigarettes have the same physical properties, similar presentation, same end use, are interchangeable for consumers and that they are classified under the same tariff heading (*Dominican Republic – Measures Affecting the Importation and Internal Sale of Cigarettes*,WT/DS302/R of 26 November 2004, para 4.28). Honduras quoted the report of the GATT Working Party Report in Boarder Tax Adjustments[88] and the AB Report in *European Communities - Measures Affecting Asbestos and Asbestos-containing Products*, (WT/DS135/AB/R of 12 March 2001, para. 101-103) in support of arriving at these criteria.

6.5. 'No Less Favourable'

As per the decision of the Panel in *United States – Section 337 of the Tariff Act of 1930*, these words in the context of GATT is an 'expression of the underlying principle of equality of treatment of imported products as compared to the treatment given to the other foreign products under the most favoured nation standard, or to domestic products under the national treatment standard of Article III of GATT' (*United States – Section 337 of the Tariff Act of 1930*, adopted on 7 November 1989, BISD 36S/345, para.5.11).

[88] *Report of the GATT Working Party on Border Tax Adjustments*, adopted on 2 December 1970, BISD 18S/97, L/3464, para. 18.

6.6. 'Necessary' to Protect Public Health

In the context of challenge to a measure introduced as necessary to protect public health under Article XX(b) of GATT, the AB noted that in determining whether a suggested alternative measure is reasonably available, several factors must be taken into account other than the difficulty in implementation. The Panel relied on the decision of the AB in *Korea – Various Measures on Beef* (paras. 166 and 163) and noted that in the context of Article XX (b) the determination of whether a WTO consistent alternative measure is reasonably available is to be determined. Also, the importance of the interest or the values pursued is important and the more vital or important the common interest of values pursued, it will be easier to accept the necessary measures designed to achieve the end (*Dominican Republic – Measures Affecting the Importation and Internal Sale of Cigarettes*, WT/DS302/AB/R of 25 April 2005, para 68).

In *European Communities – Measures Affecting Asbestos and Products Containing Asbestos*, WT/DS135/R of 18 September 2000) the Panel noted the decision of the Panel on United States – Gasoline (*United States – Gasoline*, AB and Panel Report, adopted on 20 May 1996, WT/DS2/R, in particular para.6.24.) in which the term 'necessary' was examined and it was held therein that a contracting party cannot justify a measure inconsistent with a GATT provision where an alternative measure could reasonably be expected to be employed which is not inconsistent with the other GATT provisions, Also, where a measure consistent with other GATT provisions is not reasonably available, the contracting party is required to use that measure which is reasonably available to it and which has the least degree of inconsistency with other GATT provisions (See *European Communities – Measures Affecting Asbestos and Products Containing Asbestos*, WT/DS135/R of 18 September 2000, para 3.316).

In *European Communities – Measures Affecting Asbestos and Products Containing Asbestos*, WT/DS135/R of 18 September 2000), the Panel also noted that in *Thailand – Cigarettes case* (adopted on 7 November 1990, BISD 37S/200, para.75), the Panel held that the import restrictions imposed by Thailand could be considered necessary in accordance with Article XX(b) only where there were no alternative measures consistent with the GATT or less inconsistent measures which Thailand could be expected to employ to achieve its health policy measures (See *European Communities*

– *Measures Affecting Asbestos and Products Containing Asbestos*, WT/DS135/R of 18 September 2000, para 3.317).

The EC Panel noted in the EC case that the term 'necessary' is interpreted as that where an alternative measure which can reasonably be expected to be employed and which is not inconsistent with the GATT provisions is available to a party then such party cannot justify a measure inconsistent with a GATT provisions as necessary in terms of Article XX(d) (See *European Communities – Measures Affecting Asbestos and Products Containing Asbestos*, WT/DS135/R of 18 September 2000, para 3.316). The EC Panel also noted that the Panel in the Thailand Cigarettes case adopted the same reasoning and had refused to consider the import restrictions imposed by Thailand as necessary, since such restrictions could be imposed only if there were no alternative measures consistent or less inconsistent with the GATT (See *European Communities – Measures Affecting Asbestos and Products Containing Asbestos*, WT/DS135/R of 18 September 2000, para 3.317).

6.7. Disguised Restriction on International Trade

The Panel in *Asbestos case*, held that under the GATT 1947, panels considered that disguised restriction on international trade was a restriction that had not been taken in the form of a trade measure or which has not been announced before hand or which formed the subject of a publication, or had not even been the subject of an investigation (*European Communities – Measures Affecting Asbestos and Products Containing Asbestos*, WT/DS135/R of 18 September 2000, para 233). The Panel noted that in the *United States- Gasoline* case the AB had held that disguised restriction may properly be read as embracing restrictions amounting to arbitrary or unjustifiable discrimination in international a trade taken under the guise of a measure which formally falls within the exceptions of Article XX (*European Communities – Measures Affecting Asbestos and Products Containing Asbestos*, WT/DS135/R of 18 September 2000, para 235).

Chapter Summation

The summary of the case laws as discussed above are as below:

Table 12: Table of Cases- GATT, TBT and SPS

GATT 1994

	Case	**Gist of the decision**
1	*Brazil – Measures Affecting Imports of Retreated Tyres* (WT/DS332/AB/R of 3 December 2007)	AB upheld the Panel decision that import ban can be considered to be necessary within the meaning of Article XX(B) and is thus provisionally justified under that provision.

SPS

	Case	**Gist of the decision**
1	*United States – Standards for Reformulated and Conventional Gasoline* (WT/DS2/R of 29 January 1996)	The AB held that the baseline establishment methods contained in the concerned US legislation could not be justified under paragraphs (b), (d) and (g) of Article XX of GATT 1994
2	*Australia- Measures Affecting Importation of Salmon* (WT/DS18/AB/R of 20 October 1998)	AB held that on certain matters Australia's QP 86 A violated the provisions of SPS Agreement.
3	*Australia – Measures Affecting Importation of Salmon - Recourse to Article 21.5 by Canada* (WT/DS18/RW of 18 February 2000)	Panel held that the 1999 IRA met the required level of objectivity and that Article 5.7 of the SPS Agreement allowed Members to take provisional sanitary measures when relevant scientific measures is insufficient or pending search for additional information necessary for objective assessment of risk
4	*EC Measures Concerning Meat*	The AB held that the EC by adopting

	and Meat Products (Hormones), WTO Document WT/DS26/AB/R of WT/DS48/AB/R of 16 Jan 1998)	arbitrary or unjustifiable distinction in the level of sanitary protection it considers to be appropriate in different situations result in discrimination or disguised restriction on international trade and had acted inconsistently with Article 5.5 of the SPS Agreement and by maintaining sanitary measures which are not based on existing international standards without justification under Article 3.3 of the SPS Agreement had acted inconsistently with the requirements of Article 3.1 of the SPS Agreement
5	*Canada – Continued Suspension of Obligations in the EC – Hormones Dispute* (WT/DS321/R of 21 March 2008)	The Panel held that by maintaining sanitary measures that are not based on risk assessment, EC had acted inconsistently with Article 5.1 of SPS Agreement. AB held that no risk assessment which reasonably supported import prohibitions was furnished to the Panel and that the EC import ban was not based on risk assessment under Article 5.1 of SPS Agreement.
		Panel decided that the SCVPH Opinions do not constitute a risk assessment as they do not satisfy the definition of risk assessment contained in Annex A(4) second sentence and that permanent ban on meat and meat products treated with oestradiol -17β for growth promoting

		purposes is not a measure based on risk assessment within the meaning of Article 5.1 of SPS Agreement.
6	*European Communities – Certain Measures Affecting Poultry Meat and Poultry Meat Products from the United States* (WT/DS389/4 of 16 January 2009)	United States raised request for consultation with the European Communities with regard to certain EC measures affecting poultry and poultry meat products from the United States, wherein EC prohibited import of poultry treated with substances other than water, unless such other substance is approved by EC. As on 23 September 2015, Panel has been established in this matter.
7	*Indonesia - Measures Concerning the Importation of Chicken Meat and Chicken Products* (WT/DS484/1 of 23 October 2014)	The matter is pending consultations now
8	*Russian Federation – Measures on the Importation of Live Pigs, Pork and other Pig Products from the European Union* (WT/DS475/1 of 14 April 2014)	EU alleged that Russia is applying the measures in manner that constitutes a disguised restriction on international trade and the measures do not ensure that they do not arbitrarily and unjustifiably discriminate between Members where identical and similar conditions prevail. Panel Report is awaited by Feb 2016.
9	*Korea- Import Bans, and Testing and Certification Requirements for Radionuclides* (WT/DS495/1 of 1 June 2015)	Request for consultations raised by Japan against the Korean measures against food products from Japan in the wake the accident at the nuclear plant due to the earthquake in 2011. The matter is pending consultations now.
10	*United States - Measures*	Panel held that United States had

	Affecting the Importation of Animals, Meat and other Animal Products from Argentina **(**WT/DS447/1 of 24 July 2015)	breached with Articles 8, Annex C(1)(A), Article 5.7 of the SPS Agreement.

TBT

	Case	**Gist of the decision**
1	*European Communities – Measures Affecting Asbestos and Products Containing Asbestos Panel Decision (*WT/DS135/1 of 3 June 1998)	Panel concluded that the Decree applies to Chrysotile and chrysotile cement products a treatment less favourable than that which it applies to PVA, cellulose and glass fibers and products containing them and that the provisions of the Decree prohibiting the marketing of chrysotile fibers and cement products violate Article III: 4 of GATT 1994. However it also concluded that such provisions of the Decree are justified under Article XX(b)
2	*Argentina – Measures affecting the Import of Pharmaceutical Products* (WT/DS233/1 of 30 May 2001)	The matter is pending consultations.
3	*Dominican Republic – Measures Affecting the Importation and Internal Sale of Cigarettes* (WT/DS302/AB/R of 25 April 2005	Panel concluded that the requirement imposed by the Dominican Republic that a tax stamp be affixed to all cigarette packets in its own territory and under supervision of the local authorities accords less favourable treatment to imported cigarettes than which is accorded to like domestic products

		AB upheld the findings by the Panel
4	*Armenia – Measures Affecting the Importation and Internal Sale of Cigarettes and Alcoholic Beverages* (WT/DS411/1 of 22 July 2010)	Panel creation was deferred

From the above cases and its outcome, it is clear that arbitrary imposition of restrictions to trade is not feasible in this era of WTO. WTO as a forum is evolving with many relevant principles in its jurisprudence such as 'good faith' in performing treaty obligations, 'necessary' for a measures etc. This is well so as trade restrictive measures have been imposed by nations under the multilateral agreements under the GATT 1994 and export restrictions impact the balance sheet of nations and are dealt with under the SPS Agreement and the TBT Agreements.

The SPS and the TBT agreement as seen from the study above are not by themselves trade restrictive. When countries adopt food safety standards that are not more stringent than codex standards and have mechanisms to monitor the compliance among the food producers and exports on these standards, such food safety standards are considered to be consistent with SPS provisions (WHO and WTO Secretariat 2002: 65, para 111).

