POLITICAL ECONOMY OF TRADE RELATED INTELLECTUAL PROPERTY RIGHTS (TRIPS) AND PUBLIC HEALTH IN DEVELOPING COUNTRIES

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MASTER OF PHILOSOPHY

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DECLARATION

I declare that the dissertation entitled **"Political Economy of Trade Related Intellectual Property Rights (TRIPS) and Public Health in Developing Countries"**, submitted by me in partial fulfillment of the requirements for award of the degree of **Master of Philosophy** of Jawaharlal Nehru University is my own work. The dissertation has not been submitted for any other degree of this University or any other university.

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CERTIFICATE

We recommend that this dissertation be placed before the examiners for evaluation.

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ABBREVRIATIONS

ATC	Agreement on Textile and Clothing
BOP	Balance of Payment
BIPRI	Bureaux for the Protection of Intellectual Property
CAMC	Canada's Access to Medicines Campaign
CAMEG	California Association for Measurement and Evaluation in Guidance
CBD	Convention on Biological Diversity
CEFTA	Central European free Trade Area
CIPR	Commission for Intellectual Property Rights
DSU	Dispute Settlement Undertaking
DNDI	Drugs for Neglected Diseases Initiative
EMR	Exclusive Marketing Rights
EU	European Union
FAO	Food and Agricultural Organization
FDI	Foreign Direct Investment
FDR	Foreign Direct Reserve
GATT	General Agreement on Tariffs and Trade
GATS	General Agreement on Trade in Services
GHG	Global Health Governance
GI	Geographical Indication
GMC	Genetically Modified Crops
GSP	Generalized System of Preference
ICESCR	International Covenant on Economic Social and Cultural Rights
ICC	Indian Chamber of Commerce
IDMA	Indian Drug Manufacturing Association
IFPMA	International Federation for Pharmaceutical Manufacturers Association
INN	International Non-Proprietary Name
IPC	Intellectual Property Committee
IPR	Intellectual Property Rights
ITO	International Trade Organization
IMF	International Monetary Fund
KPO	Knowledge Process Outsourcing
LDC	Least Developed Countries
LPG	Liberalization, Privatization and Globalization
MAI	Multilateral Agreement on Investment
MTO	Multilateral Trade Organizations
MFN	Most Favored Nations
MNC	Multinational Corporations
NAFTA	North American Free Trade Agreement
NASSCON	National Association of Software and Services Companies
NCE	Newly found Chemical Entity
NGO	Non Governmental Organizations
NIHCMREF	National Institute of Health Care Management Research and Educational Foundation
OECD	Organization of Economic Cooperation and Development
PCT	Patent Cooperation Treaty
PNTR	Permanent Normal Trade Relations

R&D	Research and Development
SPLT	Standard Patent Law Harmonization Treaty
SSRC	Social Science Research Council
SARS	Sever Acute Respiratory Syndrome
TM	Trade Mark
TRIPS	Trade Related Intellectual Property Rights
UCC	Universal Copyright Convention
UN	United Nations
UNAIDS	The Joint United Nations Programme on HIV/AIDS
UNCTAD	United Nations Conference for Trade and Development
UNESCO	United Nations Educational, Scientific and Cultural Organization
UNDP	United Nations Development Program
UNICEF	United Nations Children's Fund
USTR	United States Trade Representative
WB	World Bank
WHO	World Health Organization
WIPO	World Intellectual Property Organization
WTO	World Trade Organization

INTRODUCTION

Since the inception of industrial revolution, international trade has undergone tremendous changes. In the era of globalization, trade is conducted not only through the exchange of physical commodity but also through the trade of knowledge based goods in the international markets. It is a fact that in the present time, knowledge based goods have become a vital source of revenue for the countries to the extent that, now economy and market are termed as *'knowledge economy' and 'knowledge market'*. Basically in the knowledge economy 'intellectual capital' and 'knowledge' or 'technological know-how' are used to generate national wealth. Knowledge is considered to be the power of a nation, because it leads a country to the path of development. Although intellectual capital has got a very important role to play in international political economy, it is amongst the most vulnerable asset of a country. Because of the threat of misuse, intellectual property needs special protection in international market. The entire issue related with Intellectual Property Rights (IPRs) revolves around the politics of knowledge, which deals with who controls the 'knowledge'? As Jonathan Crush writes that today those who wield power they define knowledge, and they export only that knowledge and technology which can bring benefits to them. Thus the protection of intellectual property has given birth to the demand for strict IPR regime (Crush 1995:5).

IPRs ensure the protection to the creativity of human mind. Xuemei An says "walking along with its historical development, the course of intellectual property system in Western countries has gone through three main stages which are called as germination stage, development and internationalization stages". In the 13th century, British king provided patent for the first time to the innovator, that was granted in the name of 'letters patent', but that was an informal pattern of granting patent. In 1449, for the first time patent was granted to John of Utyman for manufacturing colored glass (Silberston and Boehm 1967:14). The motive behind this establishment was to encourage research and development. Later on with the advent of industrial revolution, several countries established their own system of protection of IPRs. In 1709, copy right laws were enacted in UK which was followed by many other countries including Ireland and France. It was the germination period. 1980s was the period of development, when many countries established "Intellectual Property Code". With the beginning

of 'international stage' several international organizations and IPR regime have emerged. (Xuemei An, 2009: 132-133).

US, Japan along with many other European countries were the pioneers, which demanded a strict IPR regime. Consequently in 1883 Paris Convention was signed by France, Germany and Belgium. It was meant to protect the industrial property. Later on in 1886, 'Berne Convention' was brought into operation. It was the first international convention which realized the importance of literary work and also granted copyrights to the innovators. In 1961, Rome Convention was signed which was known for the protection of physically manifested intellectual property like audio cassettes or DVDs. Demand for the protection of intellectual property gave birth to an international organization, the World Intellectual Property Organization (WIPO) in 1970, which became a specialized body of the United Nations. It was created by the Convention Establishing the World Intellectual Property Organization. It included more than 20 conventions related with intellectual property.

Since 1948, it was the General Agreement on Tariffs and Trade (GATT), which provided a framework for trade related activities but its area was limited to the trade in goods only. With the inception of World Trade Organization (WTO) in 1995, the area of commercial activity was enlarged, to include agriculture, trade in services, as well as intellectual property rights.

The provision of Trade Related Aspects Intellectual Property Rights (TRIPS), was negotiated for the first time when the Uruguay Round talks started in 1986 under the GATT, and after the WTO came in to existence, the developed as well as developing countries got a platform to put their views and problem related with this issue in a substantial manner. Any country seeking the membership in WTO must ratify the basic principles of TRIPS. TRIPS provide incentive for future research and innovations, and provide security to the innovations already made.

TRIPS covers seven areas of intellectual property: *Copyright* protect original work of authorship, *Trademark* are word, signs, or symbols that identify a certain product or company, *Geographical indication* identify a product with a certain city or region. *Industrial designs* protect the ornamental features of consumer goods, *Patents* are granting the owner the exclusive rights to

make commercial use of innovations, *layout design for integrated circuits* protect producers of semiconductors' *Trade secrets* protects business from unauthorized disclosure of confidential information (WTO, 1995).

The enshrined principle of TRIPS is the equal treatment to all the countries. In the article 3, 4 and 5 of TRIPS, it is said that with some exceptions, members must not discriminate on the basis of nationality of persons or companies (WTO, 2002). Though the principle of non discrimination was the fundamental principle of TRIPS, the developing countries found it to be discriminating on many grounds.

The most contested area of TRIPS is the granting of patent rights to pharmaceutical companies and its impact on the availability of and access to drugs to the epidemic ridden countries. Under the WTO, the product patent rights are granted instead of process patent. "Under the process patent regime, a particular way of making a product is patented. In other words, a single product may be made using different proprietary technologies under the process patent. In the product patent regime, a particular product is patented no matter how it is produced" (Mukharjee and Ray, 2006: 36-38) Developed countries prefer product patent as it provides comprehensive protection to the patent holder, whereas the developing countries are more in favor of process patent as it will make accessibility of drugs easier for poor people.

Though the developing countries are provided with some exception under TRIPS, they are hardly provided the appropriate condition to avail those benefits. These exceptions include 'Research Exception and Bolar Provision' [Article 30] which is meant to allow the researcher to use the patented invention for research, so that the researcher could understand the invention fully. There is also a provision of 'Compulsory Licensing' under [Article 31(f)]. Basically it is meant to give permission to a third party or person to produce the generic version of the patented drugs without the consent of patent holders, in the case of national emergency. However, the conditionality attached with the provision of compulsory licensing are difficult to manage, this is because, during the first three years of grant of patent, compulsory license cannot be issued. Moreover it is necessary to mention the nature of the interest of the demanding country in the matter in the case of such demand, which makes the granting of compulsory licensing almost impossible, because

in most of the cases the interests of developing countries were contradictory to the interests of big pharmaceutical companies.

Developed countries also argue that an exception like compulsory licensing and parallel importation undermine the patent rights and reduces the chances of reinvestment in R&D. Actually this claim of big pharmaceutical companies, in developed countries, cannot be accepted as the component of its market is low in developing countries, so it hardly makes any substantial impact on the profit of these companies. This is because many of the prevailing diseases in least developed countries comes under the category of neglected disease, and money is hardly spent on the research and development of drugs by big pharmaceutical companies for those diseases. Besides, the demand of these pharmaceutical companies cannot be justified on the ground that the drugs they are talking about, are meant for the diseases prevalent in developed countries on a wider scale in comparison to developing countries. So developing countries do not provide a very large market for those drugs thus the losses to these companies are also negligible.

The investment in future R&D is not hampered by this exception. Big pharmaceutical companies also demand for the abolition of the provision of parallel importation because it may lead to re-import of cheap drugs back to the western world. Here the action from government from western world is required. Developed countries should restrict parallel importation in their own territories. Only through the strengthening of their vigilance and proper regulation of the trade and commerce, they can curb out this illegal import of medicines.

Being a WTO, member India made amendment to its Patent Act of 1970 in 2005. Prior to that, India was one of the largest producers of generic drugs and could afford to supply less expensive copies of world's most expensive medicines to the poor nations, which could not afford the costly medicines. The Patent Act of 1970 established a fine balance between the interest of consumers and producers. Now after switching over to the 'product patent' India has become much more dependent on multinational pharmaceutical companies. As recently happened when the Swine Flu broke out in India, Roche from Switzerland was the only company which was supplying Tamiflu (drug to treat H1N1 Influenza virus) to the Indian market. Indian companies demanded for the supply of cheaper version of Tamiflu but they were not granted permission

under the provision of compulsory licensing. This resulted in the chaos as Roche was not able to meet the demand of patients because of the limited production and high cost of drug. Thus the implementation of TRIPS has increased their dependency on the big pharmaceutical companies of developed countries.

Similarly in South Africa, when the government brought *'Medicine and Related Substances Control Amendment Act'* in 1997, which was an effort to provide medication to the HIV-AIDS patients at cheaper rate with the help of the provision of compulsory licensing, the big pharmaceutical companies went to court, claiming that the Act abrogated their rights enshrined in African Bill of Rights. Later on these companies stopped providing medicines to the patients which resulted in higher number of deaths estimated to be around 316,559 in South Africa. It proved the hollowness of the exceptions provided to the poor countries with TRIPS. These are the reasons why developing countries wanted revision of the TRIPS Agreement and they consider that corresponding exceptions of Article 20 of GATT and Sanitary and Phytosanitary measure to be more helpful in providing protection to public health than provided by TRIPS.

In some countries, the compulsory licenses were issued to the pharmaceutical companies to produce generic drugs. Thailand, Brazil, and Malaysia have issued compulsory licenses to the companies other than the patent holders, but there are countries which are not able to utilize the provided exception as they have limited manufacturing capacity and also the weak structure of R&D. This means that the country having large market with efficient manufacturing capability, like India, US, UK, can only make optimum use of compulsory licensing provision and the countries in Africa with small market and large area affected by disease, like AIDS, can hardly gain any benefits by the exceptions provided.

At some places question arises with regard to the universal application of TRIPS. In the case of the Anthrax that broke out in America after 9/11 attack, the US government threatened the pharmaceutical company Bayer from Germany to provide cheap medicine to the patients, otherwise compulsory license could be issued against it. Consequentially Bayer AG agreed to compromise with US government to sell drugs at lower price. The decision to reduce the price was taken, considering the loss which may result after the issuance of compulsory licensing to other company.

TRIPS and GATS (General Agreement on Trade in Services), were the two issues, which clearly brought into light the differences between developed and developing countries. Moreover, these issues have far reaching impacts on the public health in developing countries. Longer period of patent protection under TRIPS made the availability of drugs very difficult. This is why developing countries were demanding lesser period of patent protection. The controversies under TRIPS brought the health related issues at the center stage of trade regime. Developing countries also demanded for more the revision of the agreement in general and the section on relaxations in particular, because the relaxations provided under TRIPS could not provide solution to the problems in LDSs. This is because the implementation of those relaxations was a tough task under the pressure from big pharmaceutical companies from developed countries.

The second major pillar of WTO was GATS, which was meant to regularize trade in services. Under GATS member countries were asked to demolish trade barriers so that transfer of services can also become a part of international trade. GATS was also a kind of manipulative strategy from developed countries. Developed countries wanted to capture foreign markets through these service providing bodies like banks, hospitals, educational institutions and telecom service providers etc. These firms and institutions were acquiring foreign markets and because of this reasons the indigenous service providers were facing cut throat competition.

GATS has also made negative impact on the public health in developing countries. The inflow of foreign investments in health services and insurance may lead to the two-tire health care system. The sophisticated and high quality health services are so much costly that only higher income patients can afford them. Whereas, the lower strata of the society does not have access to needed medicines. Thus GATS has brought a kind of inequity in poor countries (Blouin, Drage and Smith 2006:143)

Now the question arises here whether these laws are meant to serve poor or to enhance the wealth of well off community of this world? Although the problem was not a national emergency, it was proved that developed countries such as the US has got edge over these international laws. They can manipulate international laws according to their interest.

Chapter I

International Politics of Knowledge

Since the inception of civilization knowledge is not only considered as an asset, rather it is closely associated with the potential of an individual and a nation as well. Possession of knowledge increases the stature and influence of a country in world community. Knowledge gives impetus to the growth and development of countries. In contemporary world knowledge is considered to be the most important resource a country needs for its development. To have knowledge in present time is to be 'informed' and to have command over technical know-how of the modern technologies. In the contemporary digital information society, only those who are having command over information and knowledge can compete.

Basically knowledge is something capable of making a man's life easier. Knowledge gives us a sense so that the decision-making and implementation of that decision become very easy. Davenport and Prusak writes about knowledge as "a fluid of framed experience, values, contextual information, and expert insight that provides a framework for evaluating and incorporating new experiences and information" (Odigie and Li-Hua, 2008:4). Today when it comes to the possession of knowledge, all the countries are placed in hierarchical order, and maintaining the superior subordinate relationship. The concept of 'developed' and 'least developed' countries (LDC) is more or less the progeny of the knowledge structure. The structure of knowledge gives birth to the *structure of power*. In international politics countries wield power according to their possession of modern knowledge and technology. World Bank report writs:

> "Knowledge is like light, weightless and intangible, it can easily travel the world, enlightening the lives of people everywhere. Yet billions of people still live in the darkness of poverty-unnecessarily. Knowledge about how to treat such a simple ailment as diarrhea has existed for centuries- but millions of children continue to die from it because their parents do not know how to save them" (The World Bank Group. 1999:1).

The uneven spread of knowledge is very much visible in present times. On the one hand people are marching towards Moon and Mars, on the other hand the large chunk of population in LDCs are starving till death. Both within and outside the country this divide can be easily sensed. Within the country those who are well educated belong to higher

echelon in society, but those who are not fortunate enough to go to school belongs to marginalized section in society.

Knowledge and technology has given birth to the class system in international society. Robert Reich opines that entire society is divided in to three classes and they have their own contribution to the international political economy. The first class belongs to the highly educated, technocrats includes doctors, engineer, and academician etc. These *symbolic analytic* occupy very privileged position in society. Their physical labor is less than their mental labor and they maintains symbol of living. Second class belongs to *routine production workers*, who assist the symbolic analytics and they perform repetitive task. Third class belongs to the *labor* class who sell their physical labour to earn money. Among all these three classes most privileged are the symbolic analytics because they are the backbone of the economy, and deprived are the people who sell their physical labor to earn money (Reich 1991:252).

Division of world in to developed and underdeveloped countries is neither a new phenomenon nor the result of an accident; rather it has its root in the history of domination. It started since the era of colonialism, when western world began to dominate the poor countries of Latin America, Africa and Asia. They used knowledge and technology as tools to show their superiority. The other cause behind this wide gap between developed and developing countries, is the weak absorptive capacity of developing countries due to the lack of incentives and resources (Wood 1991). Underdeveloped countries import technologies from developed countries, but they are not able to further enhance the scope of the use of those technologies. These countries are having weak Research and Development (R&D) infrastructure, so they are not able to make any addition to the imported technologies, hence they fail to overcome the crunch of technology. This is the reason why they are dependent on the import of technologies from foreign countries, which is very costly, and also creates superior subordinate relationship between developed and developing countries. This superiority was not absolute; rather it was a social construct.

Debate over the Construction of Knowledge

Though knowledge has wide range of definitions and interpretations, knowledge is said to be spatio-temporal and contextual. The definition of the term *knowledge*, as it is understood at present, is recorded within our cultural references and has its primal origin in our forms and types of scripts (Segundo 2002:239). The real quest for an acceptable definition of knowledge started with the commencement of Renaissance. The problem of the establishment of an acceptable definition of knowledge acquired a form of 'discourse' at the time when scholars like Kant began to talk about philosophy of knowledge.

Renaissance was the harbinger of modernity and it discarded traditionality and orthodoxy. Prior to Renaissance people were behind the *veil of ignorance*, they did not have any idea of scientific reality, they blindly followed the authority of the church, which was taken as an institution established by the God to show the right path to people. However, during the 16th century, protestant movement started in Europe, and it gave impetus to the spread of knowledge. Now people started educating themselves and their children. They defied despotism of church and stared searching the scientific base of every social and political phenomenon. It gave birth to reason and rationality which later on laid down the foundation of 'positivism' and 'modernity'.

Positivism, which itself is the result of modernity, gives importance to rationality, and universal applicability of knowledge. Hence modernity has given immense importance to scientific knowledge and also propounded some *Meta narratives* and *Grand narratives*, which are said to be applicable universally. The critique of positivism and modernity like Max Horkheimer and Sorel say that the definitions of knowledge presented by positivist and modernist are just the imposition of superiority of west on the people who are either not developed or developing. They used the notion of knowledge and rationality to exploit people. Imperialism or colonialism was the offshoot of this egoism of superiority. This era was no better than the traditional period because in both the periods weaker sections were exploited by powerful. Human intellect gave birth to this superior subordinate relationship. So knowledge was a social construction of privileged classes for their narrow interests. The modern technology is also a part of that process of exploitation, as Heidegger writes:

"The outstanding feature of modern technology lies in the fact that it is not at all any longer merely 'means' and no longer merely stands in 'service' for others, but instead... unfolds a specific character of domination" (Heidegger 1990: 214).

During colonial period theory of 'Orientalism' came into being, which talked about white man's burden. It was said that those who are black, they are poor, uneducated and backward and God has sent white people on earth to teach blacks and to show them the path of development and progress. Eastern art, culture and values were destroyed for the so called *developmental movement.* It was an integral part of constructed knowledge structure. White people established their domination through their structure of knowledge, and they denied the worth of other forms of existing knowledge (Said, 1978). Marcuse's criticizes modern technology which is the result of modern knowledge. He argues that progress up to now has been inextricably bound up with domination and that link extends to scientific technical rationality as well. Emancipation therefore requires not just social change but a radical transformation as well. Feenberger writes:

> "As a technological universe "advanced industrial society is a political universe, the latest stage in the realization of a specific historical project- namely, the experience, transformation, and organization of nature as the mere stuff of domination. As the project unfolds it shapes the entire universe of discourse and action, intellectual and material culture. In the medium of technology, culture, politics and the economy merge into an omnipresent system which swallows up or repulses all alternatives. The productivity and growth potential of this system stabilize the society and contain technical progress within the framework of domination. Technological rationality has become political rationalit" (Feenberg1995:21).

The important debate on the discourse of knowledge is whether knowledge is constructed or accumulated? Construction of knowledge is the process, which begins after the human race came into being, but accumulation of knowledge is acquiring knowledge, which existed prior to the birth of man. While discussing the foundation of knowledge we cannot ignore the ideas of Hobbes. Hobbes argued that in the state of nature development of any kind was not possible, and this condition further lays down the foundation of sovereignty. Truth is determined in different conditions, hence it is conditional. The ontology and epistemology of the sovereignty determines its legitimacy and authority, which are determined by knowledge based on truth. In the absence of sovereignty nobody will follow rules and regulation. Sovereignty works as a necessary precondition for the production of knowledge. Knowledge later explains sovereignty under various disciplines

in different dimensions. As Hobbes writes:

> "the discipline of politics focuses on what happens inside states under state sovereignty; international relations is concerned with what happens outside states and state sovereignty; anthropology with what happens before state sovereignty; sociology with what happens "under" the structures of governance; the divide between "micro" and"macro" economics echos the same architecture, and so on" (quoted in Shaw 2004:13).

The construction of knowledge was brought in to light also by the theories of 'constructivism' and 'postmodernism'. Constructivism talks about ideas, that the ideas are contextual therefore knowledge is also related with a particular time and phase. Knowledge is the creation of man's brain so this creation is used for fulfillment of interests through the domination of poor by the powerful. In Postmodernism it is said that knowledge and ideas are contextual which cannot be universalize, and a particular type of knowledge has its utility in a particular society and phase. Hence, the creation of knowledge is used as a tool of exploitation.

Theories of Knowledge

Knowledge helps in differentiating between truth and error, and when we have get to know the truth further determines our behavior. Thus what we do is the result of what we know. According to Bertrand Russell it is not necessary that all the knowledge would always be clear and certain; in some cases the knowledge is vague and unclear. It means the knowledge may have inherent contradiction. Russell writes "we cannot confine the word "knowledge" to what the highest degree of both these qualities has; we must include some propositions that are rather vague and some that are only rather probable. It is important, however, to indicate vagueness and uncertainty where they are present, and, if possible, to estimate their degree. Where this can be done precisely, it becomes "probable error" and "probability". He is of the opinion that inference is very subjective, it may be different to different people, and they adopt deductive and inductive methodology to comprehend and to make a generalization of their knowledge. He concludes that the theory of knowledge, as we have seen, is a subject which is partly logical, partly psychological, which means we perceive thing on the basis of our reason and then we repostulate it according to understanding (Russell 1913).

Karl Popper's view about knowledge seems to be more pragmatic, he has adopted *trial*

and error method to explain the concept of knowledge. He has given the 'evolutionary theory' of knowledge. He has written a book *The Logic of Scientific Discovery*, in which he denied the view that the knowledge of science is based on induction and social theories are verified with the help of induction. He gave birth to the new method called 'evolutionary epistemology' of problem solving and error elimination. When trial and error method is applied to natural science it leads to the birth of new organism but in humanities it results in new ideas. His theory was meant to reduce the gap between humanities and sciences, because it includes traditional beliefs, criticism, logic, imagination and experimental trials. He emphasizes on the creative function of criticism, which helps in the occurrence of refined ideas. Thus his theory was quite assimilative and liberal (Mace and Passmore 1970).

Among the theorists of knowledge, Foucault is one of the great proponents of this theory. He discarded traditional method of analysis of power. He says that without the study of power, knowledge and truth cannot be studied; power and knowledge are closely related with each other. He says that the form of our thought determines the political structure. He says that power cannot be studies only with the analysis of class structure and political institutions. He says that 'power' produces truth. Foucault discarded the view that power emanates only from *sovereign king*, *history* or *anthropology*, but it also comes from a strong web of relationship among men below. Sovereign and king are not constant, they change after a period of time, but it is the reason of man which recognizes them, reason is the real producer of power, and that reason develops with the help of knowledge (Thiele 1986:244). He says that power and knowledge comes from observing others. He writes:

> "knowledge linked to power, not only assumes the authority of 'the truth' but has the power to make itself true. All knowledge, once applied in the real world, has effects, and in that sense at least ;becomes true'. knowledge, once used to regulate the conduct of others, entails constraint, regulations and the disciplining of practice. Thus, 'There is no power relation without the correlative constitution of a field of knowledge, nor any knowledge that does not presuppose and constitute at the same time, power relations" (Foucault 1977:27).

Thus we can say that knowledge is the outcome of reason of man and it also helps in making decision and following the right path. Knowledge should be used for the well being of human being and not to coerce them. With the help of knowledge errors can be

corrected and right thing can be put into the right place. Consequentially knowledge gives power, and power if judiciously used, can uplift human beings.

Karl Marx had propounded in a sociological theory of knowledge, that knowledge is not autonomous but it is a social construct. Karl Marx has given the theory of knowledge in his book *The German Ideology*; he writes that in a society a class which is a dominant material force is also the dominant intellectual force. Dominant class, rule in the society as thinker and producer of ideas. They control common sense in society. Ruling class always try to universalize its ideas to increase its influence. Hence Karl Marx has tried to establish close link between knowledge structure and social structure. He says that economic reality affects the structure of knowledge in a society (Remmling 1973:135). He says that the knowledge is a class construction to exploit weaker section in society, and these weaker sections are not given space to develop their own ideas and knowledge, they are compelled to adhere what ruling class says.

Knowledge Structure and the Division of the World

International politics is a kind of system which consists of different countries, international organizations, and non-state actors. The web of their relationship determines the structure of this system. Waltz has talked about three basic principles of this system. First principle was the *ordering principle*, second was the *principle of distribution of capabilities* and third was the *principle of functional differentiation.* Under the ordering principle Waltz has talked about the prevailing anarchy at international level. There does not exist any overarching power to govern the behavior of states, thus according to their capability countries are placed in a hierarchical order. Under the principle of differentiations he says that all the countries are identical at functional level. For us the most important principle is the 'principle of distribution of capabilities. Capabilities determine the position of a state in the international system and as the capabilities change, relative position of a state changes. Capabilities also determine the status and influence in international system. Capabilities are determined by the population, economy, defense capability, natural resources, and energy resources, possession of modern technology and knowledge resources of a country. Knowledge resources are the most important asset of a country, because in present times the economies are knowledge

driven, thus well educated population of a country enhances its capabilities, for instance Indian technocrats, scientists, and academicians are in demand all over the world, which has increased India's stature among the world community.

Joseph Stiglitz in his very famous essay *knowledge as a global public good* writes that knowledge must be taken as a public good and it should be available to every body without any discrimination. Knowledge should not be considered as an asset of a particular nation or an individual. Knowledge sharing is the foundation pillar of the modern day knowledge society. Sharing of knowledge should be in such a way that the right of the innovator and the beneficiary, protected. Stiglitz in 1999 has talked about two qualities of knowledge: nonrivalrousness and nonexcludebility. Nonrivalrousness means there is zero marginal cost from an additional individual enjoying the benefits of knowledge (Stiglitz 1999:308). An individual who is willing to utilize that knowledge should only have his/her resources to retrieve the benefits, and nonexcludebilty means one cannot be denied of gaining knowledge and take benefits out of that utilization. However, the challenges before the developing economies is the non availability of information and knowledge, there are some countries which are not in favor of free flow of knowledge and technology even after the adequate remuneration is paid. Knowledge is now being commercialized (Smith 2003).

Now a day's knowledge is sold and purchased like a commodity, so those who are having money they can buy knowledge and those who are not economically well off are suffering. The other problem associated with the spread of knowledge as a 'global public' good is that those who are capable of producing new ideas or knowledge based good they are more driven by their economic gains rather than benefits of the society as a whole. Hence knowledge is treated more as a personal property. Actually innovation needs infrastructure and money which are available in the developed countries only consequently innovation is concentrated more in developed nations only. Secondly some of the important traditional knowledge from developing countries do not come in to recognition. So the developed countries are always at advantageous position and their innovation increases profit markets for them.

In the era of high technology two processes have come into being: Business Process

Outsourcing (BPO) and Knowledge Process Outsourcing (KPO) (Sopal 2009). Multinational companies in developed countries are getting their work done through the professionals in developing countries by outsourcing their business operation. But KPO is different from BPO. "Knowledge process can be defined as high added value processes chain where the achievement of objectives is highly dependent on the skills, domain knowledge and experience of the people carrying out the activity, and when this activity gets outsourced a new business activity emerges, which is generally known as Knowledge Process Outsourcing. According to a report of National Association of Software and Services Companies (NASSCOM), the Indian Chamber of Commerce (ICC) that serves as an interface to the Indian Software industry, KPO is expected to reach USD 17 billion by 2010, of which USD 12 billion would be outsourced to India". This analysis itself shows that the knowledge resources of developing countries are utilized by developed countries for their own profits but they want to be paid for sharing their own innovation. Thus knowledge has become a currency for private pockets (Bhattcharya 2005).

