GLOBAL ENFORCEMENT OF INTELLECTUAL PROPERTY RIGHTS WITH SPECIAL REFERENCE TO COUNTERFEITING AND PIRACY

Thesis submitted to Jawaharlal Nehru University for award of the degree of

DOCTOR OF PHILOSOPHY

TAPOBRATA PAKRASHI

CENTRE FOR INTERNATIONAL LEGAL STUDIES

SCHOOL OF INTERNATIONAL STUDIES

JAWAHARLAL NEHRU UNIVERSITY

NEW DELHI 110067 (INDIA)

2017

CENTRE FOR INTERNATIONAL LEGAL STUDIES
SCHOOL OF INTERNATIONAL STUDIES
JAWAHARLAL NEHRU UNIVERSITY
NEW DELHI 110067 INDIA

Ph. (o): 011-26704338

Date: 31.07.2017

DECLARATION

I declare that the thesis entitled **"Global Enforcement of Intellectual Property Rights with special reference to Counterfeiting and Piracy"** submitted by me for the award of the degree of **Doctor of Philosophy** of Jawaharlal Nehru University is my original work. The thesis has not been previously published or submitted for any other degree of this University or any other University.

Tapobrata Pakrashi

Tapobrata Pakrashi

CERTIFICATE

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

PROF. BHARAT H. DESAI
(CHAIRPERSON, CILS)

Chairperson
Centre for International Legal Studies
School of International Studies
Jawaharlal Nehru University
New Delhi - 110067

B. S. Chimni

PROF. B. S. CHIMNI
(SUPERVISOR)

Centre for International Legal Studies
School of International Studies
JNU/ज.ने.वि.
नई दिल्ली/New Delhi
अंतर्राष्ट्रीय अध्ययन संस्थान
अंतर्राष्ट्रीय विधि अध्ययन केन्द्र

Dedicated to my Late Mother & Father,
Lopa and Grahil

Acknowledgement

This work has germinated into fruition owing to the contribution of many. My first and foremost regards are all due to my supervisor, Prof. B.S. Chimni, for his priceless guidance and support. He has been extremely cooperative in following the progress of the entire work. He has observed the work very closely and offered timely and worthy suggestions.

I express my sincerest thanks to late Prof. R.P. Anand for his prolonged persuasion and passion for the subject. His affection for the students touched one and all. I owe my interest in the subject mostly to Prof. B.S. Chimni for his invaluable guidance during the course of my studies in international law. I also thank Prof. Bharat H. Desai for his useful suggestions and support.

I would like to appreciate the support and cooperation of the librarian and the library staff at the Jawaharlal Nehru University (JNU) Central Library. I also thank the library staff of the Indian Institute of Foreign Trade (IIFT) and the Indian Society of International Law (ISIL). The staff and the research materials at the Consortium for Trade and Development (CENTAD) were also of great help.

I am short of words for the selfless support of my friends, colleagues and the staff at the centre and the university. I would never have been able to fulfil this task without their support. I do not intend to belittle them merely by thanking.

My wife has been a source of constant encouragement all throughout the tenure of this work; without her invaluable assistance, this work would not have been completed.

Last but above all, I bow down to the feet of my late parents for being there as a source of unending inspiration in spite of their physical absence.

This study is the outcome of the contributions made by so many people. All the credit for it goes to them. The shortcomings and deficiencies are all my own.

Contents

List of Tables

Abbreviations

ACTA- Anti Counterfeiting Trade Agreement

ACTN- Advisory Committee for Trade Negotiations

ASEAN- Association of South East Asian Nations

BASCAP- Business Action to Stop Counterfeiting and Piracy

CII- Confederation of Indian Industry

CJEU- Court of Justice of the European Union

DDT- Dunkel Draft Text

DMCA- Digital Millennium Copyright Act

EC- European Commission

EC- European Communities

EFTA- European Free Trade Association

EPA- Economic Partnership Agreement

EU- European Union

FTA- Free Trade Agreement

GATT- General Agreement on Tariffs and Trade

GBLAAC- Global Business Leader's Alliance Against Counterfeiting

ICC- International Chamber of Commerce

ICN- International Council of Nurses

ICTSD- International Centre for Trade and Sustainable Development

IFPMA- International Federation of Pharmaceutical and Manufacturers' Associations

IIPA- International Intellectual Property Alliance

IIPCAG- Interpol Intellectual Property Crimes Action Group

IMPACT- International Medicinal Products Anti-Counterfeiting Taskforce

IMPI- Mexican Institute of Industrial Property

Interpol/INTERPOL- International Criminal Police Organization

IP- Intellectual Property

IO- International Organization

IPC- Intellectual Property Committee

ISMA- International Security Management Association

INTA- International Trademark Association

ITU- International Telecommunications Union

MFN- Most Favoured Nation

MNC- Multinational Corporation

MSF- Médecins Sans Frontières

NCG- National Customs Bureau

NGO- Non Governmental Organization

OECD- Organization for Economic Co-operation and Development

PhRMA- Pharmaceutical Research and Manufacturers of America

PIPA- Protect Intellectual Property Act

POC- Postal Operations Council

RCEP- Regional Comprehensive Economic Partnership Agreement

SADC- Southern African Development Community

SECURE- Provisional Global Customs Standards to Counter Intellectual Property Rights Infringements

SOCTA- Serious and Organised Crime Threat Assessment

SSFFC- substandard/ spurious/ falsely-labelled/ falsified/ counterfeit

STOP- Strategy Targeting Organised Piracy

TRIPS- Trade Related Aspects of Intellectual Property

TPP/ TPPA- Trans Pacific Partnership Agreement

UK- United Kingdom

UNCTAD- United Nations Conference for Trade and Development

UNESCO- United Nations Educational Scientific and Cultural Organisation

UNODC- United Nations Office on Drugs and Crime

UNICRI- United Nations Interregional Crime and Justice Research Institute

UPU- Universal Postal Union

US- United States

USA- United States of America

USCC- United States Chamber of Commerce

USFDA- United States Federal Drug Agency

USIBC- U.S.-India Business Council

USTR- United States Trade Representative

WB- World Bank

WCO- World Customs Organization

WCT- WIPO Copyright Treaty

WHO- World Health Organization

WIPO- World Intellectual Property Organization

WPPT- WIPO Performances and Phonograms Treaty

WTO- World Trade Organization

Chapter I

Introduction

Chapter I

Introduction

1.1 Background:

> … The networks are a first step in aggregating functional processes at a global level, so necessary for the formation of a Global State.
>
> …. the critical impact of global networks is the *advancement of the normative and enforcement agenda* of global capital. These networks tend to weaken democratic authority and accountability in third world states as they often bypass duly established democratic institutions. The networks divide and relocate sovereignty in unaccountable social bodies and processes that constitute the Global State as if it were by stealth (Chimni 2007: 208-209).

Modern age has come upon several occasions when nations have been instrumental in the making of international law. But the nature and influence of the current actors on States, in the manner envisaged by Chimni and characterised by a global network of wealthy private corporations working in tandem from across boundaries of affluent nations, is extraordinary. Indeed, today's most widely accepted international intellectual property law was a perfectly constructed norm-setting schema of just twelve global corporations working collectively behind closed doors, for the sake of addressing counterfeiting and piracy (Sell 2003: 1, 96). This phenomenon is very much underway and currently in a state of upward progression (Sell 2008).

The world has been witness to intellectual property counterfeiting and piracy since a very long time[1] and currently this apparent reality has grown in proportion. Counterfeiting is principally linked to the external manifestation of goods or products. The internal, constitutional component of any product involved, are generally not deemed to be falling within the ambit of counterfeiting. Thus, as far as intellectual property (IP) is concerned, counterfeiting is essentially a trademark issue. Similarly, in intellectual property parlance, piracy is essentially associated with the domain of copyright. The copying or using of the content of a creation or matter that is

[1] There are references to piracy having taken place during the ancient Greek and Roman periods. Adam Moore has noted three such cases – the earliest one being at around 200 B.C. (Moore 2001: 10).

copyrighted, without permission or authorisation, constitutes infringement of copyright. IP piracy may take place when such infringement is carried out on a large scale for making commercial gains. There could be various consequences of counterfeiting and piracy.

IP counterfeiting and piracy could become a hazard and the production and presence of counterfeit and pirated items in the market may amplify the problem. It is no wonder that producers of the original goods suffer from a loss of credibility since the fake one is believed not to match the standards of the original one in many ways. An extensive sale of fake items or so-called 'pirated products' may cause the business entities producing the original goods to suffer from a reduction in profits as well.

Counterfeit produces may potentially add up to losses in the national exchequer of a country. The producers and manufacturers of such spurious products initially may not come to the notice of the concerned administrative authorities, so they can avoid having to pay the taxes or other public levies unlike the trademark holders or copyright owners who have been officially registered. Thus, the original producers and manufacturers, along with the respective governments at the place of such manufacture or sale, may have to suffer by putting up with an unaccounted for loss in revenues.

The general public are sometimes misled into accepting and buying replicas as original ones. The purchase of such fake or imitation goods or products may not provide the expected levels of pleasure to the customer at the time of its use. Although rare, yet certain products such as food, beverages, medicines, etc. when spurious, may sometimes cause health hazards to consumers as well (Bruce 2009; Wilson and Kinghorn 2015).

These are only some of the probable effects of counterfeiting and piracy. Public authorities have taken to several recourses in order to meet the challenges posed by such a predicament. Developing nations today are mostly at the receiving end of the technological ladder derived from the rich Western economies. In an attempt to learn, gain in skills and catch up with the contemporary technologies, individuals or entities in developing economies may imitate certain technological proceeds to create replicas. These facsimiles are often perceived to be counterfeit products.

Legislative steps such as laws, byelaws, rules or regulations have been dynamically introduced in many countries including India by applying the existing international standards. IP counterfeiting and piracy have been sought to be dealt with by legislations that have their foundation in the centuries-old industrial revolution in Europe. Most of the IP laws in developing nations, that have been erstwhile colonies of the Western powers until the last century, have elements of colonial inheritance incorporated within them. At the international level also, it was the Western economies that together decided the fate of the intellectual property system for over a century; both the former conventions on intellectual property- the Paris Convention and the Berne Convention, bear testimony to this reality. As a matter of fact, even the origin of the present international legal regime on intellectual property governed by the Agreement on Trade Related Aspects of Intellectual Property (TRIPS)[2] has been attributed to the phenomenon of worldwide counterfeiting (Matthews 2002; Sell 2003).

A variety of studies have been carried out to evaluate the outcomes of counterfeiting and piracy. A study by the Organisation for Economic Cooperation and Development (OECD), an economic organisation of advanced economies, estimated that about a decade ago global trade in counterfeit and pirated products was about US $ 200 billion (OECD 2008: 13). It was revised the following year to US $ 250 billion covering around 1.95% of world trade (OECD 2009: 3). A recent study commissioned by Business Action to Stop Counterfeiting and Piracy (BASCAP) - a group working under the auspices of the International Chamber of Commerce (ICC), and the International Trademark Association (INTA) points towards a big leap in such unlawful trade. It states that the total value of illegal goods and products in the year 2013 was globally somewhere between US $ 923 billion and $ 1.13 trillion. It projects this figure to grow further worldwide between US $ 1.90 and $ 2.81 trillion by the year 2022 (BASCAP- INTA 2017: 8). The Europol (European Police Office) report on European Union (EU) Serious and Organised Crime Threat Assessment 2017 (SOCTA 2017) states that 40 million articles worth an estimated EUR 642 million

[2] *Agreement on Trade-Related Aspects of Intellectual Property Rights*, Apr. 15, 1994, *Marrakesh Agreement Establishing the World Trade Organization*, Annex 1C, THE LEGAL TEXTS: THE RESULTS OF THE URUGUAY ROUND OF MULTILATERAL TRADE NEGOTIATIONS 320 (1999), 1869 U.N.T.S. 299, 33 I.L.M. 1197 (1994) [hereinafter TRIPS Agreement]

(719 US dollars) were seized across the EU in the year 2015. It adds that while 'China is the biggest source of imports to the EU by far', a majority of counterfeit goods arriving at the EU also originate in China (Europol 2017: 46). These studies conclude that counterfeiting and piracy are economically detrimental and suggest that developing economies are more susceptible to this phenomenon.

In recent times, intellectual property piracy has been attempted to be correlated with organised crime by certain UN organisations (UNODC 2010, UNICRI 2012). It has even been suggested that IP infringing activities are associated with funding terrorism (UNICRI 2012: 34). However, such suggestions have not been backed up by any conclusive data or evidence. It has been pointed out that counterfeiting imperils the reputation of a manufacturer's good manufacturing practices and environmental standards. The reason for such apprehension being the present outsourcing of manufacturing mainly to Asian economies, which supposedly has given rise to counterfeiters who cut down on the cost of production as their products sell cheaper in the market (UNODC 2010: 9-10). Moreover, 'counterfeit pharmaceuticals' have not only been associated with the assumed 'crime' of 'consumer fraud' but have also been presumed to acquire 'catastrophic' proportions in future as they may 'fuel the breeding of drug-resistant strains of pathogens with global implications' (UNODC 2010: 11). Even when India happens to serve as the pharmacy to the developing world, the source of such (counterfeit) medicines has been unequivocally attributed to it, along with China (UNODC 2010: 11; UNICRI 2012: 51).

Counterfeiting is generally perceived to compromise with quality and safety of a product. However, there have been incidents recently that indicate an increasing lack of safety or quality standards by reputed manufacturers themselves. Unpleasant occasions of exploding or burning of high-end products are not rare these days, even in the developed countries (Dearden 2014; Cava, et al 2015; Pratap 2016). On some occasions, it was alleged to have been associated with taking the lives of unsuspecting users (Xinhua 2013; News Corp Australia Network 2015). Owing to the rise in such incidents in the recent past, these 'branded' companies have been issued warning by consumer organisations as well (Reynell 2016).

On the other hand, there are instances lately, where piracy has been indeed found to be associated with biological or cultural resources by the name, 'biopiracy'[3]. It is well established that most of the world's biological resources are situated in developing countries. Biopiracy happens upon the misappropriation of biological or genetic resources or the traditional knowledge that concern such resources in developing countries. Western corporations collect such resources and information from the local sources in developing nations without their knowledge or providing any compensation; these often act as key ingredients of products manufactured by pharmaceutical or crop corporations from developed countries. It has therefore been characterised as such:

> 'Biopiracy' has emerged as a term to describe the ways that corporations from the developed world free-ride on the genetic resources and traditional knowledge and technologies of the developing countries. While these and other corporations complain about 'intellectual piracy' perpetrated by people in developing countries, the latter group of nations counters that their biological, scientific and cultural assets are being 'pirated' by these same businesses (Dutfield and Suthersanen 2008: 332).

The manufactured products, by dint of them being sold in the markets globally, happen to come back to those very developing states from where their ingredients have been procured. The manufacturing corporations then seek to enforce intellectual property rights over the genetic sequence, processes or genetically modified products derived from the same local biological resource belonging to those very countries from where they were once procured. The industry in advanced western economies, although largely dependent on such biological reserves in the developing countries for their IPRs, never makes any mention of this other form of rampant piracy. However, this study does not intend to address this 'other' problematic form of piracy.

A diverse variety of international agreements and standards of intellectual property enforcement have been recently sought and negotiated with a view to narrow down the existing norms dealing with counterfeiting and piracy. Such efforts are being carried out in various ways and at various levels by the industry groups and organizations which mostly originate in the developed countries. Efforts are being

[3] The term 'biopiracy' is said to have been first coined by Pat Mooney from Rural Advancement Foundation International (RAFI), which is now known as 'ETC Group' (Biber-Klemm and Berglas 2006: 24). For a better understanding and discussion on the concept, see Cullet (2006) at p134.

continuously made at forging free trade agreements at bilateral, regional or plurilateral levels with heightened IP standards. A number of international organisations, including some United Nations agencies as well, are being used as platforms to formulate soft laws and standards on IP enforcement. Some of them seek to update the enforcement benchmarks to match with the changes in various technological advancements while some others seem to be frivolous, tending to merge different areas of IP into one, treating trivial IP infringements as acts of crime or completely failing to address issues of public access to information, knowledge and their requisite essentiality and affordability. The multifarious attempts by the global corporations, their trade associations and host developed nations to influence the developing nations and a range of international organisations makes it imperative to elucidate on the definition of counterfeiting and piracy.

1.2 Definitions of Intellectual Property Counterfeiting and Piracy:

Counterfeiting and piracy, in the context of this study, have been referred to as offences related with infringement of intellectual property. The definition of both has been provided in today's most widely accepted global legislation on intellectual property – the TRIPS Agreement. The earlier international intellectual property conventions, namely the Paris and Berne Conventions, although provided for procedures for IP infringements, did not provide for any definition for counterfeiting and piracy as such. However, they may sometimes have other connotations as well, which have been discussed hereunder.

1.2.1 Definition of Counterfeiting:

Counterfeiting has been defined in many ways. The Collin's Law Dictionary associates the term with illegal duplication of currency with the objective of passing it off as valid (Stewart and Burgess 2002: 103). The Gale Encyclopaedia of Everyday Law defines it as a "process of fraudulently manufacturing, altering, or distributing a product that is of lesser value than the genuine product" (Phelps 2003: 1168).

Staake and Fleisch, have provided the working definition of 'counterfeiting'. According to them counterfeiting is, "the unauthorized reproduction of goods, services, or documents in relation to which the state confers upon legal entities a statutory monopoly to prevent their exploitation by others" (Staake and Fleisch 2008:17). According to this definition, the reproduction i.e. producing the replica or facsimile of any goods or service is not legally permitted by the state. Counterfeiting has also been simply defined as "illegally copying authentic goods with a brand name" (Yao 2005:95).

Counterfeiting is essentially a trademark offence. TRIPS Agreement in Art 51, footnote 14, refers to the definition of 'counterfeit trademark goods'. It says that, counterfeit trademark goods:

> … shall mean any goods, including packaging, bearing without authorization a trademark which is identical to the trademark validly registered in respect of such goods, or which cannot be distinguished in its essential aspects from such a trademark, and which thereby infringes the rights of the owner of the trademark in question under the law of the country of importation (fn. 14, Art 51, TRIPS).

Since the act of counterfeiting pertains to a trademark offence, it is evident that only the commercial use of any distinctive mark can constitute an infringement. As Blair and Cottier state, it is only when any business is deceptively identified or any goods or service is marketed as such, that it amounts to infringement (Blair and Cottier 2005: 138).

An explanation, as to how the trade in counterfeit goods or counterfeiting of goods occurs, has been provided by the UNCTAD-ICTSD Resource Book on TRIPS and Development. It refers to trademark counterfeiting as being the "straightforward misappropriation of the persona of a producing enterprise" (UNCTAD-ICTSD 2005: 216). The study also helps us to understand the "basic case of trademark counterfeiting". It suggests that three conditions must be found to determine whether any infringement has occurred. These are:-

(1) whether the trademarks are "similar",

(2) whether the goods or services are "similar", and

(3) whether the "likelihood of confusion" exists (UNCTAD-ICTSD 2005: 236).

The UNCTAD-ICTSD study points out that, whether two signs or trademarks are sufficiently similar such that the use of one would infringe rights in the other, is basically a question of fact. Hence, it suggests that the judge, administrator or jury should compare the two marks to determine whether they convey a similar impression. An issue of interpretation of the TRIPS Agreement might arise if a Member State decides to apply very strict standards of comparison between allegedly infringing marks making it difficult for a trademark owner to prove infringement by similar, but not identical, signs. As an illustration it states that any Member could adopt a rule under which "Coco-Cola" was not considered similar to "Coca-Cola". This may mean that any local producer may take advantage of the well-known mark. Finally it infers that the notion of similarity may be flexible like many other forms of IPRs, yet, there is a certain limit beyond which this concept may not be stretched (UNCTAD-ICTSD 2005: 236).

1.2.2 Definition of Piracy:

Piracy has been defined in many ways. Historically, and as a general term, it could be related with marine pirates, slave traders or torturers. The Oxford Dictionary of Law provides three meanings of 'piracy'. They are:

> Any illegal act of violence, detention, or robbery committed on a private ship for personal gain or revenge, against another ship, people, or property on the high seas…. (Martin 2003: 367).

It also provides another similar meaning in terms of marine insurance. The third and closest relevant meaning however, is given as:

> Infringement of *copyright, *trade marks, or other *intellectual property rights (Martin 2003: 367).

The first two meanings relate to crimes on the high seas like slave trading or torture committed by the marine pirates, and thus seem to imply that, the offence of intellectual property infringement may be construed by offering similar connotations. This is rather an endeavour to establish an analogy between aggressive assailing over humans with offences related to IP infringements.

The Black's Law Dictionary defines piracy in general similarly but in case of something suggestive of intellectual property, it is defined as "unauthorised and illegal reproduction or distribution of materials protected by copyright, patent, or trademark law" (Garner 1999: 1169). This definition is clearly indicative of an inappropriate conflation of separate intellectual property domains into one.

Piracy, in intellectual property parlance, is primarily an offence associated with copyright infringement. It has not been defined in any of the earlier relevant international instruments on intellectual property- the Berne Convention[4] or the Universal Copyright Convention[5]. The World Intellectual Property Organisation's 'internet treaties'[6], the most recently concluded twin multilateral treaties on digital environment, also do not seem to have defined the term anywhere, as such. The only concept of piracy has been provided by the most extensively established multilateral international IP agreement- the WTO TRIPS Agreement. In Article 51, footnote 14 of TRIPS, "pirated copyright goods" has been defined as:

> … any goods which are copies made without the consent of the right holder or person duly authorized by the right holder in the country of production and which are made directly or indirectly from an article where the making of that copy would have constituted an infringement of a copyright or a related right under the law of the country of importation (fn. 14, Art 51, TRIPS).