Where international standards do not exist, Members may adopt higher levels of health protection to the extent they are scientifically justified (WHO and WTO Secretariat 2002: 35, para 35). Members are allowed to take provisional measures when relevant scientific measures are insufficient or pending search for additional information necessary for objective assessment of risk (*Australia – measures Affecting Importation of Salmon – Recourse to Article 21.5 by Canada* (WT/DS18/RW of 18 February 2000). Also, a WTO Member may adopt SPS measures based on divergent or minority views so long as these views were from qualified and respected sources (*Canada- Continued Suspension of Obligations in the EC-Hormones Dispute* (WT/DS321/AB/R of 16 October 2008, para 591)). The AB in

Canada- Continued Suspension of Obligations in the EC-Hormones Dispute (WT/DS321/AB/R of 16 October 2008, para 591) accordingly reversed the finding of the Panel that the import ban imposed by EC relating to oestradiol-17β is not based on a risk assessment as required under Article 5.1 of the SPS Agreement, but the AB was unable to complete the analysis and therefore made no findings on the consistency or inconsistency of the measure with Article 5.1 of the SPS Agreement.

In *Australia – measures Affecting Importation of Salmon – Recourse to Article 21.5 by Canada* (WT/DS18/RW of 18 February 2000) while the Panel held that by requiring only consumer ready salmon product be imported into Australia and released from quarantines, Australia is maintaining sanitary measures that are more trade restrictive than what is required to achieve Australian appropriate level of protection (WT/DS18/RW of 18 February 2000, para 8.1 (v)). The Tasmanian measures were held to be not based on risk assessment as required under the SPS Agreement and therefore to be inconsistent with Article 5.1 and 2.2 of the SPS Agreement (WT/DS18/RW of 18 February 2000, para 8.1 (vii)).

There have been multiple cases before the DSB and the AB where protective measures from nations have been challenged as violative of the provisions of GATT 1994 such as the decision of the Panel in *Brazil – Measures Affecting Imports of Retreaded Tyres* (WT/DS332/AB/R) where the GATT Article XX and the *European Communities – Measures Affecting Asbestos and Products Containing Asbestos* (WT/DS135/1; G/SPS/GEN/72; G/TBT/D/15; 3 June 1998) case. In the Asbestos case the dispute settlement system under the WTO upheld the individual's right to health and upheld the measure, whereas in the retreaded Tyres case the DSB did little to advance the cause of the right to health. From the review of the various Panel and DSB reports, it can be seen that these reports have primarily a trade perspective than a public health perspective, for example *Dominican Republic – Measures Affecting the Importation and Internal Sale of Cigarettes* (See WT/DS302/AB/R of 25 April 2005), *Brazil – Measures Affecting Imports of Retreated Tyres* (See WT/DS332/AB/R), *Canada – Continued Suspension of Obligations in the EC – Hormones Dispute* (See WT/DS321/R of 21 March 2008) etc.

Developing nations have taken the benefit of the provisions of the SPS and TBT Agreements for e.g., India sought to take advantage of the TBT requirements in *Argentina – Measures Affecting the Import of Pharmaceutical Products* (WT/DS233/1 of 30 May 2001). Further, the developing countries are approaching the DSB against measures adopted in other developing countries, for. e.g. *Indonesia – Measures Concerning the Importation of Chicken Meat and Chicken Products* (WT/DS484/1) of 23 October 2014), where Brazil approached the DSB against the measures adopted by Indonesia. The challenge before the developing and least developing nations would be to be participants with proper understanding of the procedures and requirements under these agreements. Common initiatives to deal with the new regime may be an answer for developing and least developed nations. Even where decisions are given in favour of the developing nations, whether the developing and least developed nations will have the wherewithal to counteract the effect of the restrictive trade measures taken by stronger nations is a critical issue and has its basis in the efficacy of the dispute settlement process under the WTO. As Babu, Rajesh R. (2012: 457) mentions that though the WTO system professes to be rule based, it is still a power based system as when a developing country is authorised to take counter measures, it may not do so because of the significant economic effect on such nation taking the counter measure. The enforcement of remedies in the WTO is left to the injured member and consequently countries that are economically and politically weak are at a disadvantage in the WTO system and that inspite of being a rule oriented system compliance with WTO rulings stills depends on power relationships for enforcement (Babu, Rajesh R. 2012: 457).

On the whole, while the DSB provides a forum to agitate on trade and health issues, from a right to health perspective, the dispute settlement system under the WTO being a trade dispute settlement system may do little to specifically advance the cause of the right to health. All efforts need to be exercised by the international law community to ensure that decisions from WTO DSB should in no way water down the health law jurisprudence under international law.

In the context of GATS Agreement, the agreement by itself is not banal, but the impact of widespread privatization of health care by pursuing the neoliberal approach is that governments will take a back seat in the matter of providing health care and

related facilities. This is the situation which needs to be avoided. It is widely seen that the expenses associated with treatment in private facilities is exorbitantly high making the same unaffordable for the general population. Outsourcing of the health care obligations of the government to the private sector should never be the case, although private sector can work hand in hand with the governments to deliver health care to the population. As noted above, there have been concerns from the civil society that opening the health sector to globalisation under the GATS will open the domestic health polices of nations to challenge on the basis of WTO norms. For example whether the national treatment requirements will require the subsidy provided to government institutions to be provided to private sector as well, which will significantly increase the financial burden on the governments. Such scenarios should be resisted and dealt with adequately so that the health law jurisprudence is not impacted. There are flexibilities under the GATS Agreement such as Article XIV (b) of the GATS Agreement which permits measures necessary to protect human, animal or plant life or health, Article XIV (a) of the GATS Agreement which permit measures to protect public morals or to maintain public order etc. As under the GATS Agreement there is provision for members to choose the services they are to open up for trade liberalization, such rights need to be properly exercised, while the reality is that there may be developing or least developed nations which does not have the needed wherewithal to ensure such success.

CHAPTER 7

CONCLUSIONS

The preceding chapters reveals that two regimes addressed i.e. the WTO regime and the human rights regime represent two different streams with potential to conflict. While there are significant concerns raised on the impact of the TRIPS and TRIPS plus agreements, primarily due to the strong patent regime, the proponents of the patent regime have argued that respect for IPRs is very important to successfully grow the business environment of any country (See Nair, Manu S. 2012: 499). At the same time from a right to health perspective affordability of the medicines is important. Studies reveal that pharmaceutical industry is a highly profitable industry (United Nations 1996: 315) and a stronger IP regime would benefit them when they can prevent generic manufacturers from producing the medicines over which they hold patent rights. The civil society and the governments of several developing nations have voiced significant concern that this will negatively impact the right to life of the citizens who could not afford the medicines any longer as the patent holder in the absence of competition will sell the medicines at much higher prices. Research reveals that transnational pharmaceutical industry is the greatest beneficiary of the patents regime (Chimni, B.S. 1993: 236). In case of pandemics such as H5N1, broad patent claims by corporates over entire genes and gene sequences may impede research on further medicines and vaccines and also create patent thickets which are confusing mess of patent claims which will prevent research on such areas. Pharma industry can even impact the working of inter-governmental institutions such as the WHO, as they make large financial contributions to the working of the WHO (Gopakumar K.M. 2015b).

Requirements for scientific standards as stated in the SPS and the TBT Agreements prevent arbitrary measures and at the same time expose developing countries to high standards in the manufacturing process. The GATS agreement introduces commercialisation in the health sector in such a scale that affordable and quality health care for the common man will be impacted. After the elaborate examination of these issues through the various chapters above, the following are the conclusions and recommendations of the study:

1) As detailed in Chapter 2 the right to health is very well entrenched under international law through a variety of international instruments such as the WHO Constitution, UDHR, ICESCR, Indigenous and Tribal Peoples Convention, 1989, Convention on the Rights of Child, 1989, ADHR, 1961 European Social Charter, a number of United Nations General Assembly resolutions (See GA Res (2011)), Resolutions of the Economic and Social Council etc. As identified by various international instruments, access to medicines is an integral component of the right to health. The General Assembly in GA Res (2011) affirmed in its preamble that 'access to medicines is one of the fundamental elements in achieving progressively, the full realization of the right of every one to the enjoyment of the highest attainable standard of physical and mental health and that it is the responsibility of States' to ensure access for all to medicines without discrimination and in particular medicines that are affordable, safe, effective and of good quality. The Report of the Special Rapporteur of the United Nations in 2011 (Grover, Anand (2011), UN Doc. A/HRC/17/43 of 16 March 2011) concluded that access to medicines is an integral and fundamental part of the right to health and that the international community as a whole has a responsibility to provide access to medicines to all. The UNDP (2010) Report noted that right to access essential medicines is a part of the right to everyone to the enjoyment of the highest attainable standard of physical and mental health (UNDP 2010: 3). Considering such findings among many other international instruments, it can be safely inferred that the right to health is a right from which no derogation is permissible and that access to medicines forms part of this obligation.

2) The world community has held at various times that there is no conflict between the right to health and IPRs under international law and that instead what is required is the presence of adequate legal mechanism to ensure that accessibility and affordability to medicines is ensured.[89] However, the very fact that there are various intergovernmental initiatives intended to improve the access to medicines is a confirmation of the fact that there is conflict between the right to health and

[89] See WHO 2008, WHA61.21,24, para 20, discussed in Chapter 2

the TRIPS Agreements and the TRIPS plus agreements. As discussed in Chapter 3, that patents can have substantial effect on competitions and prices as well (Carlos Correa Carlos 2007a: 10). There is no doubt of this fact, in view of the medicinal pricing observed in the compulsory licensing cases in India and Thailand as discussed in chapter 4 and 5 respectively. The Special Rapporteur on the Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health identified IPRs as the most significant obstacle to access to essential medicines (Grover, Anand (2011), UN Doc. A/HRC/17/43 of 16 March 2011: 8, para 25). He went to the extent of noting that the TRIPS Agreement is an impediment to the access of medicines (Grover, Anand (2011), UN Doc. A/HRC/17/43 of 16 March 2011: 4). Further, the Special Rapporteur in the Field of Cultural Rights in her final conclusions in the 2012 report recommended that States should guard against promoting the privatisation of knowledge to an extent that it deprives individuals of opportunities to take part in cultural life and to enjoy the fruits of scientific progress. (United Nations A/HRC/20/26 of 14 May 2012:21, para 74(o)). Also, WHO in 2011 noted that patents posed the largest barrier for the least developed countries to produce medicines even in the field of HIV/AIDS, pandemic flu etc. (WHO 2011: 8). From the literature reviewed it can be said that there is definitely a conflict between the provisions of the trade law regime and the human rights regime. As E., Asif (2013) notes, the patent regime cannot be sealed off from the public policy concerns such as health and the State has the difficult task of balancing the conflicting and competing concerns of patent rights with social value, public rights and fundamental rights (E., Asif 2013: 243).

3) As discussed in Chapter 2, the Special Rapporteur identified that in 2001 the prices of antiretrovirals used for the treatment of HIV dropped from $15000 to $400 per patients per year due to the availability of cheaper generic medicines from developing countries (Report of the Special Rapporteur on Right to Health, 16 March 2011, A/HRC/17/43: 8, para 25). The MDG Gap Task Force Report (2012) noted that the prices of essential medicines tend to be multiples of international reference prices and that as a result obtaining essential medicines remains prohibitive for low income households. In many cases several family members suffer from the illness at the same time and in such scenario treatment

with even the lowest priced generic medicines becomes impossible for several low income households (MDG Gap Task Force Report 2012: xvi). That being the case the impact of the WTO on the right to health is a reality. In fact, this is so real, that the drug companies like Merck Sharp & Dohme, Medtronic, Roche, Eisai, Dr. Reddy's Laboratories are now proposing EMI schemes for medication for diseases such as Hepatitis C, to protect their key products from compulsory licensing and price controls (Rajagopal, Divya 2015: 8).