The existing economic disparity among countries is the result of their possession over knowledge resources. World Development Report 1998/99, in Figure 1.1, looks at the problem of divide between developed and developing countries, taking knowledge as one of the factors. This report has talked about two types of knowledge which are lacking in underdeveloped and developing countries, that are 'knowledge about technology' and 'knowledge about attributes'. It is shown in Figure 1.1 Knowledge about technology includes nutrition, birth control, software engineering and knowledge about accountancy, and knowledge about attributes consists of quality of product, the diligence of a worker or the creditworthiness of a firm.

The main aim of this report was to show the knowledge gap. Figure 1.1 shows that, the differences between the developed and developing countries in terms of the capacity of knowledge generation is very wide. This report says that information problems leads to market failure and also impedes efficiency and growth. It is written in this report "if knowledge gaps widen, the world will be split further, not just by disparities in capital and other resources, but by the disparity in knowledge. Increasingly, capital and other

resources will flow to those countries with the stronger knowledge base, reinforcing inequality" (WDR 1998/99:14).

Underdeveloped communication system in developing countries creates huge disparities between them and other developed countries. This divide is popularly known as 'digital divide', which results in the underdevelopment on all the fronts including health, education, and social development. People neither have access to health facilities nor do they get good education. In Least Developed Countries (LDCs) most of the government policies do not become successful because people are not informed about the programs initiated for their development. Bureaucrats take advantage of the lack of information which further leads to corruption. Most of the developing countries are suffering from the ailment of corruption, which is among one of the main causes of the underdevelopment of these countries (Sugimoto 2006:535).

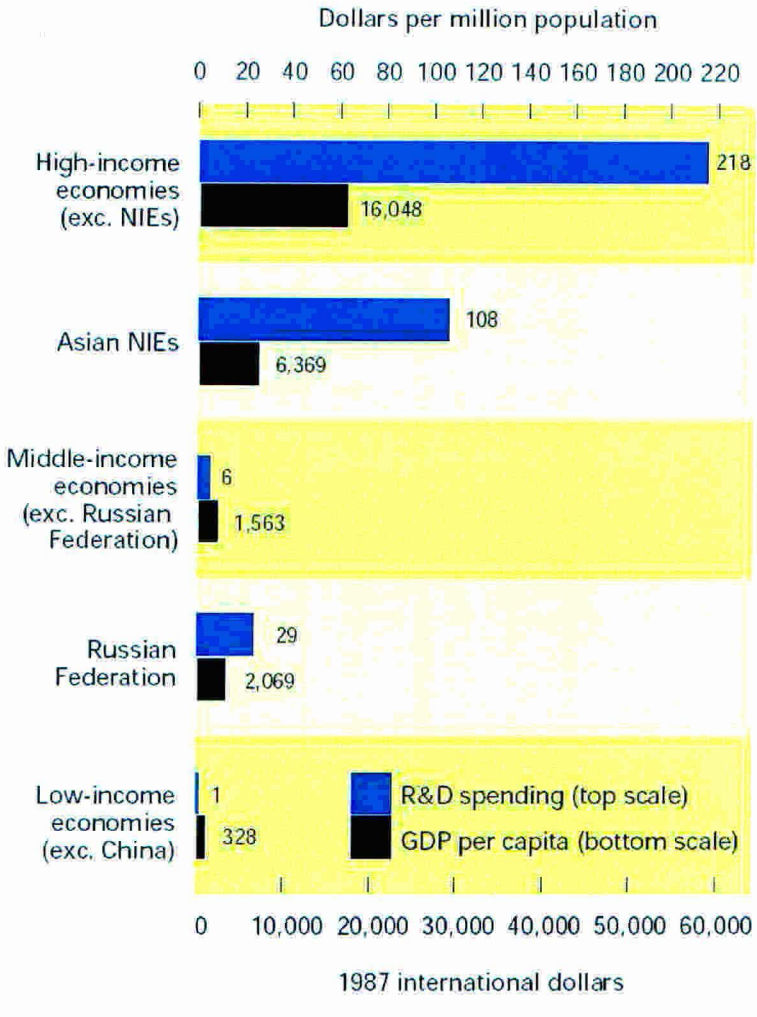
Information has become the backbone of knowledge based economy, because unless we are informed we cannot compete in today's globalized world. Information of modern technologies and knowledge make us capable in solving our problems easily and efficiently. For instance, if the people in rural areas are informed are about the importance of hygiene they can keep themselves away from diseases. However, this is possible only when there is well developed infrastructure of information dissemination.

It is predicted that the gap between the new winners and losers within the world economic order will be dominated by information and in Knowledge Economies, the gap will be much larger than the development gap that now exist between the advanced and the less developed nations (Ogunsola and Okusaga 2006:140).

Figure 1.1

R&D spending and GDP per capita

Inequalities in the capacity to create knowledge exceed even those in income.



Note: Data are for 1991. Source: European Commission 1994.

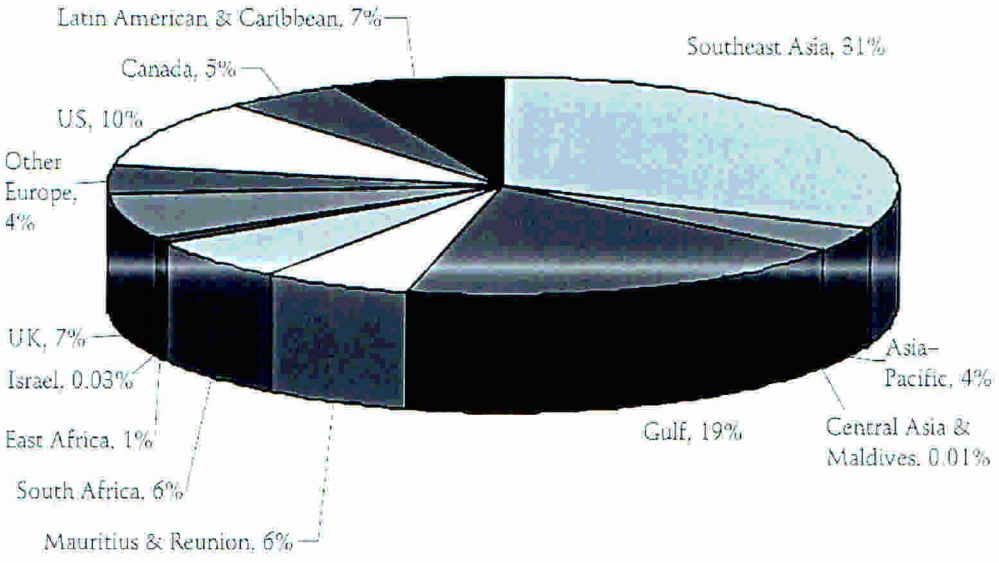
Source: World Development Report 1998/99, *Knowledge for Development,* Washington DC: World Bank, 1998-99:2.

In the era of globalization this divide is gradually increasing, which is the result of technological backwardness of the poor countries. The benefits of globalization are not equally distributed, because of the lack of needed infrastructure in LDCs that is why people in these countries are more skeptical about globalization (Mazrui and White 1991:354). UNDP in its 1999 report has clearly shown the widening gap between rich and poor countries in terms of per capita income, which was 3:1 during 1820, at the time of industrial revolution, which further increased up to 72: 1 after the commencement of liberalization, privatization and globalization (LPG).

In some of the developing countries, there exist huge and skilled man powers. These educated laborers (technocrats, medicos, academicians) migrate to developed countries because they do not get appropriate remuneration for their hard earned education. Till 1970 UK was the destination of migration of skilled labor and after that that destination has been shifted in US. If the migration of skilled labors could be stopped, it would be beneficial for poor countries. In the figure 1.2 shows the percentage of labor migration from India to other countries. The figure shows that percentage of migration of skilled labor from India is higher in Southeast Asia (31%), and second destination is Gulf (19%) and then it is US (10%).

They are bound to migrate to utilize their capabilities in developed countries. Therefore, it is multi pronged loss for developing nations. On the one hand they are failing to strengthen knowledge structure at grassroots level and on the other hand they are also failing to control the mass exodus of skilled man power from their land which can proved to be a better remedy for their ailment. Thus the divide between developed and developing countries is due to the problem prevailing within the countries.

Figure: 1.2 Percentage of Skilled Labor Migration from India to Different Countries



Source: High Level Committee on the Indian Diaspora (Indian Council of World Affairs 2001).

These problems have led to the failure of 'trickle down' theory in developing countries. According to this theory when the higher echelon of the society develops, it gradually leads to the development of lower strata of society. However, this model could not work in poor countries, because those who are well educated do not want to stay in the country and even do not want to invest their money back in their own country. Johnson Ihyeh provides a data in which he has shown that five millions Nigerians are working abroad and among them 1.2 millions are in US itself.

Comparison between developed and developing countries shows that the developing countries have lack of infrastructure to utilize their skilled man power (Ogunsola and Okusaga 2006:140). Prevailing orthodoxy and conservativism in LDCs are dragging these countries backwards and inclination towards innovation and acclimatizing capability of developed countries are creating new paths of development for them. Developed countries have sophisticated laboratories and equipments, whereas, in developing countries students sometimes do not have access to needed books, so the lack

of infrastructure at elementary level makes impact on the overall R&D structure of a country. International institutions like WTO, IMF and World Bank also could not address the problem because they do not have the adequate sense of the prevailing discrepancies in poor countries, and they imposed their programs which were not in accordance with the actual need of people. For example the conditonalities attached with the loans provided by IMF to LDCs to overcome the Balance of Paymaent (BOP) crises were more lethal than the crisis itself (Johnson Ihyeh 2000).

Creation of 'Empire of Domination' Through Knowledge

Nugent has widely debated on the issue of creation of an empire through knowledge. He talks about the three phases of changes in social sciences, which gradually expanded the area of influence of United States across the border. The first period he has talked about is the period of the 'formation of overseas empire' (1900-1940) the second phase started after the end of Second World War (1943-1972); and third phase was the reconstitution of overseas empire (1972-2001). During the first phase the US wanted to establish a commercial empire overseas with the help of production of relevant knowledge structure. Major changes were occurring in the social sciences research at that time due to expansion of the interests of developed countries. This was the time when the US government was intervening in the education sector of the country, and determining the structure and pattern of social sciences research. At that time the scholars from newly independent countries were more interested in searching the impact of industrialization, capitalism and imperialism on poor countries, their political setup, and labor migration etc.

The US with the intention of expanding its influence encouraged private actors to sponsor research to attract scholars from all over the world. Thus the Rockefeller and Carnegie philanthropies took the lead role in this effort and later on, got assistance from the Brookings Institution, the John Simon Guggenheim Memorial Foundation, the Phelps-Stokes Fund, the Julius Rosenwald Fund, and the Russell Sage Foundation (Crocker 2003:206). These institutions gave impetus to the expansion of western culture across the borders. These institutions tried to educate the elite foreign students who were coming for researches, so that when they will go back to their home land they will repair the image

of western world in the eyes of people. These institutions also worked to subsidies the research. These institutions lastly did social engineering to influence the people who were not modern. To attract people encouraged research on public health and epidemics to made people their supporters (Nugent 201:17).

The second phase started after the Second World War got over. By this time dominant role played by American in the arena of international politics was legally established. In 1943 Social Science Research Council (SSRC), presented its report titled *World Region in the Social Sciences,* it talked about the institutionalization of new geography and knowledge. Council tried provide to *privilege* the notion of culture area over other, alternative ways of approaching socio-cultural phenomena, thus it was a kind of cultural domination through the spread of knowledge (Nugent 2010:19). Now the focus was on the research over the emerging new geopolitics. US government wanted to have the grasp of the conditions across the world because they had faced a lethal war in recent past.

Third phase began after 1975, which is known for huge investment on infrastructure of training, research and publication. It was meant to establish global economic presence of US. Social sciences underwent another round of restructuring. This time the focus was shifted from area studies.

In all the three phases the nature of research and structure of knowledge were changed to extend the influence of US in world politics, which made impact on its influence in international arena. American scholars and universities were designed in order to assist the diplomats in foreign policy decision making, in the humanities and social sciences, scholars such as Beard, Carl Becker, Albert B. Hard and J. Franklin Jameson deployed their skills, as persuaders and educators, to serve government ends (Milne 2010:59). All these scholars opined that political science can provide solution to the emerging crucial problems in American foreign policy. However, Milne says that the incorporation of the views of intellectuals led to the failure of foreign policy because of the lack of the farsightedness of scholars, and they were also not aware of what is going on in the field. Thus the lack of practical knowledge and parochial attitude of the scholars harmed the national interest of the US.

The whole discourse of the role of knowledge in international politics revolves around the debate of domination through knowledge. Here the question is raised against the imposition of western stereotype models of research on the non western countries. Rudolph in this regard has talked about *imperialism of categories*, under which he writes that western research model are implied on non western sites, which is a kind of imposition of superiority through knowledge (Rudolph 2005:5). Rudolph further writes that American social and political scientists failed to understand that the entire world is different at different places, and they tried to apply one universal methodology to the non western societies. In these societies the prevailing conditions were altogether different from what were there in western societies. The universal application of theories was the result of the belief in the Lockean theory that *human nature* is common everywhere (Rudolph 2005:6). The theory of universalism was basically the byproduct of liberalism. Liberalism also laid down the foundation of the theory of modernization, which says that non western societies are not developed because they do not have that attribute of development. Basically these theories were the social construct against socialism and communism.

In 1958 National Defense Education Act was passed in the US, which gave impetus to area studies. The intention behind this law was to get strong hold over what is happening in different regions of world so that expansion of communism can be curtailed (Rudolph 2005:8).

Scholars such as Mohammed Ayoob have underlined the close relationship between power and knowledge. According to him:

"not only is knowledge power but power is knowledge as well. In IR theory, dominated as it is by American scholarship , the production and reproduction, construction and reconstruction of conceptual assumptions as well as theoretical conclusions .....privilege the experiences, interests and contemporary dilemmas of certain portion of the society, of state at the expense of the experiences, interests, and contemporary dilemmas of the large majority of states . . . The monopoly over the construction of theoretical knowledge depicts fundamentally the problem of inequality . . .this knowledge monopoly is intimately related to the monopoly over what forms the legitimate subject of study in IR . . ". (Ayoob 2002: 29).

The intention behind the politics over knowledge was domination of those who are

marginalized and less capable. Frankfurt School while propounding the 'critical theory' analyzed the social role of knowledge, for domination. The social relations based on domination are class based relations. People dominate each other and accept the domination of others in the name of technological reason and scientific rationality. Similarly the scholars from the Frankfurt school criticize the role of ideology, because ideology, in modern times, is used as a tool of domination. Ideologies are used to interpreter social and political situations to achieve narrow interests, by powerful countries. Technology is also used as an ideology to legitimize power and domination (Dant, 1991:66).

The major exponents of critical theory are Theodore Adorno, Walter Benjamin, Jurgen Habermas and Max Horkheimer, Robert Cox. The core argument of the critical theory is that the knowledge is even most scientific and commonsensical deeply imbedded in history and political in its nature. According to Cox, "theory is always *for* someone and *for* some purpose" (Cox 1981: 128). Critical theorists say that knowledge is shaped by different kind of human interests rather than being neutral, and because human interests are multiple consequentially knowledge is also pluralistic and incongruous and not monolithic. Political knowledge gives birth to political ideology, which again are interests driven. Critical theorists also criticize the concept of knowledge economy, because it is based on the domination of poor by dominant through the use of modern knowledge (Tyson 2006:56).

Diffusion of Western Knowledge and Cultural Violence

Developed countries argue that developing countries should allow the dissemination of western knowledge in their territory, which will help in their socio economic progress. However, the flow of information from developed countries is uneven and it makes many negative impacts on Third World society. For Escobar, the diffusion of western knowledge in the form of development projects marginalizes and disqualifies non-western knowledge systems and promotes "cultural violence on the Third World" (Escobar 1995:13). Indian eco-feminist and technology critics like Vandana Shiva argues that western science and technology are the results of Enlightenment thinking and positivism, which promotes for mastering over the nature for the satisfaction of greed and

destroying the harmonious relationship between nature and society (Kumbamu 2009:26).

The best example of the destructive nature of the modern technologies is that the Green Revolution in India increases the production of food crops in 1960s, but the use of chemical fertilizers and Genetically Modified Crops (GMC) led to reduced fertility of land in Punjab in India. It also enhanced the monopolistic nature of the market, as the seeds of GMC, cannot be preserved if once it is used in the field and the farmers are bound to buy those seeds from markets again and again. The irony is that the seeds market of GMC is monopolized by foreign MNCs and they demand high prices for these seeds. The inflows of modern technologies to developing countries are very superficial. Thus it creates a kind of dependency relationship among developed and developing countries. The innovations in the field of biotechnology have led to the increase of the hold of MNCs on the agriculture in developing countries.

The inflow of technologies from developed countries has also made bad impact on the promotion of collective knowledge. Collective knowledge is basically that knowledge which is owned by a community and it is transferred from generation to generation. It includes farming skills and agricultural related knowledge. It helps in bringing local people close to each other, and strengthening the bond among them. Preservation of local knowledge through socio-cultural practices enhances the intimate interaction between the primary producer and nature.

Now the question arises why developing countries go for the adoption of foreign technology even after facing the negative impacts of that. The answer of this question lies in the fact that MNCs have well developed market propagation system, through which they can easily manipulate the uneducated farmers in developing countries. As happened in the case of adoption of BT Cotton in Kadavendi, in India. To popularize the BT cotton in India the concerned MNC used mobile campaign, field demonstration and farmers' advocacy, which are the part of their market strategy (Kumbamu 2009: 28). Prior to the introduction of these new technologies farmers maintained good and sustainable relationship with nature and their social values were also embedded in it. The farmers used to worship nature as mother because nature fulfilled their demands, but gradually these cultural values are diminishing as a consequence of the dissemination of knowledge

and technologies from west.

Knowledge Crunch and the Politics of the Transfer of Knowledge

In the 21st century crunch of knowledge is the biggest challenge before developing countries simultaneously with human security and food security. Patent regime has made the availability of knowledge and technology more difficult. Patent provides monopoly over innovations and those who are not able to pay for the use of that innovation, are denied using those innovations. Patent system is the result of state's intervention for balancing the benefits of innovators and consumers. As Stiglitz has written:

> "the central public policy implication of public goods is that the state must play some role in the availability of such goods; otherwise they will be under supplied. If firms can not appropriate the returns to produce knowledge, then they will have limited incentive to produce it: in declining how much to invest, they will look at the return that they acquire, not the benefits that accrue to others" (Stieglitz 1992:311)

However the system of patent and intellectual property rights has hindered the free flow of knowledge from one destination to other because of the lack of consensus among countries over the issue of patent. Developing countries have found intellectual property regime (IPR) regime to be discriminatory. Transfer of knowledge leads to innovation and also strengthens the economies of the countries. The process of technology transfer is very complex and cumbersome as well. Six reasons have been explained for knowledge transfer hostility (Husted and Michailova 2002):

i. Potential loss of value, bargaining power, and protection of individual competitive advantage due to a strong feeling of personal ownership of the accumulated, "hard won" knowledge.
ii. Reluctance to spend time on knowledge sharing. The researcher and innovator may not be interested in knowledge sharing since the time and resources spent on it could be invested in activities that are more productive for the individual.
iii. Fear of hosting "knowledge parasites". The innovator may be reluctant to share their knowledge with someone who has invested less or no effort in his/her own development.
iv. Avoidance of exposure. By not sharing knowledge, individuals protect themselves against external assessment of the quality of their knowledge.

v. Strategy against uncertainty. Due to the uncertainty regarding how the knowledge receiver will perceive and interpret shared knowledge, knowledge sending countries may be highly cautious about revealing the relevant knowledge.

vi. High respect for hierarchy and formal power. The innovators, scientists and researchers may be reluctant to share crucial knowledge for fear of losing a position of privilege and superiority.

One more problem associated with technology transfer is the underdeveloped link of knowledge and technology transfer among LDCs themselves. Most of the researches done in developing countries are of immense importance for the other LDCs, because of the similarity of prevailing problems. Especially the medical research in developing countries can proved to be beneficial for the countries facing the same kind of challenges. These linkages can reduce the cost of technology and knowledge simultaneously with the reduction in the cost of transfer. Dougherty writes "Knowledge transfer is about connection not collection and that connection ultimately depends on choice made by individuals" (Dougherty 1999:264).

Multinational Corporations (MNCs) are the main source of the transfer of technologies and modern knowledge and also increase the foreign direct reserve (FDR) of a country. But developing countries have poor infrastructure and thus these MNCs do not want to invest their money in these countries. Eventually it disturbs the flow of knowledge. Lack of political consensus and unstable political system makes the procedures difficult in LDCs thus the MNCs get distracted. It creates the fear of loss of money and time in foreign investors.

International politics over knowledge began with the emergence of Trade related intellectual property rights (TRIPS), through which the developed countries wanted to control the world. They want to sell their innovation at the higher cost possible so that they would be able to dominate the world market. TRIPS is the most controversial regim when we talk about the transfer of knowledge. There are different viewpoints with regard to this issue. Some of them favor the strong IPR regime and some other considers it as a hindrance in the development of developing countries. The scholars like Kamil Idris, who favor strict IPR regime say that strong IPR regime gives incentive to the people involved

in research to keep on working for the generation of new knowledge and ideas, because it ensure that their research will not go unpaid and they will be rewarded for their work.

However, the people on the other side say that the strong IPR regime disturbs the free flow of information, and those who are not having money cannot buy information. Thus instead of narrowing the knowledge gap TRIPS is creating disparity between developed and developing countries. Strong economic and knowledge infrastructure make the position of developed countries strong at the international forum. International institutions also become the subservient of these nations and get distracted from their real objective of bringing equality among nations. Thus because of the several inside and outside hindrances the transfer of knowledge has become a cumbersome process which results in knowledge crunch in developing countries. Knowledge crunch make the LDCs disadvantages them in the era of globalization, where knowledge is the source of creation of wealth. Moreover TRIPS has done nothing to provide protection to indigenous knowledge structure in developing countries.

Debate over the Protection of Traditional Knowledge

In contemporary intellectual property debate protection of indigenous or local knowledge is the main issue. The modern day intellectual property protection mechanism has its origin from western world. Hence the issue of protection of indigenous knowledge under modern day protection arrangement has become the debate on the knowledge and development. Basically different societies have their cultural specific knowledge protocol to protect the local knowledge. Many a times they are not complementary to the modern day IPR system. Failure of modern day IPR in protecting indigenous traditional knowledge raises question against their legitimacy (Oguamanam 2003:137).

In the era of globalization developing countries demanded for the reconciliation between traditional knowledge and IPR regime, so that they can get benefit of their indigenous knowledge. The demand for the reconciliation was based on the fact the value of indigenous knowledge was increasing in the field of science, culture and economic and commercial field. The aim of traditional knowledge is the establishment of better society, thus the practitioner of this knowledge demanded for the protection to the traditional

knowledge. The protagonists of traditional knowledge did not demand only for material gains but they also wanted to maintain the cultural integrity of that knowledge.

The first difference between present day IPR system and the traditional indigenous knowledge that, the modern IPR confers the individual rights, whereas, the traditional knowledge needs community based system of rights to protect traditional knowledge. Secondly the traditional societies are base on collective organizational structure and they lack the required legal personality, but in present day IPR system juridical person hold the IP rights. Thirdly it is said that indigenous bicultural knowledge is the result of accumulation of knowledge from time immemorial, so that knowledge should be kept in public domain for use and no IP right should be claimed on it. Fourthly the indigenous knowledge is available in oral form which is very difficult to give a form of a text, so the IP rights claim over it is hard to realize. Lastly the indigenous communities do not have material resources to register for IPR (Oguamanam 2003:143).

The issue of traditional knowledge is relevant in the health sector. Indigenous traditional approach towards health is very different from existing notion of health under World Health Organization (WHO). The indigenous health care culture has its own theories of health, diseases, affliction and sufferings. According to traditional knowledge health of an individual is closely associated with family, community, spiritual and metaphysical linkages. Traditional medicines play very important role in the propagation of indigenous medical culture. WHO defines traditional medicine as: "the sum total of the knowledge, skills and practices based on the theories, beliefs and experiences indigenous to different cultures, whether explicable or not, used in the maintenance of health, as well as in the prevention, diagnosis, improvement or treatment of physical and mental illness" (WHO/EDM/TRM/2000: 155-157). In contrast western biomedical approach to illness is strict scientific Endeavour.

Thus traditional and western medical cultures are very different from each other. They follow diverse valises and practices. Thus it becomes very difficult to reconcile both in single IP system. Since the last decade the solidarity among the indigenous people has increased through workshops and conferences. There initiative for the protection of indigenous knowledge achieved some success also. The Mataatua Declaration on

Cultural and Intellectual Property Rights of Indigenous Peoples is one of them. It was the first international conference of its kind.69 The Declaration associates the protection of indigenous knowledge with self-determination.70 It also recognizes, among other things, that the existing protection mechanisms are inadequate to safeguard the intellectual and cultural property of indigenous peoples (Oguamanam 2003:153). The other initiative is the International Consultation on Intellectual Property Rights and Biodiversity in 1994.

Thus we can say that the indigenous knowledge protocol should be reconciled with the modern day IPR to provide adequate protection to indigenous knowledge, because they constitute the cultural heritage of world.

Conclusion

Since the beginning of humanity the mightiest has determined the social, political and economic system, so the power determines the shape of society. In the present time also the developed countries are dominating the entire information system. They determine the path of the flow of knowledge and technology. What they have is always taken as modern and competent and everything else is mediocre. Their knowledge, their society and political system everything is considered as most developed because of the power they wield. Thus the entire superiority is constructed and imposed on the wreaker. Industrial revolution in developed countries made them capable of producing modern technologies, which they used as a tool of domination. These new technologies are considered to be modern because they were fulfilling in present time the need of human beings and reducing individual's labor. Innovation in the field of technology tighten the grip of western world over the international political economy, consequently they ordered the international market according to their wish. Those who were weak began to follow the western world.

Better life and economic well being of the citizens are the main aims of a welfare state, which can be realized when a country is able to fight and survive in the competitive international environment. Gains are possible when the people are well informed of what is happening around the world and what they have to do to get their due share. However, researchers in developing countries many a times do not want to waste their knowledge

and time in their own country because they do not get any incentive for innovation. So from very basic level of elementary education to the higher level of research developing countries are suffering.

International dissemination of information and knowledge is not very smoothing rather very discriminatory. Needy countries do not have access to the modern technologies due to the lack of information, which makes impact on their internal social and political system. Those who have knowledge are not ready to share it as global public good because of their economic gains. Instead of making the system smooth TRIPS regime has made the condition worse. These countries take it as a discriminatory system. No doubt protection of intellectual property is very necessary because it gives incentive for further research and development but discriminatory IPR regime has created hue and cry which further led to the chaos in international political economy.

The problem of unavailability of information and knowledge can be addressed only when a regime, which can harmonies the interests of developed and developing countries, comes into existence, which can fulfill the needs in developing countries. Secondly all the barriers should be demolished to further the free flow of knowledge. Thirdly the developing countries should try to improve communication channel among them so that they can solve the problem at their own level, and international institution should also shoulder the responsibility of the development of LDCs by creating the condition of free flow of knowledge. Though the south-south cooperation movement can bring better results, but the problem is that almost all the countries in south are facing the problem of political, social and economic instability. Thus in that condition fruitful cooperation among them is very difficult, but if they overcome this problem their dependency on developed countries will reduce. If all these measures will be followed the problem of information can be solved.

Chapter II

The Evolution of TRIPS Regime

In the previous chapter importance of knowledge as a resource has been discussed at a length. It is also accepted that knowledge is the source of power and power gives impetus to the development of a country. Further the development determines the stature of a nation in the arena of international politics. The entire gamut of debate covers the issue of 'who owns knowledge?' and how the possession of knowledge in few hands has given way to the uneven development of countries in the world? Disparity of development has not only divided the world into 'developed north' and 'developing south' but it has also given birth to the cut throat competition among countries.

Availability of infrastructure gives incentive to the research and innovation in developed countries. Most of the developing countries have colonial past, so the time when the LDCs were fighting for their freedom developed countries were focusing on their technological development. They used to get raw material from their colonies and also the market to sell their finished goods. Thus the lack of development among poor countries is also due to the result of their exploitation in the past.

In the present era of globalization, knowledge is like a fuel to the process of development. So the countries want to possess knowledge, and they do not want to share it with others because they are concerned that sharing of knowledge may lead to the contraction of market for their goods. The controversy related to the sharing of knowledge is not new; rather it started from the time when knowledge based goods began to dominate markets. Initially the demand for the protection of knowledge was limited to the territory of a nation, but now it has become a burning issue of international political economy.

During 1970s the pattern of international trade underwent tremendous change, now the labor intensive goods have been replaced with knowledge and capital intensive goods. The production of theses goods needs huge amount of capital and time, which make these goods costly. Productions of these goods were possible only in the countries which were

having well developed infrastructure for Research and Development (R&D). Basically two major issues were there with these types of goods: *first* was the issue of price and *second* was the issue of duplication of these goods. Specifically the most vulnerable area of research of getting duplicated was the pharmaceutical research.