According to the UNCTAD-ICTSD Resource Book on TRIPS and Development, piracy, as understood from the use of the term 'pirated copyright goods' in TRIPS, signifies only that part of the copyright infringement that appears 'on its face' and could be determined with a certain degree of ease. It does not constitute the other kind of copyright infringements like substantial similarity, adaptation without the author's permission, etc. Thus, it clarifies:

> Copyright piracy within the meaning of Article 51 and its footnote 14 … requires the copying of a copyrighted good, as opposed to the above mentioned cases where a third person produces a work that is not a copy of,

[4] *Berne Convention for the Protection of Literary and Artistic Works, Paris, 1971*

[5] *Universal Copyright Convention, Paris, 1971*

[6] The *WIPO Copyright Treaty, 1996*, and the *WIPO Performances and Phonograms Treaty*, 1996 are jointly referred to as WIPO 'internet treaties'.

> but substantially similar to the protected work, or that modifies the protected work without the right holder's authorization (UNCTAD-ITCSD 2005: 610).

1.3 Economics of Counterfeiting and Piracy:

Counterfeiting may occur in various ways under different conditions. In general, there may be two types of counterfeiting that take place according to the markets that they tend to serve. There may be two types of consumer markets where counterfeiting occurs. Grossman and Shapiro point out that:

> In one type of market, consumers cannot readily observe the quality of the goods that they purchase, nor can they easily distinguish copies from authentic merchandise. In these markets with imperfectly informed consumers, trademarks protect firms' investments in their reputations and counterfeiting represents an infringement on a firm's property rights to its customers' goodwill (Grossman and Shapiro 1988: 80).

The authors clearly say that in this type of a market, the purchaser is not aware of the genuineness of the product, and a company's goodwill suffers whenever counterfeiting takes place here. This kind of counterfeiting has been termed by them as 'deceptive counterfeiting'. The same authors, however, say that counterfeiting occurs in a different manner under another set of circumstances. They explain:

> In other markets, however, consumers often know (or strongly suspect) when they are purchasing a counterfeit. They distinguish fakes from legitimate, brand-name goods either by close inspection, or because the legitimate producers can effectively signal their authenticity by restricting and monitoring the distribution channels through which their goods are sold. Many of the more familiar examples of counterfeit-product trade would seem to fall into this latter category (Grossman and Shapiro 1988: 80).

So, it appears from this discussion that there are consumer markets where the consumers are indeed aware of the authenticity of goods and products that they purchase. They term this occurrence as 'non-deceptive counterfeiting' (Grossman and Shapiro 1988: 80).

While the former construes no liability for the consumer in general, the latter kind may entail liability on part of the purchasers. Other authors also concur with the existence of these two kinds of counterfeiting (Staake and Fleisch 2008: 18). Some

even opine that the counterfeiting of non-deceptive nature is often more prevalent in case of the developing countries (Yao 2005: 95).

There may be circumstances when counterfeiting, however, prove to be beneficial. Sometimes, it may be advantageous for the consumers who are buying these articles[7] (UNCTAD-ICTSD 2005: 216). There are other similar situations, albeit, in which the benefit in the long run may actually go to the brand owners, i.e. the right holders[8] (Staake and Fleisch 2008: 6-7).

Piracy of copyrights has been characterised as something regressive and may often be connected with crime and criminals. But some of the world's biggest corporations have been found to have appropriated products or their 'codes' from others, often without acknowledging them. The biggest innovation by one of the world's largest information technology firms that spends a lot of efforts against piracy overseas, has itself acquired the same from a lesser known firm (Boldrin and Levine 2008: 17). There could be other instances as well when an entire industry was built out of an individual's creation (Boldrin and Levine 2008: 33).

1.4 Justifications of Counterfeiting and Piracy:

Certain observations have been made by scholars who view replication legitimately from the perspective of various phases of economic advancements made by nations. Zhang and Bruun, for instance, observe that:

> At the early stages of industrialization, imitation is a common means to catch up with advanced countries. To some extent, counterfeiting, piracy and IP infringement may be tolerated by policymakers. However, when domestic innovators have increasingly gained achievements in innovation and have

[7] The UNCTAD-ICTSD Resource Book (2005: 216) in footnote 234 mentions that such a phenomenon, where the consumers benefit, may occur when the counterfeiter offers high quality substitute goods at lower prices.

[8]The authors, albeit from a marketing perspective, admit that: 'A high counterfeit market share of counterfeit software products in emerging economies can, for example, constitute a barrier of entry for low-end competitors. At the same time imitations may familiarize a large user base with a product. Once intellectual property rights are more strictly enforced the market penetration of imitations is likely to translate into revenue for the brand owner…' (Staake and Fleisch 2008: 6-7).

> achieved concrete results in the market, policymakers may realize that the strict enforcement of IP laws may serve national interests rather than only the interests of foreign companies. … (Zhang and Bruun 2017: 35).

Scholars opine as well, that an imprecise term like 'piracy' is not only set with political undertones but also intentionally construed as such (Dutfield and Suthersanen 2008: 332-333).

IPR violation as a whole has not only been observed to be unproblematic but also rather reasonable by certain authors who express similar opinion. For example, Mike W. Peng et al., point out that the non-recognition of foreign IPRs by United States before 1891 made perfect sense because of its wide underdevelopment; thus, while all the benefits of those IPRs would have moved out to the foreigners, the consumers at home would have had to settle for higher costs for creations and inventions that were made abroad (Peng et al. 2017: 21). They also add that the US moved towards higher IPR levels on its own when its economy was adequately innovative, and envisage that China would seriously deal with the issue when faced with considerable overseas infringements of its own IPR. Therefore, it was more needful for a developing country (like China, as a case of reference) to make policies that support domestic innovation rather than providing the same to the foreign IP stakeholders (Peng et al. 2017: 32).

Piracy has also been associated with cultural products like books, music, films and other forms of the arts. However, it has been observed to be highly helpful in certain cases, e.g. the cultivation of culture as a whole. Laikwan Pang has acknowledged the association of the act of copying with that of the endurance of culture. The author states:

> …. the act of copying is perhaps the single most important cultural activity. Copying and culture cannot be separated; cultural boundaries can never be rigidly drawn because culture is necessarily transformed by copying, which takes place everywhere all the time (Pang 2006: 5).

In view of its significant effects in the diffusion of art and culture, she further refers to it as "… the major driving force of culture, which informs both individual creativity and cultural heritage" (Pang 2006: 5).

1.5 IP Counterfeiting, Piracy and Consumers:

The brand name of any product assures that a certain amount of quality in the product has been achieved. This promise of providing the quality generally persuades the consumers into buying the particular products bearing their distinctive trademarks. The purchaser of the particular good relies on the eminence of the particular manufacturer to convince himself of the worth of the product he buys.

The consumer is usually thought to be deceived into accepting the imitated goods as being the original one. The manufacturers of such fake goods and articles are well aware of this and they use the art of deception as the capital for sale. But nowadays, the consumers seem to be aware of the presence of the duplicate goods in the market (Grossman and Shapiro 1988; Staake and Fleisch 2008). Hence, there appears to remain a certain level of consciousness in buying the imitated goods and products.

As discussed earlier in the chapter, the consumer entails no liability when he buys the goods or products unknowingly and entire liability due to faking lies with the imitator. In the modern times, trademarks seem to be performing a new function. There is a section among the consumers, mostly dwelling in the affluent first world, who have the tendency to flaunt their purchases. They have the mindset of signifying to others that they are the consumers of the particular brand. This may happen in case of certain fashion goods like apparels, where the purchasers like to give importance to the display of the names or logos on the clothes. Even if the product is of no better quality than similar available ones, the consumer seems to care little as long as the idea of display is achieved. The manufacturer, even if a genuine one, may escape unaffected after the production of such inferior goods (Higgins and Rubin 1986: 211-212). However, such consumers do not form the larger section of ordinary consumers.

The consumers in certain market conditions, like that existing in the third world, mostly do not fall in the said category and they may be best served by the quality of any goods or product. Counterfeiting may deceive the purchaser into buying certain goods. Yet, as long as the idea of delivering a certain level of quality is achieved, the consumers may be getting standard products at an affordable price. Hence, in such cases, certain producers of counterfeit goods may actually deliver a better deal for the benefit of this large section of population in the third world countries.

However, in certain categories of consumable products, like medicines or food, deception or adulteration may prove to be hazardous where the quality is inferior enough to cause health hazards. The vulnerability of the third world masses may be even more in this case, considering their prevailing socio-economic conditions. However, for the same reason, these countries have succeeded in achieving the necessary room to make legislative policies according to the aspirations of their peoples under the existing international intellectual property right (IPR) regime.

The developed world is more concerned in its pursuits against counterfeiting and piracy. There is not only stringent legislation in the respective countries and union of nations, but also an ongoing attempt to impose such standards upon a large part of the developing world by means of bilateral, regional and plurilateral agreements. Some specific organisational manoeuvrings, besides unwarranted multilateral and plurilateral negotiations, also form part of such endeavours.

These are merely the basic understanding of the issue of counterfeiting and piracy. The detailed perspective is, nevertheless, not the aim of this study, yet there are enough reasons for some of them to be appraised of before the study gets centred on the international legal and other points of view in the chapters that follow.

1.6 Objectives and Scope of the Study:

The study seeks to analyse the existing and emerging international legal regime on counterfeiting and piracy of intellectual property, with the objective of assessing the implications of the regime for the developing countries. In so doing, the study proposes to examine the TRIPS Agreement under the WTO. In the course of examining this, the study also proposes to analyse the TRIPS-based commitments of the Member-States in the context of the various emerging regulations.

This study also seeks to examine whether the emerging international laws on counterfeiting and piracy are adequately balanced to take care of the interests of the developing countries through case studies of the various bilateral agreements, FTAs and some of the recent international plurilateral agreements concluded or are being negotiated.

The rationale for the study lies in the fact that worldwide, there is an attempt to create an institutional mechanism for strict enforcement of IPRs. Apart from the Anti Counterfeiting Trade Agreement, the Trans Pacific Partnership Agreement or other plurilateral agreements, the bilateral or regional trade agreements are concertedly setting harsher norms and rules on counterfeiting and piracy of IPRs that affect the lives of people in developing countries, without taking into account their legitimate concerns.

The study will attempt to trace the current discourse on IP counterfeiting and piracy in the context of the growing reach and expanse of various kinds of norm-setting processes via regulatory imperialism. It will also focus on the various institutional mechanisms, as to how they are likely to influence and facilitate domestic laws of IP enforcement. It will also try to analyze the role of the various non-State actors, like the trade associations and civil society, which play a vital role in such lawmaking. The case studies on the various trade agreements, both bilateral and otherwise, will look into the substantive nature of the standards that are sought to be set. Such case studies will also study these aspects from the perspective of the influence and effect these agreements may have in India's intellectual property system.

This work does not cover those aspects of international intellectual property law that relate to IP protection; it solely deals with IP enforcement. It focuses on the various facets of IP counterfeiting and piracy that primarily relate to copyright and trademark violations; certain other areas of intellectual property infringement like those relating to patents, trade secrets, industrial designs, geographical indications, etc. are also beyond the scope of the current study.

1.7 Hypotheses:

- The definition of the terms 'counterfeiting' and 'piracy' is crucial to decide the scope and range of the global IP enforcement framework.
- The stricter definitions of 'counterfeiting' and 'piracy' within the global IP enforcement regimes, is inimical to the interest of developing countries.

- The authority of the two multilateral institutions, namely, the WTO's TRIPS Council and the WIPO is being undermined by bilateral, plurilateral and regional agreements as well as the FTAs.

- The existing global IP regime on counterfeiting and piracy does not provide sufficient policy space for the developing countries to pursue their aspirations.

1.8 Research methodology:

The Study has been conducted through analytical and case study methods. For these purposes, both primary and secondary resources have been used. Analysis of the current discourse on the evolving global intellectual property regime on counterfeiting and piracy has been based mostly on secondary resources including articles in periodicals, books and working papers. The case studies largely rely on primary resources including texts of appropriate free trade agreements (FTAs), documents from key international organisations like the World Trade Organisation (WTO), the World Intellectual Property Organisation (WIPO), the World Health Organisation (WHO), and many others.

1.9 Chapterisation:

The present study has been divided into seven chapters. There are five substantive chapters besides an introductory and a concluding chapter.

Chapter II, 'Counterfeiting and Piracy under International Intellectual Property Law', focuses on the established international law on intellectual property counterfeiting and piracy existing at present – the TRIPS Agreement. Drawing from a brief history of the current international legal regime it discusses the pertinent IP legislation. The Chapter has been divided into eight sections. Section 1 gives the background of the chapter. Section 2 deals with the various international laws on counterfeiting and piracy as well as the legislative process that went into it, before arriving at the stage of the final draft of the TRIPS Agreement. It depicts the great effort and resistance put in by the developing countries led by India and Brazil not only in constructing precise

definitions, but also in ensuring various obligatory safeguards, so that IP enforcement process does not create any additional resource burden upon the shoulders of the developing countries, as against their advanced counterparts. Section 3 analyses the major changes that the TRIPS Agreement brought in vis-à-vis intellectual property enforcement that was hitherto covered under the Paris and Berne Conventions. Section 4 refers to the principles of the TRIPS Agreement. It talks about the principles of non-discrimination in international trade and also regarding the TRIPS as being a 'minimum standards' agreement. Section 5 deals with the agreement's provision on counterfeiting and piracy. It narrates the general IP enforcement provisions, as well as those dealing specifically with counterfeiting and piracy. This section bears vital importance as it covers the definition and scope of the two issues that are currently being ratcheted up via the various international agreements and institutional modes. Section 6 deals with the various 'border measures' in TRIPS, including not only the general measures to be adopted by the administrative or judicial authorities, but also the modes of IP enforcement to be followed in case of criminal infringements. In Section 7, the WTO DSB Panel Report (2009) of thus far the only case on *IP enforcement* at the WTO, the US-China IPR case, has been discussed. Section 8, analyses the role played by the multilaterally negotiated TRIPS Agreement in maintaining suitable IP enforcement procedures in countries across their levels of developments.

Chapter III, named 'Emerging Global Legal Regimes on IP Enforcement' deals with the current efforts at the global level to elevate and create stringent intellectual property counterfeiting and piracy laws at the international, regional and national levels. Section 1 introduces the chapter. Section 2 explains the various manners in which efforts are being made across the globe for ratcheting up the established standards under the TRIPS. Thus, the concept of TRIPS plus has been briefly discussed in the very next section. Section 3 refers to the instances of TRIPS plus. It assesses the various TRIPS plus modes that have been set in the different bilateral as well as free trade agreements (FTAs) with illustrations of a number of specific provisions. Section 4 deals in the border regulations that are prevalent in the European Union in a detailed manner. It firstly talks about the definitions of counterfeiting and piracy in the regulations, followed by discussion of measures like 'authorised customs

action' and 'transit procedures'. Further, it examines the changes that have been brought about in the IP law followed by the EU customs recently, referring to the regulation as well as the case law in force for the same. Section 5 discusses about the various IP enforcement measures in economic partnership agreements entered into by the EU, focusing on Africa and Asia. It inspects the various TRIPS plus enforcement standards prevalent in the EU itself, being exported mainly to the least developed and developing countries by means of such treaty arrangements. Section 6 deals with plurilateral agreements. It focuses on the recently concluded but yet to be ratified hard laws like the Anti Counterfeiting Trade Agreement (ACTA) or the Trans Pacific Partnership Agreement (TPP). It also looks at the large regional trade agreement, the Regional Comprehensive Economic Partnership (RCEP) Agreement through its IP enforcement provisions and possible outcomes. Section 7 looks at TRIPS plus via digital legal modes in the developed world, focussing on the US and the EU, and its extra-territorial effects on the other parts of the globe including the developing nations. Section 8 deals with the Indian legal structure on enforcement of intellectual property. Section 9 evaluates the consequences of the systematic amplification of IP enforcement standards for the various stakeholders in the developing countries.

Chapter IV, by the name 'International Institutions for Anti-Counterfeiting and Piracy', discusses about the institutional set-up of the current as well as impending legal regime and how they are likely to affect the domestic institutions for IP enforcement – administrative and judicial. Section 1 sets the idea of the chapter, i.e. the role played by a range of international organisations in setting international IP enforcement standards. Section 2 talks about the World Intellectual Property Organisation (WIPO) and its transformation from being a pro-developing country forum into an organisation being used today for favourable purposes of IP owners from developed States. An example shown is the programme on 'Building Respect for Intellectual Property'. Section 3 discusses about the World Customs Organisation (WCO) and its efforts in setting customs IP enforcement standards at a global level. It focuses on the instrument of such standardisation, the 'Provisional Global Customs Standards to Counter Intellectual Property Rights Infringements' (SECURE) and also considers the reasons for its withdrawal. Section 4 talks about the World Health Organisation (WHO) and the activities, including standardisation procedures initiated

by pressure groups from pharmaceutical corporations, in line with the WIPO and the WCO. It puts forward the rationale as to why the WHO, being the plenary United Nations (UN) organisation on health, should not be used for making standards by means of lobbying efforts, including the creation of International Medicinal Products Anti-Counterfeiting Taskforce, or the IMPACT. It also analyses the recently disqualified working group on substandard/ spurious/ falsely-labelled/ falsified/ counterfeit (SSFFC) medical products. Section 5 deals with the efforts that were made indirectly at the Universal Postal Union (UPU), the international postal standards authority. It also mentions about the future plans of the organisation for the purposes of the same nature. Section 6 deals with the UN's International Criminal Police Organisation (INTERPOL). It looks at its 'Programme on Pharmaceutical Crime' and its measures on trafficking of illicit goods and counterfeiting. It further examines its publication initiatives, of late, and its closed doors meetings with representatives from private multinational corporations. Section 7 talks about the International Telecommunications Union (ITU), and its initiatives in organising meetings with other international organisations engaged in activities that aim at raising IP enforcement standards. Section 8 brings up a rather unfamiliar UN organisation, the United Nations Interregional Crime and Justice Research Institute (UNICRI), that is being used to extend the range of activities that promote higher standards of IP enforcement. This UN unit mainly focuses on the issue by means of recent, one after the other, publications on organised and criminal breach of IPRs that have a bearing on Europe. Section 9 focuses on the United Nations Office on Drugs and Crime (UNODC) that engages in various activities concerning counterfeiting and piracy that have global connotations. It not only talks about the UNODC's campaigning and publications on product counterfeiting and efforts for a model legislation on counterfeiting of medicines, but also about joint exercises with other international organisations financed by private corporations. Section 10 analyses the entire chapter in light of a convergence of impending issues in all the organisations taken together, for demonstrating the future consequences of such efforts on developing countries.

Chapter V, titled 'Implications of IP Enforcement Laws for Public Health', deals with the various effects of the anti-counterfeiting measures vis-à-vis public health with particular consideration on access to medicines. Section 1 sets the stage for the

chapter, showing the variety of consequences on public health that have already been perceived as well as those which are likely to occur in the near future. Section 2 talks about public health, access to medicines and international IP enforcement regime. It denotes the importance of health under international law and refers to international public health regulations in light of internationally recognised provisions on human rights and the relevant TRIPS provisions. Section 3 deals with counterfeiting of medicines and public health in relation to the various international legal measures and attempts on raising IP enforcement standards at a multitude of international organisations. Section 4 details the IP enforcement 'agenda' of a global coalition of actors, who are mainly the developed nations alongside their industrial and trading leagues. It shows in separate subsections, a combination of legal, institutional and political modes in different parts of the world that are working to pursue the broader goals of the agenda. It articulates an analysis of a range of developing country specific push for legal changes and a host of institutional and political events aimed at the same. Section 5 summarises the chapter and mentions the various implications of the global IP enforcement agenda on access to medicines worldwide.

Chapter VI, titled 'Stringent IP Enforcement: Restricted Access to Knowledge', deals with the outcomes that the public at large are likely to face in respect of their access to educational and printed reading materials like books, articles, etc. as well as files that are shared online. It deals with the issue of 'TRIPS Plus' measures that are increasingly being employed to counter copyright piracy. Section 1 sets the tone for the chapter by relating briefly the manner by which today's powerful international players have reached the position to control the production and dissemination of knowledge. Section 2 deals with the correlation between TRIPS provisions and access to knowledge. It notes the relevant provisions on copyright for databases, explains the so-called 'three-step test' for copyright exemptions and also compulsory licensing as stated in the Berne Convention appendices. Section 3 then turns to the role of World Intellectual Property Organisation (WIPO) in helping build upon the idea of access to knowledge. It narrates the backdrop of the proposal for a Development Agenda by Argentina and Brazil at the WIPO, the preparation of the Draft Treaty on Access to Knowledge and the adoption of The Agreement on a Development Agenda consisting of forty-five agreed proposals adopted in September 2007. Section 4 broaches the

position of the World Summit on the Information Society (WSIS) within the debate on access to knowledge. It discusses the various proposals and recommendations made at the lone international forum on information society supported by the United Nations. Section 5 discusses the idea of knowledge vis-à-vis the concepts of 'commons' or the 'public domain'. Thereafter, Section 6 narrates the barriers to access the several forms of knowledge. It shows the difficulties in accessing information, educational materials as well as scientific and technical knowledge and analyses their reasons. Finally, Section 7 summaries the chapter and makes recommendations to deal with the different kinds of obstacles faced in accessing various forms of knowledge.