4) The WTO and its multilateral instruments is a reality and inspite of obligations being imposed on nations through legal instruments such as the TRIPS, it will not be possible for nations to not participate in such international trade instruments such as the TRIPS as the international trade mechanism will compel nations to participate. The world is today moving from a sovereign state system to a global system of governance presided over by an emerging global State (Chimni, B.S. 2007: 201). Such participation, wilful or not, creates opportunities for nations as well as challenges. In such backdrop, given the strong establishment of the IPRs regime in the international arena, it may not be practical to go back on the patent law enforcement. What needs to be done is to ensure that the provisions of the WTO Agreements and the TRIPS plus Agreements do not undermine the human rights regime. When individual economic interest collide with societal interest with regard to health, food, information etc. a proper balancing is to be done where maximum happiness of the maximum number can be achieved. As the concluding line in the *Trade and Development Report 2014* (UNCTAD 2014: 107) states, developing countries need to maintain a flexible system of IP protection.

5) International patent instruments, should be subject to human rights impact assessments (United Nations 2015 A/70/279: 22, para 95). The WTO bodies should take account of human rights standards and obligations and review the rules that have negative impact on the realisation of human rights (United Nations 2015 A/70/279: 22, para 96) and States should be required to complete human rights assessment of their domestic law and policy (United Nations 2015 A/70/279: 22, para 97).

6) Even developed countries have concern on the medicinal pricing and have evolved mechanisms to deal with excessive pricing of medicines by patent holders and even former patent holders. As discussed in Chapter 5 elaborate provisions were included in the 1985 Canada *Patents Act* that if the PMPRB finds that a patentee of an invention pertaining to a medicines or a medicine, itself is selling the medicines in any market in Canada at a price which is excessive, then the PMPRB may direct the patentee to cause the maximum price to be reduced to such level as the PMPRB considers to be not excessive. Similar provisions apply to a former patentee who has sold the medicines in any market in Canada at a price which is excessive. In the United States the 1983 *Orphan Drug Act* seeks to encourage research and development of those drugs which may not derive significant commercial benefit to the concerned sponsor. The 2010 *Patient Protection and Affordable Care Act* was enacted in the United States to streamline the health insurance sector and to improve access to health care. It is also heartening that the 1985 Canada *Patents Act* has elaborate provisions for permitting to manufacture medicines for international humanitarian purposes to address the public health problems of developing and least developed country members especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics. Further, even developed countries are exposed to threats of various TRIPS plus provisions, as evident from the recent arbitration proceeding *Eli Lilly and Company* vs. *Government of Canada* (UNCT/1/2) where the pharmaceutical company Eli Lilly has taken the Government of Canada to arbitration under the North American Free Trade Agreement. As discussed in Chapter 6, in this proceeding Eli Lilly and Company attempts to relitigate two Federal Court Proceedings in Canada with regard to patents on atomoxetine and olanzapine which were invalidated under Canadian law (See Counter memorial of Government of Canada: 1, para 1).

7) Countries should use the flexibilities provided under the WTO regime. Article XX(b) of GATT 1994 permits contracting parties to adopt measures necessary to protect human, animal or plant life or health to the extent such measures are not arbitrary or unjustifiable discrimination between countries or disguised restriction on trade. Article 27(2) of TRIPS Agreement enables members to exclude from patentability invention, the prevention within their territory of the commercial

exploitation of that which is necessary to protect public order and morality including to protect human, animal or plant life or health. Also, there is exemption under 27(3) under which members may exclude from patentability diagnostic, therapeutic and surgical methods necessary for the treatment of humans and animals. Such measures can go a long way in protecting the interests of the developing countries. Adoption of other measures such as parallel imports, competition policies etc. in addition to price controls, compulsory licensing (Michalopoulos, Constantine 2001: 150), sui generis regime under Article 27.3 (b) for protection of plant varieties etc. are some other options available and were discussed in Chapter 3 and 4 above. Even the *Trade and Development Report from UNCTAD* (2014: 107) concludes that it may be advisable for developing countries to maintain a flexible system of IPR protection and that they should be provided with appropriate technical support to make full use of the flexibilities to facilitate support to technology adopted and innovation at all stages of structural transformation.

8) Creation of necessary domestic law provisions in line with the flexibilities mention above will be one way forward for the nations to deal with the complex requirement to balance health rights and WTO obligations. This is permissible under TRIPS and under the 30 August 2003 Decision. The domestic laws of developing and least developed countries need to have provisions to protect health and to authorise the governments to take necessary action where the implementation of the trade/patent obligations impinge on the right to health. Some of such provisions as discussed in Chapters 3 and 4, in summary are as below:

(8) (i) Price control mechanisms are provided by the provisions of Canadian law, South African law, Indian law, Namibian law, Columbian law etc. to control the price of medicines. The market for sale of the medicines being very vast, companies with profit focus will not be able to forgo the opportunity even if certain restrictions such as these are put in place. While they may contest such provisions, they still will not be able to stop from venturing into the area and doing the necessary research to come out with new combinations, molecules, medicines etc. From a review of the legal provisions of several nations in

Chapter 5, it is clear that developing countries have attempted to take benefit from such provisions. There will however be concerns on the efficiency of functioning of such methodologies.

(8) (ii) Compulsory licensing provisions should be adopted by nations wherever required, for e.g. Kenya, Namibia, Egypt, India, Thailand etc. all have compulsory licensing provisions. Interestingly, compulsory licensing provisions have been looked at even by developed countries as a solution for bringing down the cost of pricing, for e.g. the United States and Canada in the context of the anthrax scare which resulted in three deaths in the United States and none in Canada, in 2001 (Joseph 2011: 224). As noted in chapter 5 compulsory licensing may result in significant cost savings for example the cost of drug clopidogrel used for heart medication came down in Thailand from US $ 2.00 to US $ 0.028 per tablet when compulsory license was issued, which represented a saving of 98%. It is seen that when five or more competitors enter a market then price of the product reduces dramatically[90]. However, as noted in chapter 4 there have been instances of the patent holders challenging the issue of compulsory licenses such as the challenge by Bayer Corporation of the compulsory license provided to Natco Pharma for the palliative drug Sorafenb Tosylate, which was sold under the name Nexavar for patients suffering from Renal Cell Carcinoma and Hepato Cellular- Carcinoma, at a cost of Rs.2,80,428/- in a month by Bayer Corporation, while Natco Pharma was ready to manufacture and sell the same at Rs.10,000/- per month. The challenge against compulsory licensing made by Natco failed before the IPAB as well as the Delhi High Court. This instance reminds us that the proper awareness on the compulsory licensing process to the government as well judiciary, along with good drafting of the compulsory licensing provisions can help facilitate needful use of the process and also prevent abuse of the process of the court. Further, the process of compulsory licenses is currently dependent on Government action. Wherever Government action is required, there will be delays of action or in many cases inaction, inspite of acute problems on the ground. Further, the generic pharma companies many a time are not keen on

[90] Yale Law School, "Compulsory Licensing by Thailand" ([Online: web] Accessed 12 June 2015, URL: http://www.law.yale.edu/images/ISP/A2KGA_Proceedings.pdf

compulsory license route because of the invariable protracted litigation with patent holders, loss of further business opportunities with the concerned patent holder, them being natural candidates for joint ventures, partnerships etc. Therefore compulsory licensing route itself has limitations. Options other than compulsory licenses also have to be explored and also the process of issuing compulsory license need to be kept simple.

(8) (iii) Health emergency, national security (Egypt), non-working (Egypt, Argentina etc.), contrary to public order or morality or would not protect human, animal or plant life or health (Cambodia) are all grounds adopted by nations for working exceptions to patent rights. The developing nations need to ensure that all such ground are adequately exploited to ensure the affordable access to medicines in their populations.

(8) (iv) Innovative legal provisions such as in South Africa where pharmacists are required to inform all members of the public who visit the pharmacy with a prescription the benefits of branded medicines with interchangeable medicine, is very much the need of the hour. As noted in the chapter 5, in South Africa, the pharmacist is required to dispense an interchangeable multisource medicine instead of the medicine prescribed by the medical practitioner, dentist etc. unless expressly forbidden by the patient from doing so.

(8) (v) Methodologies to reduce the scope of patenting such as formulations, combinations, dosage, slats, ethers and esters, polymorphs, Markush claims, selection patents, analogue process, enantiomer, metabolite/prodrug, methods of treatment, firsts and second indications etc. (See Carlos Correa 2007a: 15-32) as discussed in Chapter 3 above, are some areas which developing countries can focus to reduce the scope of patentability and thereby increasing access to medicines.

9) Countries should not agree to TRIPS plus provisions in bilateral and regional trade agreements. Many countries while negotiating bilateral agreements may end up agreeing to stronger provisions than what is required under the TRIPS Agreement. These can for example include longer patent term, limiting the

grounds for issuing compulsory licenses, restrictions on the use of clinical test data on pharmaceutical products, limiting the grounds on which patents may be revoked, looser criteria for patentability, restrictions on parallel imports etc.. The recent TPPA incorporates TRIPS plus provisions such as patents for new uses of a known product, new methods of using a known product, new processes of using a known product (Article 18.37.2 of TPPA), patent extension for unreasonable delays in a Party's issuance of patents, adjusting the term to compensate for such delays (TPPA, Article 18.46.1) etc.. Similarly, the CAFTA has several TRIPS plus provisions such as patent extensions, protection of test data, linkages between drug approval and patent protection wherein marketing approval is denied to generic version of a product where a patent is in place etc.. The developing countries party to the CAFTA have to agree to such terms. In the case of Costa Rica the CAFTA was ratified in 2007 after a referendum (Pusceddu, Piergiuseppe 2014: 108), where such TRIPS plus terms was agreed to by Costa Rica, though certain flexibilities such as compulsory licenses where a patent has not been worked, for secondary patents, to prevent anticompetitive practices, protection of public interest etc. were retained (Pusceddu, Piergiuseppe 2014: 109). Such commitments over and above the TRIPS Agreement, by developing and least developed countries are better avoided, while entering into bilateral or other mechanisms. Many a time such additional commitments over and above the TRIPS obligations are undertaken with the expectation that this will have a further positive impact on trade and investment, which is not supported by evidence. Chimni, B.S. (1993: 238) notes that there is no empirical evidence which showed correlation between strong system of protection and decisions to make investments. This remains true even today. Further, while the WTO is built on the notion that trade stimulates peace, policy makers are not really sure on how the volume of trade affects the human rights conditions of citizens in all scenarios for e.g., in conflict zones (See Aaronson, Susan Ariel, Abouharb, M.Rodwan 2013: 1091). Aaronson and Abouharb go on to note that more trade may not be better for some human rights (2013: 1116). At the same time, it is interesting to note that the corporates advocating the strong IP regime may not receive such economic benefit from extension of patent term in developing and least developing nations. Sarah (2011) notes a 2006 World Bank study (World Development Report 2006) which indicate that the extension of patent protection

for drugs in developing countries by 20 years equates only to a two week extension for patents in the developed nations, in terms of profits, and that compulsory licensing, deep discounts etc. in the developing world does not threaten pharmaceutical R&D (Joseph, Sarah 2011: 214). In fact, in the case of successful products, the R&D costs of successful pharmaceutical products may be easily recouped within several months of the product being marketed where such product has patent benefit and also there is no clear relation between longer patent rights and increment in FDI or transfer of technology (Pusceddu, Piergiuseppe 2014: 107). That being case blind folded approach towards patent extensions etc. with the expectation to increase in trade should be avoided.