The issue of price and duplicity brought into light the 'need for a regime' which could secure the rights of the owner of knowledge based goods and also the need of people. In the developing and under developed countries, the people were not able to feed themselves properly, the demand of per day calorie intake remained unmet, in that condition the high prices drugs for their treatment was a like a curse to them.

Change in the pattern of trade gave birth to new types of disputes, thus a new type of dispute settlement mechanism was needed. The lack of compromise and the complexity of issue worked as hindrance in the emergence of an international regime so that it could provide plausible solution to the problems of both the sides. Countries themselves were not able to solve these dispute, thus the several rounds of negotiations at international level gave birth to General Agreement on Tariffs and Trade (GATT) in, 1945. GATT was necessarily meant to regularize trade, and to work in order to reduce trade related barriers in international trade.

Contradictory Positions of the countries over the Issue of the IP Protection

Carlos Maria Correa says that the industrialized and developed countries forced developing countries to adhere the similar law system of protection to IP as was prevailing in developed countries, and asked them to come forward for the negotiation over this issue. Developing countries had no other way, but they started negotiations at GATT (Correa 2003:3). Basically the increasing importance of technology for development made the developed countries to pressurize for the adoption of strict IPR regime. Technology based development needed rigorous R&D, which also needed a great amount of fund. In developed countries including America and European countries these R&D was financed by private sector. Secondly the production of the knowledge of technology was a very extensive procedure not limited to a particular area. Verities of

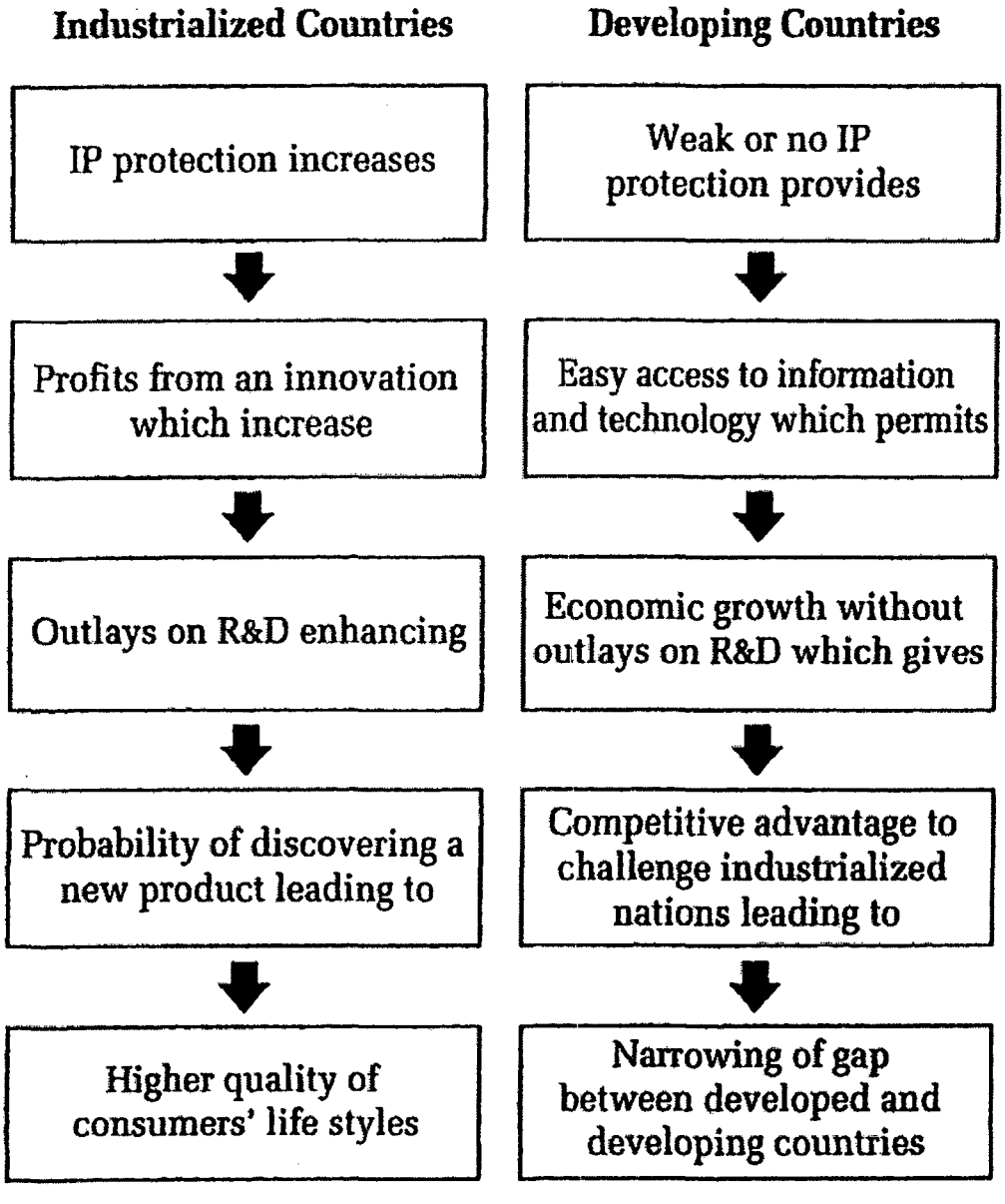
external help and resources were used which sometimes harm the benefits of innovator. The multinational companies also pressurize their government to avail easy access to the markets in developing countries, so that they could exploit the innovations in the markets of developing countries (Correa 20035). Finally the needs and awareness in several Asian countries including Japan challenged the technological leadership of US, which was also one of the most important causes behind the demand for a stricter IPR regime.

'Monopoly rights' were the only way to satisfy the demand of private sectors in developed world. Because of the less expenditure on R&D most of the developing countries were dependent on the innovations made in south. The strict IPR regime was a kind of protectionism adopted by developed countries. It was basically the demand for the universalization of certain laws and principles which were ultimately in the favor of developed countries. Prior to the inception of TRIPS Rome, Berne and Paris Conventions were existing, which were meant to provide copy rights and some sort of patent protection to industrial designs to the innovators, but they were not very comprehensive and only few countries were the member of these conventions. However, in today's time when the spread of technology and knowledge is not limited to the boundary of a nation or continent, greater protection to goods and services must be ensured. The prices of goods and services are dependent more on their chances of getting duplicated, as we can see with the case of pharmaceutical drugs and biotechnological innovations. The most pressing issue between the developed and developing countries is the harmonization of international laws with domestic laws.

Developed countries demand change within the domestic setup of IP laws in developing countries, which is next to impossible. It is not possible among the group of developed countries even. US is campaigning for a global reform agenda in this sphere, which is discarded by almost every country in the world. On the issue of the adoption of TRIPS developed and developing countries were having opposing positions. In the Figure 2.1, different perspective of developed and developing countries has been shown. US stood for the cause of Multi National Companies (MNCs). Thus it also has greater impact on the structure of the regime of the present time. Basically these big companies were giving financial support to the ruling parties in the US and secondly their lobbies were very

strong in the US Congress.

Figure: 2.1 Differing Views on Intellectual Property



Source: Jain, S. C (1996), *Problem in International Protection of Intellectual Property Rights.*

Some way or the other TRIPS came into existence on the basis of the issues raised by US. During 1980s US through the established Federal Circuit Court of Appeal and broadening the definition of patent, the US tried to convince other nations to adopt strict IP regime (Maskus and Reichmann 2005:310). In the case of TRIPS, the US was also facing the challenge to its hegemonic position. As the scholars of hegemony stability like

Van Grasstek interprets that whenever a hegemon faces the threat of competition, competitive advantage by some country, the hegemon demands for the a strict international regime to stop the competitors. Christopher May writes that the primary target of TRIPS are those developing countries that have sufficient indigenous technological capacity to qualify as potential innovators but are more likely, in short to medium term, to be imitators, or outright appropriators, of imported technology. IPR regime bears striking resemblance to US laws on patents, copy rights and trade secrets (May 2000).

Many MNCs of the US including IBM and others in joint collaboration constituted a Intellectual Property Committee (IPC), to lobby in the US Congress in favour of these MNCs. IPC worked in close association with United States Trade Representative (USTR) the most prominent governmental body of the US government. It assists government on trade related issues. In 1988, a law 'Omnibus Trade and Competitiveness Act' was passed, which authorizes US president to take decisions on trade sections against any country independently. The famous US 'Special 301' law was the baby of this law. This law made US the watchdog of the IP laws of the countries which were its trading partner. Basically the 'Super 301' law was an exploitative policy of reducing the volume of import in the country and increasing the export of knowledge based goods in international markets. It was also viewed as an effort of reducing the competitions from the countries which were making progress in the field of technology and knowledge based goods. Michael Ryan opines that US used its Super 301 laws to punish East-Asian economies because they were export led economies and they were creating challenges for the indigenous goods of American producers during 70s and 80s of the last century. 'Super 301' was the power oriented diplomacy applied by the US to punish the countries which were not functioning in accordance with its interest (Ryan 1995:29).

For the first time, US 'Super 301' law was used against South Korea in 1985, when the allegations was made that Korean IP laws provide only process patent to pharmaceutical companies, and not the product patent. Eventually this issue was taken as an instance of IPR violation, and USTR used it as a weapon. Later, in the Uruguay Round of talks the US used this incident for justifying its demand for strong TRIPS regime. South Korea

was forced to make changes in the prevailing IP laws of the country as per the US IP laws. In 1970s US government came up with another set of laws called 'Generalized System of Preference' (GSP). It was an effort of the expansion of markets for the US goods in developing countries (Onkvisit and Shaw 1989:76).

In this system a list of goods was prepared by participating countries. These were the goods, which were produced in the US and other GATT member countries as well, now as per the GSP system developing countries who are exporting listed goods to developed countries they will not have to pay any tariff for their export, until they gain potential of competition at international level. The GSP system was contradictory to the Most Favoured Nation (MSF) principle of GATS, according to which the equal tariff concession should be extended to all the trading partners. GSP was a unilateral grant of tariff concession because developing countries are not required to extend the same kind of concession to developed countries. This list included leather products, textiles, and agricultural goods etc. This law seems to be in favor of the poor countries but actually the conditionalites attached with the quotas worked as a pressure on LDCs and created havoc for their commerce and trade (Kelly 1988:25).

The GSP system had limited impact on the developing countries. The data shows that only 9.6 percent of import reached to the US market in 2005 under preferential terms of GSP. Many of the products could not become the part of this list because they were assumed to be exceeding the competitive need limits of given products. GSP tariff cuts resulted in efficiency and welfare losses in world economy because it was a discriminatory system (Borrmann, Borrmann and Stegger 1981:1980).

In its regional trade agreements also US gave immense emphasis on the implementation of strict IPR regime in the territories of its trading partners. Canada was asked to bring changes in its domestic setup of laws when it signed North American Free Trade Agreement (NAFTA) with US. Now at the request of any NAFTA member country a binominal panel may be setup to consider the affects of the operation of this agreement. A binominal review panel came into existence as a progeny of this agreement which replaced domestic judicial review when a countervailing duty or anti dumping ruling is appealed (Cameron and Watkins 1993:175)

It is not that only US was demanding for the strict IPR regime, but the problem faced by US economy was more than the other countries, Hence it took major initiative with this regard. Correa writes that during the 1980, Japan's technological capacity was increasing which was a kind of challenge to US supremacy. This was the time when US economy was also facing heavy trade deficit, which resulted in open scientific and technological system. It increased the chances of piracy of goods produced in US. Thus the US was bound to take initiative in this field. Piracy in the field of software technology and film industry gave impetus to the process of privatization, in the US and many EC countries and since the beginning of the debate over TRIPS the developed countries always had an edge over the poor countries (Correa 2001:98).

Historical Evolution of Intellectual Property Regime

Kamil Irdis traces the evolution of IPR regime, way back since the emergence of renaissance in northern Italy. In 1474, Venetian Law was passed by Republic of Venice, to protect the inventions; it was a kind of patent law at that time. Under this law if an innovation is put into the market for practice, then the innovator must inform the Republic about his innovation to get legal protection for the invention (Irdis 2003:3). Prior to the 19th century state used to be the only body to control trade within the territory. There were no so called universal laws and principles of trade. But as soon the countries began to have the sense of *comparative advantage*, since then restrictions and barriers took their shape. Simple trade of was replaced with a complex one, barter system was replaced by the system of token money. Technological advancement gave the new counters to international trade. Now the gold, silver and spices were not the only commodity to be sold rather several other knowledge based goods became a part of commercial exchange. New form of trade had changed the structure of international political economy.

After Second World War the world economy was undergoing major crisis, and the countries which fought the war were not capable enough to sustain their economies on their own. So the negotiations started under the auspices of United Nations (UN) for the

establishment of an international regime to regularize international trade. Later on proposal of International Trade Organization (ITO) came in, to give as a patronage to international trade. However, ITO never came into being. Thus the Bretton Woods Conference gave solution to the war torn international economy in the form of GATT. It was meant to reduce restrictions on trade like, trade tariffs, quantities restrictions, and uneven subsidies distribution. GATT came into existence in 1945, and in 1995 it was replaced by World Trade Organization (WTO).

GATT came into existence to regulate trade among countries, and also to interlink international market with national markets. Although it worked successfully more than 40 years, later it was replaced by WTO, because the member countries wanted to broaden the scope of the international trade regime. GATT used to regulate trade of goods only and did not talk much about knowledge based goods or intellectual property and it was also silent about trade in services. GATT was also not having any institutional foundation (Jackson 2000; 497). During 1970s the debate over the establishment of IP regime started under GATT, and three major rounds of discussion took place: Tokyo Round 1973 (the duration was 74 months), second was Uruguay Round 1986 (duration was approximately 87 months) after that Doha Round took place in 2001 and later the discussion continued in Cancun Ministerial Conference (Narula and Lall 2005: 274).

Basically the emergence of these intellectual property regimes are meant to provide property rights to the individuals who have created a certain type of intellectual property so that they can get remuneration for their work. These regimes are also meant to settle the disputes among countries and also among individuals over trade related issues. Though there were existed several indigenous intellectual property laws existed in different countries but the concrete emergence of intellectual property regimes can be traced back to the time when 'Rome' 'Paris' and 'Berne' convention came into being. *Role Convention* was for the protection of the works of performers, broadcasters, organizations and producers of phonograms. Paris Convention is known as *Paris Convention for the Protection of Industrial Property.* It came into existence on March 20, 1883. Berne Convention is meant for literary work came into being in 1886, and known as *Berne Convention for the Protection of Literary and Artistic Work.* Paris Convention

provided security to 'industrial design' and 'trade mark'. According to this treaty a party can file an application to the headquarter of this convention for the protection of its design and it can use that date of filing application in another country also to get protection for the same date. Till now there are 173 countries as its member. Member countries were free to construct the structure of protection for industrial design, and it also mandates equal treatment to insiders and foreigners (Grosse 2000:286).

Berne Convention is meant for the protection of copy right. Paris Convention and Berne Convention laid down the foundation of future World Intellectual Property Organization (WIPO). Both the convention was functioning under the aegis of *United International Bureaux for the Protection of Intellectual Property* (BIRPI). BIRPI came into existence in 1883. WIPO was established in 1967, and became a specialized body of United Nations in 1974. However, these two conventions did not prove to be that successful as countries were allowed to set their own standards and there were no internationally recognized principles in these conventions. WIPO definitely could have been proved to be a successful organization but its weak enforcement and dispute settlement mechanism made it a feeble body of UN, which was not able to punish free riders. Even it did not have the mechanism to punish those who violated the laws. Thus the demand for a strong mechanism to provide security to intellectual property grew up.

In 1973, Tokyo round was held and lasted till 1979. This round was again initiated on the request of developed countries, especially US and European Union (EU) countries for the bringing up of 'Anti- Counterfeiting Code' to stop the parallel import of counterfeited goods. Watal has written that the objective of this proposed code was to agree to broader measures for the interpretations and eventual destruction of such goods outside the channels of commerce. These countries were raising these demands to protect the interest of the big industries in their countries. In the atmosphere of lack of consensus among the countries no decision could be taken. However, this round was the stepping stone in the way of the establishment of TRIPS regime. At the second meeting held at Nairobi in 1981, the demand was forwarded by developing countries for providing some relaxations under Paris Convention of industrial design, so that the standards of the Convention could be applied in developing countries as well. The industrial development of these countries

could not reach to the level prevailing in the western world, so their demand for relaxations were obvious , which was completely denied with the conclusion of third round in Geneva in 1982 (Stewart 1999: 480-82).

Developing countries were also demanding for the right of compulsory licensing of patents. However, their demands were not accepted. There was a group of countries including Canada, Australia, New Zealand, Portugal, Spain and others were supporting the demand of preferential treatment for LDCs and developing countries, but with the conclusion of Geneva Round of talks all the hopes of these countries vanished. Watal writes that the failed Paris revision process thus marked the end of an era of lowering or weakening international IPR standards. From this time on through the end of the TRIPS negotiations, developing countries remained on the defensive with regard to IPRs (Watal 2001:16).

Evolution of TRIPS in Uruguay Round and Dunkel Draft as a Step Forward (1991)

TRIPS Agreement was meant to provide patent protection in all most all the areas of innovation and that too for 20 years. It also recommended for the implementation of rules universally in all the countries irrespective of their level of development. It also required establishing a mechanism which could punish those who infringes the IP laws, so that in future the violation of IP laws and piracy could be avoided. These were some of the issues which made TRIPS a bone of contention between developed and developing countries. Finally at Punta del Este the developed countries agreed on Agreement on Textile and Clothing (ATC), according to which they decided to phase out their quotas on textile. In response to it developing countries were asked to introduce product patent for pharmaceuticals drugs. At Punta del Este the decision to organize Uruguay Round was taken (Sander and Inotai 1996:38). The main concern of developed countries was the inclusion of TRIPS, some way or the other. However, ATC itself was discriminatory in the sense that developing countries were bound to take immediate steps for product patent from 1995 onwards, whereas the developed countries got leeway to implement the phasing out of quota by 2005. The decision was taken in 1986 at Punta del Este that

TRIPS would be the prime issue of discussion at the first phase of Uruguay Round of talks. The problem with the TRIPS was that, it was based on the western legal practices. Most of the existing patents are held by US, EU and, Japan, so it was also seen as a policy of technology protectionism (Maitra 2007:16).

Midterm review of the ongoing Uruguay Round was supposed to be held in 1988 in Montreal, thus in November a report was submitted to GATT, but unfortunately that was rejected by US for not being up to the mark. Allegations against developing countries were made that they are demanding too much. In the report Brazil did not have clear positions on the standards of IPR, on the other hand US was focusing more on dispute settlement and that standard to be followed, eventually all these disparities led to the inconclusive midterm review. Hence the responsibility of solving the dispute over TRIPS standards along with the issue of textile and agriculture was forwarded to the Trade Negotiation Committee meeting, which was expected to be held in Geneva in April 1989.

Midterm review in Geneva proved to be successful for US and other developing countries as the issue of setting up of standards were resolved and it was considered as an important issue to be discussed and also to be incorporated in TRIPS under GATT. The term 'trade related' was still closely associated with IPRs which was an ardent desire of developed countries. India was of the opinion that restrictive and anti competitive practices should only be incorporated in trade related aspects of IPRS and rest of the decisions should be left to the governments, as they are better aware of their needs and technological development. In 1990s, Korea in its report demanded for liberal compulsory licensing, and Peru demanded for the clear elaboration of rights and obligations under IPRs.

During the first half of 1990s rapid development took place. The emphasis was put on the adoption of a composite text/draft to proceed further. In March 1990 EC came up with the text which was having the language of an agreement with principles and standards. US, Switzerland and Japan also submitted their text following the same line. Lars Anell from Sweden was heading the committee and he gave deadlines for further submissions of the texts from other countries as well, but developing countries were facing problem for the recommended submission as the lack of coordination among them hindered the

process of adoption of a common text. Later on with the help of United Nations Conference for Trade and Development (UNCTAD) committee developing countries submitted 'Tallories text' W/71 in the month of May. Even after these submission developing countries couldn't put their demand forcefully as they were some way or the other facing trade related problems like sanctions and embargos.

In the Uruguay Round (1986-1994) of talk one more important issue was the dispute over the inclusion of service in the sphere of trade. Developed countries wanted the internationalization of services provided by them and also the security to those services, but developing countries were against this view, as the local establishment was necessary if a country wants to provide a certain service across its territory. Developed countries initiated General Agreement on Trade in Services (GATS), which could further enhance the competition in developing countries. So they did not agree to this provision in Uruguay Round of Talks. In Punta del Este, conference however developing countries got some success in keeping the issue of services separate from the issue of goods. However, at last when the draft was prepared these were merged tighter as the issue of goods, services and intellectual property were the three main pillars of Multilateral Trade Organization (MTO).

The other issue was related with the reduction of subsidies on Agriculture which resulted in huge disparity of prices in international market. Restrictions on foreign investment were another issue of negotiation at this round of talks. The issue on agriculture could not be resolved as it was a bone of contention between US and EU. They could not reach to the consensus that how should they implement agricultural reforms, because US wanted to liberalize the agricultural trade while EU was not favoring it. Since the establishment of GATT, agriculture did not get special attention, as it was treated as any other good, included in trade list. But agriculture enjoyed a special status in many of the countries, so these countries wanted special negotiation on that. Finally there dream came true in Uruguay Round of Talks, when attention was paid to the issue of agriculture. Later on in Dunkel Draft agriculture remained important issue. But EU rejected the draft and wanted renegotiation certain parts of it. EU was still against the huge cut in export subsidies, but later on with the Blair House Accord both the parties reached to a conclusion. Some

amendments were also made to the Dunkel Draft. Now the amount of export subsidies was reduced to 21 per cent from 24 per cent, the baseline from which the cut in subsidies was to be implemented was made more flexible. Commitment was also made to reduce in the overall support in agriculture by developed countries.

In the late 1990s the draft of TRIPS was prepared by the group called 'ten plus ten' means the draft was the result of the collaboration of ten developing countries and ten developed countries. During 1990s Canada proposed a plan for a MTO to deal with TRIPS, and it also asked for making it mandatory, either to accept or reject the TRIPS in toto by the countries. Here the dispute over the question that which body GATT or WIPO should deal with substantial and procedural issues of TRIPS, was solved. Now the MTO was expected to be given the task of establishing TRIPS regime and later on this MTO was converted into WTO.

Since the concrete decision could not be taken at Geneva conference, Brussels Conference was meant to solve the remaining issues. In this conference basically the north-south tussle was meant to be mitigated because due to this animosity any concrete decision was unable to come up. The issues related with the specifics of TRIPS including patent, lay-out design, trade secrets, anti-competitive practices, were also supposed to be of primary focus in Brussels conference. Finally at the end developing countries agreed for the application of the existing terms and conditions of patent on all the patents for twenty years. One positive outcome for the developing countries was that, that transitional provision was not to be applied on agricultural and pharmaceutical products, and these countries got Exclusive Marketing Rights (EMRs) of the drug from the date of the commencement of the agreement.

Negotiating groups kept on meeting from March to September in 1990, and they kept on trying solving the unresolved issues. Meanwhile one of the groups 'Adean Group' which was consisted of Latin American countries countered the text of Brussels conference on copy right and wanted the application of Berne Convention as it was, but they couldn't succeed. By this time the issues related with the specifics of TRIPS like patent rights, compulsory licensing, transitional period, exceptions allowed and test data etc. were solved by the chairman law officially (Stewart 1999:529). The issue of transitional period

was the bone of contention among the countries and US did not favor the longer period of transition. In 1991 US brought back the issue of 'pipeline protection' which was discarded earlier, because under this system developing countries will have to accept the patent application of the forth coming projects, while being in the transition phase. It was said that developing countries could get transition period of 10 years from the very date of filing of applications by a pharmaceutical and agricultural chemical company. On this basis US negotiated for the protection of pipeline projects.

Now the responsibility of preparing a draft for an intellectual property right regime was on the shoulder of GATT secretariat and the chairman of TRIPS negotiation committee. Finally the draft came in , but India wanted revision of that draft which did not happen, because the dominance of developed countries. The final text came into existence at the end of 1991, without any change and modifications in it. Despite of the non consensual emergence of the agreement it was expected from all the countries to implement the laws after the WTO and TRIPS come into being. Thus from 1996 onwards developing countries were asked to implement patent laws indiscriminately, for both national and foreign products. For the implementation of other TRIPS laws countries could prolong the process up to 2000, and for the protection of product in the area of technology they could extend the period till 2005. According to a proposal in Dunkel Draft, the countries which are not providing product patent early, they have to bring 'mailbox' and EMRs in their territory as soon the TRIPS comes in to existence. EMRs were meant for the period before the grant of patent to products. (Odell 2006: 71).

In 1991, surprisingly under the 'Super 301' law of US, India had been accused of not providing protection for copyright and patent. Thus India's duty free treatment was suspended, and tariffs on its exports were also increased. In 1993 same treatment was done with Brazil, because the protection provided in Brazil were considered to be weak. It was revoked in 1994, when Brazil agreed to rectify the laws related with 'pipeline protection'. Though China was not a member of the GATT but after being threatened of use of sanction against it under 'priority foreign country' of US it agreed to enforce the intellectual property protection in 1991. Till 1996 China was accused twice for not enforcing IPRs adequately, but some way or the other it got two accords signed with the

US and finally managed to escape trade sanctions (Bird and Jain 2008:81).

India kept urging for transition period of five years excluding the 'pipeline protection' and it also made some demands regarding the issuing of compulsory licensing. Lastly, two changes were brought in 1993. Watal writes that one sponsored by US, amended Article 31 of TRIPS to add restrictions on the scope of non-voluntary licenses for semiconductor technology. Another demand strongly supported by Canada, added paragraphs 2 and 3 to Article 64 on dispute settlement that non-violation type of complaints would not apply to TRIPS dispute for the first five years. After this period, a decision has to be taken, by consensus, at the ministerial level on this issue. Thus the overall success of the developed countries has several reasons including the favorable trade conditions at that time, their technological advancement, and balance of trade in their favor, fall of Berlin war and, the US victory in the Gulf war. These factors played an important role in the establishment of TRIPS regime under the aegis of WTO (Dasgupta 2009:88).

Marrakesh Conference and the Enforcement of TRIPS

In 1995 at Marrakesh the final draft was accepted. The main aim now was to create balance between trade and environment. The TRIPS framework was expected to incorporate these two areas in it. It later on emerged as a big issue of discussion of TRIPS agreement. Finally the TRIPS was taken as an agreement by both developed and developing countries. Though developing countries could not get their desired position, but up to some extent they could bring to the light the plight of the people in their territory and could make demand on their behalf. Some clause of TRIPS are the wholly the outcome of the demand by LDCs and developing countries. The major cause behind their failure to achieve any substantial amount of gain was the lack of solidarity among them, because they were under the pressure of trade sanctions and embargoes by their partners in developed countries. As we can see, while the negotiation was going on many countries were victimized by US 'Super 301' law. Watal has pointed the major reason behind the non cooperation among the developing counties, is the expectations of gains in

attracting Foreign Direct Investment (FDI) through unilateral liberalization of trade and investment policies, for which strengthened IP protection for twenty years for pharmaceutical products was needed. However, 1992, US found the laws in Thailand incompatible with the commercial interests of US, as there were no proper protection to the pipeline projects was given. US also complained that IPR laws are inefficient in Thailand. Subsequently Thailand had to go for significant amount of change in its domestic IPR laws to escape the trade embargos under the 'Super 3o1' laws of US (Watal 2001:42).

Roads from Singapore to Seattle

In the Article IV of the WTO Agreement it is mentioned that after a regular interval meetings and conferences should be held to review the working and implementation of the Agreement on trade liberalization. Singapore Conference was also a step taken to review the implementation of the decisions taken so far. The issues at this ministerial conference were investment, competition policy, transparency in government and trade facilitation. These issues were necessary to get resolved for the smooth working of WTO.

Singapore Conference is considered to be largely successful on trade linkages issue. The conference also paid in attention to 'internationally recognized core labor standards' but no working group came up to look after this issue. Thus the Singapore Conference was a step ahead in the way of working of a multilateral trading system. An important telecommunication agreement was also come up, which was in favor of developing countries. Thus one may conclude that Singapore Ministerial was a positive outcome for an infant organization WTO (Krueger 1998:410)

After the conclusion of Singapore Conference, to further review the working of the draft adopted, a conference was held in Geneva in 1998. The important issue at this conference was the discussion over the problems in implementation of regulations in developing countries and LDCs, because their system has to undergo difficult changes to implement WTO regulations. The second most important issue was electronic commerce which was discussed at length in the last conference. The outcome of this meeting was the establishment of a mechanism for the evaluation of the implementation of individual

agreements. Secondly a declaration was adopted on the global electronic commerce.