The final chapter, Chapter VII, derives the 'Conclusions'. It recapitulates and reviews the essence of each substantive chapter and then draws the conclusions based on the analyses of the précis of each of the Chapters II, III, IV, V and VI of the study. It categorises the problems identified in the study and puts forth the suitable recommendations. On the whole, it tests the hypotheses, thereby concluding the thesis.

Chapter II

Counterfeiting and Piracy under International Intellectual Property Law

Chapter II

Counterfeiting and Piracy under International Intellectual Property Law

2.1 Introduction:

The current international intellectual property regime undoubtedly owes its origin and existence to the problem of counterfeiting and piracy. Technological advancements and sophistications result in creation of newer products and merchandise that are sometimes subjected to duplication and other forms of unauthorised reproductions by illegitimate means. This Chapter tries to briefly present the laws of international intellectual property that have been guiding the international law on counterfeiting and piracy. It will try to briefly cover the various laws that have been in place ever since the inception of the concept of intellectual property. It will raise the reasons as to when and why intellectual property became a trade issue at the international level. It will further try to provide the long-drawn and hard-fought negotiations that went into the drafting and formation of the most detailed agreement within the General Agreement on Tariffs and Trade (GATT) framework, the Agreement on Trade Related Aspects of Intellectual Property (TRIPS). Thereafter, it will try to briefly explore the recent dispute on intellectual property enforcement at the World Trade Organization (WTO) instituted by the United States against China and try to derive its implications on the future of international intellectual property jurisprudence. Finally, it will give a brief overview of the TRIPS principles and an outline on the provisions that deal with counterfeiting and piracy as well as the flexibilities that are available within the TRIPS Agreement.

In such a setting, the Chapter has been divided into eight sections. Section 1 provides the background of chapter. Section 2 illustrates the international law that was followed prior to the coming of the TRIPS. It deals with the various international laws on counterfeiting and piracy as well as the legislative process that went into it, before arriving at the stage of the final draft of the TRIPS Agreement. It depicts the great

effort and resistance put in by the developing countries led by India and Brazil not only in constructing precise definitions, but also in ensuring various obligatory safeguards, so that IP enforcement process does not create any additional resource burden upon the shoulders of the developing countries, as against their advanced counterparts. Section 3 analyses the major changes that the TRIPS Agreement brought in vis-à-vis intellectual property enforcement that was hitherto covered under the Paris and Berne Conventions. Section 4 refers to the principles of the TRIPS Agreement. It talks about the principles of non-discrimination in international trade and also regarding the TRIPS as being a 'minimum standards' agreement. Section 5 deals with the agreement's provision on counterfeiting and piracy. It narrates the general IP enforcement provisions, as well as those dealing specifically with counterfeiting and piracy. This section bears vital importance as it covers the definition and scope of the two issues that are currently being ratcheted up via the various international agreements and institutional modes. Section 6 deals with the various 'border measures' in TRIPS, including not only the general measures to be adopted by the administrative or judicial authorities, but also the modes of IP enforcement to be followed in case of criminal infringements. Section 7 discusses in brief, the Dispute Settlement Panel Report of thus far the only case on IP enforcement at the WTO, the US-China IPR case (2009), has been discussed. Finally, section 8 analyses the role played by the multilaterally negotiated TRIPS Agreement in maintaining suitable IP enforcement procedures in countries across their levels of developments.

2.2 International Intellectual Property Law Prior to TRIPS:

Since the nineteenth century, a number of international treaties have been negotiated, adopted and ratified before the Uruguay Round of trade negotiations concluded with the WTO Agreement[1] in 1994. The international intellectual property law until the

[1] *Agreement Establishing the World Trade Organization*, 15 April 1994 (entered into force 1 January, 1995) [online: web], accessed 5 July 2017, URL: https://www.wto.org/english/docs_e/legal_e/04-wto_e.htm

coming into being of the TRIPS Agreement[2] mainly consisted of the Paris Convention[3], the Berne Convention[4], the Universal Copyright Convention of 1952[5] under the aegis of the United Nations Educational Scientific and Cultural Organisation (UNESCO), and the 1961 Rome Convention for the Protection of Performers, Producers of Phonograms and Broadcasting Organizations[6]. The provisions of the Paris and the Berne Conventions primarily form the basis of the current structure of international law on IP enforcement.

2.2.1 The Paris and Berne Conventions:

Until the late nineteenth century, there was no international treaty dealing in industrial property mainly due to the variations in the nature of the laws in each country.

The origins of industrial property, the antecedent to intellectual property, can be traced back to the initiation of industrial revolution in Europe that continued for more than three centuries, with the general realisation that innovation may bring about affluence. Venice has the distinction of having the first formal patent legislation in 1474. In England, the Crown had the power to hand over monopolies to the 'owners' of intellectual property. The first formal patent legislation in England was Statute of Monopolies of 1623. It has been pointed out that this piece of legislation made

---

[2] *Agreement on Trade-Related Aspects of Intellectual Property Rights*, Apr. 15, 1994, *Marrakesh Agreement Establishing the World Trade Organization*, Annex 1C, THE LEGAL TEXTS: THE RESULTS OF THE URUGUAY ROUND OF MULTILATERAL TRADE NEGOTIATIONS 320 (1999), here and hereinafter called as TRIPS Agreement and TRIPS simultaneously.

[3] *The Paris Convention on the Protection of Industrial Property*, 1883, as last revised at the Stockholm Conference, July 14, 1967, 21 U.S.T 1583; 828 U.N.T.S. 303

[4] *The Berne Convention on the Protection of Literary and Artistic Works*, 1886, as last revised at Paris on July 24, 1971 [amended in 1979], 1161 U.N.T.S. 30

[5] *Universal Copyright Convention* as revised at Paris on 24 July 1971, with Appendix Declaration relating to Article XVII and Resolution concerning Article XI 1971 [online: web] accessed 5 July 2017, URL: http://portal.unesco.org/en/ev.php-URL_ID=15241&URL_DO=DO_TOPIC&URL_SECTION=201.html

[6] *International Convention for the Protection of Performers, Producers of Phonograms and Broadcasting Organizations,* Done at Rome on October 26, 1961 [online: web], accessed 5 July 2017, URL: http://www.wipo.int/treaties/en/text.jsp?file_id=289757

mention of the particular circumstances that call for patents to be issued for rewarding the inventors and was mainly intended at restricting monopolies, rather than supporting them (Scotchmer 2004: 9). The first documented legislative response to copyright was the Statute of Anne[7] of 1710, which is significant for a couple of reasons. Firstly, it recognised the authors as the 'owners' of copyright and not the publishers or 'guilds' alone, and secondly, it also allowed the right to copy a work after the lapse of a certain period of time (Spinello and Bottis 2009: 19). The most notable feature of this legislation, as comprehensible from its name, was that it was not only intended to encourage learning but also the diffusion of knowledge.

The two most important international intellectual property treaties that were followed prior to the TRIPS Agreement were the Paris Convention on the Protection of Industrial Property, 1883, and the Berne Convention on the Protection of Literary and Artistic Works, 1886. In the context of counterfeiting, the Paris Convention deserves special mention as regards the provisions contained in it for the seizure of goods bearing unlawful trademarks and false indication of source. Before referring to some of the relevant provisions, it is important to discuss how the Paris Convention came into being.

The present day international intellectual property right (IPR) has its origins in Europe, in the aftermath of the industrial revolution. The origin of the both the Paris Convention and the Berne Convention may be attributed to the industrial expansion in several of the European countries in the last phase of the nineteenth century, although many such countries were divided over the utility of these Conventions as regards their national interests are concerned (Hegde: 2005: 94-95). The inventors of such technology, which gave them an advantage over others, were worried that their inventions may be copied by others and hence, in many European countries patent legislations were enacted. It is thought that when the Government of the Empire of Austria-Hungary invited the other countries to participate in an international exhibition of inventions held in 1873 at Vienna, participation was hampered by the fact that many foreign visitors were not willing to exhibit their inventions at that

[7] This law passed by the English Parliament was known by the name, 'An Act for the Encouragement of Learning, by Vesting the Copies of printed Books in the Authors, or Purchasers, of such Copies during the Times therein mentioned' (Spinello and Bottis 2009: 19).

exhibition considering the insufficient legal protection of inventions (WIPO 2004: 241).

This resulted in a special Austrian law that secured temporary protection to all foreigners participating in the exhibition for their inventions, trademarks and industrial designs. Another event that followed was the Congress of Vienna for Patent Reform, which was convened the same year (1873).

An international Congress on Industrial Property convened at Paris in 1878 resulted in a decision in which one of the governments was asked to convene an international diplomatic conference "with the task of determining the basis of uniform legislation" in the field of industrial property. This was followed by a final draft proposing an international "union" for the protection of industrial property prepared in France, sent by the French Government to many countries, together with an invitation to attend the 1880 International Conference in Paris. This Conference adopted a draft convention which fundamentally included the substantive provisions that are still continuing to be the main features of the Paris Convention. Thereafter, a Diplomatic Conference convened in Paris in 1883, ended with final approval and signature of the Paris Convention for the Protection of Industrial Property (or the Paris Union) by 11 States namely, Belgium, Brazil, El Salvador, France, Guatemala, Italy, the Netherlands, Portugal, Serbia, Spain and Switzerland. By July, 1884, when it came into effect, Great Britain, Tunisia and Ecuador had also entered into the treaty, bringing the number of primary member countries up from 11 to 14. The Berne Convention for the Protection of Literary and Artistic Works (or the Berne Union) also followed shortly afterwards in 1886. Both the Paris Convention and the Berne Convention form the basis of the modern intellectual property system.

The post Second World War period saw the maximum membership of countries to the Paris Convention. Beginning with the Brussels Conference in 1900, the Paris Convention saw a number of modifications and in every such amendment a new revised Act of the Paris Convention was adopted. A few of these revisions were of particular significance for the developing countries (WIPO 2004: 241). The majority

of the member-countries of the Paris Convention are currently party to the latest Act of Stockholm, 1967.[8]

The revision conferences of the Paris Convention under the auspices of the World Intellectual Property Organization (WIPO) saw the developing countries, including India, to participate and make efforts to balance in their favour the international intellectual property (IP) system which was hitherto tilted in favour of the developed nations. Such endeavours were, however, not particularly fruitful in the long run (Hegde: 2005: 94).

In the 1967 Diplomatic Conference for Revision, some changes in the copyright laws were sought. The WIPO conducted the first study on the revision of the Paris Convention keeping in mind the interests of the developing countries[9]. Six of the fourteen questions raised in this study by developing States related to trademarks. The most important issue that was raised by the developing nations was that relating to equal treatment. According to the developing countries, the principle of equal treatment, provided under Article 2 of the Paris Convention, may be applied only when the partner States are on an equal standing. They argued that the partners being on an unequal footing, there is possibility that the stronger suppresses the weaker (Vida: 1981: 166). At the 3rd Session of Governmental Experts convened by WIPO (8-15 June, 1976), the Cuban delegation, representing the developing countries, raised the issue of terminating a mark in case of its non-use for a reasonably long time on the application of an interested party. A specific period for such marks dealt in Article 5C (1) of the Convention was proposed by India, Cuba, Mexico, Yugoslavia and Tanzania. They pointed at the fact that want of such a provision to cancel the registration of such marks within the national legislation of countries was particularly harmful for the developing countries, since they could not market their own products abroad due to the continuance of these trademarks.

[8]The Paris Convention has been revised six times at Brussels (1900), at Washington (1911), at The Hague (1925), at London (1934), at Lisbon (1958) and at Stockholm on July 14, 1967. It was finally amended on September 28, 1979.

[9]WIPO (1975) Doc., PR (GE)/11) 2, Geneva, WIPO

A motion titled, 'preferential treatment for the subjects of developing countries', that also affected trademarks, was put forward at the preparatory session of the WIPO Diplomatic Conference held between 25 and 30 November, 1976. However, the reservation of the developing countries regarding the appellations of origin and a trademark, where they suggested the former to prevail, seemed to be by far the most critical of all differences between them and the developed nations. It continued for years together. The developed countries finally proposed, for the Diplomatic Conference (Geneva 1980; Nairobi 1981), an important amendment in a new paragraph for Article 10ter for solving the conflict of geographical names and trade names. It was suggested that any developing country party to the new Act of the Paris Convention may reserve for itself the use of geographical indications, under certain conditions. Overall, it contained restriction upon countries to register any such mark that relates to appellations of geographical origin which has to be notified to the WIPO by the concerned developing countries. It further fixed a time-period for any such mark as 20 or 40 years based on certain factors (Vida: 1981: 170).

The Paris Convention deals with the issue of fake goods in the following way:-

1. It lays down provisions for the seizure of goods imported unlawfully bearing a trademark or trade name[10].

2. Goods bearing false indications as to their source or the identity of the producer are also liable to be seized.[11]

3. The remedies in relation to the above and also the right to sue[12].

It includes that the goods, unlawfully bearing a trademark or trade name, shall be seized on importation into those countries of the Union where such mark or trade name is entitled to legal protection. Seizure shall take place at the request of the public prosecutor, or any other competent authority, or any interested party, whether a natural person or a legal entity, in conformity with the domestic legislation of each

[10]Article 9 of Paris Convention, 1883

[11]Article 10 of Paris Convention

[12] Article 10*ter* of Paris Convention

country. There is no provision that binds the government for the seizure of goods in transit. The Convention contains flexible provisions that allow countries to frame laws according to their own requirements for prohibition of such goods if seizure is not allowed during importation.

The international copyright protection is believed to have begun around the middle of the nineteenth century by means of a number of bilateral treaties with various limitations and mutual incompatibility. A relatively comprehensive and uniform international pact became necessary and thus the earliest international treaty on copyright, the Berne Convention emerged on September 9, 1886. The convention has been subject to revisions many times as in Berlin (1908), Rome (1928), Brussels (1948), and then in Stockholm (1967) and Paris (1971). The Stockholm and Paris revision conferences are of particular significance for developing countries as it incorporated some of the provisions that concern their specific needs (WIPO 2004: 262).

The Berne Convention that deals in international copyright contains provisions that relate to the border measures. These are regarding the seizure of IPR-infringing copies at the time of their importation and in so doing, the law of the country, where such seizure shall take place, applies. Article 16 (1) and (2) provides that infringing copies of any work should be seized in any country of the Berne Union where the work enjoys protection, even if such copies belong to a country where the work never had any protection. Article 16 (3) of the Convention states that seizure of the infringing copy shall have to be in accordance with the domestic law of the country concerned. Further, Article 13 (3) deals with the seizure of copies of recordings of musical works that are imported without the author's or any other rights' owner's permission in the country of importation.

It may be noted hence, that both the pre-TRIPS Conventions did have specific provisions that dealt with international enforcement of intellectual property rights. However, as Gervais points out, the Paris Convention along with the Berne Convention was fundamentally flawed primarily for a couple of reasons. The first being, that there was no detailed norm set for the enforcement of such rights before the domestic judicial or administrative authorities. And secondly, it was felt that an

obligatory and effective dispute settlement method was also lacking (Gervais 1999: 152).

2.2.2 Post Second World War Developments

The traditional world powers of the nineteenth century continued unabated to wrest foreign territories in the Orient, Africa and other parts of the world even in the next century. Nevertheless various reasons, including the two world wars and the consequent establishment of the United Nations (UN), were responsible for the colonial powers to lay their hands off these lands in the latter part of the twentieth century.

The United States (US) remained virtually untouched by the devastation of the two world wars, which mainly impacted upon the European States. The protectionist trade policies adopted by the US in the early twentieth century during the course of the two wars made it even more powerful as an economy. As a matter of fact trade protectionism, and the subsequent trading blocs, was an important reason for the wars. The lessons that were learnt at the two wars led to the drawing up of the Charter of the International Trade Organization (ITO). But, due to the objections raised by the US Congress at that time, the charter could not be materialised. The General Agreement on Tariffs and Trade (GATT), a set of agreements on trade in goods, was adopted instead and it continued to function as a *de facto* organization for international trade for the next five decades (Lee: 2006: 15).

In the world of international politics, the United Nations (UN) system soon included the creation of several institutions for decolonization and encouraging self-determination of the colonized territories. This resulted in the increase in the number of underdeveloped erstwhile colonized States who, in the years that followed, dictated the numbers in the UN organization. These newly liberated States used the system to further their interests in blocking any intervention in matters pertaining to them. They became conscious of the fact that their political independence would continue to remain a hollow notion if there was no economic sovereignty. It was around this time in the mid-seventies that the developing countries, by dint of a sheer majority of

numbers, managed to pass a resolution at the UN General Assembly for the establishment of a 'New International Economic Order (NIEO)'[13] (Anghie: 2006: 748). These events and others[14] boosted the voice of the developing countries in the concerning debates at the international forums. Hence, they used the WIPO, another UN organ, to further their interests and bring in changes in the contemporary international intellectual property regime. By the end of the seventies, the international economic order was set to be reordered into balancing the concerns of the developing nations with the hitherto trading system.

The US, by now, had started producing goods that were technologically much advanced. Such technological advancement in the US was unprecedented in the history of international trade. Hence, it soon started to bring motions in the international fora for the adoption of a liberal trade agenda at the GATT rounds for marketing its products around the globe. The Tokyo Round of trade talks in the GATT saw the US and some other developed countries to moot for the adoption of an 'anti-counterfeiting code', to secure the originality of their domestic industrial products. As a consequence, some new issues like those relating to services trade and intellectual property rights appeared on the negotiating tables of the GATT system.

2.2.3 GATT and Counterfeiting

Since the World War-II, international trade saw various modes of regulation. These included the trade tariffs, which are considered the first generation of trade barriers arising chiefly out of the Great Depression of the 1930s in America. The US was one of the most protectionist economies of the nineteenth and the early twentieth century. Britain, France, Germany, Sweden, Japan and many others were no exceptions. As inferred by Ha Joon Chang, these economies in trying to catch up with the frontier economies, used interventionist trade and economic policies in order to promote their

[13]The U N General Assembly passed the Resolution 3201 (S-VI), *Declaration on the Establishment of a New International Economic Order*, or the NIEO on 1 May, 1974.

[14] Following the NIEO Declaration, the same year another document favouring the economic rights of the developing countries, *The Charter of Economic Rights and Duties*, was adopted by the UN General Assembly on 12 December, 1974.

infant industries (Chang: 2003: 14). And in so doing they imposed various kinds of trade restrictions on importations. This had happened when all these countries were also developing economies. Thereafter, when these countries gained industrial and technological superiority they initiated efforts to establish universal principles and norms of free trade.

The GATT 1947 prescribed reduction in the tariff structures to be implemented in both the US and the European countries. After that there were seven rounds of trade negotiations. Till the end of the Tokyo round, the average tariff for manufactured goods saw a huge reduction from about forty percent to between four and five percent in the industrialized countries (Cottier 2005: 18). Thereafter, another set of trade barriers primarily quantitative restrictions, export subsidies, anti-dumping measures, technical norms and standards, balance of payment measures and others entered, mainly to meet some economic as well as political ends for both the developing and developed countries. Finally, the third generation of trade restrictions ushered in around the end of the Tokyo round, or during the nineteen-eighties, some of them being- supporting domestic firms, regulation of service industries and investments, and finally, the protection of intellectual property. Keeping apart the first two generation of trade barriers, these restrictions, *inter alia*, became the primary bones of contention at the Uruguay round, as these largely influenced the domestic regulations which was not well accepted by all participatory States (Cottier 2005: 19).

Some scholars have identified the reason as to why States started preferring technological superiority towards the end of the last century. According to them, technology was deemed as one of the key factors for development of nations in the 60s and 70s of the last century, and in the 1980s it emerged as one of the singular elements for capturing global markets (Hegde: 1995: 164). It has been pointed out that sophisticated and minute application of technology resulted in certain problems. It accelerated the rate of technological diffusion and the increasing capacity of countries to copy, imitate, or differentiate products. Courtesy of information technology, changes occurred in the production techniques in certain sectors instead of mass production, mainly to conquer specific markets (Hegde 1995: 164).

The developed countries started producing the technologically superior goods and articles which were marketed and made available around the globe, including the developing countries. Soon they became established companies representing the corresponding 'brands' they marketed or sold worldwide. But they felt that, a global chain of counterfeiting of these famous brands was also running parallel due to the factors as already mentioned, and thereby, made a demand for a code that effectively checks the menace of counterfeiting.

2.2.4 Tokyo Code and its implications

The very origin of the TRIPS Agreement as a manifestation of international intellectual property rights is attributed to the proliferation of the trade in counterfeit goods in the late seventies of the last century. Thus the ensuing mobilization of corporate actors on a global dimension led to the creation of the Anti Counterfeiting Coalition, an association of one hundred transnational corporations, with the common design of influencing governments of different States to toughen protection against counterfeit trademarked goods (Matthews 2002: 8-9). [15]

Concerted attempts to make common rules on tackling trade in counterfeit goods failed to take shape since State delegations in general did not take interest or even opposed it, but the corporate coalition persuaded the governments of the US and the European Communities (EC) to maintain their exertions with introduction of the draft 'Agreement on Measures to Discourage the Importation of Counterfeit Goods'[16]. This draft code had the following propositions:

1. This draft called for signatory countries to intercept counterfeit trademarked goods at the international borders by means of introducing procedures for seizure and suspension of such goods by the customs authorities, which are

[15] The author further goes to explain that, "During the Tokyo Round of the GATT between 1973 and 1979, trade in counterfeit goods had begun to emerge as a serious issue and was no longer simply considered an 'acceptable obstacle' to free trade." Another author, Matthijs Geuze, also seems to share the similar view (Geuze 1998: 589).