10) Governments need to take progressive steps to ensure that the right to health is adequately made available to the citizens. For example, while the Government of India may have taken some steps to improve the health scenario of the population, at the same time there are steps which are retrograde as well. The 2012 decision by the Government of India to provide 348 essential drugs as per NLEM free of cost medicines from NLEM, which has been done away with in 2015 and that the state governments have been made responsible for such actions is such a retrograde step. At the time when governments should be focusing on providing access to NLEM and to expand the scope of NLEM, this decision of the Government of India to do away the scheme of free provisions of such medicines is incorrect, especially with the budgetary allocation for such measures being in small numbers. Instead, the Governments should be adding on to such welfare schemes. Also, Governments should exempt the amount that is spent for purchase of medicines from taxation so that prices for medicines, treatment comes down, even if this means that the revenue that comes to the government reduces.

11) In India, the actual measures on the ground adopted by the government to provide for the health care of its citizens is abysmal. It is seen that hospitals and health care facilities are functioning with large number of patients which are beyond the capacity of such institution to cater to. At the same time there are a large number of government medical institutions which are not functioning or are under equipped. Currently it is seen that the government offers abysmal

conditions of treatment through the government institutions and has left the population at the mercy of the private sector which fleeces the population without any scruples. The common man is at risk due to the cost associated with use of medical facilities whenever they fall sick. The government should take steps to control the spiralling costs for treatment as offered by private institutions. That there are facilities which come up in the private sector for medical treatment should not be ground for the government to distance itself from offering the right facilities to the common population. It needs to be stated that the Government has failed in governance when it adopts such stance.

12) In India, there have been multiple case laws some of which advance the cause of affordable access to medicines. Some of these decisions have been in favour of steps which reduces the costs of the medicines such as the decision in *Bayer Corporation* vs. *Natco Pharma* (Compulsory License Application 1 of 2011) in which decisions favouring the population was arrived at all stages from before the Controller of Patents to the Supreme Court. At the same time some decisions such as the *exparte* decision granted by Justice Manmohan Singh in *F. Hoffman-La Roche Ltd., Switzerland and OSI Pharmaceuticals, Inc., New York* vs. *Cipla Ltd., Mumbai Central, Mumbai* (MANU/DE/4182/2012) and in *Roche Products (India) Pvt. Ltd.* vs. *Drugs Controller General of India and Others* (CS(OS) No.355/2014 before the Delhi High Court), both discussed in chapter 4, has been unmindful of the actual impact of such decision on the lives of many people. There is important need to sensitise the judiciary as well as the government to act on an even footing when it comes to medicinal pricing and health issues. The observation by the Bombay High Court in *Bayer Corporation* vs. *Union of India* (OA/35/2012/PT/MUM) as below, which has been discussed in Chapter 4 above is heartening in this context:

> Thus, an inherent objective in the grant of patent is the obligation of the patent holder to utilise the invention to meet the needs of the society. The invented product is not to be kept in the attic but is to be available to Society for use and also to form the basis for further research and development. ... It is in the above context that Sir Isac Newton has said "I have been able to see further than others is because I stood on the shoulders of giants"…

13) In India, the 2002 *Pharmaceutical Policy*, 2011 *National Health Research Policy*, 2005-06 *Report of the Standing Committee on Chemicals and Fertilisers*,

2005 *Report of the Task Force to Explore Options Other than Price Control for Achieving the Objective of Making Life-Saving Drug at Reasonable Prices*, *Indian Open Source Drug Discovery Initiative* are all various documents and initiatives to advance the cause of the right to health through access to medicines. India being a leader among the developing nations, has made such leading initiatives which other developing or least developed countries can emulate and use to advance the cause of the right to health of the citizens in their own countries.

14) Efforts similar to identifying list of essential medicines and regulating their pricing need to be extended to medicinal devices as well. There are gaps in the legal structure that is in place even in the case of countries with strong legal systems such as India. For example while there is substantial legislation and awareness in India on medicinal pricing etc., prices of medicinal devices such as 'stents' to be inserted in the heart case of heart blockages etc. are inadequately regulated and this exposes the population to a serious risk of non-access.

15) While the right to health is firmly entrenched in several international instruments and even if there are various exceptions to the patent provisions, the poverty of the people who are the ones impacted by lack of access to essential medicines, on the ground nullifies the recognition of the right in legal instruments. Efforts needs to be continued and pursued at national and international levels to improve the economic conditions of the citizens which in turn will help increase the purchasing power in the hands of the citizens. As per WHO, while health is a justiciable right in many countries, a legal entitlement to care and pre conditions of health remains a distant dream for many (Yamin, Alicia Ely 2014: 8). Available data reveals that the availability of medicines such as antiretroviral therapy for HIV related treatment has improved due to the various initiatives by about 18 percent in low and middle income countries in 2010 (MDG Gap Task Force Report 2012: 64). However, pricing of medicines continue to be very high. For e.g. A 2012 study states that in Burkina Faso, the lowest paid government worker would need to set aside 5.7 days of wage income per month to purchase lowest priced generics in the private sector and 17.1 days when needing to buy originator brands ((MDG Gap Task Force Report 2012: 64)). In Congo, the

situation is even worse where the low-income family would need half a month's salary of one family member to pay for even lowest price medicines for an adult with hypertension and a child with asthma (MDG Gap Task Force Report 2012: 64). In such scenario, in addition to the price control mechanisms, the spend from government in the health sector needs to improve in developing countries. For example as per the data provided by WHO, in 2012, spend as a percentage of GDP in health sector was 17.9% by United States, 9.4% by United Kingdom, 8.5% by Argentina, 9.3% by Brazil, 1.4% in Myanmar, 5.4% in Cambodia, 5% in Egypt, while it was 4.1 % by India.[91] As noted by the OHCHR, States have obligation to prevent third parties from interfering with the right to health (See United Nations 2008b: 26). Accordingly, States need to take all steps to ensure that there is no interference in the matter of enjoyment of the right to health by third parties such as private players who hold monopoly patents rights. Various declarations of the United Nations General Assembly such as the 1975 *Declaration on the Use of Scientific and Technological Progress in the Interests of Peace and for the Benefit of Mankind* (GA Res. (1975), 3384(XXX)), the 2011 resolution on *The Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health* (GA Res 2011, A/HRC/17/L.16), and 1974 *Declaration on the Establishment of a New International Economic Order* (GA Res. (1974), 3201 (S-VI)) all emphasised on the need to give access to developing countries to achievements of modern science and technology. It is important that efforts to protect private property through the TRIPS Agreement and the TRIPS plus agreements do not undermine this.

16) It is not necessary that the steps taken to ensure affordable access to medicines should necessarily be of detriment to the pharmaceutical companies which invest in research resulting in development and production of medicines. Granslandt Mattias, Maskus, Keither E and Wong, Elina V. (2001), suggested innovative means such as creation of a global fund which will purchase the license for critical medicines to be made available to developing countries in need, with the governments of such nations also making a part payment as per their ability to afford. Partly such suggestions have been implemented by the non-governmental

[91] http://www.who.int/countries/en/, Accessed: 02 February 2015

action such as pricing agreement between MPP and F. Hoffmann-La Roche Ltd. for supply of *valganciclovor* medicines for the treatment of HIV- related cytomegalobirus infections (CMV) in developing and least developed countries, Agreement between ViiV healthcare UK Limited (ViiV) and the MPF for license from ViiV to grant sub licenses to various third parties to promote access to paediatric formulations of antiretroviral drugs in a number of low and middle income countries etc. However at the international level at a governmental level such action is yet to take place.

17) Initiatives at the nongovernmental level such as license agreements from manufacturers by Medicines Patents Pool Foundation for fixed pricing for civil society uses, in developing and least developed countries is useful. These license agreements enable manufacture of the critical drugs for civil society uses in developing and least developed countries. This is useful and effective approach and more such efforts need to be pursued.

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18) Some scholars recommend the formation of a global treaty to establish financial flows for research and development in a robust and sufficient manner, with norms to make decision on research and development investment based on health needs etc. (Agitha, T.G., 2013: 591). This makes sense in the context on the fact that private sector investments are focused on profits and therefore the investments will be done by the private sector where the concerned medicines will be able to generate large revenues. For example, costs in the range of 500 million US$ to 1 billion US $ in the US is quoted as the cost involved in the development of new medicines in US (Nair, Manu S. 2012: 497). Consequently, it is a known fact that many diseases which affected the developing nations have received little attention. For e.g. till the Ebola virus became a threat to the developed world, the said disease was neglected though it is of terrible virulence and consequence. Similar is the case with Zika virus now. Such scenario can change only with focused approach to ensure funding and focus on research geared to ensure the right to health of all.

19) On the various RTA's, PTA's, FTA's, IIT's etc., there is concern raised that the language repeated in multiple RTA's may lead to emergence of norms of on

customary international law, if such oft repeated and stated language is to be considered as instant customary international law (Hsu, Locknie (2006: 533). In the WTO Ministerial Conferences also, various countries raised their concern with regard to the growing number of RTA's almost substituting rather than complementing the existing multilateral trading system (See Chairman's Concluding Statement, WTO Document WT/MIN (11)/11 of 17 December 2011: 5). That being a dangerous position to be in, it is all the more important that signing on 'templates' of RTA's, PTA's, FTA's, bilateral treaties etc. should be avoided by developing and least developed countries. As Farley, Christine Haight (2014: 109) notes, it is not IP laws with high levels of protection that investors seek, but the confidence that there will be predictable answers to key legal questions. Consulting the domestic law has now become only the first of many steps that is taken to discern as to what IP standards exist. By successively increasing the complexity of IP standards, the TRIPS plus standards contained in FTA's and BITs makes a host nations legal framework unknowable and highly unpredictable (Farley, Christine Haight 2014: 109). As Kleimann, David (2014) observes, the various intraregional economic integration activity in ASEAN has created a high degree of complexity than legal clarity, certainty and predictability for business (Kleimann, David 2014: 630). In such scenario, as the Trade and Development Report from UNCTAD (2014: 107) mentions, developing countries should maintain a principle of single undertaking than moving toward mandatory commitments supplemented by plurilateral agreements made by only some members, as sufficient flexibilities in policy making is required for nations.

20) Restrictions to international trade through non-tariff barrier as discussed in Chapter 6 above, is in the domain of the SPS and TBT Agreements. Three cardinal principles that are stated in the SPS Agreement as discussed already are, 'non-discrimination', 'harmonization' and 'equivalence'. The SPS Agreement permits the Members to introduce and maintain sanitary or phytosanitary measures which result in a higher level of sanitary or phytosanitary protection than those based on relevant international standards, guidelines or recommendations if there is scientific justification for such measures (See Article 3(3) of the SPS Agreement). The AB in *EC Measures Concerning Meat and Meat Products (Hormones)*, (WTO Document WT/DS26/AB/R, WT/DS48/AB/R

of 16 Jan 1998) considered this provision and held that Article 3.1 cannot be read as requiring Members to harmonize their SPS measures with international standards or to vest such international standards, guidelines and recommendations as having obligatory force and effect. Importantly, the AB held that it cannot be assumed that the sovereign states intended to assume upon themselves the more onerous obligation by mandating conformity or compliance with such standards, guidelines or recommendation and to sustain such an assumption would warrant a far reaching interpretation of treaty language which is far more specific and compelling than that found in Article 3 of the SPS Agreement (WTO Document WT/DS26/AB/R, WT/DS48/AB/R of 16 Jan 1998, para 165).