In 1999, in Seattle once again a round of talk started, which is also known as millennium round. This was the third Ministerial Round of WTO. During this round the streets of Washington D.C. was flooded with protesters, because they were quite enthusiastic of their success in non implementation of MAI. The round was protested by anti-trade protestors, environmentalists, labor unions and many others. This is for the first time civil society groups got so much attention. The issues at this meeting were wide ranging, because last four-five rounds could not solve some issue, and they kept on accumulating. Tariff reduction and non-tariff barriers were the issues which needed immediate solutions. Moreover the bilateral trade agreements were not providing benefits to poor partner countries, because they have to pay high tariff on trade, these agreements were distorting trade, so this issue also need resolution of some kind.

Since the Uruguay Round the cut in agricultural subsidies was noted but still the foreign farmers were availing, domestic subsidies, export subsidies was creating huge disparity in international markets. It was a substantial issue at that time in WTO. Among the burning issues the issue of investment again divided world into north and south. Developed countries wanted no discrimination among domestic and foreign firms when it comes to investment, which was itself highly discriminatory because our firms cannot compete with foreign firms.

Other issues at Seattle Round were controversy related with dispute settlement mechanism, extraterritoriality and IP. But this round resulted into failure as many small countries were kept out of decision making process and US denied to link labor and environment standard with international trade. Further these issues were expected to be discussed in Doha (Grady and Macmillan 1999:140).

Doha Development Round 2001

Doha development round began in November 2001. The basic purpose of this round was to discuss the issues which came in post TRIPS agreement years. The mandate of Doha

Round focused on several issues, "It covers issues related to agriculture (Paras 13,14), services (Para 15), market access for non-agricultural products (Para16), TRIPS (Paras17-19), trade and investment (Paras 20-22), competition policy (Para 23-25), government procurement (Para 26), trade facilitation (Para 27), anti-dumping and subsidies (Para 28), regional trade agreement (Para 29), dispute settlement (Para 30), environment (Paras 31-33), electronic commerce (Para 34), technology transfer (Para 37), technical cooperation and capacity building (Para 38-41), least developed countries (Paras 42, 43) etc" (Nair 2009:246). Three major declarations came after Doha Round of talks: (i) Decision on Implementation Related Issues and Concerns, (ii) Declaration on the TRIPS Agreement and Public health, and (iii) Ministerial Declaration.

Easy accessibility to patented drugs was the main issue for the LDCs. Harmonization of the interest of the innovator and the right to healthy life to poor people was the main task of the Doha declaration. As the lots of hue and cry was made when South African government showed its will to provide its HIV/AIDS patent through compulsory licensing and parallel import practice. The declaration showed its responsibility towards poor countries, and allowed the government to avail the flexibilities provided under TRIPS like compulsory licensing to provide health facilities to their people. The declaration was made that the prime attention will be paid to HIV/AIDS, Tuberculosis, Malaria, and other epidemics. One important declaration was made in paragraph 4-6 of Doha Declaration "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" (WT/MIN(01)/DEC/2). The reason why only the spread of HIV/AIDS, tuberculosis, malaria is taken as the case of national emergency because the number of death caused by these diseases were high. Moreover the relaxations under TRIPS were meant for poor countries, and these diseases were very common in developing countries, thus they become important cause behind the declaration of national health emergency.

After the Doha Round the next meeting took place in Cancun in 2003, after it the meeting was held in Hong Kong in 2005. The same kind of recognition was given to

LDCs as they were given during Singapore meeting in 1996, where the developed nations agreed to provide technical assistance to the poor countries. "In the declaration, ministers stress that it is important to implement and interpret the TRIPS Agreement in a way that supports public health- by promoting both public access to existing medicines and creation of new medicines (WTO 2002). It also consist the provision that some arrangements would be made for the LDCs those who do not have pharmaceutical manufacturing capacity to utilize flexibility provided under TRIPS. The enforcement period was extended for developing countries up till 1 January 2016. The most recent meeting took place in Geneva in 2008.

However, the countries have not agreed to accept the demand made by African Group. They were demanding for the relaxation for the ingredients used for the manufacturing of medicines and also for the medical kits used for patients. The US, on the contrary provided a list of disease, only those diseases that can be taken to declare national emergency. Switzerland and EC have also supported this stand of US. Consequentially the tug of war started between developed and developing countries on the issue of agricultural subsidies, which made the international trade in favor of developed countries only. This issue has not been solved yet.

Under paragraph 18 of the Doha Declaration GI has been given proper space. It states:

> "With a view to completing the works started in the Council for Trade Related Aspects of Intellectual Property Rights (Council for TRIPS) under the implementation of Art. 23.4 we agreed to negotiate the establishment of a multi-lateral system of notification and registration of GIs for wines and spirits by the 5th Session of the Ministerial Conference. We note that issues related to the extension of the protection of geographical indications provided for in Art. 23 to products other than wines and spirits will be addressed in the Council for TRIPS pursuant to para 12 of this declaration" (WT/MIN(1)/DEC/1, 2001).

After the Doha Declaration three issues came up:

- The establishment of a multi-lateral system for the notification and registration for geographical indications for wines and spirits by 14 September 2003.
- The extension of additional protection provided for wines and spirits pursuant to Art. 23 to products other than wines and spirits (discussions) and most recently,
- An initiative to "claw-back" the exclusive use of certain GI names even if they are currently considered as "generics" or "trademarks" (Geographical Indication and Trade

Mark: The Road From Doha 2003:12).

After Doha again the meetings were held at Cancun (2003), Geneva (2004), Paris (2005), Hong Kong (2005), Post Dam (2007) and again in Geneva (2008), but the contradiction led to the deadlock among the countries. Every next round was called to resolve the issue of last round, and differences among developed and developing countries led to the collapse of negotiations.

Why TRIPS under WTO?

The major question which arises here, when there already existed several conventions and institutions like WIPO, why the need for TRIPS like regime arose? Paris conventions and the other similar conventions were very weak at implementations, because the principles and laws mentioned in that were vague. Secondly no dispute settlement mechanism was discussed, and lastly the conventions also became outdated, as they did not talk about the protection of new technologies and many new knowledge based goods and services. The existing regime were also making the process of FDI and licensing very difficult, which was not acceptable in the fast growing period of globalization and liberalization (Maskus 2000:15).

Emergence of TRIPS under WTO has no doubt made an impact on the stature of WIPO, because TRIPS has got powerful position in comparison to the other existing IPR regimes. WTO became more important because it can issue sanctions against countries which are found guilty of breaching trade laws under its Dispute Settlement Undertaking (DSU). WIPO did not have this kind of authority. WTO also has a mechanism to provide solution if any problem occurs in the way of the implementation of TRIPS. WIPO could not harmonies the laws at national and international level, which was a major challenge to its existence. The basic difference between WIPO and TRIPS is that WIPO was meant to protect intellectual property through increasing cooperation among countries, whereas the TRIPS has adopted completely different approach. TRIPS punishes those who breach the IP laws across the globe.

WIPO currently has 184 members and it has its headquarter in Geneva, Switzerland. The statement of WIPO is "to promote through international cooperation the creation, dissemination, use and protection of works of the human spirit for the economic, cultural and social progress of all mankind" (Pantalony 2007:17). WIPO provides the service for filing application for patent for that countries are required to pay the recommended amount which depends upon the length of the application. This is done under Patent Cooperation Treaty (PCT). Under PCT those who wish to establish a patent in multiple countries submit a single application to WIPO, which acts as a clearing house for all member countries' simultaneous consideration (Bouchoux 2008:427). WIPO uses the money given as fee by countries for its expenditures, thus it is a self-sufficient body of UN. Differences of approach have also made an impact on the stature of both the institutions in the eyes of developed and developing. The most difficult problem in front of WIPO was Standard Patent Law Harmonization Treaty (SPLT). It could not universalize the minimum standard of protection and it did not have substantial enforcement mechanism as well.

TRIPS proved to be the first regulatory regime to provide a enforcing mechanism with the definition of the minimum standard of protection. SPLT did not speak anything about the differences among the US, European Union (EU) and, Japan over the issue of patent laws, while TRIPS was the mechanism on which these countries were having more or less similar opinion. Above all the SPLT mechanism was not mandatory to the every member, rather it was optional. It made negative impact on the stature of WIPO (Takenak 2008:164).

Political Economy of TRIPS

TRIPS basically functions in the seven areas (Maskus, 2000: 17-23) :

Copyright is related with the original literary works of an author.

Trademark is protects word, symbol, or a mark which signifies a particular product or a company.

Geographical Indication signifies the production of a product from a particular area or a

regionit gives special protection to wine and spirit.

Industrial Design deals with the features or design of a product.

Patent gives the right of commercial use of the innovation.

Layout Designs for Integrated Circuits gives right to the producer of semiconductors.

Trade Secrets give protection to the confidential information of a business holder.

To understand the entire process of the emergence of TRIPS regime, it becomes necessary to look at the political and economic system prevailing at that time. Prevailing political condition at that time was not very conducive for the establishment of any developed regime, as per the regime theory. Stephen D. Krasner writes about regime:

> "Regimes can be defined as sets of explicit or implicit principles, norms, rules, and decision making procedures around which actors' expectations converge in a given area of international relations. Principles are beliefs of facts causation and, rectitude. Norms are standards of behavior defined in terms of right and obligation. Rules are specific prescriptions or proscriptions for action. Decision making procedures are prevailing practices for making and implementing collective choice" (Krasner 1983:2).

Inclusion of all the principle defined by Krasnet was not possible at the time of the establishment of TRIPS regime. Robert Jervis has talked about reciprocity as the one of the components of international regime. Reciprocity should be adhered to while the process of establishment of a regime instead of short term interest, by the states. However the principle of reciprocity could only take some shape if the ultimate goals of all the countries are almost identical (Krasner 1983:158). Basically the regimes are not an end rather they are means to achieve the common goals, which are beneficial to all. Regime enhances the possibility of cooperation, and negotiations over the crucial issues. It also ensures the benefits of the members party to it.

When the negotiations were going on regarding the establishment of TRIPS regime all the countries were divided in different groups, because of their peculiar interests. Donald G. Richard writes:

> "The countries that most strongly opposed the agreement, such as, Brazil, India and, Korea, are characterized by a desire both to have access to foreign knowledge-intensive goods and services and to possess substantial indigenous technology sector of their own. The countries which supported TRIPS, in some case only weakly, have well-developed technology-incentive productive

capabilities. These countries include European nations and Japan" (Richard (2004:112).

Richard traces the emergence of TRIPS, as the subsequent result of the emergence of 'international regime of accumulation'. After the Second World War international political economy underwent massive changes, and now the focus was on the international accumulation of capital, which may lead to the growth of world economy. At that time powerful countries put forward their demand for an international regime to combat the problem of competition among different capitals from different countries, which can also foster the growth of global capital accumulation. It was meant to reduce competitions and also to provide ways to developed countries to control international economy (Richard 2004:92).

The US was the stalwart of the debate on the issue of intellectual property, and also the internationalization of IP laws. US itself was not the part of Berne Convention. As Jayashree Watal writes

> "...the Berne Convention on copy right were considered to be quite high by the US, which was still not a member of this convention. Only the clarifications of such standards are their effective enforcement, particularly at the border, was sought to be achieved under the Uruguay Round" (Watal 2001:16).

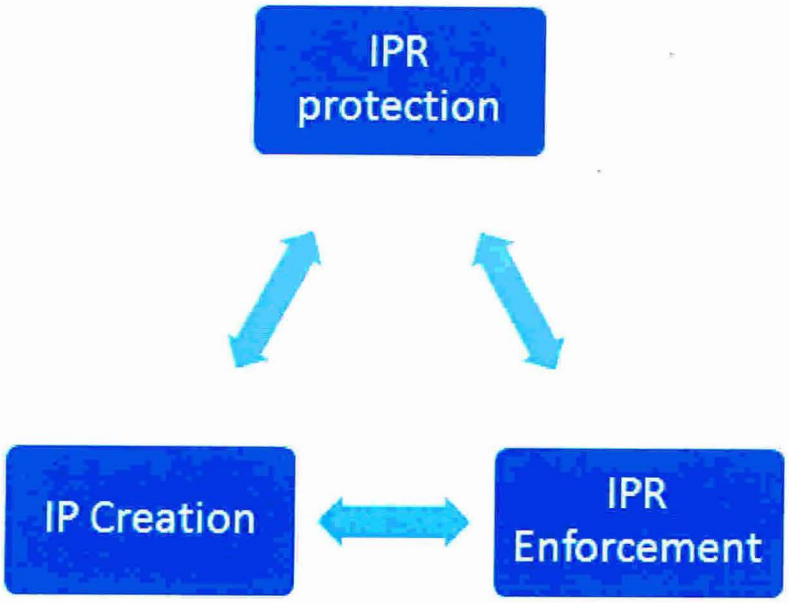
It led US to go for negotiations in United Nations Educational, Scientific and Cultural Organization (UNESCO), under the Universal Copyright Convention (UCC) in the year 1955. The US went for the laws corporate in UCC was not contradictory to the US interests, and it was also less rigid than the Berne Convention. Under Article III-3 of UCC the US could easily refrain from changing its domestic law according to the international laws. Thus to keep its system intact US supported UCC. This precisely shows that US had that potential to give shape to international regimes. Thus US has played very important role in the formation of TRIPS regime.

Major complexities in the way of the implementation of the standards of TRIPS were that, it needed the overhauling of the domestic IPR setup in the developing countries,

which was not possible without the heavy investment of money. These countries were also facing the problem of lower lever of R&D, and limited research facility. Market development in these countries was not of that level which could help them to survive ongoing the cut throat competition in the era of globalization.

Among the above standards the most problematic was the Patent. The vast majority of Patent are owned by industrial countries and they also invest largely on R&D, because this investment brings them huge economic benefits in the international markets, as shown in figure 1.1 in chapter one. In developing countries there do exist many therapeutic knowledge which are never patented. They are dependent more on the import of technology from developed countries, which is another cause why developed countries demand for stricter IP laws (Hoekman and Martin 2001:131). Economies of developed countries are dependent on agriculture and most of the R&D in this sector is owned by public sector, which is now declining, hence it also increases the dependency of developed countries on developed countries. The bone of contention between developed and developing countries regarding the issue of patent is that the uniformity of implementation of TRIPS regime, despite of variability of level of R&D in developed and developing countries. There are three main concerns of developing countries with regard to the implementation of Patent protection: first is the economic loss because of the import of goods and technologies from developed countries, second is the loss of efficiency because they are lacking the proper R&D infrastructure and lastly the monopolization of market by the firms of developed countries which reduces competition in the markets. Developed countries substantiated their demand for the protection of IP by showing it an important factor for future R&D. As shown in figure 2.2.

Figure 2.2: The Working of Patent System.



Source: Hisatitsu Arai's (1999) "Intellectual Property for the Twenty-First Century: The Japanese Experience in Wealth Creation" (Idris, Chart 4.1, 2003:82).

In the above figure Hisamitsu describes that how the protection to the IP gives incentive for future research. It also provides a help in the creation of improved version of product in future. Idris (2003), opined that IP protection revolutionize agriculture and pharmaceutical research without the strict IP regime is not possible.

In the draft of TRIPS, it was demanded that the patent protection should be provided for 20 years from the date of filling of the application. This was not acceptable to developing and least developed countries. Many of the members of GATT even did not have any such IP laws which cover the Pharmaceutical Products. Although under TRIPS an exception of compulsory licensing was provided, to give some relief to the poor countries. Under the this provision a government can allow third party with or without the consent of patent holder to use the product in the case of national emergency, but this provision was ambiguous. Secondly these developing countries were also threatened with trade sanctions against them if they demand of compulsory licensing. Thirdly heavy

compensation must be paid to the patent holder in case of the issuance of Compulsory License, so it was a costly deal too.

Countries were also asked to include the provision of civil and criminal remedies in the case of infringement of patent. According to Article 61 provision must be made for 'criminal procedures' to be applied in the case of wilful trademark counterfeiting or copyright piracy on a commercial scale. The important reason of opposition of TRIPS was that WTO ensures the mechanism of inspection of the domestic laws of the countries but they were lacking the mechanism to put check on the research in the laboratories of big Parma companies. Most of the Parma companies in the developed world are involved in the research of lifestyle medicine instead of the production of the medicines which are necessary for the prevailing life threatening diseases (Lankosza 2003:185).

The issue of patent was the last issue to be solved in Uruguay Round before the submission of the draft in 1991. Some critics of TRIPS are of the view that TRIPS became the part of the WTO under the pressure of developed countries Especially the Super 301 law of US made tremendous impact on the inclusion of TRIPS in WTO. Throughout the Uruguay Round, the US kept on complaining against the countries which were not giving adequate patent protection to the US made goods. All these laws were the product of the competition faced by telecommunication, software and entertainment industries and pharmaceutical companies of the US during 70s. Thus the leading business companies lobbied in IPR Committee, for the implementation of strict IP regime across the borders. Later on Japan and EU also raised their voice in the favor of the protection of intellectual property. EU and the US both demanded against the relaxations provided to poor countries under patent laws of TRIPS. As it was visible in the TRIPS draft:

> "limited exceptions to the exclusive rights conferred by a patent may be made for certain acts, such as right based on prior use, acts done privately and for non commercial purpose, provided that they take account of legitimate interests of the proprietor of paten"t(GATT, 1990a: 10).

In response to it, developing countries came closer and put forward their demand for the broader relaxation under patent regime. However, the demand was denied by developed countries and later on they agreed to provide some relaxation under Article 30, which

states:

> "Members may provide limited exceptions to exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimacy interests of the patent owner, taking account of the legitimate interests of the third parties"(Carvalho 2005:304).

The other issue was related with Article 27. 1 *Patentable Subject Matter* which says "patents shall be available and patent rights without discrimination as to the place of invention, the field of technology and whether products are imported or locally used", which means any domestic law which is inconsistent with the interests of patent holder shall be considered as discriminatory. Many developing countries including Brazil and Argentina stood against it as this law was not complimentary to their domestic laws. According to the Industrial Property Law of Brazil a compulsory license can be issued against a patented product if the patent is not worked in Brazilian territory. The US and EU threatened Brazil with the trade sanctions, hence Brazil agreed that in future if the government found it necessary to issue compulsory license it will issue the license only after the consultation with the US government.

The issue with India in this regard was that it crossed the deadline of complying with the patent laws of WTO and also wanted the implementation of compulsory license. According to the prevailing laws in India license can be granted on marketing rights on pharmaceutical drugs and agrochemical products in the public interest. Experts in India said that if we comply with the 1991 Act, it will make impact on the indigenous production and employment of the country, because the importation of readymade goods would be same as the working of patent locally. Thus India demanded for compulsory licensing under TRIPS, which helps in the production of generic and cheap version of medicines, which will ultimately be beneficial to the poor countries. Even the provision of compulsory licensing was supported by World Health Organization (WHO).

Geographical Indication (GI) and Trade Mark (TM) were the other major issues of TRIPS negotiation. GI is not related with new knowledge but the traditional community

based and regional knowledge. Through GI and TM, the producer tries to prove and establish the superiority of the product. GI is a part of industrial property rights and it is different from rights related with TM. Piracy of the TM and GI mark bring huge loss to the producers and sometimes makes impact on the credibility of the original producers. Developed countries wants strict regulation of TM and GI as pirates in order to provide cheap goods to consumers go for the duplication of goods, and play with the economic gain and market reputation of the producer of a particular good.

Under TRIPS, GI has been discussed in Article 22.1, but many crucial technical terms in this Article are under dispute because of the vagueness. The TRIPS Agreement defines Geographical Indication as follows in Article 22 (1): "Geographical indications are, for the purposes of this Agreement, indications which identify a good as originating in the territory of a member or region or locality in that territory where a given quality, reputation or other characteristic of the good is essentially attributable to is geographical origin." (Art. 22 (1) TRIPS)

The member countries are obliged to prevent other producer to mislead the consumers about the original product by selling the same goods with almost identical GI mark through piracy. Members are also asked not to give sanction to almost same GI and TM mark to other producer if the same kind of mark has been granted earlier. The government should invalidate the demand for identical or almost identical marks. Under the TRIPS Agreement three exceptions were provided to the GI protection. The first is that the producer can use the same GI mark if the firm is using it from last ten years, before 1January 1995. Second is related with TM. If prior to the implementation of TRIPS the identical TM and GI has been used or the application is filed for granting the mark before the commencement of TRIPS, the Agreement does not apply on that. The third one is related with the generic name of the goods, agreement is not applicable on them even because they are the local names.

When the negotiation was going on, it was proposed that a multilateral system should be established for the registration of GI and TM. No time period was fixed to discuss the issue and reach the conclusion over GI and TM. TRIPS Council at the Singapore Ministerial Conference in 1996 decided that the issue of GI and TM should a part of the

preliminary works to be done. European Communities took a concrete initiative in 1998, and made a proposal for multilateral register. The aim of the proposal of EC was to preserve each WTO member's prerogative to determine whether a certain sign, indication or geographical name does not meet the TRIPS definition of a GI (Balkeney 2009:198). In 2000 the proposal was reviewed as the other WTO members made their comment on that.

EC took initiative of GI and TM because they were the major producer of wine and spirit. EC demanded the TRIPS council to mandate the multilateral system, and it also made it clear that members would be free to participate in the system if willing. EC proposed steps with regard to the application of GI. First the countries who want to participate will have to make a list of GI marks and related goods in the territory. Then WTO would publish all the notified GIs. In the second phase the members can review the notification and ask question within 18 months. In case of bilateral conflicts over GI the countries can negotiate and solve the issue on their own. After the completetion of 18 months the GIs would be registered in multilateral register.

Though the tiring exercise was done for it but many of the countries still did not want this regulation as they wanted it to be completely voluntary. They also demanded that the system should be simple to implement and should not be an unnecessary burden on the member countries of WTO. Another dispute related with the scope of the GI protection is that it should provide protection not only to wine and spirit but number of other goods from developing countries should also come under it, like India demanded it over the 'Basmat rice'. Developing countries were demanding the strong protection to GI, as the condition of people living in these countries was miserable. In that case GI could give extra value to their produce, which can improve the financial condition of the poor people. Mauritius and South Africa are some of the countries which are demanding the strict GI laws.

Switzerland, India, Turkey, Czech Republic and Egypt were some of the proponents of the extension of the scope of GI. The USA, Canada , Japan, Chile, New Zealand etc did not accept this proposal and said that it would be the infringement of their right to implement TRIPS according to their own way. In the run up of the Seattle Ministerial

Round members wanted to have substantial discussion over the extension of the scope of the protection other than wine and spirit. They demanded it for the wide range of products including agricultural products and pharmaceutical products.

Exceptions under TRIPS for Poor countries

Demand for the exceptions was the result of monopoly rights provided to the innovators. Monopoly rights resulted in the higher cost of medicines and restriction in their imports. Developing countries were asked under TRIPS to overhaul their IP law system in accordance with TRIPS. It resulted in bad health condition of patients in LDCs. Facing huge opposition from developing countries, the negotiating members in Uruguay Round had to provide some relaxations to poor countries. Relaxations under IP laws is not new thing, rather it is prevalent from the time of 'Paris' and 'Berne' conventions.

In this regard Article 30 of TRIPS Agreement provides limited relaxations to the developing countries. It states that members may provide limited exceptions to the exclusive rights conferred by a patent provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties (Lalitha 2002:3546). The certain exceptions can be provided for experiments on the invention to improve it, preparation of medicine under individual prescription. The Bolar provision is also one of the exceptions which provide freedom for the premarket testing of the generic products during the patent term. The other exception is compulsory licensing, which allows third party to produce generic version of low cost pharmaceutical products in the case of national health emergency. The other such exception is parallel import, under which a country is allow to import a patented drugs from a country where it is available on the cheap price because of the implementation of compulsory licensing there. There are many other exceptions provided under this regime, but actually they are of no use. The developing countries are facing the problem of weak manufacturing system, moreover they do not demand for the implementation of these exceptions, because they are concerned about the trade sanctions against them by developed countries. Thus the exceptions provided under TRIPS could not make the prevailing conditions better in poor countries.

Conclusion

Since the inception of Paris and Berne Convention and even prior to that the definition of IPR is more or less same but the entire debate till yet is focused on how to implement this regime. Protection of intellectual property is equally necessary as the protection of individual rights or human rights, because one should get benefit of his/her own labor. Although TRIPS is working as a regime in international arena, but developing countries still want the revision of the laws under TRIPS. No international institution or regime is wholly accepted by every individual nation, but with TRIPS the case is bit different; it is labeled as a discriminatory regime.

Especially the LDCs are fighting for their right, and their demands are being ignored. Since the very beginning, their voices have been suppressed. Whether it is the case of South Korea or the East Asian economies, all were manipulated, to achieve some specific aims of developed world. The entire mechanism is also considered to the by-product of the laws of some influential countries like US and EC. Throughout the negotiation the impact of US law can be sensed from the argument made in the earlier pages. Super 301 law of US compelled the trade partners to comply with the trade standards dictated by US.

The expectations of the developing countries after the inception of an international trade regimes like GATT and WTO the trade would be liberal, and without any barriers, vanished as these system could not proved to be successful in protection to the interests of poor, because these regimes defended the interests of developed countries only.

Chapter III

An Analysis of the Impact of TRIPS on Public Health in Developing Countries

Since the inception of Uruguay Round developed countries were negotiating for a strong and strict IP regime. After the years of meetings and negotiations TRIPS was adopted under WTO to work for the protection of intellectual property rights. TRIPS is considered as a way of harmonizing intellectual property with the interests of member countries. Developed countries defended these rights, and insisted that the strong IP regime in developing countries, will give impetus to the transfer of technology. Strong IP regime in any country attracts foreign investors, which further increases FDI in poor countries as well (Irdis 2003).

Strong dispute settlement mechanism under WTO was another factor, which developed countries boasted for, now the dispute settlement mechanism was able to cope up with the grievances of developing countries. Developed countries argued that with the establishment of strong dispute settlement mechanism, developing countries now have a strong say under TRIPS regime, and they can get their problems heard easily at international level, but these anticipated benefits were confined only to the words. Developing countries were already facing several problems because of the monopolistic nature of MNCs. TRIPS also created challenges to the financial and administrative capabilities of these poor nations, because implementation of TRIPS needed overhauling of the judicial and administrative systems in developing countries. It was a huge like a financial burden on LDCs.

As a result of hue and cry in developing countries, during the Doha Round in 2001, Doha Declaration on Public Health was adopted. Doha Declaration on public health gave rise to many expectations among the protagonists of cheap availability of drugs to the poor patients. As discussed in the chapter two that the Doha Declaration has recognized the issue of right to good health to poor patients. It has also reiterated that it is the duty of developed countries to provide technical assistance to LDCs so that they can overcome the difficulties of underdevelopment in the area of technological advancement. Doha

Declaration recognizes the importance of cheap generic drugs for poor patients, and it encourages the production of generic for poor patients. As a result of this declaration several INGOs like Oxfam and Medecins sans Frontieres (MSF) also campaigned for the production of generic version of costly life saving medicines, because this initiative can lead the world wide availability of drugs to the patients in poor countries at cheaper rates.

One more argument is that the cost of patented drugs are exorbitantly high, not because the patients are charged only the cost of production but they are also compelled to pay the marketing cost of that drug, which is two to three times higher than what the actual cost is, which itself raises a big question against the patent rights (Chaudhuri 2005). The other major issue is about "me too" or "copycat" drugs. Basically the big pharma companies bring new drugs to the market and they are new enough to attract the consumers, but actually the innovation is not up to that level, and their therapeutic value is also very low. These companies make slight variation to the pre-existing drugs (Chaudhuri 2005).

In Doha Declaration, the poor nations were provided with the discretionary right to declare national emergency when any health related havoc arises and also to use the relaxations provided under TRIPS such as 'compulsory licensing'. At the same time it was also taken into cognizance that very few of the developing countries are having manufacturing capability and they cannot make proper use of 'relaxations' provided under this regime (Nair 2004:420). These relaxations have been elaborated under Article 30 of the rule book of TRIPS. This Article stands for the cause of poor patients in developing countries, so that they can have easy accessibility of drugs. Compulsory Licensing, Parallel Import, Bolar Provision are some of these exceptions, which have been discussed in the chapter four clearly. Doha Declaration states:

> "We recognize the WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement. We instruct the council for TRIPS to find an expeditious solution to this problem and to report to the General Council before the end of 2000". (The Doha Declaration, article 6).

However, the entire process to adopt the Doha Declaration was not that smooth, because the developed countries did not favour the implementation of this declaration in toto.

Andersen says "the Declaration should have been incorporated into WTO rules by December 2002 at the latest. It never was. The negotiations held for this purpose in Geneva at the end of 2002 came to nothing... it was only in august 2003, after bitter negotiation, that a text specifying the conditions for the implementation of paragraph 6 of the Doha Declaration was approved by TRIPS council" (Andersen 2006:77).

Hence in present time, the western framework of TRIPS agreement could not meet its goal of free flow of technology, which has made it flawed in the eyes of developing countries. Developing countries are of the opinion that if the free use of technology is restricted, it will result in worse off position of developing countries (Higgins and Rubin 1986). They submit that it is in the best interests of industrialized nations to allow free use of information. Through this way developing nations will need less financial support and can provide a larger market of consumers to MNCs.