[16] The US and the European Economic Community requested the introduction of the '*Agreement on Measures to Discourage the Importation of Counterfeit Goods*', GATT Doc. No. 1/4817 (31 July 1979)

fairly similar to the existing TRIPS provisions[17], except for the fact that the former did not attempt to deal with production of counterfeit goods within the national borders[18]. This proposal came too late and, in addition, there were too little evidences to support the contention of the industrialised nations.

2. It stated that trade in counterfeit goods prejudices the interests of legitimate traders as also deceives consumers and is harmful to their interests.

3. It recognized the variances in the legal systems and therefore the customs procedures of the Parties which may require different methods of dealing with counterfeit goods.

4. It also contained the procedures to be initiated by the country where such goods are being imported, as well as the right of appeal to any higher authority of the importing country.

5. It had proposed provision for the balance of rights and obligations for the parties.

6. It also contained provision for the consultation between parties for mutual settlement, and even about dispute resolution.

It is said that between 1980 and 1982, informal meetings were conducted between the representatives of various business houses and government officials in the US, the EC, Canada, Japan and Switzerland that concluded in revising the preceding draft anti-counterfeiting code (Matthews 2002: 27).

Thereafter, at the 1982 GATT Ministerial meeting, a limited agreement, to consider this issue and authorize the Director General of GATT to discuss its legal and

[17] See 'Special Provisions Related to Border Measures' under Articles 51 to 60 of the TRIPS Agreement (supra n. 1), resembling striking similarities to this draft code.

[18]This entire (GATT) document, *ibid* at n. 7, dealt with importation of counterfeit goods or entry of counterfeit goods within the channels of commerce. It even had a provision that is similar to *de minimis* exception in the TRIPS Agreement. Nowhere did the document mention anything about the control of production or manufacture of any such products within the borders of any country.

institutional aspects with his counterpart at the WIPO, could only be reached (Watal 2001: 12).

The main idea behind introduction of the Tokyo code on anti counterfeiting was 'to agree to border measures for the interception and eventual destruction of such goods outside the channels of commerce' (Watal 2001: 12).

The Paris Convention recognizes the duty to seize imported goods bearing unlawful trademarks or other false indication of source.[19] The WIPO, a specialist organization of the UN established in 1967[20], was hitherto responsible for supervising the Paris Convention along with the Berne Convention. But due to a couple of reasons, as identified by Helfer, the US and the EC industries pursued their case at inter-governmental levels for reallocation of the international IP regime from WIPO to some other forum where they sensed they might be in a position of influence (Helfer 2004: 20). These were, firstly, that the industry of these States was not satisfied with the treaty negotiations hosted by the WIPO, and secondly, they felt that the GATT was a much better opportunity for them to impose stricter intellectual property protections (Helfer 2004: 20). But there were other reasons as well, as put forward by Drahos, for them to be doing so (Drahos 1995: 7). Firstly, that the US industry, led at that time by powerful multinational corporations (MNCs) having significant intellectual property interests like IBM, Pfizer and Microsoft, was feeling worried over the fact that they were suffering loss of profits as their products were being increasingly faked. Secondly, they could successfully widen and impart this sense of fear within their government circles that the US was about to lose competitiveness. Lastly, the apprehension, that it was ultimately the US which was losing power (Drahos 1995: 7). Not only that, Drahos helps us make out that the US industry was facing a number of problems in the early eighties because the developing countries

[19] Paris Convention, Articles 9, 10, 10*ter*

[20] The World Intellectual Property Organization (WIPO) was established under the 'Convention Establishing the World Intellectual Property Organization', July 14, 1967. See also Yu (2004:41), referring to the fact that the WIPO was created out of the Stockholm revision Conference of the Berne Convention in the same year when the less developed countries were eager to establish an exception for themselves in the international intellectual property regime by introducing a new protocol in the Berne Convention which was, however, never ratified.

particularly were not very sympathetic towards the US industry's intellectual property interests (Drahos 1995: 8).

The US with key inputs, mainly coming from the Advisory Committee for Trade Negotiations (ACTN), a domestic body of business entities acting as a link between the industry and the bureaucratic offices, forged a relationship between the international trade regime and the development and enforcement of intellectual property standards, and thereby, successfully fulfilled the 'leverage' deficiency in dealing with the problem of copying (Drahos 1995: 8). In fact, the ACTN was 'a pipeline for US business to the US executive on trade issues' whose role was 'to advise the US Trade Representative (USTR) on where, in the eyes of the private sector, US economic interests really lay' (Braithwaite and Drahos 2002: 72). There were others influential groups such as the Intellectual Property Committee (IPC) and the International Intellectual Property Alliance (IIPA) who also played a more prominent lead role in the days and years that followed. As a matter of fact, the IPC is said to have born out of the ACTN (Braithwaite and Drahos 2000: 71).

2.2.5 1982 GATT Ministerial

The residual issues of the Tokyo Round were discussed at the 1982 GATT Ministerial Meeting. While the US campaigned for a revised draft Code, the developing countries, led by India and Brazil contested the requirement of an agreement within the GATT when WIPO, for such purposes, already presented an appropriate forum for moving up the international standards of intellectual property, and the GATT being essentially a forum for tariff negotiations on goods had no jurisdiction over an IP issue like trademark counterfeiting (Matthews 2002: 9-10).

The following Ministerial Declaration, in spite of the sustained reservations by the developing countries, asked the Director General for holding consultations with his WIPO counterpart for the legal and institutional aspects involving trade in counterfeit goods.[21] The consultations resulted in agreement that there were no reason which may

[21]Thirty-Eighth Session at Ministerial Level Ministerial Declaration, GATT BISD, 30th Supp. At 9 (1983)

relate to the jurisdiction of GATT on the issue. Thereafter, in the fortieth session of the GATT Council, an Expert Committee was appointed for working on the issue of counterfeit goods. It met six times, reported to the Council and finally prepared a report on 'Trade in Counterfeit Goods'[22]. The salient features of this report are:

1. The report attacked the adequacy of national laws in managing the matters regarding trade in counterfeits;

2. It dealt with the question of the authority of the GATT, and the means available with it for dealing with the problem;

3. The impact of anti-counterfeiting on international trade; and,

4. It remained inconclusive over the appropriateness of the GATT as being the forum for intellectual property issues (Gervais 1998: 9).

In between, however, there have been attempts on part of the developing nations to revise the WIPO treaties- the Paris and Berne Conventions[23]. Futile revision conferences to overcome the disparity between the developing and developed States over IP-related issues were held in Geneva (1980), Nairobi (1981) and again in Geneva (1982). The US made every effort to keep the issue of counterfeiting alive on the GATT agenda and in late 1982, it submitted a revised text of the original draft code[24] prepared in consultation with the EC, Japan and Canada. The important features of this Code were:

1. It met with a humble work programme for trade in counterfeit goods, and,

[22] The report of 20 December, 1984, known as "*TRADE IN COUNTERFEIT GOODS: Fortieth Session of the CONTRACTING PARTIES: Action taken on 30 November 1984*" GATT Doc. No. L/5758 (1984) said categorically that the CONTRACTING PARTIES "agree to invite the Director General of W.I.P.O. to nominate an expert to participate in the discussions".

[23] In view of the finding of an United Nations Conference on Trade and Development (UNCTAD) report that 84% of all the patents issued in the developing countries were belonging to persons of five developed States- the United States (US), Germany, France, Switzerland and the United Kingdom (UK), whereas only 1% of patents were held by persons belonging to their own States. See, United Nations Department of Economic and Social Affairs, UNCTAD Secretariat, 'The Role of the Patent System in the Transfer of Technology to Developing Countries', U.N. Doc. No. TD/B/AC.11/19 (1974) as cited in Matthews 2002: 11.

[24] This was the draft '*Agreement on Measures to Discourage the Importation of Counterfeit Goods*', GATT Doc. L/5382, October 1982.

2. It reiterated the appropriateness of the GATT "without prejudice to the competence of the WIPO and any relevant work which may be undertaken there"[25].

IP-dependant industries, mainly from the US, reported that the growth of counterfeit and pirated goods was unrelenting. The Sub-committee on Trade of the United States House of Representatives on Oversight and Investigations was informed by the Auto industry in the US that it lost to the extent of $12 billion due to counterfeiting of spare parts, as also did the agro-chemical industry.[26] But such findings were never beyond misgivings, since there were hardly any figures that were verified or produced with application of any standard methodology, and hence, these ran the risk of being overstated, and more so, when the US government itself lacked any mechanism to verify the same.[27]

The failure to revise the WIPO Conventions accentuated the requirement of getting into bilateral approach wherein trade and intellectual property could be interlinked. In 1984, the US Congress, courtesy to demands from the industry, amended Section 301 of Trade and Tariff Act of 1974. This amendment was significant because of three reasons:

1. The USTR's Office obtained the right of initiating investigations in another countries' IP system without the requirement of any formal complaint by any US-based company;

2. It incorporated into its fold any act, policy or practice that apparently denies intellectual property protection that is up to the 'adequate and effective' standards demanded by the US industry as 'unjustified and unreasonable'; and,

[25] Ibid

[26] This figure was provided by the Automotive Parts and Accessories Association of the US. Similarly, the video industry in that country also reported losses to the extent of $6 billion owing to piracy (Mathews 2002: 13-14).

3. It also did not fail to associate lack of intellectual property protection as a new criterion for removal of tariff privileges for imports from developing nations into the US (Matthews 2002: 15).

The US's extraordinary success at the GATT negotiations in connecting its IPR trade policy with trade laws is credited to its coercive tactics of applying the US Special 301 (Watal 2001: 18). It initiated the first action of application of this provision upon Korea in 1985. Scholars estimate that this was a major step in the sense that Korea subsequently relented in making changes to its national IPR laws due to its heavy export-dependency on the US as a key destination, hence serving as an example to other major developing countries to start rethinking about their respective positions (Watal 2001: 18). The same year, when the GATT Council directed the Preparatory Committee to identify issues for the forthcoming round, the US proposed to include all aspects of IPRs in the GATT, and not just that of counterfeit trademark goods that was considered in the 1982 Ministerial Work Programme. In July 1985, the US submitted its goals for new multilateral negotiations in trade which included the necessity to deal with the issue of trade in counterfeit goods, but actually in the long term, the cutback in trade distortions ensuing from the deficient management of all kinds of intellectual property rights.[28]

At this point in time, however, the developing countries led by India and Brazil *et al*, albeit still opposed to the jurisdiction of GATT in matters of IPRs, had not been unanimous in their views regarding other issues. Some among the 'Group of Ten'[29], as they were called, especially the newly industrialised ones in the South East Asia, seemed to have started to accept the idea since they may have felt the need to provide protection of IPRs for their own industries. Others started to view the GATT as a multilateral forum as regards the issue of dispute settlement which may not only be

[28] This document was called, *United States Goals for New Multilateral Trade Negotiations*, GATT Doc. L/5846 dated 12 July 1985.

[29] The group included Argentina, Brazil, Cuba, Egypt, India, Nicaragua, Nigeria, Peru, Tanzania and (former) Yugoslavia. See Watal: 2001: 19 at footnote 17.

devoid of any unilateral coercion or sanction, but may also effectively offset bilateral pressure.[30]

The bones of contention between the developing countries as well as those between them and developed countries about the competence of GATT was reflected thereafter in the mandate of the negotiations. In June 1986, the first comprehensive text on a draft Ministerial Declaration was presented by a group of developed countries led by the US, EC and Japan that included trade in services, investment-related issues and trade related aspects of intellectual property. Consultations continued, and some twenty developed and twenty developing countries made possible the first text outside the GATT that became the basis for consultations. This draft was submitted by the Swiss and the Columbian ambassadors on their behalf.[31] Texts were also submitted by Brazil and Argentina on behalf of the developing countries opposing IPRs, investment and services trade. But, the text of the group of forty was accepted with minor changes. The Declaration at Punta del Este[32] gave the mandate to 'clarify GATT provisions' and also 'elaborate' some 'new provisions'. But what is worth mentioning here is the fact that this declaration authorized to develop 'a multilateral framework' for dealing with trade in counterfeit goods.[33]

2.2.6 The Uruguay Round

The Uruguay Round of trade negotiations is regarded as the lengthiest of all the GATT negotiating rounds. This round had in its background, the newfound coercion tactics by the US for getting even about its trade interests. It was also marked by stiff opposition on part of the major developing countries on their propositions. Not only

[30] 'Intellectual Property Rights, A Guide to the GATT Uruguay Round', Department of Foreign Affairs and Trade, Canberra, March 1990, p. 11.

[31] This draft was submitted on the 30th of July, 1986.

[32] *Ministerial Declaration*, 20 September, 1986, BISD, 33S, 1987, 1987, 19 at p. 25-26.

[33] It said, *inter alia*, 'Negotiations shall aim to develop a multilateral framework of principles, rules and disciplines dealing with international trade in counterfeit goods taking into account work already undertaken in the GATT.'

were there differences over the issue of IPRs but also the jurisdiction of GATT on the issue. Therefore this round was not meant to end early.

In this round, most of the industrialized nations pursued a comprehensive approach that went far ahead of the issue of counterfeiting. They meant to include copyright, neighbouring rights, patents, trademarks, geographical indications, integrated circuits, industrial designs and trade secrets. India, on the other hand, argued for restricting the negotiations to only the issue of a counterfeiting code that would deal with the copyright and trademark violations for the reason that the matters concerning patents and trade secrets went far outside the mandate of the TRIPS Negotiating Group (Evans 1994: 162). In the context of the character of the proposed legal instrument, the developed nations proposed to have an article in the GATT instrument that would have in its content, an annexe including an all-inclusive agreement. And on the other hand, the developing countries of the Group of Ten wished to have an agreement in the form of a code only against counterfeiting of IPRs. It has been perceived that the developing nations went for such a code because the adherence to such a code was voluntary, whereas, the amendment or inclusion of any GATT article requires undisputed consent and commitment on part of all the contracting parties (Evans 1994: 162).

As regards the enforcement provisions, the US and the EC proposed that the agreement should be providing information about 'minimum standards' on requisite judicial and administrative procedures both at the borders as well as within, so that the issues, of empowering the customs with authority to seize counterfeit goods at the request of the right-holder along with criminal penalties for wilful violation on commercial scale, could be raised later with the Member States for legislation (Evans 1994: 163-164). Since there was no homogeneity about the domestic standards at that time, the minimum standards was proposed to be in line with the respective WIPO-administered treaties. It is noteworthy that the United States, along with several other developed States, was not party to some or most of the WIPO-governed treaties, especially the Paris and Berne Conventions, at this time. There were sharp differences among the rich States on this issue (Evans 1994: 164). Hence, it may not be wrong to say that the US became a party, to the Berne Convention at a later time, solely to have its way into making other countries oblige to its propositions at the GATT. The

developing countries, especially Brazil and India, were also severely critical of the substantive propositions regarding shaping and enforcement of such minimum standards since they saw it as an 'interference' with their ability to manage these issues, a surrender of their sovereign decision making power and also an 'unnecessary penalty' on the Third World nations by the first world due to their relative lack of protection (Evans 1994: 166).

The Group of Ten argued that the WIPO's future efficacy might be undermined by the activities of the proposed overseeing of IPR issues by the WTO. On the other hand, the major exporting countries like the US, the EC and Japan argued that the effect of counterfeiting of intellectual property on their respective trade balances was a sufficient evidence to prove the value of intellectual property as a commercial asset and its relevance as an issue of trade, hence the apparent jurisdiction of the WTO over it. The argument of the former group appeared to be well substantiated in light of the fact that the GATT itself was then a provisional instrument which had been institutionalised by the WTO (Evans 1994: 168). Nevertheless, the WIPO itself attempted to put an end to the disagreement over jurisdiction when it submitted a paper to the negotiating group accepting some generally identified institutional norms in intellectual property.[34]

The period of 1989-90 was a turning point in the TRIPS negotiations when it saw India, which was hitherto leading the oppositions, in principle accepting the international enforcement of the trade-related aspects of intellectual property rights within the framework of the Uruguay round of negotiations due to threat perceptions when the US had put it in its Sec. 301 Priority Watch List (Drahos 2002: 775). However, in the following GATT Negotiating Group debates that followed, India's reservations, on issues like observing principles of natural justice in enforcing IPRs, compensating persons wrongly accused of infringements and providing both civil and administrative remedies for rights abuse, deserve special mention since many of them may have found their way in the final TRIPS Agreement. Regarding enforcements,

[34] *International Bureau of WIPO, Existence, Scope and Form of Generally Internationally Accepted and Applied Standards/ Norms for the Protection of Intellectual Property*, GATT Doc. MTN.GNG/NG11/W/24 Rev. 1; WIPO Doc. WO/INF/29, September 1988, as provided in Evans 1994: 168.

India had said that the developing states should not be expected to finance such mechanisms, in keeping with the solidarity with the Third World so that they are not burdened with the increase in regulations (Evans 1994: 170). One of the two distinct agreements in the final submission of the Chairman of the TRIPS Negotiating Group, the Agreement on Trade in Counterfeit and Pirated Goods provided broadly for the establishment of adequate border measures for discouraging international trade in counterfeit goods.[35] The scheduled four year time-period for the completion of the round could not be met by the parties as the agreement sought more and more substantive provisions in place of the original arrangement of having only an agreement on border measures to curb trade in counterfeits. The following discussions saw the States and groups of States negotiating strongly on substantive matters relating to IPRs instead of arrangements for border restrictions.

In the meantime, during the 1990s, the US went on mounting the intellectual property standards before anybody noticed, in getting into bilateral agreements containing even firmer arrangements, using its Trade Act by surveillance of intellectual property standards of other countries and enforcing its sought standards through threats of sanctions (Drahos 2001: 791).

There has not been much of a deliberation on the enforcement measures, as a whole since, it is apparent that the final TRIPS text's provisions are essentially similar as they were in the Brussels Draft.[36]

The different kinds and periods of patent protection was the core issue to have been discussed during the negotiations post Brussels Ministerial, when there happened to be more and more agreements on different matters. But, there have also been

[35] The Final Draft Agreement (the Geneva Draft) submitted by the Chairman, Ambassador Lars Anell of Sweden, comprised of two separate agreements, of which, the agreement on trade in pirated and counterfeit goods was a slender one. This one sought to discourage the international trade in counterfeit goods by a spirit of cooperative prevention against counterfeiting and a willingness to clarify existing intellectual property laws than by a series of detailed undertakings. On the other hand, the draft 'Agreement on Trade- Related Aspects of Intellectual Property Rights, including Trade in Counterfeit Goods' provided for standards meant for implementation at domestic level with their enforcement to be aided by the GATT consultation and dispute settlement mechanisms (Evans 1994: 172).

[36] The Brussels Draft was called the 'Draft Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations', Revision, Trade-Related Aspects of Intellectual Property Rights, Including Trade in Counterfeit Goods, MTN.TNC/W/35/Rev. 1, 3 Dec. 1990

considerable disagreements on certain issues. Finally, the Chairman of the negotiating group and the GATT Secretariat organized their best efforts to judge what may be acceptable to all participatory States. This draft text is known as the Dunkel Draft, after the name of Arthur Dunkel, the Director General of GATT (Watal 2001: 37). This text, containing almost the same content as the final agreement, was offered on 'take it or leave it' basis (Evans 1994: 174).

The Dunkel Draft Text (DDT) was not beyond criticism because of its universalisation of standards and provisions for cross-retaliation of one sector by another with sanctions by countries. At a time when it was just offered and yet to be adopted, Chimni had argued that cross retaliations had been permitted between sectors that stand primarily opposed to each other; like in other areas 'liberalization' had to be enforced, in case of IPRs it amounted to an act of 'protectionism'. Further, through the universalisation of norms it narrowed down the policy space for countries to set policies according to their peculiar requirements (Chimni: 1992: 157). Nevertheless, under an atmosphere of sustained threat of sanctions through US 301 process, the bigger developing countries like Brazil and India started to relent. In so doing, their strength of unity was broken down and they started to feel weaker due to an isolation of interests. Under such circumstances, finally, the TRIPS Agreement was adopted on April 15 1994, along with many other texts covering specific areas of binding international trade law, embodying the results of the Uruguay Round, just as a prescribed 'package' offered in the DDT.

2.3 TRIPS Agreement and IP enforcement:

One of the main reasons that were stated by major parties for the commencement of negotiations to the TRIPS Agreement was the increase in the amount of product counterfeiting and copyright piracy at an international level. This was perceived especially in those countries where technologically superior American, European and Japanese products were being exported (Evans 1994; Gervais 1998).

Now, the participants in the various WTO conferences recognized the need for provisions on enforcement by procedural law were already at an early stage. The Paris

and the Berne Conventions, that were governing the international IPR enforcement regime till the time when TRIPS arrived, were perceived by these parties to be lacking in the following five areas:

(1) deficiency in personnel support and insufficient means of control by seizures at the border,

(2) apathetic access to the courts or authorities,

(3) extremely strict rules of evidence for the IPR holders,

(4) perceived requirement of preliminary legal protection and

(5) absence of criminal provisions that were to act as a deterrent (Vander 2009: 679).

'Border measures' have been regarded as an important tool to regulate counterfeit and pirated goods. A known and identified counterfeit or pirated good that violates IPRs is not expected to be allowed to cross the international borders of a country. These measures or regulations that are to be taken at the borders, however, are subject to national laws of the respective authority concerned.