21) However, an analysis of various WTO case decisions in the domain does not give much strength to the aspiration that health issues will receive its due before the various panels/AB. The DSB of the WTO provide only limited opportunity to protect the life and health of the individual and cannot be relied upon as a forum to improve the cause of the right to health, the same being a trade dispute settlement forum. Certain decisions of the DSB upheld the validity and importance of health related provisions for e.g. the *European Communities – Measures Affecting Asbestos and Products Containing Asbestos* (WT/DS135/AB/R of 12 March 2001). These definitely forward the cause of health related jurisprudence. However, there are multiple instances where the WTO refused to uphold health related measures adopted by governments, when trade law provisions were not complied with fully, for e.g., *Brazil – Measures Affecting Imports of Retreaded Tyres* (WT/DS332/AB/R of 3 December 2007), the Panel Report in Beef Hormones case - *Canada- Continued Suspension of Obligations in the EC-Hormones Dispute* (WT/DS321/R of 21 March 2008) which was reversed in the AB etc. The *Brazil – Measures Affecting Imports of Retreaded Tyres* (WT/DS332/AB/R of 3 December 2007) was an important case where import restrictions were placed on used tyres for public health considerations. In this dispute before the DSB public health objectives were highlighted. However the Panel did not appreciate the public health requirements and did not uphold the Brazilian measures. The matter was however favourably decided on public health considerations before the AB. The failure of the

measure before the Panel on technical grounds inspite of significant public health impact gives the perspective that the dispute resolution forum is inherently a trade forum where public health considerations may not receive its due. This is affirmed from a review of the other WTO decisions as well on such matters.

22) a) In *EC Measures Concerning Meat and Meat Products (Hormones)*, (WT/DS26/R, WT/DS48/R of 13 February 1998) and in *Canada- Continued Suspension of Obligations in the EC-Hormones Dispute* (WT/DS321/R of 21 March 2008, para 9.1) the Panel had held that the EC had acted inconsistently with Article 5.1 of the SPS Agreement and that the EC had adopted arbitrary and unjustifiable distinctions in the levels of sanitary protection which had resulted in disguised restriction on international trade. The Panel had held the SCVPH opinions did not constitute a risk assessment as they did not satisfy the definition of risk assessment under Annex A(4) second sentence of the SPS Agreement and the scientific evidence referred in the opinions did not support the conclusions therein (WT/DS321/R of 21 March 2008, para 511). The Panel report, clearly, did not have a right to health approach. The AB in its report however held that a WTO Member may adopt an SPS measures based on divergent or minority views so long as they views from qualified and respected sources, that EC's rights to due process were infringed when the Panel inappropriately relied on the testimonies of certain experts in the course of its determination on the risk assessment by EC on oestradiol -17β and that SPS Agreement does not require compliance with risk assessment techniques developed by international organisations in so far as such techniques are taken into account by the risk assessor which was done by EC in preparing the SCVPH opinions (WT/DS321/AB/R of 16 October 2008, para 503) etc. The AB reversed the finding of the Panel that the EC ban on oestradiol -17β is not based on a risk assessment within the meaning of Article 5.1 of the SPS Agreement (WT/DS321/AB/R of 16 October 2008, para 619 and para 736 (b) (vi)). Also, the AB reversed the finding of the Panel that the provisional import ban relating to testosterone, progesterone, trenbolone acetate, zeranol and MGA does not meet the requirements of Article 5.7 of the SPS Agreement (WT/DS321/AB/R of 16 October 2008, para 736 (b) (vi)).

b) The AB while it reversed some of the Panel observations, still did not contribute to health law jurisprudence. In the face of the argument by EC that precautionary principle is customary international law, the AB noted that precautionary principle at least outside the field of international environmental law still awaits authoritative formulation (WT/DS26/AB/R, WT/DS48/AB/R of 16 Jan 1998, para 123). This clearly showed the reluctance of the trade forum to gives precedence to health concerns over trade concerns.

23) In the WTO case *Dominican Republic – Measures Affecting the Importation and Internal Sale of Cigarettes* that the tax stamp affixation was to be done on the finished product entering Dominican Republic vis-à-vis the tax stamp affixation on unfinished product locally being manufactured in Dominican Republic, and this impacting the aesthetic appearance of a product, led to the Panel decision being adopted against the Dominican Republic on such tax stamp affixation. Here, therefore the rationale for such decision was purely trade law provisions, while health issues were sidelined in view of strict adherence to trade law provisions. While in this case health protection was raised as a ground in the AB proceedings, the AB refused to entertain this ground as the same was not raised during the Panel proceedings. This further gives ground to the view that the WTO cannot be a forum to rely on to protect health issues, though *European Communities – Measures Affecting Asbestos and Products Containing Asbestos* (WT/DS135/AB/R of 12 March 2001) was a significant decision where measures adopted for health protection was upheld. The silver lining here is that, if there were no avenues earlier to impress the importance of health related provisions through international adjudication mechanisms, today the presence of the forum such as the WTO dispute settlement process does provide a venue for highlighting and also upholding the health related issues though, the WTO being a trade forum it is not inherently geared to address health issues.

24) There are instances when developing nations has taken the benefit of the provisions of the SPS and TBT Agreements. India sought to take advantage of the TBT requirements in *Argentina – Measures Affecting the Import of Pharmaceutical Products* (WT/DS233/1 of 30 May 2001) as the Argentinean Decree 11/93 required that pharma products be manufactured in facilities

approved by the governmental bodies of countries listed in Annex I of the decree, or in the case of certain other countries as listed in Annex II of the decree, in facilities inspected and approved by the Ministry of Health in Argentina. India was not mentioned in both these Annexes. However, from a review of the case WTO DSB decisions, what evolves is that the ability of nations to take steps while it is still available under the SPS Agreement is extremely open for international scrutiny and litigation. For e.g. the multiple cases in which EC was brought to the DSB in the hormones cases - *Canada- Continued Suspension of Obligations in the EC-Hormones Dispute* (WT/DS321/R of 21 March 2008), *European Communities – Certain Measures Affecting Poultry Meat and Poultry Meat Products from the United States* (WT/DS389/4 of 16 January 2009) etc. For a developing country it would not be possible to enter into protracted litigation with countries such as Canada and US as it happened in the EC Hormones case.

25) In the context of GATS Agreement, the impact of widespread privatization of health care by pursuing the neoliberal approach is that governments are likely to take a back seat in the matter of providing health care and related facilities. As the 2000 General Comment No.14 noted, States are duty bound to adopt legislation or other measures to ensure equal access to health care and that privatization of the health sector does not constitute a threat to the availability, accessibility, acceptability and quality of health facilities, goods and services and also that States are required to control the marketing of medical equipment and medicines by third parties. (See United Nations (2000), Economic and Social Council, E/C.12/2000/4., para 35). Also, the need for the private sector to be mindful of human rights obligations, which is brought out through the UN Global Compact, Report of the Special Rapporteurs etc. (discussed in Chapter 2 above)[92] reminds us that commercialisation of the health sector without regulation is not envisaged under international law. Outsourcing of the health care obligations of the government to the private sector should never be the case, while private

[92] The *Human Rights Guidelines for Pharmaceutical Companies in relation to Access to Medicines* called upon companies to respect the letter and spirit of the Doha Declaration on TRIPS Agreement and Public Health and not to impede the implementation of the provisions of the Doha Declaration such as compulsory licenses for exports to countries without manufacturing capacity (See United Nations (2008a), A/63/263 of 11 August 2008, article 28).

sector can work hand in hand with the governments to deliver health care to the population. Flexibilities under the GATS Agreement, such as Article XIV (b) which permits measures necessary to protect human, animal or plant life or health, Article XIV (a) of the GATS Agreement which permit measures to protect public morals or to maintain public order etc., provision for members to choose the services they are to open up for trade liberalization, need to be properly exercised.

26) The study of the various decisions of the DSB and the AB does bring out that the WTO DSB and AB as a forum is evolving with many relevant principles in its jurisprudence such as 'good faith' for performing treaty obligations, 'necessary' in the matter of measures etc., but as already noted, the forum cannot be relied upon to improve the cause of the right to health, the same being a trade dispute settlement forum. To ensure that human rights issues are not ignored in its reports or adversely considered, the WTO may consider inclusion of subject experts in its panels constituted for decision making under the DSB, considering that the impact of the decisions of the WTO DSB on nations involved is significant. The inclusion of subject matter expert on human rights may help in having decisions which consider all aspects including human rights and may go a long way to ensure that the WTO decisions do not water down the health law jurisprudence under international law. This is critical as at the multilateral level, there are decisions of the WTO which significantly impact the right to health. This is all the more important as an important function of the WTO dispute settlement system is to "to clarify the existing provisions of [covered] agreements in accordance with customary rules of interpretation of public international law" (DSU, Article 3.2). This has also been reaffirmed by the decisions from the DSB such as the panel report on the dispute *India – EU: Patent Protection for Pharmaceutical and Agricultural Chemical Products* (WT/DS79/R 24, para 5.4).

27) On justiciability of the right to health in international law, that the right to health of the citizen is impacted adversely may not be a matter which can be brought before the forums of public international law such as the International Court of Justice as the individual or various nongovernmental organisations will not have the standing to appear before the ICJ. In the WHO case (1996, ICJ Reports) even

intergovernmental organisations such as the WHO was held not to the *locus standi* to bring matters to the ICJ. Therefore any such matter will have to be taken up by the States and lot will depend on whether such States and the State against which it wants to bring such issue has given such jurisdiction to the ICJ. For a proper realization of human rights, courts while deciding cases pertaining to the issue of protection of human rights *vis-s-vis trade* law principles need to adopt a natural law approach than a positivist approach, to ensure that the relevant human rights can be correctly realized. This however, has not been the case in some of the DSB decisions. For e.g. the decision of the Panel in *Canada – Patent Protection of Pharmaceutical Products* (DS114 of 17 March 2000), while it upheld regulatory review exceptions and considered Article 27 and also exceptions under Article 30 of TRIPS Agreement, still the Panel did not uphold the provision in Canada's law to enable stockpiling of generic medicines during the patent term.

28) In international law, on the jurisprudential front, though there is no single body which can override the decisions of other international bodies, under public international law where human rights have attained the status of customary international law then such customary international law prevails. The repeated and unwavering exposition made by the international community that the right to health is a fundamental right in various human rights instruments discussed above (such (United Nations (2000), Economic and Social Council, E/C.12/2000/4., para 1)) etc. all lend credence to the argument that the right to health is customary international law. From a human rights perspective, it has even been argued that the right to health is also *jus cogens* from which no derogation is feasible. *Jus Cogens* norms constitute the inner core of customary international law from which no derogation is permitted (Joseph 2011: 47). Therefore if there are provisions in any of the trade law instruments that conflict with the right to health the same need to be considered void.

29) Law emerges in public health as a tool to be used where appropriate to promote and protect public health goals (Dorairaj, Prabhakaran 2009: 200). The regulation of public and individual behaviour becomes necessary where there is imminent danger to public health (Dorairaj, Prabhakaran 2009: 201). Earlier

under the human rights jurisprudence if there was advancement of the right to health, now in the changed context of the WTO agreement the movement is not progressive alone. Rather there are two conflicting interests which are competing for space and precedence. Norms of international law may interact in two ways i.e. they may accumulate or conflict (Pauwelyn, Joost 2003). Where the norms do not conflict they necessarily accumulate and where they conflict they do not accumulate. Only when two norms can be applied together without contradictions can they be said to accumulate (Pauwelyn, Joost 2003: 161). Where there is contradiction as in the case of health rights and the WTO regime, all steps need to be undertaken by the international community to ensure that the individual's rights are protected against State and non-State actors. If there are steps taken by the State that violate individual's rights, even if it is due to WTO obligations, then international human rights law need to provide protection to the individual. International human rights law is unable to deliver on its promise today as global economy is controlled by states and social forces that do not take human suffering and human rights seriously, particularly the economic, social and cultural rights (Chimni, B.S. 2007: 206-207). While initially human rights as concept was to be used by the State to protect the citizens, but later it evolved to protecting the individual even against the State, which protection need to be real today. There is urgent need today that the primacy of international human rights law over economic laws should be recognised. In this the WTO as a forum does not do sufficient justice to health rights.