Impact of GATS on Public Health in Developing Countries

Another important and new outcome of Uruguay Round was GATS; it governs countries in the area of trade in services, including banking, education and tourism and health related services etc. The important debate related with the emergence of GATS is 'whether it will be *helpful in facilitating health services* or not? The system of GATS was declared to be very effective and strong to tackle health related issues, better than its predecessors, by the health policy community and developed countries. GATS has four important implications (Blouin2006:149-50), as shown in Figure 3.1:

i. Firstly it talks about general obligation applied on all the measures affecting trade in services; it is *top-down* approach,
ii. Secondly it talks about the specific commitments of the member countries regarding the access to the markets. It is voluntary undertaking and related only with service sector,
iii. Thirdly it talks about further round of talks to increase the level of liberalization in trade in services, and,
iv. Lastly it talks about the institutionalization of the Agreement, so that arising disputes could be given plausible solutions.

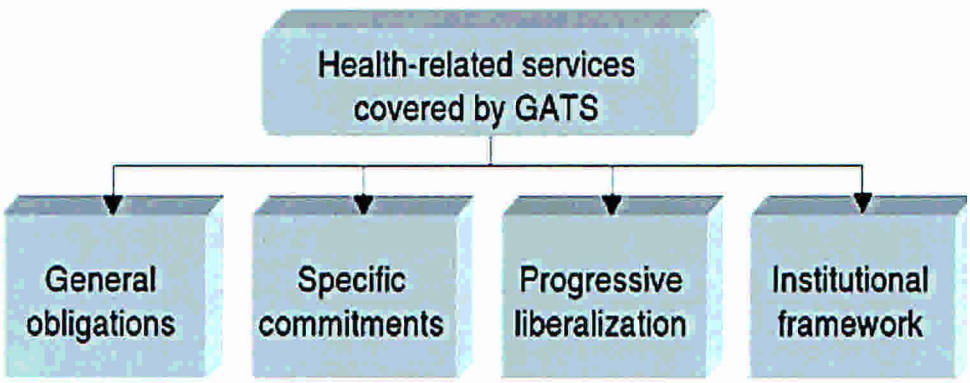
Prior to GATS, several international conventions to stop the spreading of infectious diseases were existing, but in 1969 International Health Regulation (IHA) came as a revised form of earlier regulations under WHO (WHO, 2005:188). Under Article 22 of WHO all the member countries are bound to follow IHR, it provides *maximum security* to the members against the spread of disease (Fidler, 1999:59). The IHR and GATS could not work effectively as the brake out of Sever Acute Respiratory Syndrome (SARS), proved the weakness of the system in preventing the spread of communicable diseases (Knobler, 2001:112).

GATS, instead of incurring benefits for developing countries, created inequity in developing countries. GATS demanded the member countries to liberalize the market system so that effective transfer of service could take place. Developed countries were of the opinion that the foreign service providing firms would help in decreasing the prices of services in international markets, which will be in the favour of developing countries. However, the result of trade liberalization went against the interests of developing countries. Foreign firms undermined the competition in markets in poor countries, because the indigenous firms could not provide higher level of sophisticated medication. Thus it resulted in the two-tire system in the health sector. These foreign firms were serving the higher classes in developing countries because they were capable of bearing the cost of expensive medication, while the poor patients could not get cheaper medicines (Blouin, Drage and Smith 2006:143).

GATS demanded for the privatization for health services in member countries, which was again not good for poor countries because it will have direct impact on the cost of health services. Secondly the foreign investors are least interested in investing in LDCs which are facing acute health related problems. Foreign investors are willing to invest in the regions where they can easily get social and political stability, ready markets, and high rates of returns, inexpensive and highly skilled laborers, cheap local input, and adequate infrastructure. Therefore the foreign investment goes to higher income developing countries (Schmidt and Culpeper 2003:3).

These agreements are problematic because they are vague at the place where the developed countries could utilize that vagueness in their favor and at some point these countries become ardent follower of the precise rules where precision could also work against the interests of developing countries (Wade 2003: 630).

Figure 3:1 Four important implication of GATS system.



Source: International Trade in Health Services and the GATS: Current Issues and Debates by Blouin Chantal, et al (2006).

When the developed countries started to develop they followed extreme protectionism, and they were not hindered by any world institution or regime, but today the poor countries have to toil a lot to catch up with the developed countries. They are also governed by international regimes, in international arena. They have to comply with the demand of liberalization of today's globalized world.

Debate over the Implementation of TRIPS

There were two problems when it came to the implementation of TRIPS: first was that TRIPS has got western framework, which was a grave issue among the third world countries. TRIPS is an initiative of developed countries, so the aim of the implementation of TRIPS was to secure the interests of innovators in developed countries. TRIPS has nothing to do with the problems prevailing in poor countries, infact the implementation of

TRIPS made the condition even worse to worst. Secondly the inefficiency of administrative and judicial system and lack of other resources in third world countries gave TRIPS a demon like statute. Uruguay Round brought three major pillars of international trade with it: Trade Related Investment Measures (TRIMS), General Agreement on Trade in Services (GATS) and Trade Related Intellectual Property Rights (TRIPS).

TRIPS came into force just after the Uruguay Round was concluded in 1994. It compelled states to provide product and process patent to goods, technologies irrespective of their place of origin and their qualitative values. It put several political as well as economic restrictions on countries and the worst sufferers were the developing countries. In terms of possession of patents, the maximum numbers of patents are possessed by developed countries, so they sell them at the prices they want. On the other hand the poor countries do not possess high technologies to get patent over, and also to make benefit out of that.

Mexico was a fast developing economy and a member of Organization for Economic Co-operation and Development (OECD), and it filled only 389 patent applications in 1996, in comparison to 30,000 applications filled by foreign residents, so the flow of rent was always towards north from south (Wade, 2003:264). Wade has discussed the political side of this agreement, and writes that rights and obligations are limited respectively to developed and developing countries, developed countries do not follow any obligation, and most of the time developing countries are denied of their rights. Despite the weak enforcement mechanism, if mistakenly any patent right is infringed in poor countries they are dragged to the dispute settlement mechanism of WTO. These developing countries are also threatened of several direct and indirect trade and economic sanctions if they take any firm measure against these countries.

The main problem with regard to the implementation of TRIPS was the prevailing uneven level of development between north and south. TRIPS could have brought good results if the problem of disparity was solved, which is impossible in near future. So the main quest of developing countries was to get some positive and substantial relaxations under TRIPS regime which could compensate for the lack of development. Four types of

benefits have been discussed when it comes to the implementation of TRIPS: **first** the MNCs feel secure for their assets when it comes to the investment in some other country when the IP laws are strict there, **second** was against the strong legal background, that the transfer of technology becomes hassle free, **third** was that when the intellectual property laws are strict locally, it leads to higher domestic innovation, and **finally** the unilateral trade sanctions from the super powers become less likely because there exist a body to protect the rights of countries, and to settle disputes among them as well (Matthew, 2002:108).

Strong IPR regime gives stimulus to the economic growth by giving impetus to innovation and investment. Simultaneously when the IP regime is strong enough to provide safety to innovations, new innovations are more likely to take place, in the areas like diseases and agriculture. Weak IP regime not only gives birth to the sense of insecurity among foreigners but also the domestic investors feel threatened of getting their products duplicated. So development and innovation and adoption of strong IP regime are like a cyclic process. Development in economy leads to more investment in the sector of R&D, which results in high degree of innovation. Eventually the demand for the protection of that property becomes strong, and when strong IP regime is established it leads to further development. Like 'tiger' economies of Hong Kong, Singapore, South Korea, began to support TRIPS since Uruguay Round because of the rapid development taking place in their territory (Acharya: 1996:159).

However, the above argument seems to be unacceptable when we take the example of Argentina, Brazil, North Korea and China, because these countries are the biggest violator of IP laws and they are among the few countries which receive maximum inflow of US FDI (Abbott 1996:396). Chinese IPR system was not the result of compliance to any international regime, rather it was meant to create a balance between individualist and collectivist thought (Bejesky, 2004:446). Chinese economic reforms have been remarkable, as the transplantation of the IPR system was like *a square peg in the round hole*, making it more of a wish list for foreign investors than a realistic and effective system (Shi, 2008:89). More than that there are several other factors which impede or further the FDI inflow like import policy, tariffs, rules on the employment of foreign

experts make sometimes negative impact on the FDI and R&D as well (Emmert 1990:1359). United Nations Conference on Trade and Development (UNCTAD) report of 1996 says that developing countries should make an effort to balance their need of innovative firms and their licenses for protection from easy appropriation, with need of follow-on competitor and consumers.

When we see the post TRIPS era we find that there are two levels of adoption of this regime, one is the level of implementation and the other one is the level of enforcement. When it comes to implementation, it is not a difficult task as it results only in the change in the rules and laws of the country. But the problem arises when it comes to the real enforcement of those rules, because the lack of technical and legal expertise in developing countries create problem in the understanding of rules and laws of international regimes.

An Analysis of Right to Health under TRIPS Regime

Right to good health has become an integral part of the debate over human security. Cullet Writes "Health is one of the fundamental basic needs of all human beings. In legal terms, fundamental human rights treaties recognise the right to the 'enjoyment of the highest attainable standard of physical and mental health" (Cullet 2001:1). For the first time health issues got central stage at international level under a trade regime, when the negotiation for TRIPS was going on. TRIPS was opposed by developing countries made the availability of drugs difficult due to the higher costs of medicines. Patients in developing countries cannot afford expensive medication; this was issue which drew a line of differentiation between developed and developing countries. Studies of United Nations Children's Fund (UNICEF),THE United Nations Joint Programme for HIV/AIDS (UNAIDS) and WHO shows that less than 10 per cent HIV/AIDS patients in poor countries have access to antiretroviral drugs (UNICEF, UNAIDS and WHO 2004:10). There are several factors which causes un-affodability of medicines but most important factor is the price of drugs, and patent rights give monopoly to the drug producers. Hence the arbitrarily determine the price of drugs which is not in the interests of developing countries.

Cullet opines "There is, for instance, no attempt in TRIPs to delineate the relationship between patents and the human rights to health. Patent treaties only recognize that there should be a balance between the rights that are conferred to an inventor and the broader interests of the society in having access to the results of scientific advance"(Cullet 2001:1). Human rights treaties also paid heed to the scientific and technological development and rights of innovators but they always try to balance the interest in the favour of society in general. Thus TRIPS is a kind of hurdle in the way of realization of International Covenant on Economic Social and Cultural Rights (ICESCR) which gives recognition to right to health as an important right to human beings. ICESCR was adopted in 1966 to ensure the all around development of human beings,. It considers right to health as an essential condition for the proper development of human beings (Guruskin 2005:194).

Implementation of TRIPS has demonstrated that patent protection does not give incentive to the research on diseases prevailing in poor countries. Guruskin write: "from the health perspective, TRIPS is justified because while it protects the interests of private sector pharmaceutical industry, it also promotes increased R&D in health sector. Going beyond controversies over the actual nature of the increases in R&D fostered by the patent system , it has become clear over time that, at very least , the incentives provided by the patent system do not lead the private sector to invest preferentially in the most common disease of the poor" (Guruskin 2005:194).

Doha Declaration in this regard made an arrangement Trips should not prevent member countries from protecting public health. They should be allowed to use the exception to meet the demand of patients in the case of national health emergency (Haracoglou 2008:96). Hence the entire debate is about the reconciliation between patent rights and right to health, which has become very difficult after the implementation of TRIPS Agreement. Big pharma companies demand for strict patent regime, which is the main cause behind the price rise of drugs. They give priority to their financial gains and they do not pay heed to the problems prevailing in poor countries. They invest on R&D for the diseases existing in developed countries, because it can bring higher financial gains to them. Patients in developed are capable enough to afford costly medication. Thus the aim

of ensuring right to health to poor is very difficult under the prevailing patent regime.

National and International Initiatives on Access to Medicines and Availability of ARVs

After the implementation of TRIPS Agreement the price rise of drugs became a bone of contention between developed and developing countries. In the wake of price rise several campaigns were launched to overcome the problem of price rise of drugs. Eventually in 2000 many pharmaceutical companies like Abbott, GlaxoSmithkline, Roche tighter with UNAIDS, WHO, WB, UNICEF and United Nations Population Fund (UNPF) launched an initiative called "Accelerating Access Initiative". The "Accelerating Access" initiative of UN was meant to provide the anti-retroviral drugs at cheaper rates to HIV/AIDS affected poor countries. Burkina Faso and Gabon were among the first few countries to avail this facility. The trading groups which developed 'hybrid' strategies, they achieved largest price reduction. (Wagstaff and Cleason 2004:125). Though this program made the availability of drugs to maximum number of OAPI countries, these programs did not prove to be successful, because the pharma companies could not meet the massive demand of drugs in poor countries. It was said that this initiative was meant to protect the big pharma companies from the burden of compulsory licensing in other poor countries.

In developed countries health infrastructure is so well developed that people do not have to suffer in the want of proper medical care. Basically in developed countries citizens are asked to get health insurance on their own or through the firm which they are working for, that is why the medication cost does not work as a burden on people. However, in developing countries the concept of health insurance is comparatively new, and the citizens are also not capable enough to afford health insurance (Srinivasan 2000). In developing countries the responsibility to provide cheap drugs lies with the government, and sometimes the overburdened governments fail to provide adequate medical facilities to patients.

The other international initiative for the availability of drugs was the "Drugs for Neglected Disease Initiative" (DNDI). DNDI was started in 2003 by MSF together with Kenya Medical Research Institute, Indian Council of Medical Research, Malaysian

Ministry of Health, Oswaldo Cruz Foundation in Brazil, and France's Institut Pasteur. WHO was the observer of this initiative. This initiative had three important goals:

1. To develop new field-relevant treatment for patients suffering from neglected disease;
2. To raise awareness through advocacy on research and development of drugs for neglected diseases;
3. To make the existing research capacity strong and effective in countries where
4. Neglected diseases are endemic (WHO 2006: 56).

Neglected Diseases includes sleeping sickness, visceral leishmaniasis and Buruli ulcer etc. These diseases are responsible for number of death in poor countries, but they are not figured on the disease control agenda of the developed countries (WHO 2006:56). However, all these initiatives could do little to solve the problem of unaffordability of medicines. The reason behind the failure of all these initiatives was the lack of support from developed countries, because most of the pharma companies were located in developed countries. These companies were not ready to make concession and more than that they focused on the research on those drugs only which can bring substantial amount of benefits to them.

Realizing the duty towards its people South African Government in 1997, introduced a 'Medicines and Related Substances Control Amendment Act'. It has three components: firstly it gives emphasis to parallel import of drugs, so that the availability of drugs could be made easy, secondly the pharmacists were asked to distribute generic and off-patent drugs when it is prescribes, and thirdly this amendment established a pricing committee to make the entire system of pricing of the drugs transparent (Devereaux, Lwarence and Watkins 2006:121). However, there were some problems with this act that, it did not contain any provision of compulsory licensing and also it was silent about the import of lost cost generic version of drugs. In March 2001, in Pretoria the subsidiaries of big pharma companies filed a case against this act that, it abrogates their rights granted under African Bill of Rights (Annaxure 2). This Act grants the freedom from arbitrary deprivation of property. These companies demanded for the implementation of TRIPS to compensate for their loss caused by the 1997 laws. Later this suit lost its relevance

because of the massive public protest; which caused defamation of these countries greatly (Tayler 2004:117).

Allegations were made that even if the developing countries are provided with cheap generic version of costly drugs, it will result in the uneven distribution among patients, because of the lack of administrative capabilities in these countries. However, this allegation was completely denied as Brazil one of the worst affected countries with HIV/AIDS, followed a very complex system of the anti-retroviral therapy, and also proved to be successful in that. In 2001, US came up with a suit against Brazil in the WTO, for the violation of TRIPS. It was all the result of the domestic pressure from the big pharmaceutical companies in US, because Brazil went for the price reduction of expensive medication which brought loss to these companies. Later on Brazil was threatened by the US government, as it might face trade sanctions from US.

However, after sometime complain in the WTO against Brazil was dropped by US, which also made the other countries relaxed of the threat of unilateral sanctions against them by US. Sell writes "Brazil's successful AIDS programs, widely touted upon the heels of the withdrawn South African law suit, made the United States' WTO case against Brazil looking increasingly unsavory" (Sell 2003:158).

After the similar problem faced by patients in Uganda in 2001 an expert member's body consisting of the members from WTO and World Health Organization (WHO), came up with an idea of differential pricing system for developed and developing countries (UN Millennium Project, 2005:130). This system has a provision according to which the drugs would be sold at low prices in developing and poor countries but in developed countries there would not be any change in the existing prices of drugs. However, the issue of TRIPS could not get any plausible solution in WTO till 2001. All the above measures were temporary, and could not be implemented uniformly. The reason why no plausible solution came out because developed countries were threatened that if the relaxations are given to poor countries, it may lead to the parallel import of cheaper version of drugs back to developed countries. Hence the MNCs in these countries pressurize the government to not stop the implementation of any kind of relaxation which may harm their interests.

The other major access to drug initiative under WTO was 'International Trachoma Initiative'. It was founded in 1998 to provide relief to the patients of blinding trachoma. This initiative took place in joint collaboration of the Health Ministers of the affected areas and WHO (Jhonson and Stoskopf 2010:393). The major problem with this initiative was that the availability of data on the number of infected patients and also the lack of awareness about this disease among patients. However, the institutions related with this initiative are still struggling to cope up with the situations in poor countries. (Ruit and Wyckoff 2006:126).

In 2005, WTO allowed Canada to issue compulsory license to those countries which are having weak manufacturing power. Thus Canadian government established a process called Canada's Access to Medicine Campaign (CAMC). It was an initiative for the access to drugs to poor patients suffering from HIV/AIDS. However, several problems were there with Canadian government to make this initiative a success. The first problem was the specification of the person or entity to which the product is to be sold. Secondly, to whom the product should be sold; to government or to government authorized body. After this initiative came into existence the several allegations were made against it, that CMAC allows for the fixed quantity of export of pharmaceutical products and allowed that quantity to come from a specified supplier. The other drawback of this initiative was that only handful of countries has implemented this decision, and the other eligible countries are not coming forward to implement the initiative. This initiative is silent about the problems of importing countries who have weak manufacturing capacity, and technical and educational backwardness. Thus all these initiatives did not prove to be helpful for poor countries because of the lack of support from developed countries and their own inherent structural problems (Cooper and Kirton 2009:)

'TRIPS Plus' and the Case of Developing countries

'TRIPS plus' is defined as "The TRIPS-plus concept covers both those activities aimed at increasing the level of protection for right holders beyond that which is given in the TRIPS Agreement and those measures aimed at reducing the scope or effectiveness of limitations on rights and exceptions" (Musungu and Dutfield 2003:2). TRIPS has made greater effect on the health conditions of less developed countries. The worst thing it did

that, it indirectly prohibited developing countries from producing low cost generic version of costly medicines. TRIPS has created an additional series of barriers to access to treatment in the poorest countries. The issue of the impact of TRIPS on healthcare was brought to the forefront by less developed countries were they were asked to bring massive changes in their rules and regulation at par with the rules and regulations prevailing in industrialized countries.

In 1996, Highly Active Antiretroviral Combination Therapies (HAART), was introduced which created difference between the victims of AIDS in developed and developing countries. The prices of HAART were ten to twelve thousand dollar per person per year, which was too costly to be afforded by the AIDS victim in developing countries. Though some of the exceptions have been provided to the poor countries like the provisions of *parallel import and compulsory licensing* but the conditions attached with these exceptions were more taxing. Article 31of the TRIPS Agreement talks about the provision of compulsory licensing. However, its use is restricted on certain grounds. Article 27.1 restricts its use on the basis of lack of local working, similarly Article 31(b), prohibits the use of license when the patent owner has logical commercial reasons to prohibit compulsory license. Under Paragraph 5(b) of Doha Declaration it is said that countries are free to determine the condition of national emergency to use the provision of compulsory licensing, but actually under Article 1.1 of the TRIPS Agreement it has been already mentioned that countries can determine the ground of national emergency on their own, so Doha Declaration does not make conditions extraordinarily better (Carvalho, 2005:234).

The major reasons why the exceptions could not work properly in the favor of low and middle income countries (LMIC), were the manufacturing incapability of these countries and the regional and bilateral Agreements called 'TRIPS plus' or 'WTO plus' The exceptions like compulsory licensing did not work because it allowed the production of generic medicines for domestic purpose only, so the LMICs still were not able to get medicines. The important change with Doha Declaration was the waiver of Article 31(f). This declaration allows the export of generic drugs across the border. However, Doha Declaration came in, to resolve the problem of poor countries, the LMICs were still did

not exercise the exceptions under TRIPS because they were threatened of trade sanctions against them by developed countries. The developed countries could put several trade embargoes and sections which was more threatening. 'TRIPS plus' which is associated with bilateral and regional agreement among countries, hinders the use of flexibilities provided under TRIPS. Like many bilateral Free Trade Agreements (FTA), stand for the extended period of data exclusivity. Data Exclusivity means the protection of the secret data of a drug for certain period. Among EU member states it extends up to eight to ten years, which makes bad impact on further R&D (Kerry and Lee 2007).

In June 2001, in Doha, TRIPS council held a meeting to discuss all these issues, and thus came the *Doha Declaration on Public Health.* Prior to this the industrialized countries of south were demanding the use of exceptions provided under TRIPS in the situation of national health emergency only and not in ordinary situations, which was further an issue of contention between north and south. Though Doha Declaration has no legal status but it recognized that international IPR standards have made damaging effects on health conditions in poor countries. It was just a political declaration and not a part of authoritative interpretation under Article IX.2 of the Marrakesh Agreement. Authoritative interpretation is a part of Article 3.9 of Dispute Settlement Understanding (DSU), which allows discriminating interpretation from those adopted by a Panel or Appellate Body which legally are only binding on the Parties to a dispute in respect to the case at hand. It means Doha Declaration is not legally binding because it was not a part of the provision of Authoritative interpretation (Torremans, 2008:184). It was mere a declaration and not a decision.

In 2004, a Commission on Intellectual Property Rights, Innovation and Public Health was established to focus on the intersection between intellectual property rights, innovation and public health. This commission made six important recommendations after reviewing the results Doha Declaration: (1) new products of health care should be discovered; (2) the development of drugs from preclinical and clinical research, and the regulatory process; (3) availability of new medical products to LMICs; (4) encouraging R&D in developing countries; (5) WHO should play more responsible role (Noehrenberg, 2006:419). The commission recommended for broad range of policy change. It

emphasized on the need of more recourses allocation to poor countries for R&D, from developed countries. All these recommendations are still on papers and could not become reality.

Impact Generic Production of Drugs on Poor Countries

By 2000, Indian firms also began to penetrate in to Sub-Saharan African market. Thus the competition of supplying drugs at low cost began among different the producers of generic version of medicines, which ultimately resulted in low prices of drugs. Later on in the year 2003, WHO started another program called 'Three by Five' (3x5), which aims at supplying HAART to three million people by the end of 2005. In this program the recommendations were made regarding the intake of drugs and it was suggested that the countries should choose 'first line' treatment initially, and after that limited number of second line treatment. The first line treatment drugs are highly recommended drugs till now. The committee which made all these recommendations took this decision after the study of toxicity of molecules of drugs. This recommendation was made, considering the producers of drugs, because in the first line treatment maximum drugs were supplied by generic producers of drugs.

For the second line combined treatment also several generic version of drugs were available. Thus it gave birth to competition among the firms who were producing generic version of these medicines, which helped in lowering the prices of drugs.

Table: 3.1 Comparison of ARV prices before and after the price reduction of June 2001 (California Association for Measurement and Evaluation in Guidance (CAMEG) data for Burkina Faso)

Types of ARV	Price in CFA* Before June 2001	Price in CFA* After June 2001	Price reduction in %
Retrovir	55055	34060	0.3813
Epivir	56733	14460	0.7451
Combivir	110835	46375	0.5815
Videx	28060	10245	0.6348
Zerit	80289	2975	0.9629
Zerit	83292	3375	0.9594
Stoccrin	139349	35705	0.7437
Crixivan	199662	42840	0.7854

Note: * 1 Euro = 650 CFA

Source: Bansee, Zigani and Traore (2003)

Since 1980, AIDS movement started in Brazil; it resulted in the incorporation of Right to Health in 1988 constitution of Brazil. During the second half of 1090s Brazil adopted new treatment guideline for AIDS patient, which recommended the use of more ARV drugs. Government also worked to replace older ARVs with the newer ones like efavirenz, lopinavir, antazanavir and tenofovir ectc, because of the pressure from civil society. Inclusion of new drugs inflated the price of HAART, but in 1999, Brazilian government centralized its drug production policies, now it was producing eight drugs locally and importing eleven drugs from different MNCs.

Since 2001, Brazil began to negotiate for price reduction from these MNCs for which the generic completion was taking place; it became the most fruitful negotiation. Brazil also scaled up its AIDS treatment and it was noted that from 2001 to 2003 the average and total cost of HAART reduced (Nunn 2009). Similarly in 2001, the Indian generic drug producer Cipla Ltd., offered to produce and supply three important ARVs to Africa, through MSF and the cost of the drug would be less than 1$ per day, and if the government is purchasing those drugs the cost would be 600$ per year. Introduction of generic drugs reduced the cost further, as another pharma company from India; Aurobindo began to provide the same drugs at $209 per year. Thus the prices came down to $200 per year from $10000 per year, and resulted in the reduced cost of HAART

(Irwin, Millen and Fallows, 2003:75). Tbale 3.4 shows the decline in the prices from 1998 to 2006.

The only limitation was that this competition could prove to be helpful in reduction of prices of those drugs which were not patented. In OAPI countries the five ARVs with fixed dose combination drugs like Lamivudine, Nevirapine, Lopinavir, Saquinavir and Nelfinavir were patented by GSK, they were in the first line treatment, and they cannot be replaced by any other molecule. The last three molecules were the essential part of the second line treatment recommended by WHO. These patents also stopped OAPI countries from buying generics from India as they all contain the molecules of Lamivudine and Nevirapine. Thus because of all these reasons and transportation cost, storage of medicines and clinical management still made the availability of drugs difficult in many poor countries.

TRIPS and Regional Agreements

Till 1950s most of the African countries were European colonies. After 1962 when these colonies got independence, twelve of them came together to form an organization which can govern them in the area of IPRs. Consequently on 13 September 1962, trough 'Libereville Agreement' the Office and Malagasy de Propriete Industrielle came in to existence. Their main aim was to form a common and uniform industrial policy for these twelve countries, and to establish a common office to supervise the working of the agreement for all. Later on in 1977, through 'Bangui Agreement' Organization Africanine de la Propriete Intellectuelle (OAPI) was established, to maintain joint administrative mechanism (Martor 2002:297). It was a king of national law for all the member countries. This body was responsible for granting patent, when the application was filled, which automatically considered to be granted by all the countries.

This agreement also gave recognition to the patent to pharmaceutical drugs indiscriminately. The basis of granting patent was the local exploitation of the invention, and the patent was granted for ten years initially from the date of registration, which can be extended twice consecutively for five years. The patentee has to give proper evidence of the local exploitation of the product within five years and if he fails to do so, he cannot

go to any court against the infringement of the integrity of his produce. This agreement also made a provision according to which any of the residents of OAPI could demand for compulsory licensing on any product if that is not exploited locally for three years. Secondly compulsory license was possible only for local product not for the import from foreign countries. It also provided member countries with *'ex officio* license' for foreign imports in the case of national emergency as a substitute of compulsory licensing.

However, when TRIPS came into existence, many of the provisions of Bangui Agreement provisions found to be incompatible with it. Thus it became mandatory for Bangui Agreement to make revision, to maintain its uniform applicability, as all the members of this agreement did not come under the same category of transitional period provided by TRIPS agreement. So changes in the laws of one country tend to bring change in the laws of other countries as well. Consequently the Bangui Agreement has to abolish the provision of '*ex officio* license' and it also had to increase the period of patent. The revision in the Agreement is known as 'TRIPS plus' because it was more constraining than the TRIPS itself. The provisions of Bangui Agreement were not complementary to the TRIPS Agreement, the duration of protection under TRIPS is 20 years, whereas, under Bangaui Agreement the protection was given for the period of ten years only. It also made impact on the number of cases of HIV/AIDS, as the number of HIV/AIDS patients increased in South Africa.