The Preamble of the WTO's TRIPS Agreement[37] lays down one of the justifications of the agreement as being "the need for a multilateral framework of principles, rules and disciplines dealing with international trade in counterfeit goods"[38].

Article 1.1 of the TRIPS Agreement provides as:

> Members shall give effect to the provisions of this Agreement. Members may, but shall not be obliged to, implement in their law more extensive protection than is required by this Agreement, provided that such protection does not contravene the provisions of this Agreement. Members shall be free to determine the appropriate method of implementing the provisions of this Agreement within their own legal system and practice.

This provision is of paramount importance since it articulates the scope of this treaty. It expressly mentions that a State party to the agreement cannot implement any legislation that breaches the provisions of the TRIPS Agreement. It also states that

[37] See the 'Preamble' to the TRIPS Agreement.

[38] See ibid.

States are at liberty to implement its provisions in accordance with their own respective domestic legal structures and characteristics.

However, there is no doubt that the border measures in the TRIPS Agreement have raised the standards of inflicting compulsory implementation by a considerable margin as because the earlier enforcement provisions pertaining to trademarks and copyrights as under the Paris Convention were optional in nature. The border measures is one of the foremost testimony of the fact that the major players during the negotiations had indeed wanted a cutback in barriers to international trade[39], while at the same time making sure, that the enforcement of such intellectual property rights themselves do not become a hindrance to trade. Additionally, Articles 7 and 8 of the Agreement on the 'objectives' and 'principles' respectively, also provides for special developmental concerns. Article 7 speaks of, promotion of technological innovation and … the transfer and dissemination of technology … in a manner conducive to social and economic welfare." Also, Article 8 talks about public interest exceptions to IPRs such as public health and nutrition. It further expands the same to include other areas as well, which are "of vital importance to … socio-economic and technological development", and also aims to ensure "the international transfer of technology". Article 66 talks about the "need for flexibility to create a viable technological base", that should be read along with the other provisions that are in favour of such countries.

2.4 Principles and features of TRIPS Agreement:

The Agreement on Trade Related Aspects of Intellectual Property has certain basic features or principles that should find presence in the application of any and every

[39] Counterfeiting of trademarked products had been perceived by the business community from the industrialised States as being one of the main factors that hamper their international trade. Some of them even made their observations public by citing losses to the business and industry that stretched to millions of dollars, besides having some considerable effect on their jobs (Drahos 1995, Sell 2003). Even recently, the successive studies made by the Organisation for Economic Cooperation and Development (OECD), an intergovernmental economic body of affluent States, view the same way in this regard (OECD 2008) (OECD 2009). Some the organisations that are associations of transnational trading bodies as well as international law enforcement have also expressed similar opinions (BASCAP–INTA 2017) (Europol 2017).

provision of TRIPS. These principles, namely the 'national treatment' and 'most favoured nation', are essentially founded upon the hallmarks of non-discrimination within the GATT as a whole. In the next two subsections, these principles shall be discussed in brief.

2.4.1 The National Treatment Principle:

The principle of national treatment has found mention in Article III of GATT 1994. However, this principle differs in the way it is applied in case of the TRIPS Agreement. In so far as in GATT, this principle applies to finite or tangible things, whereas in TRIPS it applies to intangible intellectual property. However, this principle has found its way into TRIPS from its predecessor treaties- the Paris and Berne Conventions.

The Paris Convention includes national treatment in Articles 2 and 3. Article 2 states, the same conditions or advantages that nationals of any country enjoy shall have to be applied to nationals of any other State party to the Convention. In so doing, as Article 2 (1) states, some judicial or administrative procedural formalities imposing certain special conditions on foreigners may also validly be invoked against foreigners (that are nationals) of member countries. Article 3 of the Convention provides that the national treatment rule shall also have to be applied to non-member nationals, if they are domiciled or have their industrial or commercial establishment in the member country.

The Berne Convention does not spell out the term 'national treatment' as such; however, it is included within the provisions as under Article 5. It essentially requires that, a nation shall have to grant authors of member countries to the Berne Union all those rights that are declared under its domestic law, currently in force and also those in the future.

Article 3 of TRIPS speaks about the principle of 'national treatment'. It binds Members to provide, as a minimum, the same treatment to nationals or entities of

other States as it provides to its own nationals in matters concerning IP protection.[40] The term 'protection' however, has a broader meaning in the context of the principles of trade incorporated in TRIPS. It shall refer to "matters affecting the availability, acquisition, scope, maintenance and enforcement of intellectual property rights as well as those matters affecting the use of intellectual property rights specifically addressed in this Agreement"[41]. Therefore, it includes matters concerning the enforcement of IPRs.

2.4.2 The Most Favoured Nation Principle:

Article 4 of TRIPS endorses another established standard of international trade, the principle of 'most favoured nation' (MFN). This provision implies that any concession granted by a Member State to another has to be provided to every other Member 'immediately' and 'unconditionally'[42]. It entails that the nationals of the other Member States should be treated without any discrimination. Matthews, however, asserts a number of exceptions to this principle. These are, as he states:–

> .. for any advantage, favour, privilege or immunity of a general nature and not confined to intellectual property protection; granted under the Berne or Rome conventions and authorising that the treatment accorded be a function not of national treatment but of the treatment accorded in another country; in respect of the rights of performers, producers of phonograms and broadcasting organisations not provided under the TRIPs Agreement; or deriving from international intellectual property agreements which entered into force before the WTO Agreement, provided such agreements do not constitute an arbitrary or unjustifiable discrimination against nationals of other Members (Mathews 2002: 48).

[40] Article 3 of TRIPS Agreement states, 'Each Member shall accord to the nationals of other Members treatment no less favourable than that it accords to its own nationals with regard to the protection of intellectual property…'

[41] fn. 3 to Art 3 in Part I of TRIPS

[42] "… With regard to the protection of intellectual property, any advantage, favour, privilege or immunity granted by a Member to the nationals of any other country shall be accorded immediately and unconditionally to the nationals of all other Members. …" (Article 4, TRIPS Agreement)

The twin principles of national and most favoured nation treatment are thus founded upon the idea of non discrimination between nationals from both within the country as well as outside.

2.5 Other standards: TRIPS – a minimum standards agreement

In addition to the two abovementioned principles, the TRIPS Agreement also lays down the 'minimum standards' for protection as well as enforcement of intellectual property rights globally[43]. Duncan Matthews had rightly observed on this aspect of TRIPS that also approved some other key components along. He states:

> …. its novelty lay in the fact that for the first time in international law there was an obligation to provide minimum standards of intellectual property protection of a real and binding character. In particular, the transparency arrangements, enforcement mechanisms and linkage to the dispute settlement procedure of the WTO… added much to the arrangements that already existed under WIPO (Matthews 2002: 46).

In contrast to the Paris and Berne Conventions not having recommended any specific standard for IPRs, the TRIPS laid down the minimum standards not only for protection but also procedures of enforcement within respective domestic legislations (Evans 1994: 139). The foundational idea for including such near-universal standardisation was laid few years before the agreement was concluded and entered into force[44]. Watal observes, that TRIPS enforcement provisions "… specify the *minimum procedures and remedies that must be available so that rightsholders can effectively enforce their private rights* in domestic judicial, quasi-judicial, or administrative institutions, in accordance with certain general principles" (Watal 2002: 361) (emphasis added). This particular feature of the agreement implies that the state parties to the agreement have to comply with a certain threshold; they have the liberty to vouch only for more extensive or higher protection or enforcement of IP as stated in Article 1.1 of TRIPS that the agreement does not intend to harmonise, and

[43] For a detailed discussion on the concept of 'minimum standards' in the TRIPS Agreement, see generally, Reichman, J H (1995).

[44] The consensus for having minimum standards of intellectual property and enforcement was arrived at during the Geneva Ministerial Meeting of the Uruguay round (Matthews 2002: 34).

that it is upon the Members themselves to decide on its application within their individual laws and procedures. It is this attribute, as we shall see in later chapters, which is being utilised by the developed nations and their business entities to continuously rummage around for more and more far-reaching and stringent IP enforcement provisions, in certain national legislations and international trade agreements at various levels.

2.6 TRIPS Agreement provisions on Counterfeiting and Piracy:

The TRIPS Agreement lays down the fundamental basis of the current international legal regime on intellectual property counterfeiting and piracy. Counterfeiting and piracy, as included in 'Border Measures' under the TRIPS Agreement, essentially forms a part of the section on enforcement mechanisms (Part III) provided therein.

Part III of the TRIPS Agreement contains five sections on IPR enforcement. Counterfeiting and piracy are essentially acts of infringements of IPRs. Therefore, like any other form of IPR infringement, counterfeiting and piracy will draw the same general provisions on enforcement as within the TRIPS. However, these two issues are precisely dealt with in the 'Special Requirements Related to Border Measures' of Part III.

2.6.1 Enforcement provisions in Part III of TRIPS:

Part III of TRIPS consists of five sections in all. The first section includes Article 41 which articulates the basic premise upon which the entire enforcement regime stands, thereby setting the 'general obligations' that all enforcement procedures are required to qualify. These are particularly aimed at ensuring effectiveness as also that certain basic principles of due process are met (Geuze 1998: 404). It basically lays down the fundamental principles that are generally applicable to all the provisions of enforcement that follow. As Reichman suggests, it outlines the 'four cardinal principles' of enforcement provisions within the TRIPS. They are, namely,

1. specified procedures must be made available under the domestic laws to "permit effective action" against present and future acts of infringement;

2. pertinent judicial and administrative procedures must be "fair and equitable" and not "unnecessarily complicated," or likely to cause "unwarranted delays;"

3. courts and administrators must base decisions on evidence available to all the parties, and should normally deliver written, reasoned opinions; and

4. there must be some form of appellate review for decisions handed down by administrative or judicial agencies of first instance (Reichman 1997: 340).

These foundational principles, as they found their way in the other provisions that follow, are now being discussed in detail.

Article 41.1 states that it is obligatory for Members to ensure that enforcement procedures are available under their law that permit ‘effective’ action against any act of infringement of intellectual property rights under the TRIPs Agreement, including expeditious remedies to prevent infringements and remedies which constitute a deterrent to further infringements. However, it has to be ensured that the enforcement procedures are related to trade, and scrutinise as to whether they create barriers to legitimate trade and provide safeguards against their abuse.

Article 41.2 requires the procedures to be fair and equitable. Standards of fairness and equity are incorporated in the provisions throughout this Part. It also says that such procedures must not be unnecessarily complicated or costly, and must not entail unreasonable time-limits or unwarranted delays.

Article 41.3 entails the fundamental principle, that a decision on the merits of a case is to be reasoned, and the preferable means of communicating it, will be in writing. It further says that such decisions must be entirely based upon evidence in respect of which the parties were offered opportunity to be heard.

Article 41.4 obliges Members to provide for review of final administrative decisions by independent judicial authorities. As to judicial decisions in civil matters, the agreement is limited to a minimal standard. Members are free to define the threshold of jurisdiction for appeals corresponding to importance of the cases (for e.g., those

relating to pecuniary limits), wherein they need to have provision for review of legal issues as a minimum, based on the merits. Such judicial review is required for convictions only, in cases that invite punitive measures, but not for the acquittals.

However, the last paragraph of this section, Art. 41.5 points out the safety measure which are required to be observed while conforming to the above provisions. These safeguards are mainly that, any of such provisions does not bind any national government to have in place, any separate mechanism for IPR enforcement than the general enforcement of civil and administrative law in that country; neither does it oblige them to bring about any separate capacity or resource enhancement for such IPR enforcement. The issue of a separate system altogether for adjudicating IPR violations and their enforcement, was an essential concern of the developing countries during the course of negotiations preceding the finalization of TRIPS Agreement.[45] There was apprehension on their part that such enforcement measures might themselves become a barrier to trade carried out legitimately, as such a blanket grant of monopoly rights might lead to abusive practices. Therefore, it was submitted that there was requirement of adhering to the principles of natural justice during such enforcement, compensating persons who may be wrongly accused of infringements and providing both administrative as well as civil remedies for the abuses (Evans 1994: 170).

The second section entitled, 'Civil and Judicial Procedures and Remedies' mentions about the civil judicial remedies that must exist in case of infringement of any of the intellectual property rights stated in the TRIPS. These are in respect of the fairness of the procedure[46], the evidence to be required[47] as also the remedies in form of injunctions[48], damages[49] and other remedies[50].

[45] This was an important aspect pointed out by India, on behalf of the developing countries, during the negotiations prior to the TRIPS Agreement. In fact, the very inclusion of Article 41.5 may be attributed to the representation provided by India, raising concerns over a possible inclusion of separate adjudicatory bodies for intellectual property enforcement within national territories. This communication by the Indian delegation also provided for a realistic and viable alternative on the issue. See the negotiating document, MTN.GNG/NG11/W/40, 5 September, 1989, 'Enforcement of Trade Related Intellectual Property Rights: Communication from India', at p 4, [online: web] accessed 5 July 2017, URL: https://www.wto.org/gatt_docs/English/SULPDF/92080041.pdf

[46] Art. 42, TRIPS

Implementation of Part III is supported by obligations of Members to cooperate in international law enforcement in accordance with Article 69 of the Agreement. Members are obliged to establish and notify contact points in their administrations and be ready to exchange information on infringing goods. Particular emphasis is laid on cooperation and exchange of information between customs authorities "with regard to trade in counterfeit trademark goods and pirated copyright goods" (Cottier: 2005).

2.6.2 Definition of Counterfeiting and Piracy:

The terms 'counterfeiting' and 'piracy', or the acts constituting the same, have not been particularly defined as such in the TRIPS. However, the footnote to Article 51 provides the definition of goods that have to be treated as counterfeit and pirated.

Counterfeit goods: Counterfeit goods have been defined here as:

> … any goods, including packaging, bearing without authorization a trademark which is identical to the trademark validly registered in respect of such goods, or which cannot be distinguished in its essential aspects from such a trademark, and which thereby infringes the rights of the owner of the trademark in question under the law of the country of importation[51].

There are certain things that require to be noted in this definition of counterfeit goods:

i. The counterfeit article has to bear a trademark violation, and this violation has to be in respect of the trademark that has been registered as a certain trademark in the country concerned where such a violation is alleged to have taken place by the intellectual property right holder concerned.

ii. The infringing trademark has to be deceptively similar to the trademark that has been validly registered in the country concerned where such infringement has taken

---

[47] Art 43, TRIPS

[48] Art 44, TRIPS

[49] Art. 45, TRIPS

[50] Art 46, TRIPS

[51] Art. 51, footnote 14 of the TRIPS Agreement

place, so as to say that, such infringing goods that are being imported have to be identical to those that have been registered in the country under whose laws such infringement has taken place.

iii. It covers infringement of counterfeit trademark goods only and does not cover infringement of service marks.

iv. It covers the counterfeit goods as well as the labelling and packaging for such goods.

v. Border measures are evidently not available except under the surmise of a probability of confusion.

vi. The registration of the concerned trademark that has been violated should be valid as on the date of infringement.

Pirated goods: Pirated goods, has been defined in Article 51, footnote 14 of TRIPS as:

> any goods which are copies made without the consent of the right holder or person duly authorized by the right holder in the country of production and which are made directly or indirectly from an article where the making of that copy would have constituted an infringement of a copyright or a related right under the law of the country of importation[52].

There are certain things that require to be noted in the above definition of pirated goods. They are:

i. The pirated article has to bear a copyright violation, and this violation has to be in respect of the copyright that has been registered as a certain copyright in the country concerned where such a violation is alleged to have taken place by the intellectual property right holder concerned.

ii. The infringing (allegedly pirated) product has to be deceptively similar to the copyright that has been validly registered in the country concerned where such infringement has taken place, so as to say that, such infringing goods that are being

[52] Ibid

imported have to be identical to those that have been registered in the country under whose laws such infringement has taken place.

iii. It covers infringements of the nature of pirated copyright goods only, and does not cover infringement of any other nature.

iv. It covers the pirated copyright goods as well as the related rights.

v. Border measures are evidently not available except under the surmise of a probability of confusion.

vi. The concerned copyright that has been violated should be registered and valid as on the date of infringement.

2.6.3 Scope and Application of Counterfeiting and Piracy:

Article 51 of the TRIPS Agreement obligates Member States to set up administrative and judicial procedures to be abided by the customs officials for the suspension of release into domestic circulation of counterfeit goods and pirated articles at the national borders. The main points that transpire from this important provision are:

1. There is no requirement of applying this Section to patented products, industrial designs, layout-designs, or geographical indications. Hence, it may inferred, that it clearly limits the application of this provision for counterfeiting and piracy to violations of trademark and copyright only, and does not usually extend to other forms of IPRs.

2. If border measures are expanded to cover other forms of IPRs, those must be discharged in accordance with the procedures set forth in the Agreement.

3. Members can also provide the same measures against infringing goods destined for export from their own respective territories; but this is not mandatory as in case of importations.

4. The Member States are obligated to provide laws enabling the owner of the IPRs, upon suspicion of infringement of their rights, to lodge a complaint with the

'competent authority' concerned, administrative or judicial. But, nowhere here has it been mentioned as to who the authority should be. This may be due to the reason that each country may have its own peculiarity as regards the authority to deal with such enforcement of IPR infringement issues. It may be also noted that there is no mention of whether multiple authorities in the same country who may deal with this shall have to be approached by the IPR owners, or only one, as designated for the particular violation. In case if it happens to be so, what should be the procedure to deal with this multiple-forum problem.

5. There is no clear mention about what exactly constitutes the "valid grounds" for suspicion except that the infringing trademark, on the goods or its labelling or packaging, has to be unauthorized and cannot be distinguished in its essential aspects from the original trademark.

2.7 Border Measures under TRIPS- salient features:

There were several efforts to enforce intellectual property rights at various levels, but one very important feature of the TRIPS Agreement is the fact that it entrusts the customs authorities as agencies for responding to the perceived menace of intellectual property violations (Matthews 2002: 69). The Member States are obligated to make arrangements for administrative as well as judicial procedures for the suspension of the release of goods at the territorial borders of the respective States concerned.

The idea behind introduction of the provision on border measures is to prevent inward flow of these goods within the territory of a country. Some scholars are of the view that the counterfeit goods are best intercepted at the point of introduction at the border. They are of the opinion that once they are at the distribution channels, enforcement of law becomes more onerous due to the fact that the complaints, in such cases, may have to be filed in different jurisdictions within the same country (Cottier 2005; Geuze 1998: 592).

The TRIPS Agreement, inter alia, lays down under Section 4 of Part III, the provisions for the "special requirements relating to border measures" (TRIPS Agreement). Section 4, containing eleven sections, namely Articles 51 to 61, lays

down the measures that deal exclusively with the issue of the courses of action that need to be taken at the territorial borders of countries by the respective authorities. These provisions of the Agreement primarily provide for the measures ordered by custom administrations with respect to the importation of counterfeit trademarked or pirated copyrighted goods. In the following discussions, we take a look at some of these provisions.

The following are the procedural formalities that have to be maintained by the right holders and the respective customs authorities as provided under the border measures in TRIPS:

The applicant (right holder) has to provide *prima facie* satisfactory evidence of an imminent infringement and also a sufficiently detailed description of the infringing goods to such extent that they are easily recognized by the custom authorities (Article 52). Upon acceptance of the application, the authority informs the applicant as to the duration of the measure taken and then, in accordance with Article 54 of the same agreement, both the applicant and the importer are immediately notified about the suspension of the release of the goods at stake. The burden of proving the infringement is clearly stated to be upon the right holder whose rights are perceived to have been infringed (Article 52).

The applicant is required to keep a security deposit or any other surety with the authorities in order to protect the interests of the defendant as well as the authorities. This measure is presumably to prevent the misuse of the border measures at least in those cases where any action is taken by mistake or wrongfully. But, the requirement of deposit should not unreasonably deter the use of such procedures. Such suspended goods will be released upon the payment of an amount that is sufficient to protect the defendant. The payment of this security should not prevent the right holder to resort to any other form of remedies. The security shall have to be returned if the right holder does not take any step within a reasonable period of time (Article 53).

The notice shall immediately have to be given to the importer and right holder about the suspension of release into the domestic market of such goods (Article 54).

If the customs authorities are not informed within a period of 10 days about the initiation of judicial proceedings, then such goods will be released by them provided that, all the other conditions for import and export have been met. The period of release, however, may be postponed for another 10 days (i.e. in total 20 days) if only the case is appropriate. If such action leads to any decision that is made upon the merits of the case, then upon a request from the defendant only, a proceeding, including a right to be heard, may be initiated (Article 55). In case any importer is wrongfully detained, then in that case the importer, consignee or owner of the goods shall have to be compensated for the injury suffered by such party due to such detainment (Article 56).

The power of inspection is to be conferred upon the competent authorities to help the right holders as well as the importers verify their respective claims regarding the detained goods (Article 57). In case any such determination as to infringement has been successfully made, then such authorities may be conferred with the capacity to inform the right holders about the names and addresses of the consignor, importer and consignee of such goods as also their quantities.

The competent authorities are also empowered, but not obligated, to act *suo motu*, for the suspension of release of the goods, when they are faced with a prima facie evidence of infringement of any form of intellectual property. But, the importer has to be provided with an opportunity to appeal with such administration. The competent (administrative/ judicial) authorities shall have to be gratified of any liability if in good faith any action is engaged in (Article 58).

The authorities are permitted to dispose of the goods in question that infringe the intellectual property rights. Moreover, this also provides that such authorities shall generally not allow re-exportation of such goods in the same unaffected condition as also not allow any other customs authority to decide on them. The traveller is exempted from any liability of infringement when there contains a small quantity of such infringing goods in his personal baggage for his personal use or the same being sent in small consignments, and not for profits (Article 59).