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APPENDIX 1

HUMAN RIGHTS GUIDELINES FOR PHARMACEUTICAL COMPANIES IN RELATION TO ACCESS TO MEDICINES[*]

Preamble

a. Almost two billion people lack access to essential medicines; improving access to existing medicines could save ten million lives each year, four million of them in Africa and South-East Asia.

b. Millennium Development Goals, such as reducing child mortality, improving maternal health, and combating HIV/AIDS, malaria and other diseases, depend upon improving access to medicines.

c. One of the Millennium Development Goal targets is, "in cooperation with pharmaceutical companies, (to) provide access to affordable essential drugs in developing countries."

d. Medical care and access to medicines are vital features of the right to the highest attainable standard of health.

e. Access to medicines depends upon effective, integrated, responsive and accessible health systems. In many countries, health systems are failing and collapsing, constituting a grave obstacle to increasing access to medicines. While a range of actors can take immediate steps to increase access to medicines, health systems must be strengthened as a matter of priority and urgency.

f. States have the primary responsibility for realising the right to the highest attainable standard of health and increasing access to medicines.

g. In addition to States, numerous national and international actors share a responsibility to increase access to medicines.

h. As confirmed by the United Nations Global Compact, the Special Representative of the Secretary General on Human Rights and Transnational Corporations and Other Business Enterprises, the Committee on Economic, Social and Cultural Rights, the Business Leaders Initiative on Human Rights, and many others, the private business sector has human rights responsibilities.

i. Pharmaceutical companies, including innovator, generic and biotechnology companies, have human rights responsibilities in relation to access to medicines.

j. Pharmaceutical companies also have other responsibilities, for example, a responsibility to enhance shareholder value.

* Published in the report to the General Assembly of the UN Special Rapporteur on the Right to the Highest Attainable Standard of Health (UN document: A/63/263, dated 11 August 2008).

k. Pharmaceutical companies are subject to several forms of internal and external monitoring and accountability; however, these mechanisms do not usually monitor, and hold a company to account, in relation to its human rights responsibilities to enhance access to medicines.

l. Pharmaceutical companies contribute in various ways to the realisation of the right to the highest attainable standard of health, such as providing individuals and communities with important information about public health issues. Enhancing access to medicines, however, has the central place in the societal mission of pharmaceutical companies. For this reason, these non-exhaustive, inter-related Guidelines focus on the human rights responsibilities of pharmaceutical companies in relation to access to medicines.

m. Pharmaceutical companies' human rights responsibilities are not confined to the right to the highest attainable standard of health. They have human rights responsibilities, for example, regarding freedom of association and conditions of work. These human rights responsibilities, however, are not addressed in these Guidelines.

n. While most of the Guidelines address issues that are highly relevant to all pharmaceutical companies, including innovator, generic and biotechnology companies, a few of the Guidelines address issues of particular relevance to some companies within the pharmaceutical sector.

o. These Guidelines apply to pharmaceutical companies and their subsidiaries.

p. These Guidelines are based on human rights principles enshrined in the Universal Declaration of Human Rights, including non-discrimination, equality, transparency, monitoring and accountability. The Constitution of the World Health Organisation affirms that the "enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being". This fundamental human right is codified in numerous national constitutions, as well as international human rights treaties, including the Convention on the Rights of the Child and International Covenant on Economic, Social and Cultural Rights. Accordingly, these Guidelines are informed by some features of the right to the highest attainable standard of health, such as the requirement that medicines are of good quality, safe and efficacious. The Guidelines also draw from other widely accepted standards, such as instruments on medicines adopted by the World Health Organisation.

q. For the purposes of these Guidelines, medicines include active pharmaceutical ingredients, diagnostic tools, vaccines, biopharmaceuticals and other related healthcare technologies.

r. For the purposes of these Guidelines, neglected diseases are defined as those diseases primarily affecting those living in poverty, especially in rural areas, in low-income countries. Sometimes called tropical or poverty-related diseases, they include, for example, leishmaniasis (kala-azar), onchocerciasis (river blindness), Chagas disease, leprosy, schistosomiasis (bilharzias), lymphatic filariasis, African trypanosomiasis (sleeping sickness) and dengue. Although

in recent years HIV/AIDS, tuberculosis and malaria have attracted increasing attention and resources, they may also be regarded as neglected diseases.

s. These Guidelines adopt the World Bank definition of low-income, middle-income and high-income countries.

General

1. **The company should adopt a human rights policy statement which expressly recognises the importance of human rights generally, and the right to the highest attainable standard of health in particular, in relation to the strategies, policies, programmes, projects and activities of the company.**

2. **The company should integrate human rights, including the right to the highest attainable standard of health, into the strategies, policies, programmes, projects and activities of the company.**

3. **The company should always comply with the national law of the State where it operates, as well as any relevant legislation of the State where it is domiciled.**

4. **The company should refrain from any conduct that will or may encourage a State to act in a way that is inconsistent with its obligations arising from national and international human rights law, including the right to the highest attainable standard of health.**

Commentary: Formal, express recognition of the importance of human rights, and the right to the highest attainable standard of health, helps to establish a firm foundation for the company's policies and activities on access to medicines (Guideline 1). Such recognition, however, is not enough: operationalisation is the challenge (Guideline 2). Many of the Guidelines signal ways in which right-to-health considerations can be operationalised and integrated into the company's activities. There are numerous national and international (including regional) legal provisions that safeguard aspects of the right to the highest attainable standard of health. It is axiomatic that they must be respected, at all times, by all pharmaceutical companies, in accordance with elementary principles of corporate good governance (Guidelines 3-4).

Disadvantaged individuals, communities and populations

5. **Whenever formulating and implementing its strategies, policies, programmes, projects and activities that bear upon access to medicines, the company should give particular attention to the needs of disadvantaged individuals, communities and populations, such as children, the elderly and those living in poverty. The company should also give particular attention to the very poorest in all markets, as well as gender-related issues.**

Commentary: Equality and non-discrimination are among the most fundamental features of international human rights, including the right to the highest attainable standards of health. They are akin to the crucial health concept of equity. Equality, non-discrimination and equity have a social justice component. Accordingly, the right

to the highest attainable standard of health has a particular pre-occupation with disadvantaged individuals, communities and populations, including children, the elderly and those living in poverty. Like equity, the right-to-health also requires that particular attention be given to gender. All the other Guidelines must be interpreted and applied in the light of Guideline 5, which has fundamental importance.

TRANSPARENCY

6. **In relation to access to medicines, the company should be as transparent as possible. There is a presumption in favour of the disclosure of information, held by the company, which relates to access to medicines. This presumption may be rebutted on limited grounds, such as respect for the confidentiality of personal health data collected during clinical trials.**

7. **In conjunction with other pharmaceutical companies, the company should agree to standard formats for the systematic disclosure of company information and data bearing upon access to medicines, thereby making it easier to evaluate the performance of one company against another, as well as the performance of the same company over time.**

8. **Either alone or in conjunction with others, the company should establish an independent body to consider disputes that may arise regarding the disclosure or otherwise of information relating to access to medicines. This body may be the monitoring and accountability mechanism referred to in Guideline 14.**

Commentary: Transparency is another cardinal principle of international human rights, including the right to the highest attainable standard of health. It is not possible to properly understand and meaningfully evaluate access to medicines policies and practices without the disclosure of key information. There is a presumption in favour of disclosure, which may be rebutted on limited grounds (Guideline 6). Commonsense confirms that the principle of transparency not only requires that information be made publicly available, it also requires the information be made publicly available in a form that is accessible, manageable and useful (Guideline 7). An independent, trusted and informal body should be established to consider any disputes that may arise about whether or not a particular piece of information relating to access to medicines should be disclosed (Guideline 8). This body should also provide guidance on the legitimate grounds of non-disclosure. While Guidelines 6-8 have general application to access to medicines, other Guidelines apply the cardinal principle of transparency in specific contexts, such as public policy influence, advocacy and lobbying (Guidelines 17-19).

Management, monitoring and accountability

9. **The company should encourage and facilitate multi-stakeholder engagement in the formulation of its policies, programmes, projects and other activities that bear upon access to medicines. In keeping with Guideline 5, this engagement should include the active and informed participation of disadvantaged individuals, communities and populations.**

10. **The company should have a publicly available policy on access to medicines setting out general and specific objectives, time frames, reporting procedures, and lines of accountability.**

11. **The company should have a governance system that includes direct board-level responsibility and accountability for its access to medicines policy.**

12. **The company should have clear management systems, including quantitative targets, to implement and monitor its access to medicines policy.**

13. **The company should publish a comprehensive annual report, including qualitative and quantitative information, enabling an assessment of the company's policies, programmes, projects and other activities that bear upon access to medicines.**

14. **In the context of access to medicines, internal monitoring and accountability mechanisms have a vital role to play, but they should also be supplemented by a mechanism that is independent of the company. Until such a mechanism is established by others, the company should establish an effective, transparent, accessible and independent monitoring and accountability mechanism that:**

    i. **assesses the impact of the company's strategies, policies, programmes, projects and activities on access to medicines, especially for disadvantaged individuals, communities and populations;**

    ii. **monitors, and holds the company to account in relation to, these Guidelines.**

Commentary: All human rights, including the right to the highest attainable standard of health, require effective, transparent and accessible monitoring and accountability mechanisms. The mechanisms have a variety of forms; usually a mix of mechanisms is required. While some mechanisms are internal, others are external and independent; both types are needed. Guidelines 9-13 address the issue of internal corporate monitoring and accountability regarding access to medicines. Guideline 14 addresses the issue of an external, independent monitoring and accountability mechanism regarding access to medicines.

CORRUPTION

15. **A company should publicly adopt effective anti-corruption policies and measures, and comply with relevant national law implementing the United Nations Convention against Corruption.**

16. **In collaboration with States, the company should take all reasonable measures to address counterfeiting.**

Commentary: Corruption is a major obstacle to the enjoyment of the right to the highest attainable standard of health, including access to medicines. Those living in poverty, for example, are disproportionately harmed by corruption because they are less able to pay for private alternatives where corruption has depleted public health

services. Numerous features of the right to the highest attainable standard of health, such as transparency, monitoring and accountability, help to establish an environment in which corruption can neither thrive nor survive. In short, a right-to-health policy is also an anti-corruption policy. As emphasised in the Preamble, improving access to medicines is a responsibility shared by numerous national and international actors; Guideline 16 provides one specific example of this shared responsibility in relation to counterfeiting.[1]

PUBLIC POLICY INFLUENCE, ADVOCACY AND LOBBYING

17. **The company should disclose all current advocacy and lobbying positions, and related activities, at the regional, national and international levels, that impact or may impact upon access to medicines.**

18. **The company should annually disclose its financial and other support to key opinion leaders, patient associations, political parties and candidates, trade associations, academic departments, research centres and others, through which it seeks to influence public policy and national, regional and international law and practice. The disclosure should extend to amounts, beneficiaries and channels by which the support is provided.**

19. **When providing any financial or other support, the company should require all recipients to publicly disclose such support on all appropriate occasions.**

Commentary: Like many other businesses, pharmaceutical companies devote considerable resources to advocacy, lobbying and related activities. While some of these activities may impact positively on access to medicines, for example, lobbying to lower taxes on medicines, other activities may impact negatively. Guidelines have already emphasised, in general terms, the central importance of transparency in relation to access to medicines (Guidelines 6-8). Guidelines 17-19 apply this general principle of transparency to the specific context of public policy influence, advocacy and lobbying.