In February 2000 MSF, WHO and UNAIDS, debated on the impact of the revision of the Agreement on poor patients. In the month of May MSF made an announcement in press that the 'TRIPS plus' provision has made negative impact on the availability of generic drugs in Bangui Agreement member countries, as the essential drugs became 'ten to twenty' times more expensive. Table 3.1 presents the data of the increased number of HIV patients in different regions of African continent. Realizing the severity of problem MSF, WHO and UNAIDS staff tried to train official about the implication of different approaches to TRIPS implementation for public health in the OAPI member countries (Deere, 2009: 273). They also worked to raise public awareness about the negative impacts of the revision of the Agreement. WHO, MSF collaborated with Health Action

International (HAI), AIDS Coalition to Unleash Power (ACT UP), and CPTech, to lobby OAPI government officials in Geneva to publish research and to make people aware of what is going on. In 2001, at WHO Annual Health Assembly the health ministers from OAPI countries supported the proposal of MSF, but this campaign did not prove to be successful, as the secretariat of the OAPI countries declared that there is no contradiction between revised Bangui Agreement and Doha Declaration (Deere, 2009:276). Table 3.1 shows the spared of disease in different regions of world.

Table: 3.2 Indicators of HIV Epidemic in Different Regions in the World in 2003.

Regions	Children and Adult living with HIV/AIDS (millions)	New cases of HIV infection in children and adults (millions)	Prevalence among Adults (%)*	Death of children and adults due to AIDS (millions)
Sub- Sahara Africa	25.0-28.2	3.0-3.4	7.5-8.5	2.2-2.4
North Africa and Middle East	0.47-0.73	0.43-0.067	0.2-0.4	0.035-0.05
South and South East Asia	4.6-8.2	0.61-1.1	0.4-0.8	0.33-0.59
East Asia and Pacific	0.7-1.3	0.15-0.27	0.1	0.032-0.058
Latin America	1.3-1.9	0.12-0.18	0.5-0.7	0.049-0.07
Caribbean	0.35-0.59	0.045-0.08	1.9-3.1	0.030-0.05
Eastern Europe and Central Asia	1.2-1.8	0.18-0.28	0.5-0.9	0.023-0.037
Western Europe	0.52-0.68	0.03--0.040	0.3	0.0026-0.035
North America	0.79-1.2	0.036-0.054	0.5-0.7	0.012-0.018
Australia and New Zealand	0.012-0.018	0.0007-0.001	0.1	0-0.0001
Total	35-46	4.6-5.5	0.9-1.3	2.7-3.3

The margin around the estimations define the limits with in which the real figures are located, based upon the best information available.

* Proportion of adults (aged between 15 and 49) living with HIV/AIDS, according to demographic statistics for 2003.

Source: UNAIDS (2003)

In 2000, several pharmaceutical companies and United Nations Organizations, collaborated and came up with a new program called Accelerated Access Initiative. With the help of this program ARV were provided at a very low cost. Prior to it the costs of medicines were very high, as it is shown in Table 3.2.

Table: 3.3 Structure of ARV supplies and prices in US $ in Certain Countries in July 1999

ARV	Burkina Faso	Mali	Burundi	Guinea	Senegal	Ivory Cost	Niger	Suppliers
Retrovir- 100 mg	54.70	92.67	92.67	NA	64.17	51.50	NA	GSK
Retrovir-250mg	113.11	NA	92.67	NA	NA	51.13	NA	GSK
Epivi-r	94.56	NA	160.67	NA	160.67	88.50	NA	GSK
Videx 150 mg	98.24	111.67	89.52	NA	NA	NA	131.00	BMS
Videx 100 mg	73.90	75	59.68	76.28	59.68	60.00	433.30/6	BMS
Zerit-40mg	144.00	149.33	131.22	166.67	131.22	131.60	158.78	BMS
Zerit-30mg	154.23	144.50	126.43	162.95	NA	126.43	152.98	BMS
Crixv-an 200 mg	NA	NA	305.00	NA	NA	311.40	NA	Merck
Crixv-an-400 mg	372.79	345.38	305.00	NA	311.00	311.10	NA	Merck

NA: not available, GSK: Glaxo Smith Kline, BMS: Bristol-Myres Squibb

Source: Dumoulin and Maville (1999:3), (Andersen: 2006:88).

Before the AAI (Annexure 3) the African countries used to buy ARVs from the big pharmaceutical companies at higher prices. These countries justified their high prices on the basis that to maintain high level of further R&D these prices are charged. Till the half of 2000 these companies denied to supply drugs at dual price (actual price in the countries of north and reduced price in the countries of south).

Table: 3.4Per Patient per year price declines from price negotiations.

Drug	1998	1999	2000	2001	2002	2003	2004	2005	2006	%Decline from launch Price	%Decline from first purchase Price
Atazanavir 150 mg	–	–	–	–	–	10,074; 2,373a	2,373	2,190	–	78	8
Atazanavir 200 mg	–	–	–	–	–	10,074; 2,373a	2,373	2,285	–	77	4
Efavirenz 200 mg	–	2,540	2,540	920	920	–	–	–	–	77b	77b
Efavirenz 600 mg	–	–	–	–	–	767;577	577	577	–		
Nelfinavir 250 mg	2,585	5,329	2,482	3,942; 3,650	1,935	1,989	1,716	1,716	–	69	69
Lopinavir 133 mg + ritonavir 33 mg	–	–	–	6,504; 4,139	3,504	3,285	2,847	2,847	–	84	75
Lopinavir 200 mg + ritonavir 50 mg	–	–	–	–	–	–	–	–	1,022		
Tenofovir 300 mg	–	–		–	–	5,037;3, 296;2,905 d	2,803	2,803	1,387	72	58

Data source: Nunn, da Fonesca, Bastos, et al (2007).(Nunn, :154)

Note: ' -' Denotes no negotiation that year because drug not in guidelines or price remained stable. Cells with two entries reflect two ARV purchase price for that year. 'a' Reflects initial negotiation price and first purchase price, 'b' One daily dose of efavirenz 600 mg replaced thrice daily doses of efavirenz 200 mg, 'c' Heat stable version, 'd' Reflects initial negotiation price, first purchase price, second purchase price.

NGOs, 'Access to Medicine' Campaign and Doha Declaration on Public Health

Accessibility of medicines to the patients in poor countries was a kind of performance test for Doha Development Round. Lack of availability of medicines and coercive actions of developed countries against poor countries were the two major issues in this round of talks. Many critics are not against patents, but rather against the unbalanced nature of global rules which, they argue, prioritize private patent 'rights' over public health goals (Mayne: 2004:310). Though, developing countries have been recorded with low child mortality rates and increased life expectancy rates gradually, but the crisis is not over as yet. The investments on R&D in developed countries are more on the diseases prevailing in rich countries, because the patients in these countries are able to afford the cost of medicine. There are several factors which restrict the availability of medicines to the patients in poor countries. These factors include- poverty, lack of political will, inadequate finance, poor infrastructure, and weak drug selection policies (Mayne, 2004:311). Oxfam is an INGO which works for the alleviation of poverty, in a study documented that when the prices of drugs soar poor patients take their children out of school and sell their cattle to meet the need of medicine.

After the TRIPS came into existence the prices of triple antiretroviral cocktail medication for HIV/AIDS patent came to around $ 10,000 per person per year. Later on when the international community and several INGOs stood against it and India came up with the low cost generic version of these medicines, big pharma companies began to reduce their prices but still those drugs were costlier than the drugs provided by Indian Firms. Oxfam in its study found that if the generic version of medicines were used to treat people in Uganda, the number of the patients who are availing medical care would have been two hundred percent more than the actual percentage (Mayne: 2004). Since the mid of 1990s, many NGOs like Health Action International, Consumer Project on Technology and Medecins Sans Frontieres etc. have been working in Global Health Governance (GHG).

Basically the GHG (Annexure 1) is "the totality of collective regulations to deal with international and transnational interdependence problems in health" (Bartsch and

Kohlmorgen 2005: 64). GHG works to create a balance among the conflicting interest of developed and developing countries, and also to regularize the international health mechanism. It aims at securing right to health to everyone equally. It is the sum total of the interaction among different international and transnational actors. Four roles of these non state actors have been identified in global governance (Arts, 2003):

- They involve in decision making at international level;
- They put legal pressure on rule making authorities, as they gradually gain legal expertise;
- They also utilize their resources like funding, knowledge and information to influence decision making, and;
- They also have discoursive power.

In international arena states follow their interests and these transnational actors work for harmonization of the national interests and the collective interests of all to create a global rule.

In 1999 MSF started a campaign to provide 'essential medicines' to poor countries. To prove the legitimacy of its work MSF began to publish its articles in *The Journal of the American Medical Association* and *Lancet.* MSF joined hand with other NGOs like Consumer Project on Technology (CPT) and Oxfam. In 1999 MSF launched 'World Tuberculosis Day'. MSF wanted WTO to adopt balanced approach to harmonies the interest of poor patients and innovators together. In 1999 with the collaboration of HAI and CPT, MSF organized a conference in Geneva to examine the effectiveness of compulsory licensing provision. During the Seattle Round the MSF wanted WTO to create one Working Group on Access to Medicine, but the Seattle Round proved to be a failure (Devereaux, Lawrence and Watkins, 2006:88).

During 1990 Civil Society Organizations (CSOs) became more active for the campaign of Access to Essential Medicines. In 2001 Oxfam International started a campaign 'cut the cost of medicine', against the high prices of drugs. Initially the developed countries

were not ready to take any action against the price rise of medicine, but later on due to international pressure they began to think over it and eventually in 2000 President Clinton issued an executive order to ensure the world community that now US will not threaten sub-Saharan African countries with trade sanctions now.

From 2000 to 2001, several UN agencies like United Nations Development Program (UNDP), UNAIDS and the World Bank launched several program to overcome the problem of patients caused by the implementation of TRIPS. Issue of African Union, US trade dispute with Brazil, India's effort to provide cheap version of generic drugs, and the consideration given by Canadian and American government for the use of compulsory licensing were some of the issues which bound WTO, to take the problem of patients in poor countries, in to consideration. During the Doha Round developed countries seemed to be agreed to the pro-public health clarification of the TRIPS Agreement provided by developing countries, which gave priority to public health above everything. In the year 2000, UK government constituted an Independent Commission on Intellectual Property Rights (CIPR), to review the TRIPS Agreement and its negative impacts, on development and public health, and it also urged developed nations to adopt flexible measures to deal with the problem.

These reasons compelled developing countries to demand for the reinterpretation of Article 30 of TRIPS agreement. Article 30, talks about the exceptions provided under TRIPS, and if the exceptions are also written in the domestic rule book of a country, generic producers would have to respond to the request for compulsory license from an importing country, which will hasten the supply of generic version of medicines. Many NGOs and WTO appreciated the relaxations provided under Article 30. Developing countries also demanded that the proposed reforms should not be country and disease specific, rather it should open ended. In opposition to this the pharma companies demanded for the temporary waiver. The US and EU countries also stood by the cause of these companies. European Union proposed that an amendment should be made to TRIPS Agreement in favor of compulsory licensing restrictions on export for pharmaceutical products.

NGOs criticized this proposal of EU, as it made importing countries dependent on the

political will in exporting country to meet its health need. It would also not give any incentive to the producers of generics to go for production of cheap drugs. Developed countries were also concerned about the diversion of generic exports back to their own territory. However, NGOs like MSF supported the view that, it should be the responsibility of countries to check the diversion of generic drugs. Developed countries also demanded for the adoption of disease and country specific exceptions, but NGOs advocated for the uniform applicability of exceptions (Porter and Ronit 2010:154).

During 2002 negotiations, the US and EU Countries put pressure on poor countries to concede the ground of negotiation, and to comply with whatever amendments made to the TRIPS Agreement. On 16 December 2002, TRIPS council came up with a text which proposed for the interim wavier of compulsory licensing. As per this amendment, the medicine would be supplied to some LDCs only. The problem with the revised TRIPS text was that it not only hampered the export but also the production of generics. It eventually lessens the competition among the generic producers which resulted in the high prices of drugs. Developed countries were of the opinion that the TRIPS is the short term cost which developing countries have to pay, but the incurred long term benefits would be higher. In response to that opinion Oxfam studies showed that the short term cost of TRIPS is highly destructive for LDCs and the long term benefits are very uncertain.

According to Commission for Intellectual Property Rights (CIPR) report, big pharma companies are not willing to invest for the diseases prevailing in the developing countries, and not because of lack of patent protection, but it is because of the lack of market. In poor countries patients are not able to afford expensive medication, which may affect the profit of MNCs that is why they were apprehended for the investment in poor countries. CIPR report says that if the benefits touch the US $ 1 billion annually than only the pharma companies would like to invest for that disease. Secondly the CIPR report says that it's not the weak IP protection system rather the lack of technological capacity hampers domestic innovations. Basically the NGOs like Oxfam demands that IP laws should be implemented in that sector of innovation where the LDCs are already

having stronghold, so that healthy trade competition can be ensured among countries. Mayne writes that Oxfam and other NGOs opined on the global alliance on access for medicine:

- An end to rich country and corporate pressure on developing countries to introduce unnecessarily stringent patent protection.
- More aid resources to help governments buy medicines and improve health systems and greater public funding for, and increased corporate commitments to R&D into neglected disease.
- Corporate commitments to lower prices as part of a transparent global system of tiered pricing Mayne (2004:5).

Though because of intense public pressure some companies and governments agreed for reducing the prices of drugs but that was ad hoc step taken by them and also depended on the good will of companies and governments. But the suggestions were provided by NGOs that tiered pricing should not be taken as the substitute of generics, because the aim of tiered prices would be to charge affordable cost to poor patients. Which is close to the marginal cost of production, but the companies do not reveal, the actual cost of production, so it would be difficult to access the actual margin cost.

Conclusion

Just after the adoption of TRIPS in WTO, the direct impact on public health was that, it made the availability of medicine to the poor countries difficult, first because of the soaring prices of drugs and secondly the unavailability of generic version of cheap drugs. Big pharma companies demanded for higher prices for drugs in the name of money spent on R&D and for also the future research to upgrade the medicinal values as the need arises. However the close analysis of the entire structure of these companies brought into light that they spend more money on the propagation and marketing of drugs than they spend on R&D. Thus their demand for higher prices for drugs in the name of future R&D cannot be justified.

Politically these companies are very powerful as they have got strong lobbying group in legislation and they also provide funding to the political parties, who put their demand at national level. Thus with the help of monetary power these big pharam companies are able to pressurize their government to take their demand at international level. These are known as Drug Lobby in the US. It was noted that these pharma companies donated $900 million on lobbying from 1998 to 2005 (Read, Mosher and Bentall 2004:127). There prevails a rich poor dichotomy in the production of drugs. The big pharmacy companies produce drugs keeping in view the patients in rich countries and ironically the majority of the patients from poor countries suffer from the very different kind of disease from which the patients of rich countries suffer.

NGOs also demanded for the revision of TRIPS Agreement so that it can provide some relaxations to LDCs. These NGOs worked at grass root level to find out the real cause of the suffering of patients in poor countries and launched several campaigns to provide some relief to poor countries. These NGOs also assisted in policy making of international institutions so that the policies should be made more favorable to poor patients.

Though the complete revision of TRIPS Agreement would not root out the prevailing health crisis but to some extent it will really reduce the burden on developing countries. It will help in reducing the prices of drugs and it can also ensure the wide availability of drugs.

Chapter IV

An Analysis of the Working of the Exceptions Provided under TRIPS, in the Health Sector

Since the WTO came into existence, developing countries and LDCs opened up their markets for foreign investment. These countries did this, keeping the ongoing corporate competitions in mind. In the era of globalization, the national markets are getting interlinked with international market. This change in international political economy has brought better opportunities for developing countries. If these countries open up their markets judiciously it would increase their FDR, which is very necessary to survive the ongoing competition, and to maintain balance of trade in their favour. Their success is based more on the use of modern resources. These modern resources include modern technologies, and modern knowledge, which give the countries edge over others. , but the problem is that the developing countries are struggling to acquire modern resources, which itself is a very costly affair. Musungu writes in this regard

> "with major changes in the factors of production and business practices, however, their success in economic growth is increasingly dependent on their capacities to generate, acquire and use existing technology including medical and pharmaceutical technology" (Musungu 2008:423).

However, the development and innovation in the field of pharmaceutical drugs do not root out the problem. There still exists massive inequality in the health status of people between poor and developed countries. The exorbitantly high costs of patented medicines makes it very difficult for NGOs, health centers and governmental agencies involved in the health care sector, to do justice to people in poor countries, because they fail to meet the demand of medicines from patients. That is why the deaths due to communicable and infectious disease in developing and poor countries are very high. The loin's share of government spending goes for the supply of medicines, which results in the reduction of expenditure on other health related needs, like proper nutrient food supply, and sanitation system to the dwelling areas. To illustrate this point, only 20% of India's total health expenditure goes on drugs, as in most other developing countries. Of this 20%, every drug on India's essential list of 74 is already generic, meaning its patent has expired, so

production is cheap. Despite this these drugs are still not accessible to all who need them (Debroy 2007).

Major development in the field of medical technology has made the realization of right to health to poor people thinkable now, which was not an easy task earlier. Similarly the IP protection to the pharmaceutical drugs in developing countries creates another problem for the poor patients. Musungu writes that developed countries, which represent nearly 90 per cent of the global pharmaceutical sales, represent only 10 per cent of the 14 million plus global death that occur annually due to infectious diseases, while developing countries which represent 90 per cent of the 14 million deaths represent only 10 per cent of the global pharmaceutical sales (Musungu 2008:424) .

The other issue in this regard is the variability of the research in the medical field. A research conducted by National Institute of Health Care Management Research and Educational Foundation (NIHCM), found that US with maximum number of pharmaceutical patents, in 12 years period from 1989 to 2000 got the approval for 1,035 medicine, and only 35 per cent of them contained new active ingredients, remaining were the just up gradation of the preexisting drugs. Only 15 per cent of that 35 per cent was highly innovative (NIHCM: 2000).

However, they demand patent for even upgraded drugs, and the irony is that, that they are most often granted patent on the upgraded version of drugs, which are not in favor of patients. The issue here is that, the money spent on up gradation of drugs, if spent on the research for new drugs for different diseases, it would be beneficial for patients all over the world. Hence the basis of the demand for granting patent from big pharma companies, that patent protection would ensure future research and innovation, are sometimes seems flawed. This chapter will discuss the practicability of the exceptions provided under TRIPS Agreement, and the causes behind their failure in solving the problem of unavailability of drugs to the poor patients.

Reality of the Provisions over Public Welfare in TRIPS Agreement

Though the injudicious implementation of the TRIPS Agreement made it a most criticized regime in the history of WTO, it is consists of several provisions which talk about the welfare of people. There are 20 provisions including the preamble of TRIPS which talks about public welfare in general in public health in particular in TRIPS Agreement. Firstly to make its implementation easy, paragraph three of the preamble of the agreement recognizes IPR as an essential private right, so that the one who creates intellectual property can also avail benefits of his creations. Fourth paragraph focuses on public policy objective of implementing IP laws properly, with equal effort of giving impetus to R&D. This paragraph basically emphasizes the problem of developing countries, and also puts moral burden on the developed counties to spread technology among these countries.

Finally paragraph five of the preamble recognizes the need of LDCs. It is related with the flexibility provided to these countries to implement the agreement, so that they can develop competitive advantage in the field of technology. The developed countries are having modern technologies in their possession because when the developmental processes begun in those countries they were not bound by any restrictive international regimes, and they also did not face any domination from other countries. However, developing countries are undergoing all these problems in present time, so they must be given freedom in complying with any international regime. Paragraph five has been extensively dealt under Article 66, which stipulates that poor countries lack the viable technological base, so they need not comply with the Agreement within ten years of its application, except Article 3, 4 and 5, which talk about equality treatment with foreign nationals and the citizens of the countries.

However, all these provisions are challenged by the difficulties faced by poor countries, TRIPS instead of giving them autonomy, took away their freedom over indigenous IP law system. These countries were asked to comply with TRIPS Agreement in too, and the transition period to comply with TRIPS, given to them was not sufficient to develop a viable system to accommodate this huge change in law structure of the country.

After going through the preamble, we need to scrutinize the actual provisions of TRIPS, to know the reality of the rhetoric it maintained. Article 1 of the agreement says that WTO members 'may', but shall not be obliged to, implement in their laws more extensive protection than is required...' and that they 'shall be free to determine the appropriate method of implementing the provisions' of the Agreement. In the first part it is said that the Agreement talks only about the minimum standard of protection provided to the patent holders and member countries have nothing to do more than that, not even the extension to patent for any reason. Countries are also free to adopt suitable judicial structure to implement the Agreement (Matthews 2002:141).

The second part of this provision allows member countries to implement the agreement in a manner conducive to the further innovation, R&D and also easy accessibility of pharmaceutical drugs to patients. However, the WTO and Appellate Body (AB), will have the right to scrutinize whether the chosen method of implementation fulfils the obligation or not. Except the provisions Article 3 & 4 which talk about the equal treatment to the nationals of other member countries *vis-à-vis the* nationals of the country.

Further, Article 7 of the Agreement notifies:

> "The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and the transfer and dissemination of technology, to the mutual advantage of the producers and users of technological knowledge and in a manner conducive to the social economic welfare , and to balance of right and obligation" (Carvalho 2005:122).

The declared aim of the Article 7 was to foster innovation and to establish a balance between innovators and consumers, but it failed to do that. Later, Article 8 of the Agreement, permits member countries to implement the provisions in a way, which does not harm public interest. Though both the above articles tried to create balance between public and private interests, it resulted more as a safeguard to private interests, because the strong lobby of MNCs from developed countries did not allow the free flow of technology.

The other provision is mention in Article 29, which makes special provisions for future

research. It makes it mandatory for an applicant under TRIPS, to make revelation of the method of invention so that it can help in ongoing researches, with the filling of the application for the grant of patent. Article 29 of TRIPS, makes some arrangements for the dissemination of technology without any hindrance. It will help in the field of pharmaceutical research to make a patented medicine and also to carry- out pharmaceutical research. It will reduce the chances of unnecessary monopolization of market by patent holders, because if the information regarding innovations come to the public domain, chances of the introduction of additional and upgraded version of goods to the market, increases. Hence the monopoly of one firm can be challenged and the competition among producers will help in the reduction of the cost of product, which would be in favour of consumers in poor countries.

This provision is also helpful to the patent application reviewing authorities. If the information regarding innovation is presented before the authorities, they can easily assess the quality and the actuality of that innovation. Though this provision, if properly implemented, is good for human welfare, the innovators in developed countries create hurdles in the actual implementation of this article. Either they do not make proper revelation of the information, or if they do so they do not allow others to use it for further research, till the time patent is granted.

Besides the above mentioned provisions, there are several other Articles in the TRIPS Agreement which are said to ensure the protection to public health in poor countries. Article 27 of the TRIPS Agreement talks about patentability. Article 27(1) states that patent shall be available for all the innovations, product or process, provided that it should be new and capable of industrial application. Article 27(2) further empowers the innovator to stop others from exploiting the patent, or selling and copying it, except in the case of human health and environment. Article 27(3) was the most contentious among them, because it provides patent over diagnostic, therapeutic and surgical methods for human, animal and plants and developing countries did not grant patent over these (Carvalho 2005). Hence the articles which are said to be meant for the protection of public interest in poor countries, actually ensures benefits to big stake holders in R&D in developed countries. Poor countries are in need of a regime which could ensure them the

availability of basic amenities including life saving drugs, more than a strong intellectual property regime like TRIPS, which has made them die in the want of medicines.

Health Related Exceptions Provided under TRIPS Agreement

Exceptions are considered to be an essential part of the patent rights, since the emergence of TRIPS Agreement. Exceptions create a balance between the rights of poor and innovators, and curtail the absolutism of patent holders. The US was the first country to introduce any such exception. In 1984, United States Drug Price Competition and Patent Term Restoration Act, introduced exceptions with the granting of patent rights. However, *the statue of monopoly* is the first trace of the provision of exceptions to the right of patent (Correa, 1999:1). Under this law the king of England was authorized to give monopoly right to a particular firm or person to produce certain goods. For the first time the statute of monopoly in the name of "letters patent" was granted to Flemish man by Henry IV in 1449, on the manufacturing of stained glass. This was the start of granting monopoly to favored persons in England. Later on this statute brought negative results against the healthy market competition. To overcome this problem during the reign of Queen Anne, in 1668 the changes were brought against the cartels that now the grant of monopoly needs a legislation passed by parliament (Price 2006). Actually from then onwards necessity of exceptions under IP laws was felt.

However, internationally, exceptions were granted when the Paris Convention was adopted in 1883. Under this convention one exception of national treatment principle was adopted, according to which the countries which are not sufficiently developed, have the choice to adopt different standard of IP protection. It was adopted considering the asymmetry of development among different countries (Yu 2007:306). It laid the foundation of the adoption of the minimum standards by TRIPS Agreement, according to which minimum slandered of IP protection has been described by WTO, which the member countries are supposed to provide.

Under TRIPS, these exceptions are meant to achieve the goals enshrined in Article 8. Article 8 talks about the protection of public health and nutrition and also talks against

the abuse of IPRs. In Article 30 it is written that exception must be provided with patent rights under TRIPS, but the exceptions should not create chaos. Musungu writes "the rule is that exceptions to the patent rights must be limited; and should not unreasonably prejudice the legitimate interest of the patent owners, taking into account the legitimate interests of third parties" (Musungu 2001:435).

The provisions which are related with the above argument is mentioned under Article 28, which has two dimensional implications. It is taken from traditional patent system, under which the innovator has been conferred the right of monopoly over his/her product and process. Patent holder can determine the price of innovation to make material benefit out of it. Later this Article talks about the transferability of patent right. Innovator can transfer the patent by succession. It talks about the passing on of the exclusive right to third party. Exception of compulsory licensing under TRIPS is the progeny of this Article only.

In Article 30 of TRIPS Agreement exceptions were discussed elaborately. It empowers countries to grant exceptions against the private IP rights. It mentions:

> "Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the owner, taking account of, taking account of the legitimate interests of third parties" (Carvalho 2005).

Further, Article 31 talks about the exception of compulsory licensing, which can be used by governments and agents similarly. Article 31, under TRIPS, talks about certain conditions under which the application for granting of compulsory license can be made. The applicant must show that the earlier failure of the request for voluntary license. There are several conditions under which compulsory license can be issued, like high prices of medicines, anti completive practices by big pharma companies, emergency public health situation etc. Compulsory license is issued by the government to a third party, to lessen the negative impact of strict IP regime. Thus it makes availability of drugs easy and patients get cheap drugs.

Article 31 stipulates certain provisions which are to be respected while granting

compulsory licensing (Nair, 2004: 416):

a) Authorization of such shall be considered on its individual merits.
b) Such use may only be permitted if, prior to such use, the proposed user had made efforts to obtain authorization from the commercial terms and conditions and that such efforts have not been successful within a reasonable period of time. This requirement may be waived by a member in the case of national emergency or other circumstances of extreme urgency or in case of public non-commercial use;
c) The scope and duration of such use shall be limited to the purpose for which it was authorized;
d) Such use shall be non-exclusive;
e) Such use shall be non assignable;
f) However, the problem with the exceptions is that, the actual implementation of the any such use shall be authorized predominantly for the supply of the domestic market;
g) Authorization of such use shall be liable, subject to adequate protection of the legitimate interests of the person sp authorized;
h) The right holders shall be paid adequate remuneration;
i) The legal validity of any decision relating to the authorization of such use shall be subject to judicial review;
j) Any decision related to remuneration provided in respect of such use shall be subject to judicial review;
k) Members are not obliged to apply conditions set forth in sub paragraph (b) and where such use is permitted to remedy a practice determined after judicial or administrative process to be anti-competitive; and
l) Where such use is authorized to permit the exploitation of a patent (second patent) which cannot be exploited without infringing another patent (The first patent).(Nair, 2004: 416)

Subsection (b) of the Article 31, makes it clear that the license can be issued only when the earlier application for granting license has been defied, even on reasonable

commercial terms. Further Article 31 (f), restricts the use of license strictly for domestic purposes otherwise the license may get cancelled. Licenses can be issued only to those countries who are suffering from health crisis and health related emergencies, and where the patients are not able to afford the cost of medication. Subsection (h) talks about the payment of 'adequate remuneration' to the patent holder, based on the economic value of the license. So actually there are a lot of restrictions attached with the granting of compulsory licenses, to secure the patent holder's right from any abuse, and also restricts the mishandling of the exceptions (Mercurio: 2004).

However, in practical terms these exceptions cannot be used by the countries having weak manufacturing capability, as they cannot import drugs from the countries who are producing generic version of the costly medicines, and if they somehow manage to get medicines they are not capable to circulate them among patients. Lack of awareness among the buyers and sellers are also one of the factors behind the unaffordability of medicines. In the markets where the generic production is allowed, drugs are available at lower prices. Sometimes the generic producers have to compete with the costly branded drugs because the generic firms are sometimes least known to the market, and in some cases they are the new entries in the market, hence it takes lots of time to develop faith about the authenticity of medicines among patients.