Otten and Wager point out that, in the area of provisional judicial measures, significant attention has been given to see that these stipulations are not used as a

means to harass legitimate trade. Measures such as maintenance of a security or equivalent assurance by the applicant, duration of suspension by the customs authorities pending further action, prompt notification to the affected parties with a prompt right of review, and indemnification of the adversely affected parties where the goods had been wrongfully detained, etc. are evidently reflective of this (Otten and Wager 1996: 406).

The fifth section of the third part of the TRIPS Agreement obligates the States to provide for criminal measures in cases of wilful trademark counterfeiting that is carried out on a commercial scale. The sanctions, in such cases, must be sufficient enough to provide a deterrent as also consistent with the level of penalties that are applied for in the national laws for a crime of corresponding gravity. The criminal remedies in the appropriate cases should also provide for seizure, forfeiture and destruction of such goods, materials and instruments that are used for their production (Article 61).

2.8 US-China Dispute:

The US-China IPR case[53] apparently happens to be among the most important formal disputes that had been exclusively referred to as an intellectual property (enforcement) violation through the World Trade Organization's (WTO) Dispute Settlement Understanding (DSU). It has also been mentioned as being the very first litigation that specifically dealt with intellectual property (IP) enforcement at the WTO (Li: 2010: 640). Till date, the decision in this case is also regarded as being the only one of its kind raised through the WTO DSU, as it is the "first detailed WTO ruling on an IP enforcement dispute" (Watal: 2010: 607). It also bears significance because it was the first instance under international intellectual property regime, when domestic criminal regulations have been subjected to interpretation vis-à-vis national IP laws (Watal: 2010: 616). This was unlike few such disputes that had been brought before the WTO. Although this dispute was raised against China by the US, it has

[53] *China—Measures Affecting the Protection and Enforcement of Intellectual Property Rights*, WT/DS362/R

larger implications that are likely to touch upon the IP enforcement mechanism of countries globally.

The United States' complaint against China to the WTO's Dispute Settlement Panel[54] was mainly based on the following three grounds:-

i. that China denies copyright protection for censored works.

ii. that China's method of disposal (by donation and auction of seized counterfeit goods) violates the TRIPS standards; and

iii. inadequate criminal sanctions for counterfeiting and piracy of trademark and copyrights, other than above certain set thresholds (WTO 2009: 2-3).

The first ground of complaint pertains to the 'protection' of IPRs as provided in China. Although of no less importance, it is not aimed to be covered within the ambit of the topic of this thesis that concerns itself about the 'enforcement' of IPRs alone. The last two grounds of the US complaint pertain to the domestic enforcement of IPRs. Therefore, only these will be briefly stated, referring them as 'A' and 'B' respectively. In so doing, only the Panel's decision and explanation shall be discussed.

A. That China's method of disposal of IPR infringing goods violated TRIPS standards:

The United States (US) alleged that the requirement in the Chinese customs regulations and measures, that IPR infringing goods be released into the channels of commerce within certain situations, were inconsistent with China's obligations under Articles 46 and 59 of TRIPS. The US complained that China was under an obligation under Art. 59 (TRIPS) to have its customs authorities to *ex officio* destroy the IP infringing goods.

The Chinese Customs Rules provided for donation of seized counterfeit goods to charitable organizations as well as auctions of these goods after the infringing

[54] Panel Report, *China—Measures Affecting the Protection and Enforcement of Intellectual Property Rights*, WT/DS362/R (Jan. 26, 2009) (adopted Mar. 20, 2009), [online: web] accessed 5 July 2017, URL: https://www.wto.org/english/tratop_e/dispu_e/find_dispu_cases_e.htm#results

trademarks have been removed. The US complained on both these counts.[55] The Chinese regulations provided that the seized counterfeit goods are to be used in social or public welfare activity[56]. In the event when these could not be used for such a scheme and the holder of the intellectual property rights did not intend to buy these goods, customs authorities could auction them off, after the infringing features have been got rid of [57]. Where the infringing features were impossible to eradicate, customs authorities could then order the destruction of the goods[58]. This implies that, the Chinese regulations comprise of a chronological order that confers upon the authorities the power to proceed for destruction of the seized goods but not before verifying that the other methods of disposal have been exhausted. Article 59 of TRIPS says that,

> "Without prejudice to other rights of action open to the right holder …, competent authorities *shall have the authority* to order the destruction or disposal of infringing goods in accordance with the principles set out in Article 46." (emphasis added)

In this context, the panel found that the obligation on part of the competent authorities, while referring to the term 'shall have the authority' to take certain actions, is not an obligation that competent authorities shall exercise that authority in a specified way, if not stated otherwise[59]. The panel further explained that the "terms of Article 59 do not indicate that the authority to order the specified types of remedies must be exclusive"[60], thereby signifying the fact that this term does not oblige any country to confer any exclusive power for initiating action on such issues upon any authority.

---

[55] Para. 7.197 of Panel Report, Ibid.

[56] Para. 7.193 of Panel Report, Id.

[57] Id.

[58] Id

[59] Para 7.238 of Id

[60] Para 7.240 of Id

B. That China's criminal sanctions for counterfeit trademark goods and pirated copyright goods are inadequate especially because of the (high) qualifying threshold for warranting criminal action:

The US argued that under Art 61 of the TRIPS Agreement provides that for infringements on a commercial scale, criminal penalties must be available[61]. However, there is no established standard as to what constitutes 'commercial scale' as such within the WTO jurisprudence, possibly because this may vary, especially between developed and developing countries. The Chinese Criminal Law under Article 213 provides that when the "circumstances are serious", criminal penalties must be provided.

The US also pointed that, trademark counterfeiting and copyright piracy taking place on a commercial scale in China that do not meet the thresholds laid down in Chinese law, were not subject to criminal procedures and penalties in China – this seemed to be inconsistent with TRIPS requirements as under Articles 41.1 and 61[62].

The Panel's view seems to be an assorted one, favouring none of the parties in this respect. It however discarded the US argument, saying that it was not supported by any proper evidentiary document. It had also remarked that the US had failed to provide any data for products, markets or other factors to demonstrate what constitutes 'commercial scale' in China (WTO 2009).

This decision, howsoever interpreted, has not only defined some of the contours of TRIPS obligations extensively, but also helped prevent the intention of certain developed country Members to manipulate or misconstrue its provisions upon those who may be at the receiving end of technological edge. These countries may end up getting at the wrong end of the stick, and that can only facilitate the advanced nations' interests to raise the international IPR enforcement standard upwards as from the hard-negotiated TRIPS Agreement. Indeed, as one commentator suggested, this decision of the Panel "thus made it difficult for the United States to realize its TRIPS-

[61] Para 7.182 of Id

[62] Ibid

plus intentions not only in this China case but also in the case of other WTO members in the future" (Li: 2010: 648).

2.9 Conclusion

The international intellectual property enforcement mechanism adopted within the TRIPS agreement of the GATT-WTO framework, is a product of decades of multilateral negotiations by countries from both ends of the developmental ladder. The developing countries were barely in a position to produce technologically superior goods or services; they lacked the requisite interest to seek any such agreement; therefore, they never initiated any of such moves. Most of the provisions within Part III of the TRIPS Agreement that deals with 'Enforcement' of IPRs have been borrowed from whatever standards that were contemporary to the EU and US, up to the final phase of the TRIPS negotiations. It has been observed, time and over, that the various powerful developed countries' trade bodies, the multinational pharmaceutical companies and owners of various copyrighted materials have pressurised national governments in developing countries to ratchet up their national intellectual property legislations in order to facilitate large-scale enforcements. All this is being done in order to facilitate their trade interests in the developing countries.

Intellectual property is a legal right of monopoly in the market, and internationally, the market is dominated by corporations from the developed world. Maskus and Reichman point out that access or acquisition of new technologies by developing country firms, especially those from the least developed ones, may be inhibited as the minimum requirement standards may, in effect, give rise to proliferation of legal monopolies. They say:

> It seems increasingly likely that stronger global IPRs could reduce the scope for such firms to acquire new, and even mature, technologies at manageable costs. The natural competitive disadvantages of follower countries may become reinforced by a proliferation of legal monopolies and related entry barriers that result from global minimum intellectual property (IP) standards. Such external restraints on competition could consign the poorest countries to a quasi-permanent status at the bottom of the technology and growth ladder (Maskus and Reichman 2004: 282).

Enforcement of IPRs may be subjected to abuse as well. India, being a developing country, distinctively insisted on potentially wrongful use of enforcement laws and machinery, application of the principles of natural justice and non-acceptance of the idea of employment of state resources for IPR enforcements during the Uruguay round negotiations. As Evans had pointed out that:

> In particular India's submission, its first on international enforcement, reflected its concerns that intellectual property rights might themselves become a barrier to free trade and that abusive practices might accompany the granting of monopoly rights. Consequently, key elements in the submission concerned the need to observe the principles of natural justice in enforcing intellectual property rights, to compensate persons wrongly accused of infringements, and to provide administrative and civil remedies for the abuse of rights. In keeping with its concern that Third-World countries would be penalised by increased regulation, India submitted that developing countries should not be expected to finance whatever mechanisms for enforcement finally emerged from the negotiations (Evans 1994: 170).

Thus, Article 41.5 has been inducted in the TRIPS as a major instrument in order to safeguard the greater interest of the developing countries' resource constraints vis-à-vis taking care of the general enforcement of IPRs. It is also significant in the sense that the enforcement of intellectual property right, being a private right, does not warrant the utilization of public resources that come at the cost of the public exchequer. Thus, it seemingly becomes more important when many among the developing and least developed countries still continue to lack resources even for basic public welfare areas like sanitation, health or education.

The only case on IPR before the WTO's DSU process, the US-China IPR dispute, bears testimony to the importance that countries with comparative technological advantage afford on overseas IPR enforcement standards and procedures. It is also significant for its potential global repercussions, especially in the developing world, which may be influenced by its diverse outcomes that had literally thwarted the US among other developed nations, from imposing their own, heightened framework of IPR enforcement.

Chapter III

Emerging Global Legal Regimes on IP Enforcement

Chapter III

Emerging Global Legal Regimes on IP Enforcement

3.1 Introduction:

The Paris[1] and Berne Conventions[2] were considered to be the primary international laws that governed intellectual property until when the Agreement on Trade Related intellectual Property Rights[3] (TRIPS) came into being. The TRIPS, by dint of the reason of having added a number of additional obligations upon the State parties that adhered to the terms of the General Agreement on Tariffs and Trade (GATT), is considered to be bearing higher standards than its two predecessors. Hence, it can be identified to be Berne and Paris-plus (Otten and Wager 1996: 397). On a similar note, the current trend of setting newer and even higher standards of IP protection and enforcement may generally be treated as TRIPS-plus. In this chapter, such elevated standards of IP enforcement will be discussed.

The established international intellectual property enforcement regime is governed by the TRIPS Agreement. However, a rising number of national and international legislations are strengthening it with new measures. These are contained in agreements that are being pushed by the advanced industrialised nations at various levels – bilateral, regional and plurilateral. Many least and developing counties are being taken as partners on board in such treaties, in lieu of market access. TRIPS was already putting extra burden on many least developed nations that were just introduced to the IP system for a couple of decades now. Being parties to treaties that

---

[1] *The Paris Convention on the Protection of Industrial Property, 1883,* as last revised at the Stockholm Conference, July 14, 1967, 21 U.S.T 1583; 828 U.N.T.S. 303.

[2] *The Berne Convention on the Protection of Literary and Artistic Works, 1886,* as last revised at Paris on July 24, 1971 [amended in 1979], 1161 U.N.T.S. 30.

[3] *Agreement on Trade-Related Aspects of Intellectual Property Rights*, Apr. 15, 1994, *Marrakesh Agreement Establishing the World Trade Organization*, Annex 1C, THE LEGAL TEXTS: THE RESULTS OF THE URUGUAY ROUND OF MULTILATERAL TRADE NEGOTIATIONS 320 (1999), 1869 U.N.T.S. 299, 33 I.L.M. 1197 (1994)

exceed even the TRIPS standards, makes them even more exposed to unjustified demands, that puts many of their vital interests at risk, including developmental needs like access to education or public health requirements like access to essential medicines or treatment. The industrialised nations push for newer and higher levels of IP standards owing to their virtually interminable technological edge in modern times, and enforcement has always been one of their priorities. In the present situation the thrust seems to be on negotiations that are secretive in nature, being used for forging bilateral, regional and plurilateral treaties at various geographically diverse fora that are expected to converge into a global standard in the near future. As discussed in the previous chapter, this was one of the two-fold tactics used by the developed countries led by the US during the run up to the TRIPS negotiations, in order to create a new 'normal' in global IP standards. The current global political confusion began with the Trump administration taking over in the US, marking an egress from the traditional US patronage for plurilateral and regional agreements, globally. There are however ongoing efforts by the leading developing countries like China via plurilateral partnerships like the Regional Comprehensive Economic Partnership Agreement (RCEP) to help set the newer standards. Such concerted endeavour at multifarious fora has generated huge pressure upon the shoulders of developing countries.

In this backdrop, Section 2 introduces the concept of TRIPS Plus. This is followed in Section 3 by a discussion of some of the instances of TRIPS Plus agreements, entered into by the United States with countries around the globe, across different levels of development. In Section 4, the recent legal regime on IP counterfeiting and piracy is discussed by focussing on various EU border measures. Section 5 highlights TRIPS Plus enforcement provisions in certain free trade agreements that are being pursued by the EU at bilateral and regional levels in Africa and Asia. Section 6 contains some cases in point, of specific TRIPS Plus treaties on IP enforcement whose negotiations have been concluded: the Anti Counterfeiting Trade Agreement (ACTA) and the Trans Pacific Partnership Agreement (TPPA). It also discusses about the RCEP which is still being pursued at a regional level. Section 7 shows how the various digital modes of IP enforcement are being used to exceed the TRIPS standards and which potentially have an extra-territorial bearing, in spite of the fact that IP is essentially territorial in nature. Section 8 describes the Indian laws and standards on IP

enforcement. This includes the established rules as well as the changes that have been brought about recently, and also a brief discussion on India's ongoing FTA negotiation with the EU and its possible corollaries. Section 9 examines the implications of such elevated standards of IP enforcement across various national and international levels.

3.2 What is TRIPS Plus

The WTO TRIPS Agreement introduces the *minimum standards* of protection and enforcement of intellectual property; Members are allowed to provide for higher standards of protection and enforcement (Reichman 1995). The standards provided in TRIPS Agreement are essentially those that were existent in the developed country Members of the WTO at the time of it adoption (Mercurio: 2012: 363). Yet, certain flexibilities for implementation were provided for the developing and least-developed Member States which fought hard to win these leeways. Recent trends though portray an intricate phenomenon characterized by a breach of these standards.

Concerns have been articulated regarding endeavours of seeking higher levels of protection and enforcement that go beyond the minimum standards requirement as authorised by TRIPS. These efforts seek to harmonize IP regimes with those countries which are economically and technologically superior (Mercurio: 2012: 364). This harmonization trend is being encouraged in bilateral and regional treaties and in certain recent plurilateral legal initiatives. There is reasonable apprehension among the developing countries that this may lead to further restriction of their policy space. These provisions are termed as TRIPS-plus requirements or measures. They will prevent countries from using the flexibilities embedded within the TRIPS Agreement.

In short, the TRIPS Agreement is generally considered by economically affluent nations as not adequately reflecting the highest standards of IP protection required to promote international trade. The developed economies led by the USA, as a consequence, have followed a clear and explicit bilateral trade policy of going beyond the TRIPS Agreement by including TRIPS-plus provisions in bilateral and free trade agreements pursued by them. This US-led agenda of bilateralism actually reveals

most of the issues it (the US) already talked about at various international fora, even before the TRIPS came into being. Nonetheless, TRIPS-Plus is not solely a bilateral phenomenon; powerful Western economies, primarily the US along with the European Union, have also indulged in regional and plurilateral accords that are modelled in such a manner so as to provide enough leeway in realizing IPR benefits for their own international trading entities.

3.3 Some instances of TRIPS-Plus

The Free Trade Agreements that the US has entered into with the developed countries have shown significant departure from the standards that are mandated under the TRIPS. Some of the provisions of these agreements which relate to the issue of counterfeiting have been listed in Table I.

Table I

TRIPS-Plus Features in Border Measures	**Free Trade Agreements**
1. Obligatory *ex officio* border measures on importation, merely upon suspicion and without any requirement of *prima facie* evidence, and, not subject to procedural safeguards as under Article 55 of TRIPS Agreement.	US- Australia FTA[4], CAFTA[5].

[4] See, *United States – Australia Free Trade Agreement,* [online: web] accessed 5 July 2017, URL: https://ustr.gov/trade-agreements/free-trade-agreements/australian-fta/final-text

[5] See *CAFTA-DR (Dominican Republic-Central America Free Trade Agreement)*, or *CAFTA*, [online: web] accessed 5 July 2017, URL: https://ustr.gov/trade-agreements/free-trade-agreements/cafta-dr-dominican-republic-central-america-fta/final-text

2. Non-wilful and non-profit infringements also made criminal offences.	US-Australia FTA, US Singapore FTA[6]
3. Obligatory *ex officio* measures for goods imported as well as exported.	US-Singapore FTA, US-Columbia FTA[7], US-Peru FTA[8]
4. Obligatory *ex officio* border measures on importation, exportation and 'in transit' goods.	US-Columbia FTA, US Panama FTA[9], US-Morocco FTA[10], US-Chile FTA[11] CAFTA, US-Peru FTA.
5. Provision for initiation of *ex officio* legal action.	US-Columbia FTA, US-Chile FTA.
6. Obligatory initiation of criminal actions even for non-wilful	US-Columbia FTA,

[6] See *United States – Singapore Free Trade Agreement* [online: web] accessed 5 July 2017, URL: https://ustr.gov/trade-agreements/free-trade-agreements/singapore-fta/final-text

[7] See *United States – Columbia Trade Promotion Agreement*, [online: web], accessed 5 July 2017, URL: https://ustr.gov/trade-agreements/free-trade-agreements/colombia-fta/final-text

[8] See *United States – Peru Trade Promotion Agreement*, [online: web], accessed 5 July 2017, URL: https://ustr.gov/trade-agreements/free-trade-agreements/peru-tpa/final-text

[9] See *United States – Panama Trade Promotion Agreement*, [online: web], accessed 5 July 2017, URL: https://ustr.gov/trade-agreements/free-trade-agreements/panama-tpa/final-text

[10] See *United States – Morocco Free Trade Agreement, [online: web]*, accessed 5 July 2017, URL: https://ustr.gov/trade-agreements/free-trade-agreements/morocco-fta/final-text

[11] See *United States – Chile Free Trade Agreement*, [online: web], accessed 5 July 2017, URL: https://ustr.gov/trade-agreements/free-trade-agreements/chile-fta/final-text

violations.	US-Morocco FTA.

Source: United States Trade Representative (USTR) website links to various country-specific texts [online: web], accessed 5 July 2017, URL: https://ustr.gov/trade-agreements/free-trade-agreements

Table I above has shown the various TRIPS-Plus measures that some developing countries have accept in the FTAs that they have negotiated with the developed countries. Some of the measures are as follows:

a. The Customs authorities have been mandated to initiate *ex officio* measures on importation of goods on an obligatory basis. They can do so merely upon suspicion and there is no requirement of any *prima facie* evidence as under Article 52 of TRIPS. Moreover it is also not subject to any of the procedural safeguards provided under Article 55 of the TRIPS Agreement. As illustrated in Table I, this standard has been laid down in the US- Australia FTA[12] and the CAFTA[13] (See, Table I).

b. Provisions are included in FTAs that make the infringements that are unintentional in nature as criminal offences. Even if the infringements have occurred without any profit motive involved, the FTAs solicit to treat them as crimes. This is a clear shift from the requirements under TRIPS Article 61. The US-Australia[14] and the US-Singapore FTA[15] contain such provisions (See, Table I).

[12]Article 17:11:22 of the *US-Australia FTA* states, "Each Party shall provide that its customs authorities may initiate border measures ex officio with respect to imported merchandise suspected of infringing being counterfeit trademark or pirated copyright goods, without the need for a specific formal complaint."

[13] Article 15:11.23 of *CAFTA* states as: "Each Party shall provide that its competent authorities may initiate border measures ex officio, with respect to imported, exported, or in-transit merchandise suspected of infringing an intellectual property right, without the need for a formal complaint from a private party or right holder."

[14]Article 17:11:26(a) of *US-Australia FTA* states: "Each Party shall provide for criminal procedures and penalties to be applied at least in cases of wilful trademark counterfeiting or copyright piracy on a commercial scale. Wilful copyright piracy on a commercial scale includes:

(i) significant wilful infringements of copyright, that have no direct or indirect motivation of financial gain; and
(ii) wilful infringements for the purposes of commercial advantage or financial gain."

c. Some FTAs have laid down provisions that put an obligation upon the customs authorities of the country for resorting to *ex officio* measures during importations as well as exportations. TRIPS lays down under Article 51 that this kind of measure during exports is non-obligatory and may be adopted only during importations. The FTAs that the US has entered into with Singapore[16], Columbia[17] and Peru[18] contain such provisions (See, Table I).

d. Customs have been obligated to take *ex officio* measures for not only the exports and imports, but also at the time when the goods are 'in transit'. This amounts to a stark shift from the TRIPS standards under Article 51 which gives no powers, whatsoever, to the States or their authorities to adopt such measures during the transit route of any goods. On the contrary, footnote 13 to Article 51 of TRIPS expressly prohibits the usage of such measures in transit. The US has managed to include this standard in its FTAs with Columbia[19], Morocco[20], Chile[21], Peru[22], Panama[23] and CAFTA[24] (See, Table I).