Quality

20. **The company should manufacture medicines that comply with current World Health Organisation Good Manufacturing Practice Guidelines, as well as other appropriate international regulatory requirements for quality, safety and efficacy.**

Commentary: Guideline 20 reflects the elementary right-to-health requirement that all medicines must be of good quality, safe and efficacious.

CLINICAL TRIALS

21. **A company's clinical trials should observe the highest ethical and human rights standards, including non-discrimination, equality and the requirements of informed consent. This is especially vital in those States with weak regulatory frameworks.**

[1] Counterfeit drugs (medicines) are defined by the World Health Organisation in *FAQ's on Counterfeit Drugs*, 2008.

22. **The company should conform to the Declaration of Helsinki on Ethical Principles for Medical Research Involving Human Subjects, as well as the World Health Organisation Guidelines for Good Clinical Practice.**

Commentary: The right to the highest standard of health encompasses medical ethics. Guidelines 21-22 emphasise the right-to-health responsibility of pharmaceutical companies to observe the leading international standards on ethics and clinical trials. Guidelines 9-14 emphasise the importance of effective, transparent and accessible monitoring and accountability mechanisms; these mechanisms should monitor, and hold to account, pharmaceutical companies in relation to their policies and practices on clinical trials.

Neglected diseases

23. **The company should make a public commitment to contribute to research and development for neglected diseases. Also, it should either provide in-house research and development for neglected diseases, or support external research and development for neglected diseases, or both. In any event, it should publicly disclose how much it contributes to and invests in research and development for neglected diseases.**

24. **The company should consult widely with the World Health Organisation, WHO/TDR[2] and other relevant organisations, including leading civil society groups, with a view to enhancing its contribution to research and development for neglected diseases.**

25. **The company should engage constructively with key international and other initiatives that are searching for new, sustainable and effective approaches to accelerate and enhance research and development for neglected diseases.**

Commentary: By providing an incentive for pharmaceutical companies to invest in research and development, the intellectual property regime makes a major contribution to the discovery of new medicines that save lives and reduce suffering. Where there is no economically viable market, however, the incentive is inadequate and the regime fails to generate significant innovation. For this reason, a different approach is needed to address the vitally important right-to-health challenge of neglected or poverty-related diseases. Defined in the Preamble, neglected diseases mainly afflict the poorest people in the poorest countries. The record shows that research and development has not addressed key priority health needs of low-income and middle-income countries. More specifically, research and development has given insufficient attention to neglected diseases. There is evidence, however, that some pharmaceutical companies are taking active measures to reverse this trend.[3] The right to the highest attainable standard of health not only requires that existing medicines are accessible, but also that much-needed new medicines are developed as soon as possible. Neglected diseases demand special attention because they tend to afflict the

[2]UNICEF, UNDP, World Bank, World Health Organisation Special Programme for Research and Training in Tropical Diseases.

[3]Moran.M and others, *The New Landscape of Neglected Disease Drug Development*, The Wellcome Trust, 2005.

most disadvantaged (Guideline 5). Guideline 23 does not make the unreasonable demand that all companies provide in-house research and development for neglected diseases. Rather, all companies should make some contribution towards research and development for neglected diseases. Guidelines 23-25 signal other steps that companies should take to address the historic neglect of poverty-related diseases.

Patents and licensing

26. The company should respect the right of countries to use, to the full, the provisions in the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) (1994), which allow flexibility for the purpose of promoting access to medicines, including the provisions relating to compulsory licensing and parallel imports. The company should make and respect a public commitment not to lobby for more demanding protection of intellectual property interests than those required by TRIPS, such as additional limitations on compulsory licensing.

27. The company should respect the letter and spirit of the Doha Declaration on the TRIPS Agreement and Public Health (2001) that recognises a State's right to protect public health and promote access to medicines for all.

28. The company should not impede those States that wish to implement the World Trade Organisation Decision on Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health (2003) by issuing compulsory licences for exports to those countries, without manufacturing capacity, encompassed by the Decision.

29. Given that some least-developed countries are exempt from World Trade Organization rules requiring the granting and enforcing patents until 2016, the company should not lobby for such countries to grant or enforce patents.

30. As part of its access to medicines policy, the company should issue non-exclusive voluntary licences with a view to increasing access, in low-income and middle-income countries, to all medicines. The licences, which may be commercial or non-commercial, should include appropriate safeguards, for example, requiring that the medicines meet the standards on quality, safety and efficacy set out in Guideline 20. They should also include any necessary transfer of technology. The terms of the licences should be disclosed.

31. As a minimum, the company should consent to National Drug Regulatory Authorities using test data (i.e. the company should waive test data exclusivity) in least-developed countries and also when a compulsory licence is issued in a middle-income country.

32. In low-income and middle-income countries, the company should not apply for patents for insignificant or trivial modifications of existing medicines.

Commentary: The preceding Commentary recognises the major contribution made by the intellectual property regime to the discovery of life-saving medicines. Crucially, this regime contains various 'flexibilities' and other features that are designed to protect and promote access to existing medicines. Carefully constructed, they were agreed, after protracted negotiations, by the world community of States. Because they protect and promote access to existing medicines, which is a key component of the right to the highest attainable standard of health, these 'flexibilities' and other features should not be limited, diminished or compromised. Some of the key 'flexibilities' and other features are addressed in Guidelines 26-29. In brief, pharmaceutical companies should not seek to limit, diminish or compromise the 'flexibilities' and other features of the intellectual property regime that are designed to protect and promote access to existing medicines. Voluntary licences have a vital role to play in extending access to medicines (Guideline 30). Consistent with a company's responsibility to enhance shareholder value, commercial voluntary licences are designed to generate revenue for the patent holder. The terms of the licences should include appropriate safeguards, for example, relating to the quality, safety and efficacy of the product. Non-exclusive licences are more likely to extend access than exclusive licences. Voluntary licences respect, and depend upon, the intellectual property regime. Because data exclusivity has the potential to hinder access to medicines, companies should waive such exclusivity in all appropriate cases; while Guideline 31 identifies two occasions when the company should waive data exclusivity, there will be other occasions when a waiver is appropriate as a way of enhancing access to medicines for disadvantaged individuals, communities and populations. Access to medicines may be hindered when a company applies for a patent for improvements to an existing medicine; Guideline 32 is designed to mitigate this problem in low-income and middle-income countries.

PRICING, DISCOUNTING AND DONATIONS

33. When formulating and implementing its access to medicines policy, the company should consider all the arrangements at its disposal with a view to ensuring that its medicines are affordable to as many people as possible. In keeping with Guideline 5, the company should give particular attention to ensuring its medicines are accessible to disadvantaged individuals, communities and populations, including those living in poverty and the very poorest in all markets. The arrangements should include, for example, differential pricing between countries, differential pricing within countries, commercial voluntary licences, not-for-profit voluntary licences, donation programmes, and Public Private Partnerships.

34. The arrangements should take into account a country's stage of economic development, as well as the differential purchasing power of populations within a country. The same medicine, for example, may be priced and packaged differently for the private and public sectors within the same country.

35. The arrangements should extend to all medicines manufactured by the company, including those for non-communicable conditions, such as heart disease and diabetes.

36. The company should have a board-approved policy that fully conforms to the current World Health Organisation Guidelines for Drug Donations.

37. The company should ensure that its discount and donation schemes and their delivery channels are:

i. as simple as possible e.g. the schemes should place the minimum administrative burden on the beneficiary health system;

ii. as inclusive as possible e.g. the schemes should not be confined to delivery channels that, in practice, exclude disadvantaged individuals and communities.

38. The company should disclose:

i. as much information as possible about its pricing and discounting arrangements;

ii. the absolute quantity and value of its drug donations;[4]

iii. where possible, the number of beneficiary patients treated each year;

iv. the amount of any tax benefit arising from its donations.

Commentary: While recognising they have a responsibility to enhance shareholder value, companies also have a human rights responsibility to extend access to medicines for all, including disadvantaged individuals, communities and populations (Guideline 5). In this context, pricing has a critical role to play. Lower prices do not necessarily mean lower profits. Sometimes the goal of enhancing access to medicines coincides with commercial interests. There are numerous arrangements that may reduce prices and increase sales, some of which are mentioned in Guidelines 33 and 34. Because the lives and health of millions are at stake, companies must approach such arrangements with urgency, creativity and boldness. They cannot act alone: here is another example of the shared responsibility emphasised in the Preamble. Inventive arrangements should neither be confined to a company's 'flagship' products nor a narrow range of communicable diseases (Guideline 35). Although unsustainable in the long-term, a carefully constructed donation programme may extend access (Guidelines 36-37). Guidelines have already emphasised, in general terms, the central importance of transparency in relation to access to medicines (Guidelines 6-8); Guideline 38 applies this general principle of transparency to the specific context of pricing, discounting and donations.

ETHICAL PROMOTION AND MARKETING

39. The company should take effective measures to ensure that all information bearing upon the safety, efficacy, and possible side effects of

[4] 'Value' as defined in Guideline 11, World Health Organisation Guidelines for Drug Donations.

a medicine are easily accessible to individuals so they can take informed decisions about its possible use.

40. **The company should have a board-approved code of conduct and policy that fully conforms to the current World Health Organisation Criteria for Medicinal Drug Promotion. In the context of this code and policy, the board should receive regular reports on its promotion and marketing activities.**

41. **The company should publicly disclose its promotional and marketing policies and activities, including costs.**

Commentary: Guidelines have already emphasised, in general terms, the central importance of transparency in relation to access to medicines (Guidelines 6-8); Guidelines 39-41 apply this general principle of transparency to the specific context of ethical promotion and marketing. Promotion and marketing give rise to a wide-range of access to medicines issues, such as advertising to health professionals and the general public, packaging and labelling, and information for patients. Based on ethical considerations, the World Health Organisation Criteria for Medicinal Drug Promotion provides authoritative guidance on these important matters (Guideline 40).

Public Private Partnerships

42. **When participating in a Public Private Partnership, a company should continue to conform to these Guidelines.**

43. **If a company joins a Public Private Partnership, it should disclose any interest it has in the Partnership's decisions and activities.**

44. **So far as these Guidelines bear upon the strategies, policies, programmes, projects and activities of Public Private Partnerships, they shall apply equally to such Partnerships.**

45. **A company that joins a Public Private Partnership should take all reasonable steps to ensure the Partnership fully conforms to these Guidelines.**

Commentary: Public Private Partnerships can make an important contribution to enhancing access to medicines. They are subject to right-to-health considerations corresponding to those set out in these Guidelines. Where conflicts of interest may arise, disclosure is important, consistent with the human rights requirements of transparency.

Associations of pharmaceutical companies

46. **So far as these Guidelines bear upon the strategies, policies, programmes, projects and activities of associations of pharmaceutical companies, they shall apply equally to all such associations. The Guidelines on lobbying (Guidelines 17 and 26) and financial support (Guideline 18), for example, shall apply equally to all associations of pharmaceutical companies.**

47. A company that is a member of an association of pharmaceutical companies should take all reasonable steps to ensure the association fully conforms to these Guidelines.