There are several grounds mentioned under which the compulsory license can be issued (South Center Organization: 2006). First among them is the 'refusal of deal'. This system is prevalent in US and UK. Under this condition when patent results in anti-competitive practice, the compulsory license is issued against that product. Compulsory license is also issued in the case, when the need of medicine is not met by the patent holder. Sometimes the patent holders also refuse to provide license to the third party, in that condition also the license is issued against patent holders. Nair writes that until 1990, Canada used to issue license for parallel import, if the import is justified on the lower price ground. South Africa also issued license for importing cheaper drugs for its poor patients, who were not able to afford costly medication. After 1995, US issued license against several companies even on 0 per cent royalty when anti-trust law came into existence. So the issue of compulsory licensing has all to do with the national laws (Nair 2004:418).

The other ground on which the license can be issue is the 'public interest' ground. But it is very subjective, as different countries have their own definition of public welfare and public interest. Like in US high prices of drugs are not taken as a hurdle to the fulfillment of public welfare. But in Germany access to life saving drugs is considered as a very important right of people. In Germany unavailability of drugs and high prices of drugs are the plausible cause for issuing compulsory license against the patent holder. Another major reason of granting compulsory license can be the issues related with 'public health'. It was conceived during the Doha Round of Ministerial talk, that public interest must get precedence over the private interest of patent holder. It also reiterated that no discrimination should be made on the MFN ground, between nationals and foreign nationals. Under Article 66.2 member countries are now given the right to determine the ground for introducing compulsory licensing, in tandem with Doha Declaration on Public Health.

Non-Commercial use of the patent is another ground for issuing compulsory license. Apart from it the license is issued for government purposes also. Under such conditions government does not need to negotiate for the use of patent, any government employ can use, or authorize the use of patent or copyright, but right owner is entitled of compensation. Right from 1883, UK had used the "Crown Clause" in its Patent Act for grant of compulsory licenses not only for production of the goods against which compulsory license has been issued, but also for the imports of any source or goods outside the country (Nair, 2004:420).

Many poor countries and international nongovernmental organizations demanded India to make use of compulsory license to produce generic drugs, so that in availability of drugs can be ensured in poor countries. But the condition with the issuing of compulsory licensing was that, it can be issued only in the territories which grants patent to the medicines. But many firms do not file application for granting patents in LDCs. Hence, even if India is issuing compulsory license and produce generic version of medicines, only those counties can import medicines who have already given patent protection to that medicine. Secondly these countries under transition period were asked to provide

Exclusive Marketing Rights (EMR) to those companies whose products have got patent protection in other member countries of the WTO. So the conditionality attached with the exceptions under TRIPS made it difficult for poor countries to use those exceptions in their favor (Leskin and Flitner 1997:5).

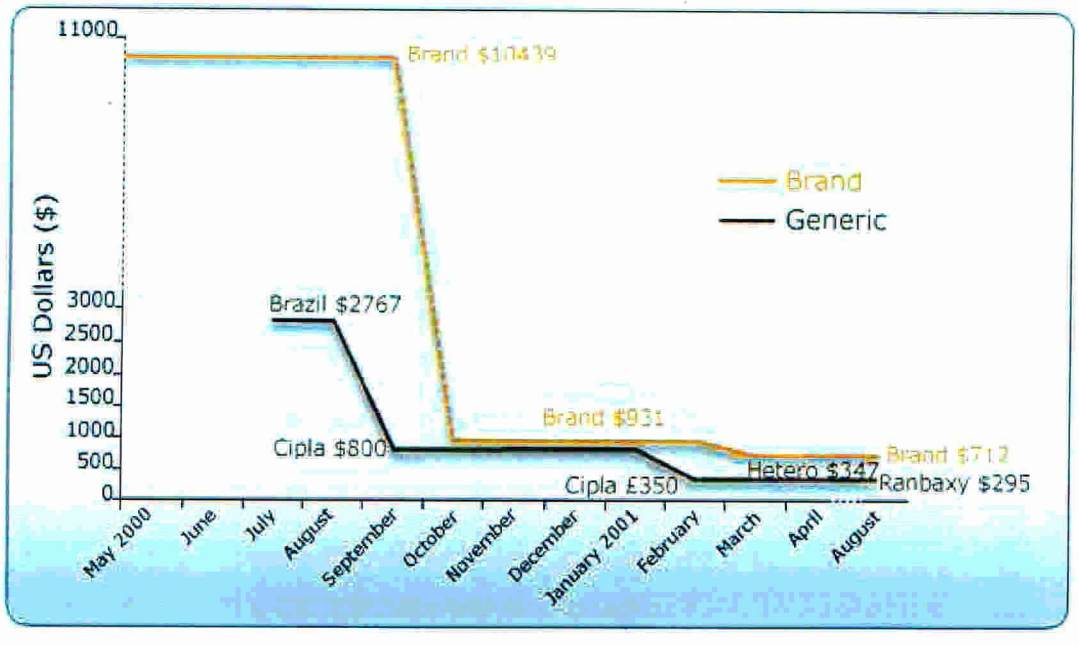
'Bolar Provision' under TRIPS gives right to a researcher to carry on further research on the basis of pre existing product or process, but later if the researcher is able to discover a new and different product and demand for patent for his product then he will be bound to pay royalty to the patent holder of the existing product. Article 30 of TRIPS mentions 'Bolar Provision'. Using this provision, India also adopted this provision under section 107 A (a) of Patent Amendment Act 2005, which says "any act of making, constructing, using, selling or importing a patented invention solely for uses reasonably related to development and submission of information required under any law for the time being in force, in India, or in a country other than India, that regulates the manufacture, construction, use, sale or import of any product" (Patent Amendment Act 2005:107 A (a).

Section 170 A (b) of Patent Amendment Act 2005 also talks about the exception of Parallel Import. Parallel import is a provision under TRIPS according to which "Importation of patented products by any person from a person who is duly authorized under the law to produce and sell or distribute the product, shall not be considered as an infringement of patent rights (TRIPS Agreement 1994:28).

TRIPS also provide some exceptions for educational purposes. Section 47 (3) of Patent Amendment Act 2005 states "any machine, apparatus or other article in respect of which the patent is granted, or any article made by the use of the process in respect of which a patent is granted, may be made or used, by any person, for the purpose merely of experiment or research including the imparting of instructions to pupils" (Patent Amendment Act 2005). So these were some of the exceptions provided under TRIPS which can be utilized by developing and poor countries in their favor, and if used judiciously it can also make the availability of drugs to poor patient if not certainly, easy. Using these exceptions, India has become the biggest supplier of generic version of HIV/AIDS drugs to poor countries. As in the figure 4.1 it is shown that the prices decreased when India begun to produce generic version of costly medicines.The graph

below shows the effect of generic competition on proprietary drug prices between 2000 and 2001. It shows the lowest price per patient per year of triple combination therapy made up of d4T (stavudine) + 3TC (lamivudine) + nevirapine, it happned because of the availability of generic version of drugs.

Figure: 4.1 Effect of generic competition on proprietary drug prices between 2000 and 2001.



Source: AIDS, Drug Prices and Generic Drugs (MSF 2001:3).

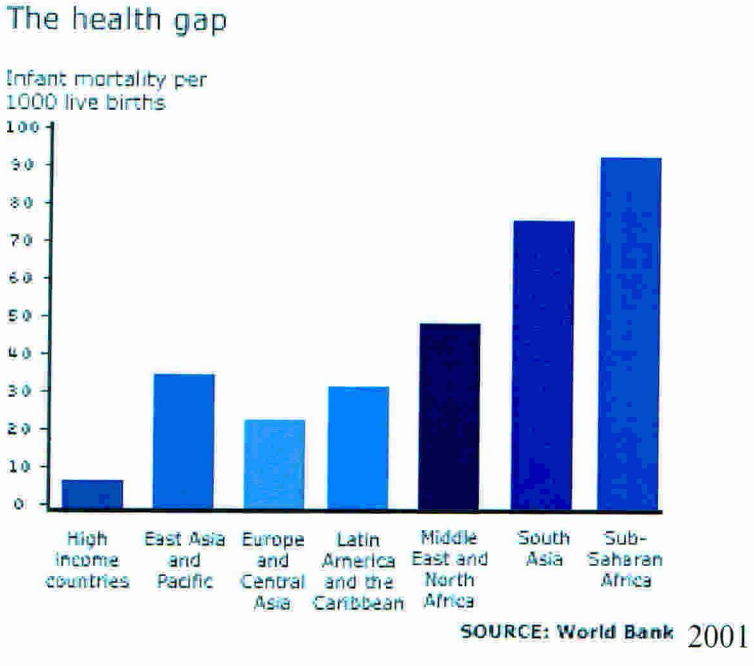
URL:http://www.avert.org/generic.htm

Implementation of TRIPS and Access to Drugs in Asian Continent

Poverty and lack of development has divided the world between the north and the south. As shown in figure 4.2 the differences in adult mortality in different countries. Northern countries are having high rates of development while some of the southern countries are so poor that 1/3 of its population even does not have access to life saving drugs. Maximum numbers of deaths in these countries are happening due to infectious and communicable diseases, which are curable. However, the lack of health infrastructure and high prices of drugs make the availability of medicines difficult. International institutions are not providing adequate financial and technical support to overcome this difficult

situation and on top of that TRIPS has done little to alleviate this situation. Chaudhuri writes "TRIPS is being implemented at a time when the developing countries are growing through a severe health crisis" (Chaudhuri 2005). Organizations such as Oxfam opine that product patent under TRIPS increases the prices of medicines which makes adverse effect on the accessibility of medicines (Oxfam 2001).

Figure: 4.2 Health gap between rich and poor



Chaudhuri (2005) in his research on 'Trips and affordability of medicines' has focused on two question (i) does product patent protection increases the prices of medicines (ii) does the rise in price reduce accessibility? In most of the poor countries, the health expenses are the responsibility of individual, and since they do not have any health insurance, a major portion of their income goes in buying life saving drugs. This debate has two contradictory perspectives. MNCs are of the view that there exist hardly any link between the patent protection and high prices of drugs. The International Federation of Pharmaceutical Manufacturers Associations (IFPMA) argues that patents are not monopoly- new drugs almost always compete with other drugs in the same therapeutic

class. Despite of the competitions in the drug markets sometimes reduce the cost of medicines but more effective and more efficient drugs are likely to be more costly. Chadhuri in his research concludes that despite of the presence of large number of sellers in drug market leading drug firms always enjoy significant market share and exercise significant market power which make them capable of charging higher prices of drugs. It happens because of the poor drug control administration in developing countries the products available in the markets in developing countries are not considered as safe and effective (Chaudhuri, 2004:225).

Several reports of WTO as well as WHO brought the fact to the light that other than patent, the factors which make impact on the prices of drugs are the structure of the market, purchasing power parity and cost of production (WHO AND WTO 2002:95). These reports say that patent might be one of the factors of high prices of drugs, but the lack of government efficiency, inadequate market supply, lack of health infrastructure, etc are also the major causes which create impediment in the accessibility of drugs. However, all these report cannot over shadow the fact that generic version of patented medicines increases the accessibility of drugs, so the generic version of drugs should be produced at an extensive level to meet the demand of poor patients. There does exist many costly medicines under even generic production, but they are the minimum cost of production and if these medicines are not affordable to people, it becomes the responsibility of international welfare organization and the national government to buy those medicines and provide them to poor patients.

In a number of developing countries due to high prices of drugs and poor economic condition of patient prevent them from going for medical treatment, or cut short the treatment (Oxfam 2001:13). Because of the less number of health insurance in poor countries, the percentage of private expenditure by individuals on public health is more than in developed countries. In sub-Saharan Africa, private expenditure on health is about 60 per cent and in South Asia even higher at around 75 per cent (Oxfam, 2001:14). The private expenditure on health in Ethiopia in 2002 is 60 per cent, 77.8 per cent in Kenya, 78.8 per cent in Sudan and 62 per cent in Sudan. In contrast, out of pocket expenditure in developed countries is very low. It is 10.6 per cent in Germany, 10.6 per cent in UK, and

15.4 per cent in New Zealand. In US the private expenditure on medicines is 55.7 but 62.5 per cent of that is incurred on prepaid insurances (WHO 2002, Annex Table:5).

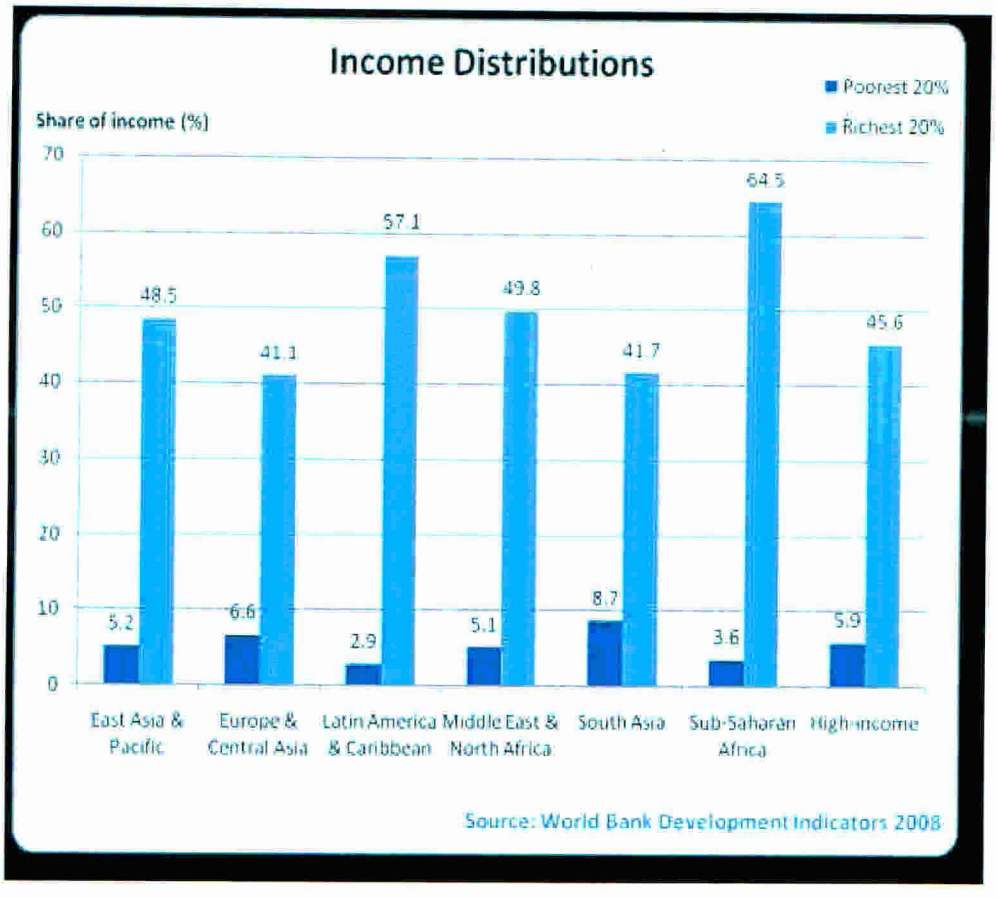
Big pharma companies also use marketing technique to increase the sale of drugs so they hire medical representative, and try to convince the doctor to prescribe the medicines of a particular company. So even if the doctor is aware of the availability of the cheaper version of drugs he will avoid prescribing it, because of his own interest as he receives gifts and monetary gains from the big pharma companies. When the patient goes to the retailer of the medicines, sometimes retailer himself is not aware of the availability of the cheaper version of that medicines, so he can not suggest the poor patient to get the substitute medicine, hence lack of information on the part of patient also makes him pay higher prices of drugs (Chaudhuri 2005).

In all the south Asian countries, poverty is the most common problem which acts as an impediment to the accessibility of all kind of medical facility. In figure 4.3 uneven global income distribution is shown. Balasubramaniam writes "poverty is the deadliest of all and the commonest cause of ill-health in the world, the biological manifestations of this socio-economic disease are referred to as 'disease of poverty' which are common communicable diseases. The consequences are very low standards of health characterized by unacceptable high infant, maternal and general mortality rate, and high prevalence of malnutrition of children less than five years. A majority of South and Southeast Asian countries are poverty stricken" (Balasubramaniam 2003:135). UN Committee for Development Policy has identified seven countries in South and Southeast Asia, and considers India, Indonesia, Vietnam, Pakistan and Sri Lanka, as the countries which meet certain criteria for the inclusion in the list of LDCs. In South and South-East Asian region 600 million people are below poverty line. These people are so poor that they cannot afford their medical treatment on their own, so they have to be dependent on the public sector for their health expenditure. But ironically the health sector investments in these countries are very low, it is only 1 per cent of the GDP, and in some other countries it is about 2 per cent (Balasubramaiam, 2003:318).

Implementation of patent regime under TRIPS has brought massive change in the conditions of Low and Middle Income Countries (LMICs). Prior to 2005, when India did not implement product patent in its territory, the generic version of drugs made the availability of costly drugs at cheaper rate easily, to these poor countries of South and Southeast Asia. Indian Drug Manufacturing Association (IDMA), anticipated that the implementation of TRIPS in India will lead to a national health disaster, because only 30 per cent of the total population in India is able to afford the cost of generic drugs and hence situation is likely to get worse, if they will have to pay high costs of medicines. Subramanian's study shows that the implementation of TRIPS resulted in welfare losses for India from US$ 162 million to US$ 1261 million and annual profit transfer to foreign firms between US$ 101 million to US$ 839 million (Subramaniam 1995:8).

Hence we can say that LMICs are facing two problems at this point of time. On the one hand they are lacking the adequate infrastructure to overcome health crisis they are undergoing. On the other hand the implementation of TRIPS regime has created new challenges for these countries. They have to overhaul their entire legal system to comply with this regime. Though these countries have been provided with some flexibilities under TRIPS regime, but these exceptions proved to be inappropriate in the conditions prevailing in these countries. People in these countries have low purchasing power, and they are undergoing income inequality, so the exceptions are not able to fulfil the demand of patients in these countries.

Figure: 4.3 Global distribution of income.



Impact of TRIPS on Indian Generic Drug Market

The entire drug market can be divided into bulk market and formulation market. In bulk drug market basically the active ingredients of drugs are produced, and there are many producers at this level. In formulation market, finished goods like capsules, syrups and ointments are sold, and this market is dominated by few dominant firms only. For instance, around 5877 drug manufacturing units are working in India, 1333 of them are involved in bulk drug manufacturing. In the formulation market there are only few companies dominating, including Cipla, GlaxoSmithKline, Ranbaxy, and Nicholas Piramal at the top, because only these companies are having needed R&D infrastructure structure, and they have credentials to compete in international markets. Rests of the companies are either small or less capable (Chaudhuri, 2003:47).

The entire drug market is further divided into several therapeutic markets, and a drug of a particular therapeutic class cannot be used as an alternative to the other drug of different therapeutic class. So the competition is among the same therapeutic drug producing companies. It leads to the concentration in the market, and the big companies have got lion's share in manufacturing such drugs. The share of the above four firms in the production of drugs from the antibiotic therapeutic class, is much higher. These firms provides new therapeutic medicines for different diseases to the market, thus they have strong hold over markets. These four firms produce 61.1 per cent of cephalosporins, 98.6 per cent of streptomycin, and 93.1 per cent of chloramphenicols. The top firm among them contribute to 88.7 per cent of the production of streptomycin and 53.4 per cent of chloramphenicols(ORG-MARG, 2004:155).

Initially the Indian drug research was based on the use of natural products, like plants and herbs. Chaudhuri writes that later on the quality of naturally produced drugs began to decline, because at that time British were having control over the market and they used to import the high quality medicinal plant at very cheaper rate from their colonies, especially from India, and leaving low quality of plants for indigenous use. It led to the low therapeutic value of the indigenous drugs in India (Chaudhuri 2005:25).

Indian markets, from the very early times based on the indigenous production of drugs. Later with the commencement of the British rule in India, foreign firms began to grow, because now the entry for these firms in the Indian market was not a difficult task. The Britishers prepared a list of medicines to be sold in market under a list called British Pharmacopoeia. During that time Indian medical firms were not very developed and they did not concentrate much on manufacturing and the propagation of the indigenous drugs, because their main aim was to fulfill the needs of local people. Moreover at that time India was under British rule so they cannot have their independent market policies. When they started facing competition from the foreign companies, several pharmaceutical groups like Bengal Chemicals and Pharmaceutical Works came in to existence in 1892, with the effort of people like Prafulla Chandra Ray. In 1898, Council of Indian Medical Congress took place; the main issue here was the inclusion of the drugs produced in India

in to British Pharmacopoeia, to make indigenous medicines more popular within the nation. It was also meant to reduce the reliability of patients on foreign medicines. This kind of exploitation continued till the end of Second World War. The Second World War marred the British economy, because of their huge colonial empire they faced huge economic loss, and they also lost control over the markets in colonies, which resulted in the strengthening position of indigenous firms in India.

Later, in 1905, a spirit factory was opened in Baroda. Further in 1919, Bengal Immunity was established, which was a major step ahead. All these efforts were made to gain self sufficiency in the field of pharmaceutical manufacturing. But despite of their immense effort they could produce only 13 per cent of the total manufacturing in the market (Chaudhuri, 2005). All the drugs can be classified into five categories (i) antibiotics; (ii) synthetic drugs; (iii) drugs of plant origin; (iv) drugs of animal origin and; (v) sera and vaccines. All these ranges are completely met by Indian firms even after relatively low percentage of production, because now the research became diversified in pharmaceutical sector in India. Hence they are able to produce veracity of drugs. Indian manufactures used to extract the components from medicinal plants and it was completely indigenous technology of producing new drugs.

One more thing to be noted here is that during the eighteenth and nineteenth century, neither the foreign firms nor the indigenous firms did anything for the discovery of new medicines, R&D efforts were hardly made to invent in new drugs. The firms relied mostly on old discoveries, and they only put some effort to upgrade the quality of the preexisting medicines. Many scholars while writing the history of pharmaceutical drug firms in India consider the decade of 1950s, as the decade of therapeutic revolution, which resulted in the domination of indigenous firms in the national market. Therapeutic revolution brought some changes in the markets and production technique, now MNCs from west began research for the production of new drugs so that they can face the ongoing competition in market effectively.

However, when the Indian firms faced competition from the West they took initiative in the field of R&D and began the production of new medicines. For the first time Bengal Immunity produced 'sulpha' drugs. In 1953, R.N. Chakravarti of the School of Tropical

Medicine, Calcutta made an important discovery that a species of discorea that is, dioscorea deltoidea, is a medicinal plant with higher theraputic value (Chaudhuri 2005:26). The manufacturing technique developed by government laboratories and Council of Industrial and Scientific Research (CSIR), resulted in the wide range of bulk drug production.

The increase in the range of drugs, and their increased production made patent protection very important. 1950s was the time when License Raj was prevailing in India, which restricted the entry of MNCs to some extent in Indian market. Later, during the 1970s the market structure became much more liberal for MNCs and they began to capture Indian Markets, and they got around 68 per cent of share in Indian market, which is shown in table 4.1. Government allowed Glaxo, Wellcome, and Cyanamid etc. to enter the Indian boundary. Government gave them right to formulate the bulk drug, which did not need any special knowledge and technique, because it is just the research for the invention of substitute of active therapeutic ingredients, and for bulk drug these firms heavily relied on indigenous firms. They also started giving competition to Indian firms in many therapeutic classes such as the production of vaccine, where the Indian firms already got an independent and strong position.

The Patent Act of 1970 was brought due to the upcoming change in the IP regime all over the world, and now the area of IP protection became very extensive. India brought some changes to the its patent laws and the Indian government also realized its duty towards indigenous firms, because of the increasing competetion in international market. Government started giving support to these firms to grow. Since, 1970s many public sector firms like Hindustan Antibiotics Ltd. and Indian Drugs and Pharmaceutical Ltd. came into being. 70s was the time when many changes took place in Indian policy regulation. In 1970, Patent Act was enacted, in 1973, changes were brought to foreign Exchange Regulation Act, and in 1978, Indian government introduced New Drug Policy. Under the new patent law of 1970, patent can be given only for process and methods of manufacturing and not for the products. Secondly the patent duration for drugs was fixed for seven year from filing the application or five years from sealing, and for other products the patent protection was given for fourteen years. This law reduces the

monopoly of the big pharma companies of foreign countries, because now they were able to get the patent of process only when that process is new, and for one medicine only the one best known method can be patented.

Now the indigenous firms could produce the same and cheaper version of drugs if they knew any older method or different method of producing that drug. This law made the availability of drugs from generic market at cheaper rate, which was beneficial not only for Indian patients, but for other countries who used to import generic drugs from Indian markets. The short term of patent also helped indigenous firm to develop fast.

Under the 1970's law the provision of compulsory license was there, which can be issued at the payment of royalty at of 4 per cent of the ex-factory sale to the patent owner, before the expiry of 3 years from the date of sealing. License can be issued at by the government at the time of national health emergency against the patent owner. Because of the process patent provisions, Indian government did not need to seek compulsory license as the indigenous firms were able to produce drugs at cheaper rate with other process than the patented one. Now the generic drug industries began to produce latest drugs at cheaper rates. Thus the Patent Law of 1970 gave impetus to the production of bulk drugs in India. The table 4.2 shows the increase in the bulk drug formulation production during the decade of after 1970s.

Increase in the production of generic drugs resulted in the increase in the consumption of drugs as well. It also increased the Foreign Direct Reserve (FDR), of India as Indian export of drugs began to increase. Firms like Cipla and Ranbaxy developed at a very fast pace after the implementation of 1970 Patent Act. It also gave an incentive to the establishment of new laboratories and firms. Like Sun Pharmaceuticals came into existence in 1983 and Dr. Reddy's Laboratories got established in 1984.

Today in India the domestic drug market is not controlled by the MNCs, which started gaining dominance in the 1970s. That was the time when Indian companies began to curtail their spread in pharmaceutical sale, because they were focusing more on the imitation of drugs rather than providing innovative drugs for diseases. Hence the MNCs from Europe and America got strong hold over the market in India. However after 1990s

the market structure began to change. Government adopted several developmental policies, and pharmaceutical companies were encouraged to produce innovative drugs. Since then the market share of MNCs are gradually declining, which is well represented in the statistical data of Pharmaceutical Enquiry Committee given in table 4.1.

Table 4.1: Market share of MNCs and Indian Companies in the Pharmaceutical Industry in India.

year	MNCs (%)	Indian Companies (%)
1952	38	62
1970	68	32
1978	60	40
1980	50	50
1991	40	60
1998	32	68
2004	23	77

Source : for 1952, Pharmaceutical Enquiry Committee 1954:20-1 an 60-1; for 1970, Ministery of Petrolium and Chemicals 1971:1; for 1978, Chaudhuri 1984:176(based on ORG 1978); for 1980, 1991, and 1998, Kalsekar 2003; for 2004 Chaudhuri 2005:19, table 2.3. (Chaudhuri,2005:18).

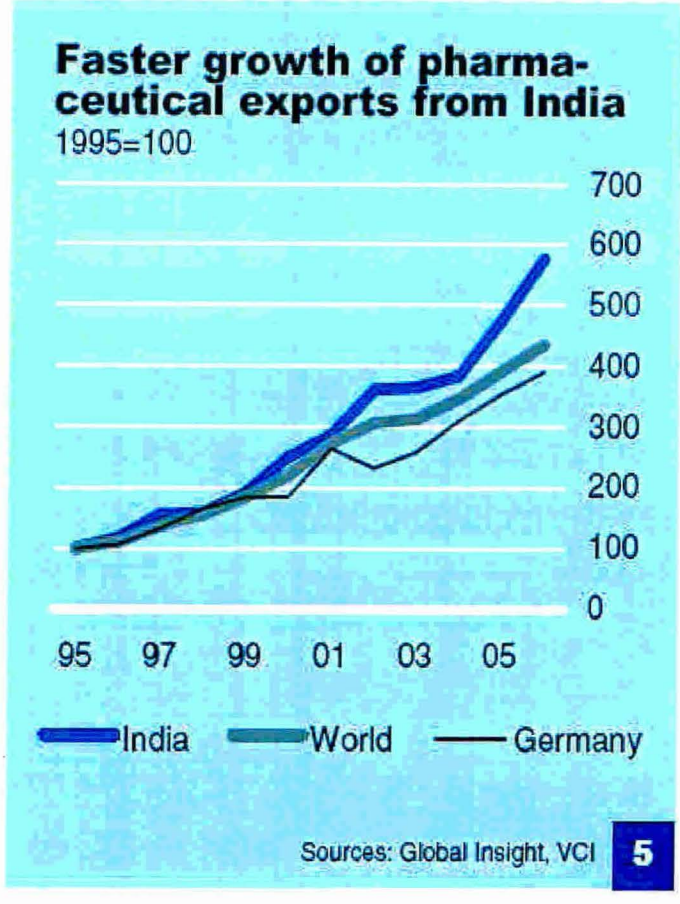
Only 32 companies of 298 companies registered by ORG-MARG in 2004 in the Indian market are MNCs and accounted for only 23 per cent of pharmaceutical sale (Chaudhuri 2005). This has been made possible because by giving encouragement to the indigenous firms to work in the area of production of innovative drugs.