---

[15]Art. 16.9:21 of the *US-Singapore FTA* mentions "Wilful copyright or related rights piracy on a commercial scale includes (i) significant wilful infringements of copyright or related rights that have no direct or indirect motivation of financial gain, as well as....."

[16] Article 16.9: 16 of the *Singapore-US FTA* provides that: "Each Party shall provide that its competent authorities may initiate border measures ex officio, without the need for a formal complaint from a private party or right holder. Such measures shall apply to shipments of pirated and counterfeit goods imported into or exported out of a Party's territory, including shipments consigned to a local party……."

[17] The *US-Columbia FTA*, under Article 16.11: 23, states, "Each Party shall provide that its competent authorities may initiate border measures ex officio with respect to merchandise for importation, exportation, or in transit, without the need for a formal complaint from a private party or right holder. Such measures shall be used when there is reason to believe or suspect that such merchandise is counterfeit or pirated."

[18] Article 16: 11.23 of *US-Peru FTA* states as:" Each Party shall provide that its competent authorities may initiate border measures ex officio with respect to merchandise for importation, exportation, or in transit, without the need for a formal complaint from a private party or right holder. Such measures shall be used when there is reason to believe or suspect that such merchandise is counterfeit or pirated."

[19] See Article 16.11:23 of the *US-Columbia FTA*.

[20] The *US-Morocco FTA* in Article 15.11:23 reads as, "Each Party shall provide that its competent authorities may initiate border measures ex officio, with respect to imported, exported, or in-transit merchandise suspected of infringing an intellectual property right, without the need for a formal complaint from a private party or right holder."

e. Some of the FTAs require that the customs are obligated to initiate actions that are juridical in nature. The judicial institution seems to become a non-requirement in this case and there is no way that a fair proceeding can be carried out in case of a misuse of *ex officio* powers by the customs. This seems to be conferring the judicial function of deciding on complex IPR issues by the customs authorities, who lack the technical knowledge to deal in such issues. This is again an exception to since there is no mandate provided by the TRIPS to the customs authorities for acting in such a role. The US-Columbia FTA[25] and the US-Chile FTA[26] contains such provisions (See, Table I).

The FTAs also mandate that actions for criminal offences be initiated for the infringements that are not wilful in nature. This is in contrast to the TRIPS which under Article 61 states that criminal actions may be initiated only for wilful

---

[21] The *Chile-US FTA* provides under Article 17.11:21 as, "Each Party shall provide that the competent authorities are permitted to initiate border measures ex officio, without the need for a formal complaint from a person or right holder. Such measures shall be used when there is reason to believe or suspect that goods being imported, destined for export, or moving in transit are counterfeit or pirated."

[22] See Article 16.11.23 of the *US-Peru FTA.*

[23] Article 15.11:23 of the *US-Panama FTA* provides as, "Each Party shall provide that its competent authorities may initiate border measures ex officio, with respect to imported, exported, or in-transit merchandise suspected of infringing an intellectual property right, without the need for a formal complaint from a private party or right holder."

[24] Article 15:11.23 states as: "Each Party shall provide that its competent authorities may initiate border measures ex officio, with respect to imported, exported, or in-transit merchandise suspected of infringing an intellectual property right, without the need for a formal complaint from a private party or right holder."

[25] Article 16.11:27(d) of the *US-Columbia FTA* provides as, "…that its authorities may initiate legal action *ex officio* with respect to the offenses described in this Chapter, without the need for a formal complaint by a private party or right holder."

[26] Art 17.11:22(e) of *US-Chile FTA* states as, "Appropriate authorities, as determined by each Party, have the authority, in cases of copyright and related rights piracy and trademark counterfeiting, to exercise legal action ex officio without the need for a formal complaint by a person or right holder."

violations. This has been provided in the FTAs of the US with Columbia[27] and Morocco[28] (See, Table I).

Table II

TRIPS-Plus enforcement provisions	**Name of Free Trade Agreements**
1. Provision for the initiation of 'private' criminal actions	US-Singapore FTA
2. Provision for mandatory *ex officio* border measures for the violation of any form of intellectual property.	US-Panama FTA
3. Wilful violation of intellectual property leads to direct criminal	US- Panama FTA

[27] Article 16.11:26 of the *US-Columbia FTA* provides: "Each Party shall provide for criminal procedures and penalties to be applied at least in cases of wilful trademark counterfeiting or copyright or related rights piracy on a commercial scale. Wilful copyright or related rights piracy on a commercial scale includes:

(a) significant wilful copyright or related rights infringements that have no direct or indirect motivation of financial gain; and

(b) wilful infringements for purposes of commercial advantage or private financial gain."

[28]Article 16.11:27(a) of the *US-Morocco FTA* states: "Each Party shall also provide for criminal procedures and penalties to be applied in the following cases, even absent wilful trademark counterfeiting or copyright piracy:

(a) knowing trafficking in counterfeit labels affixed or designed to be affixed to: a phonogram, a copy of a computer program, documentation or packaging for a computer program, or a copy of a motion picture or other audiovisual work; and

(b) knowing trafficking in counterfeit documentation or packaging for a computer program."

penalty for both importation and exportation.	
4. Criminal penalty for intellectual property violation in high pecuniary terms.	US-Jordan FTA[29]
5. Obligatory standards for enforcement of intellectual property rights under 'highest international standards'.	EU-Chile FTA[30]

Source: United States Trade Representative (USTR) website links to various country-specific texts [online: web], accessed 5 July 2017, URL: [https://ustr.gov/trade-agreements/free-trade-agreements]. The *EU-Chile FTA* is available [online: web] at the link mentioned in footnote 30.

Some specific FTAs are significantly in deviation from the TRIPS standards. These FTAs lay down provisions that are not only extreme in their ambit but also severe in nature. Some of these have been discussed below:

i. For the first time, any trade agreement has provided for a remedial criminal action that is private in nature, so as to say, it is not carried out by the State authorities. This is far from any jurisprudential rationale given the fact that IPRs are private rights and the State is the only authority for initiation of criminal actions. The US- Singapore FTA has provided such a measure[31] (See, Table II).

[29] See '*Agreement Between The United States Of America And The Hashemite Kingdom Of Jordan On The Establishment Of A Free Trade Area*', or *US- Jordan FTA* [online: web] accessed 5 July 2017, URL: https://ustr.gov/trade-agreements/free-trade-agreements/jordan-fta/final-text

[30] See, '*AGREEMENT establishing an association between the European Community and its Member States, of the one part, and the Republic of Chile, of the other part*', 30.12.2002, or *EU-Chile FTA* [online: web], accessed 5 July 2017, URL: http://eur-lex.europa.eu/resource.html?uri=cellar:f83a503c-fa20-4b3a-9535-f1074175eaf0.0004.02/DOC_2&format=PDF

[31] Article16.9.21 (b) of the *US-Singapore FTA* states, "Each Party may provide procedures for right holders to initiate private criminal actions. ....."

ii. Provision for mandatory *ex officio* measures at the border has been included in the US-Panama FTA[32]. The concerned authority at the border is authorized to initiate *ex officio* measures for the violation of any form of IPR without formal complaint by any right holder. Border measures may be adopted only in case of trademark and copyright violations as under footnote 14 of Article 51 of TRIPS. If it is used for other forms if IP, it must meet the procedural requirements of TRIPS (See, Table II).

iii. In case of any form of IPR, if any wilful violation has taken place, the State parties become obligated to treat such a violation as a crime. The US-Panama FTA states that it will directly lead to criminal action[33]. Not only this, this provision is meant to include goods that are destined for export as well. The liability level shall have to be commensurate with that of smuggling or similar activities under domestic criminal laws. Article 61 of TRIPS states that there is no obligation for such criminal action other than trademark and copyright matters. There is no requirement to carry out such action in cases of exports (See, Table II).

iv. Criminal penalty has been imposed in case of wilful violation of an IPR in form of monetary penalty, which is significantly high. This stipulation has been included in the US-Jordan FTA[34]. For the first time any trade agreement has mentioned any particular pecuniary term as criminal penalty for IP rights violation (See, Table II).

---

[32] See Article 15.11:23 of the *US-Panama FTA*.

[33] Article 15.11: 26(a) of the *US-Panama FTA* provides as: "..... Each Party shall treat wilful importation or exportation of counterfeit or pirated goods as unlawful activities and provide for criminal penalties to the same extent as the trafficking or distribution of such goods in domestic commerce."

[34] Paragraph 3 of the 'Memorandum Of Understanding on Issues Related to the Protection of Intellectual Property Rights under The Agreement Between The United States and Jordan on the Establishment of a Free Trade Area' stipulates as: "With respect to Article 4.25 of the Agreement, Jordan shall raise its criminal penalties to JD 6,000, so as to meet its obligation to ensure that statutory maximum fines are sufficiently high to deter future acts of infringement."

Free Trade Agreements may sometimes result in provisions that have in them some vital implications. One such provision is included in the EU-Chile FTA. The FTA requires the parties to provide for mandatory provisions for enforcement of IPRs in accordance with 'highest international standards'. This implies that the highest standards that may be available internationally under any treaty or agreement shall have to be applied, notwithstanding the fact that the levels of economic development of the two parties are not the same (See, Table II).

3.4 The European Union Border Regulations:

The EU has been traditionally quite stringent when it came to infringement of intellectual property rights. The EU began its journey of drafting rules on border measures back in the eighties of the last century[35]. The EU had in 1994 enacted a law[36] that basically adopted the definition in the TRIPS Agreement concerning the counterfeit goods. Besides introducing *ex officio* procedures, it also included provisions on infringement of design rights (Petersen-Padberg 2008: 315).

However, until few years ago, the regulation that was in place in the territory of the entire groups of Member States of the Union had provisions that are much harsher than its previous equivalent[37]. Article 2(1) of this Regulation dealt with counterfeit trademark, pirated copyright or design goods, but was not limited to them only. It also included within its ambit other intellectual property rights such as patents, supplementary protection certificates, plant variety rights, designations of origin and geographical indications (Petersen-Padberg 2008: 314).

[35] The first such regulation on border controls was *Council Regulation 3842/86 [1986]* OJ L357/1, which entered into force on 1 January 1988. It allowed trade mark owners to lodge an application with the designated competent national customs authority to request the suspension of release for free circulation, of goods suspected of infringing trade mark rights.

[36] *Council Regulation 3295/94 [1994]* OJ L341/8, which entered into force on 1 July 1995, broadened the domain of protection to include copyright, neighbouring rights, and designs. The introduction of *ex officio* procedures and widening the scope to have the goods subject to other customs procedures were its other features. An amendment to Regulation 3295/94 in 1999 extended the border control measures to patents and supplementary protection certificates.

[37]The European Council until 2013, had in place the *Council Regulation (EC) No. 1383/2003*, dealing with 'Regulation on Customs Action' of 22 July 2003 concerning customs action against goods suspected of infringing certain intellectual property rights and the measures to be taken against goods found to have infringed such rights.

3.4.1 Definition of counterfeit goods under EU Regulation 1383/ 2003:

The EU Regulation 1383/ 2003 was worrisome as regards its domain of defining counterfeit trademark goods. Under Article 2(1) (a), it defined 'counterfeit goods' within the domain of 'goods infringing an intellectual property right', as:

> (i) 'goods, including packaging, bearing without authorization a trademark identical to the trademark validly registered in respect of the same type of goods, or which cannot be distinguished in its essential aspects from such a trademark, and which thereby infringes the trademark-holders' right under Community law, as provided for by Council Regulation (EC) No. 40/94 of 20 December 1993 on the Community trademark or the law of the Member State in which the application for action by the customs authorities is made;
>
> (ii) any trademark symbol (including a logo, label, sticker, brochure, instructions for use or guarantee document bearing such a symbol), even if presented separately, on the same conditions as the goods referred to in point (i);
>
> (iii) packaging materials bearing the trademarks of counterfeit goods, presented separately, on the same conditions as the goods referred to in point (i); (Petersen-Padberg 2008: 331).

However, the context of defining counterfeiting here does not limit itself merely to trademarks, but comes under the domain of intellectual property as a whole. As Petersen-Padberg comments,

> The definition of 'counterfeit' and 'pirated goods' pursuant to art. 2(1) of the Regulation is different to the common understanding of these terms. These two terms are often associated with the copying of an original or intentional large-scale production. However, under the Regulation, goods need not be identical to the original, and infringement of an intellectual property right does not have to be deliberate or on a commercial scale. This is particularly relevant as regards patents, supplementary protection certificates or plant variety rights (Petersen-Padberg 2008: 314).

The most striking features of the above regulation are:

i. Non-requirement of goods as being identical to the original one whose IP rights are suspected to have been infringed as a *prima facie* precondition for the imposition of the regulation.

ii. Infringement of the IP rights need not be deliberate, and,

iii. Such infringements also need not be carried out on a commercial scale.

iv. Infringement of any form of IPRs shall be actionable, and it need not be merely a trademark violation only.

Hence, what appears from these points is that, the present customs regulation in the European Union is perhaps the most stringent border enforcement law of IPR in operation, much more than that offered under the TRIPS Agreement.

3.4.2 Authorized customs actions:

Under this regulation, the definition of 'counterfeit goods' appears to be much broader in scope than that applied under TRIPS Agreement. The span of the definition has been expanded considerably in the following ways:-

i. Such goods do not necessarily have to be identical to the original ones, but, must be the 'same type of goods' when compared with the goods with which the trademark has been registered under the Community Trademark Regulation or the national trademark legislation of the country where the action takes place. Goods that do not bear any trademark symbol but found together with labels or packaging materials are to be considered as one unit, and, the customs authorities can act on such goods.

ii. Customs action is authorized, again, in case of goods that have identical signs, or signs that are not essentially distinguishable from those registered as trademarks. This sense must be understood to mean a sign which is almost impossible to distinguish from the registered trademark. However, the customs authorities may not take actions in cases where the signs are merely similar to registered trademarks, and, there is a likelihood of confusion, wherein the complex question of 'likelihood of confusion' cannot be decided by the customs authorities.

iii. The customs will not render a decision on infringement of trademark rights, which is left to an ex post decision, albeit the customs officers merely require a suspicion of infringement. Action can only be taken on goods suspected of

such infringement which are registered in their respective countries or if, the Community trademark protection exists in such country. No such action can be taken upon goods that are suspected of infringing trademark right of another Member State, which is of relevance for the transit proceedings.

iv. Actions can also be taken by customs authorities even if the articles bearing infringing trademarks, i.e. packaging or labels, and the goods are presented or shipped separately (Petersen-Padberg 2008: 334).

3.4.3 Transit Procedures:

Under the Regulation (EC) No. 3295/94, this regulation was introduced by the European Community in the year 1994 'for the perceived risk that goods infringing intellectual property rights could fraudulently enter the Community market' (Petersen-Padberg 2008: 327).

Under articles 84(1) (a) of the Community Customs Code[38], suspensive procedures including external transit procedure may be initiated. External transit procedure in particular comes within the purview of articles 91-97 of Community Customs Code. When broadly interpreted, 'placed' in a suspensive procedure, customs action under Articles 91 (1) and 1 can be taken at the place where the goods entered the Community territory, in each transit country and in the destined Member State where goods leave the Community territory (Petersen-Padberg 2008: 328). It may be noted here that the placing of goods in transit procedures is in general not considered as an infringing act under the European and national substantive intellectual property laws (Petersen-Padberg 2008: 328).

[38] The basic customs legislation of the EU is provided in the *Customs Code (Council Regulation (EEC) No 2913/92)* and the Code's implementing provisions *Commission Regulation (EEC) No 2454/93* [online: web] accessed 5 July 2017, URL: http://ec.europa.eu/taxation_customs/business/customs-procedures/general-overview/community-customs-code-cc-implementing-provisions-guidelines-current-legal-provisions_en

Customs action on counterfeit goods from third countries in transit is admissible in EU since there is risk that 'counterfeit goods placed under the external transit procedure may be fraudulently brought onto the Community market'[39].

3.4.4 Recent changes in EU Law- landmark CJEU decision and new regulation:

Owing to worldwide criticisms and lodging of complaint at the TRIPS Council followed by approaching the dispute settlement procedure by India and Brazil at the WTO. Thereafter, the European Union had brought in newer regulations with perceivably minor changes in its previously held legal position vide a certain provision. However, the apex court of the EU had in 2011, passed a judgement that effectively did away with the contemporary procedure applied by the EU customs officials for IP infringements in case of goods in transit. Both of the remarkable judicial conclusion as well as the alterations in the EU regulations have been outlined underneath.

3.4.4.1 Landmark judgement by CJEU:

In May 2010, India[40] and Brazil[41] individually took up the issue of seizure of legitimate generic medicines in transit through the EU for consultations at the WTO Dispute Settlement Board against the EU and Netherlands in two separate cases. These cases have neither witnessed formation of any dispute settlement panel, nor withdrawal or a mutually satisfactory solution until this date. However, soon after the lodging of these cases at the WTO, a couple of cases came up involving similar matters before the Court of Justice of the European Union (CJEU), the highest judicial

[39] Para 34, *The Polo Lauren Company LP v. PT. Dwidua Langeng Pratana International Freight Forwarders*, ECJ 6.4.2000, Case C-383/98, ECR [2000]; I-2519, GRUR Int. 2000, 748; IIC 2001, 209 or *Polo/Lauren* — as cited in Petersen-Padberg 2008: 328.

[40] See, *DS408: European Union and a Member State — Seizure of Generic Drugs in Transit*, [online: web] accessed 5 July 2017, URL: https://www.wto.org/english/tratop_e/dispu_e/cases_e/ds408_e.htm

[41] See, *DS409: European Union and a Member State — Seizure of Generic Drugs in Transit*, [online: web] accessed 5 July 2017, URL: https://www.wto.org/english/tratop_e/dispu_e/cases_e/ds409_e.htm

authority of the European Union. It delivered a landmark verdict that presently acts as the case law for the customs procedures for potential European IP infringement in case of goods in transit. The case pertains to potential infringement of IPRs granted within the EU by goods originating from and destined outside the EU, in transit through the EU, that are suspected of entering the EU territory.

The CJEU ruling essentially meant that suspected goods in transit through the EU cannot routinely be considered as infringing IPRs within the EU, unless there was sign that the goods could be deceptively diverted into the EU territory. This judgment is significant because, this is arguably the first time that the highest EU judicial authority has ruled in favour of natural justice as envisaged under TRIPS, in a matter involving IPR infringement by certain goods in transit that had originated from and were destined for countries that are located outside the EU.

The Court, in the joint cases of *Koninklijke Philips Electronics NV v Lucheng Meijing Industrial Company Ltd, Far East Sourcing Ltd, Röhlig Hong Kong Ltd, Röhlig Belgium NV, (C-446/09)* and *Nokia Corporation v Her Majesty's Commissioners of Revenue and Customs (C-495/09)*[42], ruled that:

> *goods coming from a non-member State which are imitations of goods protected in the European Union by a trade mark right or copies of goods protected in the European Union by copyright, a related right or a design cannot be classified as 'counterfeit goods' or 'pirated goods' within the meaning of those regulations merely on the basis of the fact that they are brought into the customs territory of the European Union under a suspensive procedure*; …[43]

It drew attention to the possibility when the goods may infringe upon the rights of IPR owners in the EU, as well. In this context, the Court referred that:

> … *those goods may, on the other hand, infringe the right in question and therefore be classified as 'counterfeit goods' or 'pirated goods' where it is proven that they are intended to be put on sale in the European Union, such*

[42] Court of Justice of the European Union (2011), JUDGMENT OF THE COURT (First Chamber) 1 December 2011 (*), In Joined Cases C-446/09 and C-495/09 *Koninklijke Philips Electronics NV v Lucheng Meijing Industrial Company Ltd, Far East Sourcing Ltd, Röhlig Hong Kong Ltd, Röhlig Belgium NV, (C-446/09)* and *Nokia Corporation v Her Majesty's Commissioners of Revenue and Customs (C-495/09)*, ECLI:EU:C:2011:796

[43] See, Ibid.

> *proof being provided, inter alia, where it turns that the goods have been sold to a customer in the European Union or offered for sale or advertised to consumers in the European Union, or where it is apparent from documents or correspondence concerning the goods that their diversion to European Union consumers is envisaged …*[44];

In addition, the Court distinctly earmarked the clues, upon which the suspicion by the customs authorities may be based. Thus, it specified them as:

> *… those indications may include, inter alia, the fact that the destination of the goods is not declared whereas the suspensive procedure requested requires such a declaration, the lack of precise or reliable information as to the identity or address of the manufacturer or consignor of the goods, a lack of cooperation with the customs authorities or the discovery of documents or correspondence concerning the goods in question suggesting that there is liable to be a diversion of those goods to European Union consumers …*[45].

Nevertheless, shortly after this decision of the CJEU, a new customs regulation on pan EU infringements of intellectual property, Council Regulation (EC) No. 1383/2003, was passed by the European Council. It is this regulation that is currently in force across the EU at present.