Commentary: A company has a responsibility to ensure that its professional associations are respectful of the right-to-health considerations set out in these Guidelines, otherwise a company could use an association as a way of avoiding its human rights responsibilities.

APPENDIX 2
GUIDING PRINCIPLES ON BUSINESS AND HUMAN RIGHTS

A/HRC/17/31
21 March 2011
Human Rights Council, Seventeenth session, Agenda item 3

Promotion and protection of all human rights, civil, political, economic, social and cultural rights, including the right to development

Report of the Special Representative of the Secretary- General on the issue of human rights and transnational corporations and other business enterprises, John Ruggie

Guiding Principles on Business and Human Rights: Implementing the United Nations "Protect, Respect and Remedy" Framework Guiding Principles on Business and Human Rights: Implementing the United Nations "Protect, Respect and Remedy" Framework

General principles
I. The State duty to protect human rights
A. Foundational principles
1. States must protect against human rights abuse within their territory and/or jurisdiction by third parties, including business enterprises. This requires taking appropriate steps to prevent, investigate, punish and redress such abuse through effective policies, legislation, regulations and adjudication.

2. States should set out clearly the expectation that all business enterprises domiciled in their territory and/or jurisdiction respect human rights throughout their operations.

B. Operational principles
General State regulatory and policy functions
3. In meeting their duty to protect, States should:
(a) Enforce laws that are aimed at, or have the effect of, requiring business enterprises to respect human rights, and periodically to assess the adequacy of such laws and address any gaps;
(b) Ensure that other laws and policies governing the creation and ongoing operation of business enterprises, such as corporate law, do not constrain but enable business respect for human rights;
(c) Provide effective guidance to business enterprises on how to respect human rights throughout their operations;
(d) Encourage, and where appropriate require, business enterprises to communicate how they address their human rights impacts.

The State-business nexus
4. States should take additional steps to protect against human rights abuses by business enterprises that are owned or controlled by the State, or that receive substantial support and services from State agencies such as export credit agencies and official investment insurance or guarantee agencies, including, where appropriate, by requiring human rights due diligence.

5. States should exercise adequate oversight in order to meet their international human rights obligations when they contract with, or legislate for, business enterprises to provide services that may impact upon the enjoyment of human rights.

6. States should promote respect for human rights by business enterprises with which they conduct commercial transactions.

Supporting business respect for human rights in conflict-affected areas

7. Because the risk of gross human rights abuses is heightened in conflict-affected areas, States should help ensure that business enterprises operating in those contexts are not involved with such abuses, including by:
(a) Engaging at the earliest stage possible with business enterprises to help them identify, prevent and mitigate the human rights-related risks of their activities and business relationships;
(b) Providing adequate assistance to business enterprises to assess and address the heightened risks of abuses, paying special attention to both gender-based and sexual violence;
(c) Denying access to public support and services for a business enterprise that is involved with gross human rights abuses and refuses to cooperate in addressing the situation;
(d) Ensuring that their current policies, legislation, regulations and enforcement measures are effective in addressing the risk of business involvement in gross human rights abuses.

Ensuring policy coherence
8. States should ensure that governmental departments, agencies and other State-based institutions that shape business practices are aware of and observe the State's human rights obligations when fulfilling their respective mandates, including by providing them with relevant information, training and support.

9. States should maintain adequate domestic policy space to meet their human rights obligations when pursuing business-related policy objectives with other States or business enterprises, for instance through investment treaties or contracts.

10. States, when acting as members of multilateral institutions that deal with business related issues, should:
(a) Seek to ensure that those institutions neither restrain the ability of their member States to meet their duty to protect nor hinder business enterprises from respecting human rights;
(b) Encourage those institutions, within their respective mandates and capacities, to promote business respect for human rights and, where requested, to help States meet their duty to protect against human rights abuse by business enterprises, including through technical assistance, capacity-building and awareness-raising;
(c) Draw on these Guiding Principles to promote shared understanding and advance international cooperation in the management of business and human rights challenges.

II. The corporate responsibility to respect human rights A. Foundational principles

11. Business enterprises should respect human rights. This means that they should avoid infringing on the human rights of others and should address adverse human rights impacts with which they are involved.

12. The responsibility of business enterprises to respect human rights refers to internationally recognized human rights – understood, at a minimum, as those expressed in the International Bill of Human Rights and the principles concerning fundamental rights set out in the International Labour Organization's Declaration on Fundamental Principles and Rights at Work.

13. The responsibility to respect human rights requires that business enterprises:
(a) Avoid causing or contributing to adverse human rights impacts through their own activities, and address such impacts when they occur;
(b) Seek to prevent or mitigate adverse human rights impacts that are directly linked to their operations, products or services by their business relationships, even if they have not contributed to those impacts.

14. The responsibility of business enterprises to respect human rights applies to all enterprises regardless of their size, sector, operational context, ownership and structure. Nevertheless, the scale and complexity of the means through which enterprises meet that responsibility may vary according to these factors and with the severity of the enterprise's adverse human rights impacts.

15. In order to meet their responsibility to respect human rights, business enterprises should have in place policies and processes appropriate to their size and circumstances, including:
(a) A policy commitment to meet their responsibility to respect human rights;
(b) A human rights due-diligence process to identify, prevent, mitigate and account for how they address their impacts on human rights;
(c) Processes to enable the remediation of any adverse human rights impacts they cause or to which they contribute.

B. Operational principles
Policy commitment

16. As the basis for embedding their responsibility to respect human rights, business enterprises should express their commitment to meet this responsibility through a statement of policy that:
(a) Is approved at the most senior level of the business enterprise;
(b) Is informed by relevant internal and/or external expertise;
(c) Stipulates the enterprise's human rights expectations of personnel, business partners and other parties directly linked to its operations, products or services;
(d) Is publicly available and communicated internally and externally to all personnel, business partners and other relevant parties;
(e) Is reflected in operational policies and procedures necessary to embed it throughout the business enterprise.

Human rights due diligence
17. In order to identify, prevent, mitigate and account for how they address their adverse

human rights impacts, business enterprises should carry out human rights due diligence. The process should include assessing actual and potential human rights impacts, integrating and acting upon the findings, tracking responses, and communicating how impacts are addressed. Human rights due diligence:

(a) Should cover adverse human rights impacts that the business enterprise may cause or contribute to through its own activities, or which may be directly linked to its operations, products or services by its business relationships;
(b) Will vary in complexity with the size of the business enterprise, the risk of severe human rights impacts, and the nature and context of its operations;
(c) Should be ongoing, recognizing that the human rights risks may change over time as the business enterprise's operations and operating context evolve.

18. In order to gauge human rights risks, business enterprises should identify and assess any actual or potential adverse human rights impacts with which they may be involved either through their own activities or as a result of their business relationships. This process should:
(a) Draw on internal and/or independent external human rights expertise;
(b) Involve meaningful consultation with potentially affected groups and other relevant stakeholders, as appropriate to the size of the business enterprise and the nature and context of the operation.

19. In order to prevent and mitigate adverse human rights impacts, business enterprises should integrate the findings from their impact assessments across relevant internal functions and processes, and take appropriate action.
(a) Effective integration requires that:
(i) Responsibility for addressing such impacts is assigned to the appropriate level and function within the business enterprise;
(ii) Internal decision-making, budget allocations and oversight processes enable effective responses to such impacts.
(b) Appropriate action will vary according to:
(i) Whether the business enterprise causes or contributes to an adverse impact, or whether it is involved solely because the impact is directly linked to its operations, products or services by a business relationship;
(ii) The extent of its leverage in addressing the adverse impact.

20. In order to verify whether adverse human rights impacts are being addressed, business enterprises should track the effectiveness of their response. Tracking should:
(a) Be based on appropriate qualitative and quantitative indicators;
(b) Draw on feedback from both internal and external sources, including affected stakeholders.

21. In order to account for how they address their human rights impacts, business enterprises should be prepared to communicate this externally, particularly when concerns are raised by or on behalf of affected stakeholders. Business enterprises whose operations or operating contexts pose risks of severe human rights impacts should report formally on how they address them. In all instances, communications should:
(a) Be of a form and frequency that reflect an enterprise's human rights impacts and that are accessible to its intended audiences;

(b) Provide information that is sufficient to evaluate the adequacy of an enterprise's response to the particular human rights impact involved;
(c) In turn not pose risks to affected stakeholders, personnel or to legitimate requirements of commercial confidentiality.

Remediation
22. Where business enterprises identify that they have caused or contributed to adverse impacts, they should provide for or cooperate in their remediation through legitimate processes.

Issues of context
23. In all contexts, business enterprises should:
(a) Comply with all applicable laws and respect internationally recognized human rights, wherever they operate;
(b) Seek ways to honour the principles of internationally recognized human rights when faced with conflicting requirements;
(c) Treat the risk of causing or contributing to gross human rights abuses as a legal compliance issue wherever they operate.

24. Where it is necessary to prioritize actions to address actual and potential adverse human rights impacts, business enterprises should first seek to prevent and mitigate those that are most severe or where delayed response would make them irremediable.

III. Access to remedy
A. Foundational principle
25. As part of their duty to protect against business-related human rights abuse, States must take appropriate steps to ensure, through judicial, administrative, legislative or other appropriate means, that when such abuses occur within their territory and/or jurisdiction those affected have access to effective remedy.
B. Operational principles

State-based judicial mechanisms
26. States should take appropriate steps to ensure the effectiveness of domestic judicial mechanisms when addressing business-related human rights abuses, including considering ways to reduce legal, practical and other relevant barriers that could lead to a denial of access to remedy.

State-based non-judicial grievance mechanisms
27. States should provide effective and appropriate non-judicial grievance mechanisms, alongside judicial mechanisms, as part of a comprehensive State-based system for the remedy of business-related human rights abuse.

Non-State-based grievance mechanisms
28. States should consider ways to facilitate access to effective non-State-based grievance
mechanisms dealing with business-related human rights harms.

29. To make it possible for grievances to be addressed early and remediated directly, business enterprises should establish or participate in effective operational-level

grievance mechanisms for individuals and communities who may be adversely impacted.

30. Industry, multi-stakeholder and other collaborative initiatives that are based on respect for human rights-related standards should ensure that effective grievance mechanisms are available.

Effectiveness criteria for non-judicial grievance mechanisms

31. In order to ensure their effectiveness, non-judicial grievance mechanisms, both State based
and non-State-based, should be:

(a) Legitimate: enabling trust from the stakeholder groups for whose use they are intended, and being accountable for the fair conduct of grievance processes;

(b) Accessible: being known to all stakeholder groups for whose use they are intended, and providing adequate assistance for those who may face particular barriers to access;

(c) Predictable: providing a clear and known procedure with an indicative timeframe for each stage, and clarity on the types of process and outcome available and means of monitoring implementation;

(d) Equitable: seeking to ensure that aggrieved parties have reasonable access to sources of information, advice and expertise necessary to engage in a grievance process on fair, informed and respectful terms;

(e) Transparent: keeping parties to a grievance informed about its progress, and providing sufficient information about the mechanism's performance to build confidence in its effectiveness and meet any public interest at stake;

(f) Rights-compatible: ensuring that outcomes and remedies accord with internationally recognized human rights;

(g) A source of continuous learning: drawing on relevant measures to identify lessons for improving the mechanism and preventing future grievances and harms;

Operational-level mechanisms should also be:

(h) Based on engagement and dialogue: consulting the stakeholder groups for whose use they are intended on their design and performance, and focusing on dialogue as the means to address and resolve grievances.