In 1949, in India the declaration was made that now the Indian government will follow the policy of non discrimination among national and foreign firms. In 1966 Indian Government passed a law according to which foreign firms may diversify up to 25 per cent of production and expand up to 25 per cent of capacity licensed, without any

additional license. This provision was utilized by the MNCs to the maximum extent because they had links and variety of resources (Chaudhuri, 2005:28). Now it became very easy for foreign firms to strengthen their hold over Indian market, because now they did not have to undergo strict license laws. This kind of non supportive policy of government towards indigenous firms made their condition worst. Their control over market reduced, and the MNCs expanded in the indigenous markets. As shown in table 4.1 that from 1952 to 1978, the number of MNCs increased from 38 to 60 in Indian markets, which was the result of non cooperative policies of the Indian government

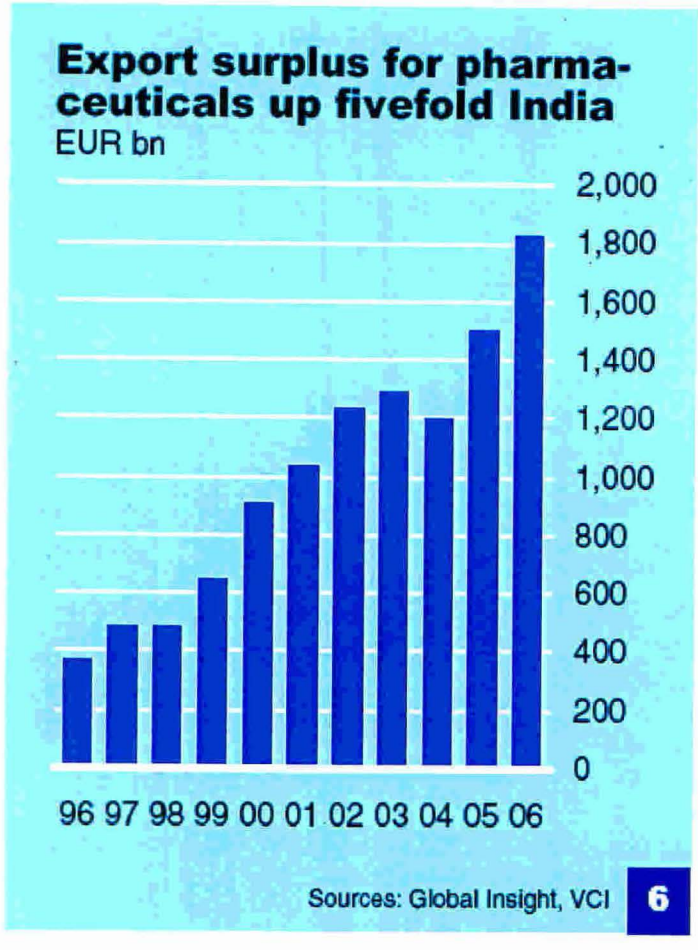
Gradually from the 1990s the Indian bulk drug and formulation production increased rapidly and it kept on increasing till date. It only benefited the domestic consumers but also to the poor patients residing in other countries, because now India was providing the drugs at cheaper rate to these countries as well. India emerged as a big pharmaceutical exporter as shown in figure 4.4 and 4.5.

Figure: 4.4 Growth in Indian Pharmaceutical Sector from 1996 to 2005



Increase in export led to the structural change, which was consisted of change in law patterns. In developed countries entry in to the market is not easy because of the strict trade regulations, but despite of the regulatory nature of the market, Indian firms began to export to the markets of developed countries, including the US. The Indian firms also opened their subsidiaries in foreign countries. Earlier these companies were dependent on foreign distribution channel, but now they could rely on their own sources. Indian companies began to take the shape of MNCs, by establishing their subsidiaries and distribution channels in foreign countries. Later on many biotech companies like Biocon and Shantha Biotechnics were focusing on the production of new generation biopharmaceuticals.

Figure: 4.5 Growth in Indian pharmaceutical sector from 1996 to 2006.



But the situation changed when Indian President issued an ordinance on 26th December 2004 in order to implement TRIPS from January 1st. When India implemented product patent system on January 1st, 2005, it made worst impact on the generic production of drugs. Now the companies cannot produce the patented drugs by adopting new manufacturing process, because the same product cannot be produced or copied without the permission of the patent holder. It may according to one study by result in the hike of price up to 200 per cent of the prevailing cost (Scherer and Watal 2002:18) One of the bad impacts of the implementation of TRIPS is the end of reverse engineering by the Indian firms. Now it will have to rely on basic research. Although the developing countries were given the transition period till 2005, to implement TRIPS, but WTO adopted a method called 'mail box', according to which the patent applications in poor countries can be filled 1995, onwards and whenever the developing countries are

implementing TRIPS, they provide 20 years of patent security to that product (Medicines Sans Frontieres 2005). Hence it was a kind of compulsion on them, and the proposals which were there in mail box, compulsory license cannot be granted against them.

Nair (2008) writes that there are three important areas of TRIPS which will make an impact on the pharmaceutical industry of India: patent, trademark and trade secret. Trademark gives recognition to a pharmaceutical product and also makes it easy for consumers to assess the quality of a product. It basically gives brand name to the medicine. Under Section 13, of the India Trade Marks Act, it is written that if WHO recognizes newly found chemical entity (NCE), then the resembling name of that International Non-Proprietary Name (INN), cannot be granted to any generic version of medicine. However, it is a very common practice in India to grant resembling name to the generic pharmaceutical product. Secondly, India will have to work on providing security to the trade secrets to any formula, pattern, devices etc (Nair 2008:434). Under Data Exclusivity the drug regulatory authorities do not allow the dossier or regulatory documents of an originator to be referred or used to register a therapeutically equivalent generic version of that product. (http://www.citizen.org/documents/DataExclusivityMay04.pdf).

Thus the implementation of TRIPS to some extent has led to the monopolization of market. Developing and poor countries do not have proper R&D structure and manufacturing capacities, so they cannot make use of the exceptions provided under the Agreement. Abbott (2002:18) writes "the TRIPS Agreement helps to create powerful monopolies that control the market for often essential knowledge-based products such as life-saving medicines. Patents, by design, increase the price of medicines to consumers because they enable pharmaceutical firms to keep prices much higher than their marginal costs of production by discouraging the emergence of competitors". The developed countries also feel threatened because if they provide the medicine at low cost to the developing and poor countries, patients and protesters will demand for low cost drugs in developed countries as well (Lanoszka 2003).

Anthrax Scare in the US and the Real Test of TRIPS in Developed Countries

In 1997, South African government came up with an amendment, known as Medicines Amendment Act, because the deaths from HIV/AIDS were gradually increasing. The main aim of this amendment was to make the availability of drugs easy and faster in the region. However, this amendment was condemned by USTR. The amendment allowed government to use two exceptions, namely compulsory licensing and parallel import for public use. Under the parallel import government can import medicines, in the time of need, from the cheapest resources available, without the permission of the patent holding authority (Lanoszka 2003). Consequentially the pharmaceutical industries of US lobbied in USTR, and demanded for the strict actions against African government, in the violation of IP laws, and no heed was paid to the prevailing HIV/AIDS crisis in Africa.

The whole issue of accessibility of medicine came to lime light when the pharmaceutical companies filed a case against South African government against its 1997, Amendment Act (South Africa Medical and Related Substances Control Act, 1997), which allowed government to use the exception of compulsory licensing and parallel import. This resulted in the miserable condition of AIDS patients in South Africa (Boseley, 2001). The pharam companies in South Africa like AstraZeneca and others also could not discuss the issue of AIDS crisis and rather kept discussing the problem of compatibility of the Amendment Act with TRIPS. Thus the world community could not sense the severity of problem existing in South Africa. South Africa was eventually put under the watch list of 'Super 301', for not complying with the patent laws as per the recommendation made by US.

In 1998, the group of 40 companies Pharmaceutical Manufacturers filed a lawsuit, that alleged that the Amendment Act violates TRIPS Agreement, and it also makes the Health Minister of South Africa over powerful to manipulate IP laws in their own favor by not complying with international IP regime. This lawsuit hindered the supply of medicines to the market in South Africa, because of the several indirect trade sanctions. It led to the

world wide protest against the US pharma companies on the ground of humanity, as the number of deaths began to increase in South Africa. Because of the growing international criticism of this act of US in 2001, the pharma companies took back their lawsuit (Heal 2008:101).

Later the bioterrorism in the wake of 11 September 2001, attack on the US brought to light the reality of discriminatory implementation of TRIPS Agreement between developed and developing countries. After the attack on twin towers in America, Anthrax broke out in the country as a result of bioterrorism. The disease was spreading rapidly, and Canadian government was worried about the spread of this disease in Canada as well, because few cases of Anthrax were diagnosed in Canada. In 2001, Canadian government asked one of its pharmaceutical company Apotex to produce generic version of the medicine Cipro, for the treatment of Anthrax. Cipro at that time was patented by a German company called Bayer. But Canadian government was criticized by the US government for this act, because this act could make adverse impact on the ongoing TRIPS negotiations. Bayer used to charge US $2.5 per pill for Cipro, whereas Apotex was providing it at US$0.99 per pill.

However, only 5 death cases and 17 infection cases came into light in US, but when this problem was perceived to be out of control in the US, US government asked Bayer to drop the prices of drugs otherwise the government would issue compulsory license against the company. There was no option left for Bayer, and it reduced the prices, which made the medicines available to the Anthrax patients in US as well as Canada, because Canada also took back its decision of allowing Apotex to produce low cost generic version of Cipro (Misra 2007:497). This example makes it very clear that how the laws are made flexible as per the need of patients in developed countries, whereas the patients in poor countries are left to die in the want of medicine.

Doha Declaration and Access to Medicines

With the commencement of TRIPS Agreement, it was realized that several loopholes are existing in these agreements which are making negative impact on the poor countries. The strict IP regime under the aegis of WTO made the health condition bad to worse

especially in LDCs. Several NGOs and developing countries demanded for the reconsideration of the entire agreement by highlighting the problems faced by poorer nations. These groups got success in getting their issue tabled at the Third Ministerial Conference, held in Settle in 1999, but they could not achieve real success until the Fourth Ministerial Conference at Doha in 2001.

During the Doha Round of talks, members adopted a declaration on public health, amongst many other provisions popularly known as Doha Declaration. This declaration was meant to assist poor countries to combat health related problems prevailing in their territories. Doha Declaration also gave priority to public health over the rights of private intellectual property holders. Basically the exceptions provided under TRIPS were meant to reduce the negative immediate negative impact of the implementation of the agreement. But they did not proved to be of any utility for poor nations, because the lack of needed infrastructure they could not make use of those exceptions.

Doha Declaration from its very beginning gives recognition to the issue of public health. It also gives member countries the rights to use exceptions for public welfare. Mercurio has briefly provided the provisions provided under Paragraph 5 of Doha Declaration, which recognizes the rights of member countries of WTO:

- 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 the purpose of the Agreement as expressed, in particular, in its objectives and principles.
- Each member has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses 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 crisis, including those related HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency.
- The 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 challenges, subject to the most-favored nation and national treatment provisions of Article 3 and 4 (Mercurio 2004:226).

Despite all these support provided by declaration, the unresolved issue was how to make provision of compulsory license useful for the countries having weak manufacturing capacity. Article 31(f) allows the use of compulsory license strictly for domestic purpose only, whereas many LDCs did not have supportive manufacturing power. Developed countries wanted to add an exception according to which the compulsory licensing provision can be issued in the territories of those countries only, where the patent has been granted to that medicine, which was not acceptable to many of the developing countries.

These countries later on reached an agreement according to which, now the generics can be exported in the case of public health crisis. Under the TRIPS Agreement the countries are obliged to submit the name and quantity of the product needed. Exporting countries has to submit the list of medicine and amount to be exported, and how much is needed in exported country. But they still could not resolve certain issues like scope of disease and product coverage, eligible countries to use that system, issue of adequate remuneration and safeguarding against the diversion of product etc (Mercurio 2004:235).

There were uncertainties regarding the number of diseases and pharmaceutical products to be included, against which compulsory license can be issued. The second problem related with the interpretation of paragraph 6 is how to determine that which country qualifies to get the benefits of exceptions. Though it is mentioned that the courtiers undergoing public health crisis and having no manufacturing power can use the exceptions, it does not take place in reality.

When it comes to the payment of adequate remuneration for the use of exceptions provided under TRIPS, confusion arises again because of the internal contradiction of the Articles, as Doha Declaration says that the countries are having right to assess the condition and declare national emergency. In the case of emergency if they use the exceptions provided under TRIPS, they will have to make minimal payment in return. However, Article 31(h) of the TRIPS Agreement states that the countries which are using

the exception will have to make payment for the use of exceptions as per the criteria mention in the Article. As per this criteria the countries will have to pay the compensation to the patent owner, but it is not determined by laws that how much should be the minimum compensation to be paid. In Paragraph 3 again the word adequate remuneration is used which is very confusing. Similarly no strong mechanism has been established under TRIPS to check the parallel import of drugs back to the country which is providing drugs at cheaper rate to the poor nations. It may result in heavy losses to the patent owning firm. Thus there are many issues yet to be resolved to make the Doha Declaration a real success.

Conclusion

The whole analysis of the TRIPS Agreement makes it clear that it is an important regime which can work in the direction of ensuring the safety to the work of an innovator. It also gives incentive for further research. But the prevailing condition in world is so uneven that the implementation of TRIPS, instead of resolving the problem of health crisis makes it worse. It makes the availability of drugs difficult. As in the case of Indian generic market, we have seen that the generic production and import of drugs could solve the problem related with health in poor countries with insufficient manufacturing power, but the implementation of TRIPS Agreement marred the growth of generic markets.

Secondly in the case of HIV/AIDS health crisis in Africa and anthrax scare in US and Canada showed that the international laws are implemented differently in different countries. There is a lack of uniformity of implementation of international laws. Countries who have got advantageous position are able to utilize the exceptions provided under the Agreement in their favor, but poor countries due to the lack of infrastructure and manipulating power could not make use of the provided support under the Agreement.

In 2001, when Doha Declaration was adopted, it was meant to resolve the problem of public health crisis in poor countries. Although the main focus of this declaration was to provide adequate support to poor countries through some amendments in the TRIPS Agreement, the internal contradictions of the amendments and original Articles of the

TRIPS Agreement, made the implementation of the declaration difficult task. There are many loose ends in the declaration, and there is a need to rework on the amendments to harmonies the interest of LDSc with the existing Agreement.

Some scholars like Irdis and Chaudhuri write that patents protections are not a hurdle to the access to the medicine for poor countries. Many a times when the big pharama companies reduce the prices of drugs for the cause of poor it could not work, because of the inefficiency of the government. They then argue that Patent should not be taken as the only cause behind the problem faced by poor countries as they have been given extensive period to comply with the Agreement, and in that period if they could not cultivate an adequate alternative to overcome the problem of availability of drugs, then it's their own fault. Despite of these arguments from the scholars the negative impact of TRIPS regime cannot be denied. Though developing countries are not having very efficient governance system and they are also facing the lack of modern resources, TRIPS has made the condition worse, now countries have to toil a lot to get access to modern technologies and knowledge.

After the analytical study of the working of TRIPS, we can conclude that the major reason behind this hue and cry is that international organizations are not able to work efficiently, because of the pressure from developed countries. These countries are the major donor to these organizations, thus they can mould the polices according to their wish. Secondly the decision making body of these organizations are dominated by developed countries and are not ready to pay heed to the problems prevailing in poor countries, so the policies made by them are not very effective in LDCs. Lastly the governing system in LDCs are ineffective, so the developmental policies do not bear fruit in these countries. Thus the problem lies both at planning and implementation level.

CONCLUSION

Globalization has brought two simultaneous changes in international arena. On the one hand we are talking about borderless world, but on the other hand most of the international conflicts are the result of issue of the ownership of resources, natural or manmade. The entire debate over the political economy of TRIPS is also the outcome of the conflict over the ownership of knowledge based resources. Knowledge can be classified under two categories, 'acquired' and 'produced'. Acquired knowledge is that knowledge which is gained by searching and observing the object, whereas knowledge is produced when we make further addition to acquired knowledge, with the help of our analysis. Both types of knowledge are closely associated with human beings, as only they have the capacity to acquire and produce knowledge; it ensures their ownership over knowledge.

The first chapter of the study analyses the importance of knowledge and technology as resources in the period of knowledge driven economy. The chapter argues that those who own modern knowledge and technology eventually own power in international arena. In this chapter knowledge is considered as a social construct, because those who wield power determine the knowledge structure and *vice versa,* as said by Foucault "knowledge is power". This chapter analyses the existing division in the world due to the possession of modern knowledge and technologies by few. Those who possess knowledge use it as capital in international market. Possession of knowledge and technologies in few hands has created a kind of 'empire of domination' at the international level, where the powerful countries dominate the poor and developing countries.

These developed countries demand exuberantly high prices for knowledge based goods produced in their territories. LMICs have no option left and they buy those goods at high prices because they are in need. The structure of domination has hindered the process of free flow of technology and consequently more than half of the countries in this world are going through knowledge and technology crunch, which has made worse impact on their social, political and economic system.

The focus of the second chapter is on the evolution of IP regime, to provide security to

the owner of knowledge or intellectual property. It traces the evolution of regime from the commencement of Paris and Berne conventions, which are considered to be the oldest regulation on intellectual property at international level. This chapter focuses the political economy of TRIPS, and the causes which laid down the foundation of TRIPS Agreement. TRIPS Agreement is one of the most controversial Agreements in international arena, because of the differences between developed and developing countries. In this chapter it is shown that how the conflicting interests of developed and developing countries, created impediment in the emergence of a consensus based regime, which could harmonize the interests of innovators and consumers.

Clash of interests was the main issue behind the emergence of TRIPS regime under the WTO. Developed countries do not want to share their knowledge and technology with the developing countries. Developed countries, due to their influential position, have better say in international organizations. Developed countries are the major donors to international organization, so they can easily influence the policy making in these organizations. Developed countries have expanded their trade to a large extent across the border, and the increased trade is mostly handled by MNCs. These MNCs demand for more liberal trading pattern and restriction fewer markets across the border to gain maximum benefits. Hence they pressurize their governments to get such rules passed internationally which could help them in enhancing their trade.

When it comes to the issue of intellectual property regime, developed countries demand for the establishment for a stricter regime. They want protection for their knowledge based goods. Since the Uruguay Round, these countries have been demanding for the establishment of a regime which can ensure safety to their goods. They argue that the protection to knowledge will help in future R&D. If the researchers feel secured they would go for further research. Secondly, they argue that proper remuneration should be paid to the one who sacrifices time and money in the field of research. This is very necessary to give incentive for future research. This dissertation has basically focused on the demand for greater protection to pharmaceutical innovations, which has made negative impact on the public health in poor countries.

The third chapter of this dissertation elaborates the impact of the implementation of TRIPS Agreement, for instance, in South Africa OAPI countries had to bring change in their regional agreement to comply with this agreement. Revision in the 'Bangaui Agreement' made direct impact on the prices of drugs in that region, which further led to the unaffordability of medicines by the sufferers of HIV/AIDS. It is not the case with South Africa alone but many countries in the world are suffering with the negative impact of the implementation of TRIPS Agreement. Though these countries have been given some exceptions under Article 31 of TRIPS, like 'compulsory licensing' and 'parallel import' but all these relaxations are not very effective. The reason behind their ineffectiveness is that, the poor countries are not having needed manufacturing power to utilize these provisions in their favour.

Under compulsory licensing, manufacturing power is required for two reasons. First is that the poor countries have to import the medicines from other countries, but in the want of proper market mechanism, they cannot import and then circulate the medicines among the patients. Secondly, if on the basis of license developing countries want to produce generic version of costly medicines, they need infrastructure and efficient laboratories for that, which are not available. Lastly, even if they are able to produce the generic version of medicines, the information of that drug production should reach to the patients, so that they can purchase the available cheap drugs. Hence, this is also the area where effective mechanism is needed, which is lacking in developing countries.

The fourth chapter of this dissertation reveals the reality of these exceptions provided under TRIPS Agreement. The analysis reveals the fact that these exceptions have not benefited poor patients, because the LDCs are not able to demand for their right, as they are threatened of trade sanctions by developed countries. If these countries demand for compulsory license to produce generic version of the costly drugs, big pharma companies pressurize their government to not let it happen. Consequentially, the developed countries threaten poor countries that if they demand for the use of such exceptions, they will have to undergo trade sanctions and trade embargos. Hence the poor countries do not go for the use of these relaxations. Though after the Doha Round of Talks, 'Doha Declaration on Public Health' was issued. It gave some hope to the LDCs, but it was not a legal

statute so it did not have that much effect on the prevailing situations. In this declaration public right to health was given priority over private intellectual property rights, and it also recognized the problems faced by poor patients, but it remained in documents only. The protest is still going on.

In the era of globalization, Global Health Governance (GHG) is a burning issue. Several NGOs working for the easy availability of drugs like MSF, Oxfam etc. are demanding for the global governance system for health, to provide cheaper drugs to patients in poor countries. Under GHG they are demanding the international organizations to control the prices of drugs and also to ensure proper circulation of drugs among patients. These NGOs demand that scarcity of drugs due to their high prices should be checked. The international organization should work to harmonize the interest of innovators and patients.

Thus in conclusion we can say that implementation of TRIPS in LDCs, instead of proving helpful created several hurdles for patients, in the way of access to medicines. Though the idea of TRIPS was not bad, but Its injudicious implementation has led to the emergence of problems in poor countries. There is a need to restructure the system of TRIPS to make it more applicable. TRIPS should be restructured in such a way that it can create a balance between the interests of developed, developing and underdeveloped countries, and then only a consensus base regime can be established at international level.

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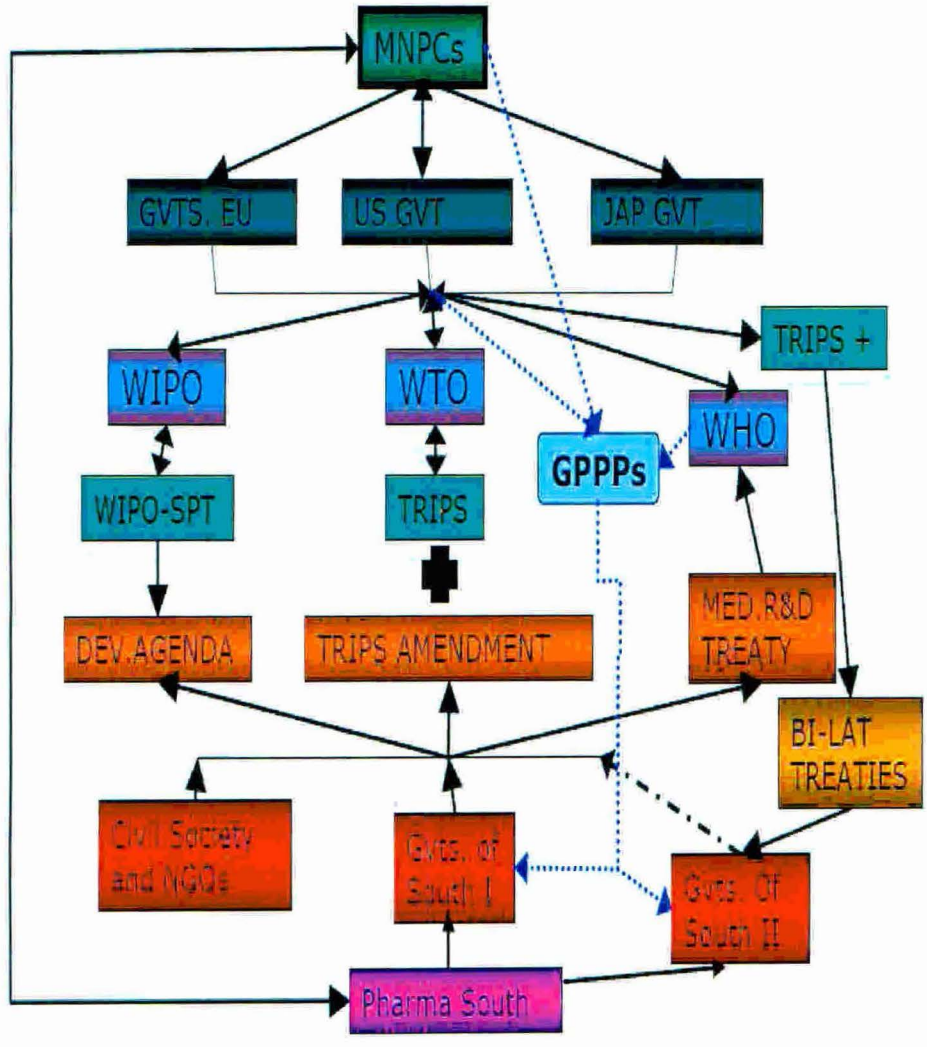
ANNEXURE 1

How Global Health Governance Works in Present Time



Notes: = legal interfaces
= discoursive interfaces
= organizational and resource-based interfaces

Source: Authors' compilation.

Source: "AIDS, Access to Medicines, and the Different Roles of the Brazilian and South African Government in Global Health Governance", September 2008, GIGA Working Paper

ANNEXURE 2

Summary of the South African Bill of Rights

- **Equality:** You cannot be discriminated against. But affirmative action and fair discrimination are allowed.
- **Human Dignity:** Your dignity must be respected and protected.
- **Life:** You have the right to life.
- **Freedom and security of the person:** You cannot be detained without trial, tortured or punishes cruelly. Domestic violence is not allowed.
- **Slavery, servitude and forced labor:** Slavery and forced labor are not allowed.
- **Privacy:** You cannot be searched or have your home or possessions searched.
- **Freedom of religion, belief and opinion:** You can believe and think whatever you want and can follow the religion of your choice.
- **Freedom of expression:** All people (including the press) can say whatever they want.
- **Assembly, demonstration, picket and petition:** You can hold a demonstration, picket and present a petition. But you must do this peacefully.
- **Freedom of association:** You can associate with whomever you want to.
- **Political rights:** You can support the political party of your choice. If you are a citizen, and at least 18 years old, you can vote.
- **Citizenship:** Your citizenship cannot be taken away from you.
- **Freedom of movement and residence:** You can go and live anywhere in South Africa.
- **Freedom of trade, occupation and profession:** You can do whatever work you choose.
- **Labor relations:** You may join trade unions and go on strike.
- **Environment:** You have the right to a healthy environment.
- **Property:** Your property can only be taken away from you if the proper rules are followed.
- **Housing:** The government must make sure people get access to proper housing.
- **Health care, food, water and social security:** The government must make sure you have access to food and water; health care and social security.

- **Children:** Children under the age of 18 have special rights, like the right not to be abused.
- **Education:** You have the right to basic education, including adult basic education, in your own language (if this is possible).
- **Language and culture:** You can use the language you want to and follow the culture that you choose.
- **Cultural, religious and linguistic communities:** Communities can enjoy their own culture; practice their own religion; and use their own language.
- **Access to information:** You have the right to any information, which the government has.
- **Just administrative action:** Actions by the government must be fair.
- **Access to courts:** You can have a legal problem decided by a court, or a similar structure.
- **Arrested, detained and accused persons:** This right protects people who have been arrested, imprisoned or accused.

NOTE: All these rights can be limited if it would be fair to do so.

ANNEXURE 3

The Accelerating Access Initiative (AAI)

Country: Global **Date of Activity**: December 2004 onwards

Description of Activity:

The Accelerating Access Initiative (AAI) is a cooperative Endeavour of UNAIDS, the World Health Organization, UNICEF, the UN Population Fund, the World Bank, and seven research-based pharmaceutical companies (Abbott Laboratories, Boehringer Ingelheim, Bristol-Myers Squibb, GlaxoSmithKline, Gilead Sciences, Merck & Co., Inc. and F. Hoffmann–La Roche).

Participants in AAI are committed to working with governments, international organizations, and other stakeholders to find ways to broaden access while ensuring rational, affordable, safe and effective use of drugs for HIV/AIDS-related illnesses.

While it is widely recognized that affordability is just one of the many barriers to access, the companies, individually, have offered to substantially improve access to, and the availability of, a range of medicines by providing more affordable prices in developing countries.

These efforts are bearing fruit. More than 80 countries have signaled to the UN agencies that they plan to implement HIV treatment programs and wish to collaborate with the AAI.

Of these countries, 49 already have national plans in place and have reached agreement on prices with the individual companies concerned. By June 2003, the number of people in Africa receiving treatment under the AAI was eight times higher than when the program began in 2000 and stood at roughly 75,000.

By March 2005 the number of treatments delivered by the AAI in Africa reached more than 427,000 patients.

Benefits of Activity:

Intended to benefit people in developing countries, this public/private cooperation

□ is designed to accelerate their sustained access to, and increase their use of, appropriate, good quality interventions for the prevention, treatment and care of HIV/AIDS-related illnesses, and the prevention of prenatal transmission of HIV;

□ strives to ensure that care and treatment reach significantly greater numbers of people in need, through new alliances involving committed governments, private industry, the UN system, development assistance agencies, Non-governmental organizations and people living with HIV/AIDS;

□ will be implemented in ways that respond to the specific needs and requests of individual countries, with respect for Human rights, equity, transparency and accountability.