3.4.4.2 The current EU law – Council Regulation (EC) no. 608/ 2013:

In June 2013, a new regulation was passed by the European Council. The new EU regulation for customs IP infringement matters is Regulation 608/ 2013[46] that effectively replaces the previous regulation 1383/ 2003. Paragraph 11 of the regulation refers particularly to the Doha Declaration on TRIPS and Public Health[47]. It states:

> Under the 'Declaration on the TRIPS Agreement and Public Health' adopted by the Doha WTO Ministerial Conference on 14 November 2001, the

[44] Ibid

[45] Ibid

[46] See, *REGULATION (EU) No 608/2013 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 12 June 2013 concerning customs enforcement of intellectual property rights and repealing Council Regulation (EC) No 1383/2003*, [online: web] accessed 5 July 2017, URL: https://ec.europa.eu/anti-fraud/sites/antifraud/files/docs/body/r608_2013_en.pdf

[47] See *Declaration on the TRIPS agreement and public health* (World Trade Organisation 2001)

> Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all. Consequently, in line with the Union's international commitments and its development cooperation policy, with regard to medicines, the passage of which across the customs territory of the Union, with or without transhipment, ware housing, breaking bulk, or changes in the mode or means of transport, is only a portion of a complete journey beginning and terminating beyond the territory of the Union, customs authorities should, when assessing a risk of infringement of intellectual property rights, take account of any substantial likelihood of diversion of such medicines onto the market of the Union.

However, this recital has been found inadequate and failing the very objective of the international public health commitment that it mentions. It is not only ambiguous but also does not mention any clear set of directions or guidance for the customs authorities to follow.

EU regulations 1383/2003 and 608/2013 are very different in a number of ways. The following table (Table III) shows the distinction between the former and the current customs regulation for IPR infringements in EU:-

Table III: Distinction between EC regulations 1383/2003 and 608/2013

Areas of difference	Regulation 1383/2003	Regulation 608/2013
Different kinds of persons in a given situation necessitating customs action	Only one definition of a 'right holder', as: the holder of a trademark, copyright or related right, design right, patent, supplementary protection certificate, plant variety right, protected designation of origin, protected geographical indication or a representative of the right holder or authorised user.	Four new inclusions: 'right holder', i.e. the holder of an IPR [Article 2.8]; 'holder of the decision', i.e. the holder of a decision granting an application [Article 2.8.13]; 'holder of the goods', i.e. the person who is the owner of the goods suspected of infringing an intellectual property right or who has a similar right of disposal, or physical control, over such

		goods [Article 2.8.14]; and also the 'declarant'— the declarant as defined in point (18) of Article 4 of Regulation (EEC) No. 2913/92 [Article 2.8.15].
Extent of information from customs authorities that may be used by right holders	information to initiate proceedings only for the purpose of establishing whether the goods were counterfeited or pirated	information may also be used to initiate proceedings to determine whether an intellectual property right has been infringed, to initiate criminal proceedings, to seek compensation and to obtain the owner's consent for destruction of the goods [Article 21]
Areas of IPR protection	trademark, copyright or related right, design right, patent, supplementary protection certificate, plant variety right, protected designation of origin, protected geographical indication [Article 2 (1)]	Newly - protected rights: utility designs, trade names and the topography of semiconductor products. Devices designed primarily for the purpose of enabling or facilitating the circumvention of technological measures that prevent or restrict acts in respect of works which are not authorised, i.e. the so-called 'circumvention devices'. [Recital (5)]
Recognition of trademarks under international treaties	No mention	Trademarks that are registered under the Madrid Agreement and Madrid Protocol have been included. [Art. 2 (2) c]

Source: (Hasik and Łapinska 2015)

3.4.5 EU Customs Action Plan:

The European Council has in recent times set in motion a scheme to draft and adopt action plans for the EU customs authorities that aim to oversee the various manners in which IPR infringements may be tackled by the customs authorities. In March 2009,

the Council adopted a resolution[48] upon this contemplation that was to cover the years from 2009 to 2012. It aimed at working on the existing IPR legislation, cooperation between various EU customs authorities and with right-holders, advancing international cooperation on IPR enforcement, publicise problems in online sales and training customs officers on an ad hoc basis. This plan also sought preparations for reviewing the former customs regulation on IPR enforcement and an annual review of border detentions by the customs (Council of the European Union 2009).

Its current plan was adopted via another resolution of December 2012, on EU Customs Action Plan to Combat IPR Infringements for the years 2013-2017[49]. The current Action Plan aims to oversee the effective application of the new EU regulation No. 608/2013, tackle the chief developments in the trade in IP infringing goods both in the EU as well as in the global supply chain and build up cooperation with the European Observatory and the law enforcement authorities in general (Council of the European Union 2012: 4).

3.4.6 The European Commission's COPIS Database:

In accordance with Article 32 of the Regulation (EC) No 608/2013[50], the EU maintains a central database called COPIS[51] which is supposed to function as 'single information system' of all the 'applications for action'[52] on IPR infringements that come before the customs officials across EU. It may be accessed by all the EU

[48] Council of the European Union (2009), *COUNCIL RESOLUTION of 16 March 2009 on the EU Customs Action Plan to combat IPR infringements for the years 2009 to 2012*, (2009/C 71/01)

[49] Council of the European Union (2012), *Resolution on the EU Customs Action Plan to combat intellectual property rights infringements (2013 to 2017)* , 3208th COMPETITIVENESS (Internal Market, Industry, Research and Space) Council meeting Brussels, 10 December 2012

[50] See 'Purposes' and 'Legal basis/ Lawfulness' in DPO-3670.2, *Infra*

[51] See, European Commission (2015), Register of the Data Protection Officer, "DPO-3670.2 Processing in the COPIS database of data contained in application for action for the enforcement of intellectual property rights by customs authorities in the Member States", Directorate-General: DG Taxation and Customs Union , Controller: LARRIEU Pierre-Jacques, Publication: 07-07-2015, hereinafter called as 'DPO-3670.2'.

[52] See DPO-3670.2, *Ibid*

Member States. The database is intended for 'the enforcement of intellectual property rights by customs authorities in the Union. It mainly aims to harmonise the actions taken in every IP infringement case by customs officials across the different national jurisdictions in the EU by exchanging information among them. It either connects their national database to it, or directly makes the COPIS their own database. The database requires updating the decisions granting applications (including the application and its attachments), the decisions extending the period during which the customs authorities are to take action, the decisions revoking the decision granting the application or amending it, and, the suspensions of decisions granting an application (Articles 6(3), 14 and 31 respectively, Regulation (EU) 608/2013).

3.4.7 EC Notification on the customs IPR enforcement on goods in transit:

The European Commission updated, via a notification, the EU guidelines for the customs enforcement of IPR in order to publicise the repeal of regulation 1383/2003 and its substitution by regulation 608/2013. It also includes the "trade mark package" under Regulation (EU) 2015/2424 for "goods coming from third countries without being released for free circulation, including goods in transit, through the territory of the EU" (European Commission 2016a: 4). This notice of the commission replaces the "Guidelines of the European Commission concerning the enforcement by EU customs authorities of intellectual property rights with regards to goods, in particular medicines, in transit through the EU." These guidelines used to address specifically the concerns raised by India and Brazil as regards the EU's IPR standards on (generic) medicines legitimately in transit through the EU. Para 3.3 of this notification contains specific reference to the issue of facilitation of 'the smooth transit of legitimate medicines across the EU' as having been covered under three different legislations[53], including regulation 608/2013 (European Commission 2016a: 4, 5).

[53] The specific legislations that are being referred to, besides *Regulation (EU) No 608/2013* (recital 11), are *Regulation (EU) 2015/2424* (recital 19) and *Directive (EU) 2015/2436* (recital 25). See, European Commission 2017a, *Infra.*

3.4.8 Report on implementation of Regulation 608/ 2013:

Very recently, the European Commission's report[54] on the implementation of the regulation 608/2013 between 2013 and 2017 has been published. The report prepared under Art. 37 of the regulation, explicitly admits that the new regulation followed across the union goes beyond the TRIPS requirements. It says:

"The Regulation even implements the non-binding requirements of TRIPS in terms of border enforcement such as controls on counterfeit goods in export and transit, thereby reflecting the EU's commitment to high protection of IPR" (European Commission 2017a: 5). The findings of this report indicate that the new EU regulation that "provides for a wide range of protection and procedures" is being applied quite suitably all across the territory of the union, and there was no basis for amending any of its provisions currently. However, there were apparently no major incidents of generic medicine consignments being apprehended at the European ports, according to the aforementioned report (European Commission 2017a: 20).

The EU border IP enforcement regime thus contains lot of reasons to be worried about. The former regulation was clearly in violation of the TRIPS principles and further superseded it considerably. It also violates Article V of the General Agreement on Tariffs and Trade (GATT) that deals with 'freedom of transit'[55]. The present resolution, albeit includes a very brief proviso, does little to strike a chord with the EU's obligations under the TRIPS Agreement and the GATT. It, along with its predecessor, stands out to be merely procedural and does little to clarify on the criteria being used for the detention of alleged IPR infringing goods, which is guided by the previous resolution. It nevertheless has a clear provision mandating customs authorities to detain goods in transit upon suspicion of infringement of IPR granted within the EU. Moreover, considering the application of the previous resolution in

[54] See, European Commission 2017a, 'REPORT FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT AND THE COUNCIL on the implementation of Council Regulation (EU) No 608/2013', Brussels, 15.5.2017 COM(2017) 233 final, [online: web] accessed 5 July 2017, URL: http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52017DC0233&from=en

[55] See, GATT, ARTICLE V, 'FREEDOM OF TRANSIT' [online: web] accessed 6 July, 2017, URL: https://www.wto.org/english/res_e/booksp_e/gatt_ai_e/art5_e.pdf

case of the repeated and random seizures of Indian generic medicine shipments[56] passing through the countries within the EU territory, the picture appears even clearer at this juncture- that the goods transhipments from outside the EU that have any bearing on IPRs in the EU, continue to find it hard to pass through the EU territorial limits while in transit. A routine sense of fear looms large for anybody opting to use the EU as a transit route. Incidents of seizures have reduced since the CJEU ruling in the *Philips/ Nokia case*. Yet, general goods trade with other countries through the EU territorial routes, or the supply of legitimate generic medicines to the underprivileged in developing countries that cannot afford the costly branded ones, are not beyond perils in the near future. Some such inferences have also been discussed in Chapter V.

3.5 TRIPS Plus in European Economic Partnership Agreements (EPAs):

Europe had its own share of history in regulatory overreach. Although the United States has been the first to scrutinise trading practices of countries across the world, Europe has its own history of having made moves almost in a similar manner. In the eighties of the last century itself, the EU had seen the passage of an overseas regulatory legislation called 'New Commercial Policy Instrument' that would oversee 'illicit trade and commercial practices' of countries outside the Union[57]. European Union economies do not seem to have been satisfied with the enforcement obligations as laid down under the TRIPS Agreement. The fact that they indeed wanted an upward revision in stringency levels is very much understandable from the kind of moves that they had to make within the first ten years of its entering into force.

In 2003, the European Commission had conducted a survey to assess the prevailing situation on the enforcement of intellectual property rights in third countries[58] and

[56] Indian shipments of generic drugs have been seized at the Netherlands recently, by the customs authorities in that country. Please refer to the following Chapter (Chapter IV), for discussions on this issue.

[57] This EU-wide legislation was *EU Council Regulation EEC No 2641/84* O.J 1984, L 252/1.

[58] Those countries that are outside the European Union are apparently referred to as 'third countries'.

identify the most challenging areas of IPR infringements and the countries where it happen[59]. The survey is continuing systematically and identifies such 'priority countries' since 2006[60]. In 2014, the survey had been carried out by a specialised IPR agency of the Commission launched in 2009[61], the EU Observatory on Infringements of Intellectual Property Rights (IPR).[62] In 2005, the European Commission prepared its 'Strategy for the Enforcement of Intellectual Property Rights in Third Countries'[63]. This apparent shift in policymaking however owed to a perception that there were too much IPR violations in countries outside the EU and therefore some policy had to be undertaken to contain them. This was closely followed by underpinnings in the European Commission's 'Global Europe' strategy[64] that not only acknowledged IPR as a new area of growth but also clearly pointed out at intellectual property enforcement as having swelled up into a worldwide problem for the owners of various forms of intellectual property. It stated that:

> The value of new market access for EU businesses is seriously reduced without sufficient IPR protection provided by the countries concerned. IPR violations deprive right-holders of the revenue from their investment and ultimately put at risk the viability of the most innovative and creative companies. The biggest challenge at present is the enforcement of existing commitments, particularly in emerging economies[65].

One of the notable aspects of this strategy is its laying credence to the issue of global counterfeiting and piracy and the imminent efforts to tackle it in collaboration with

---

[59] See *Overview: Survey on enforcement of intellectual property rights in third countries*, visited 7 July 2017, URL: http://trade.ec.europa.eu/doclib/docs/2004/august/tradoc_113229.pdf

[60]See, *Report on the protection and enforcement of intellectual property rights in third countries,* Commission Staff Working Document, Brussels, 1.7.2015, SWD (2015) 132 final, European Commission: Brussels, p 1

[61] See, Commission Press Release, 'Internal Market: Commission launches European Observatory on Counterfeiting and Piracy', IP/09/497, 30 Mar. 2009. (European Commission Press Release Database 2009)

[62] Ibid n. 45, p 1

[63] *Strategy for the Enforcement of Intellectual Property Rights in Third Countries*, (2005/C 129/ 03) OJ C129

[64] See European Commission (2006), *Global Europe: competing in the world* [online: web] visited 5 July 2017, URL: http://trade.ec.europa.eu/doclib/docs/2006/october/tradoc_130376.pdf

[65] See Ibid, p. 7.

economically corresponding countries that are outside the EU.[66] It further stresses upon the need to induct stringent IP enforcement provisions of the likes of the EC Enforcement Directive[67].

IP enforcement measures have been inducted within the various provisions of the Economic Partnership Agreements (EPAs) negotiated by the European Union (EU) with African, Caribbean, and Pacific (ACP) states. Some such agreements have also been negotiated with the Central and South American states besides Asian countries. Some of these, that seem to be relevant for being TRIPS Plus by their standards, are being briefly discussed here.

3.5.1 Africa:

The quest for entering into trade agreements in Africa has been a long time agenda of the European Union; it had been clearly mentioned in the Cotonou Agreement[68] concluded in the year 2000. The chapter on 'New Trading Arrangements' not only refers to taking 'all necessary measures to conclude Economic Partnership Agreements, but also asks for removing 'barriers to trade between them'[69]. It further mandates that "these new trading arrangements shall be introduced gradually"[70]. Chapter 5 of the Agreement that covers 'Trade related Areas' has a precise provision

[66] Thus, it further notes, "The Commission has devoted considerable resource to fighting counterfeiting and improving IPR enforcement in key third countries such as China. We have stepped up co-operation with partners like the US and with Japan on IPR ….." See European Commission (2006), Ibid, at p 7-8.

[67] It suggests that, "FTAs should include stronger provisions for IPR and competition, including for example provisions on enforcement of IP rights along the lines of the EC Enforcement Directive." See European Commission (2006), Ibid, at p 11.

[68] See, "*The Partnership Agreement between the members of the African, Caribbean and Pacific Group of States of the one part, and the European Community and its Member States of the other part"* or the *Cotonou Agreement*, O.J. L 287, 04 November 2010.

[69] See *Cotonou Agreement*, Chapter 2 'New Trading Arrangements', Article 36.1. It states: "… the Parties agree to take *all the necessary measures to ensure the conclusion of new WTO-compatible Economic Partnership Agreements*, *removing progressively barriers to trade between them* and enhancing cooperation in all areas relevant to trade". (emphasis added)

[70] See Ibid, Article 36.3.

on intellectual property rights[71]. . Art. 46.1 states that, "Without prejudice to the positions of the Parties in multilateral negotiations, the Parties recognise the need to ensure an adequate and effective level of protection of intellectual, industrial and commercial property rights, and other rights covered by TRIPS including protection of geographical indications, in line with the international standards with a view to reducing distortions and impediments to bilateral trade." The formal entering into such trading arrangements has been mainly carried out region wise. Thus, seven main regions have been identified. They are: (i) West Africa, (ii) Central Africa, (iii) Eastern and Southern Africa (ESA); (iv) East African Community (EAC), (v) the Southern African Development Community (SADC) EPA Group, (vi) Caribbean (CARIFORUM) countries and, (vii) the Pacific region. (European Commission 2017b) Amongst these, the EU's treaty with the CARIFORUM States and its interim trade agreement with the Southern African Development Community (SADC) have been found to contain TRIPS Plus provisions. These have thus been discussed below.

3.5.1.1 CARIFORUM:

The European Union (EU) has concluded an Economic Partnership Agreement (EPA) with the CARIFORUM States (excluding Haiti)[72] in December 2007, which was signed in October 2008[73]. Haiti signed the treaty at a later time, in November 2009[74], but is yet to ratify it. This EPA contains a number of IP obligations, including those on enforcement that exceed the TRIPS standards. The Chapter on 'Intellectual Property and Innovation', for example, contains some such TRIPS Plus provisions. Article 131 (2) that forms the 'context' of the treaty suggests recognising that "protection and enforcement of intellectual property plays a key role in fostering

[71] Article 46 of the *Cotonou Agreement* deals with intellectual property rights. See Ibid, Article 46.

[72] These CARIFORUM states consists of Antigua and Barbuda, The Bahamas, Barbados, Belize, Dominica, Grenada, Guyana, Jamaica, Saint Lucia, Saint Vincent and the Grenadines, Saint Kitts and Nevis, Surinam, Trinidad, Tobago, and the Dominican Republic.

[73] See, *ECONOMIC PARTNERSHIP AGREEMENT between the CARIFORUM States, of the one part, and the European Community and its Member States, of the other part*, OJ (2008) L 289/I/3

[74] See, the European Commission website, TRADE, 'Countries and Regions: Caribbean' [online: web] accessed 5 July 2017, URL: http://ec.europa.eu/trade/policy/countries-and-regions/regions/caribbean/

creativity, innovation and competitiveness, and are determined to ensure increasing levels of protection appropriate to their levels of development." While it is debatable to contend that IP actually has a substantial role in creativity or innovation, TRIPS does not mandate to ensure any increase in levels of IPR protection that could be subsequently enforced in future.

TRIPS Plus has also been suggested in the Chapter on intellectual property. It mandates the prevalence of this treaty over the existing international IP enforcement standards of the TRIPS Agreement[75]. Exports and goods in transit have been included, besides expanding the scope of various IP infringements as additional features in respect of border measures on intellectual property rights[76].

The EU- CARIFORUM treaty holds enormous significance in terms of future framework of IP negotiations and conclusions. It is not only the first such agreement to enter into with any group of countries in that region, but also supposedly sets a higher benchmark for IP enforcement in any of the future EU partnership agreements, globally.

3.5.1.2 Southern African Development Community:

The European Union had entered into an interim agreement with the Southern African Development Community (SAEPA) in 2009[77]. In June 2016, the EU signed an EPA[78]

[75] The very first provision of subsection 3, which is on IP enforcement, says: "Without prejudice to their rights and obligations under the TRIPS Agreement, and in particular of its Part III, the EC Party and the Signatory CARIFORUM States shall provide for the measures, procedures and remedies necessary to ensure the enforcement of the intellectual property rights covered by this Section." (Art. 151.1)

[76] Art.163 of the *EU–CARIFORUM EPA* provides for the 'Border measures' on intellectual property.

[77] *Interim Agreement with a view to an Economic Partnership Agreement between the European Community and its Member States, of the one part, and the SAEPA States, of the other part*, Council document no. 14062/08 of 2 February 2009.

[78] '*Economic Partnership Agreements Between The European Union And Its Member States, Of The One Part, And The SADC EPA States, Of The Other Part*', or the *EU-SADC EPA* [online: web] accessed 5 July 2017, URL: http://trade.ec.europa.eu/doclib/docs/2015/october/tradoc_153915.pdf

with six countries of the Southern African Development Community (SADC)[79]. Although these countries are yet to ratify the treaty, it contains some sorts of IP enforcement provisions that are TRIPS Plus. Article 16 of the agreement not only warrants 'measures for the enforcement of such rights against infringement thereof,' it also says that these shall have to comply with 'provisions of the international agreements to which they are parties'[80]. This provision has an element of TRIPS Plus in it. The TRIPS does not have any mandatory requirement for any Member of the WTO to comply with any international agreement, although it does offer WTO Members the option of being party to any such agreement as long as it does not depart from the TRIPS agreement itself.

3.5.2 Asia:

The European Union has been steadily exporting to Asia their own schema of legislations and other norms on intellectual property rights that especially apply for the online environment. They had entered into agreements with countries like Singapore and Korea, wherein they had tactfully infused obligations for online protection of intellectual property[81] which is not a compulsion under the TRIPS Agreement.

---

[79] The Southern African Development Community consists of fifteen countries. The six among them who signed the EPA with the EU are Botswana, Lesotho, Mozambique, Namibia, Swaziland and South Africa. See EC Press release, 'EU signs Economic Partnership Agreement with Southern African countries', Brussels 10 June 2016, [online: web] visited 5 July 2017, URL: http://trade.ec.europa.eu/doclib/press/index.cfm?id=1509

[80] Article 16, *EU –SADC EPA*

[81] Both Singapore and Korea in their trade agreements with the European Free Trade Association (EFTA) had accession to the WIPO internet treaties, namely the *WIPO Copyright Treaty* and *WIPO Performances and Phonograms Treaty*, having inducted as one of the provisions. While the *EFTA-Singapore 2003* had asked for a deadline of January 2005 for the said accession, the *EFTA-Korea 2006* had a deadline of 2008. See 'International Conventions', Annexe XII, Article 2 of *Agreement Between the EFTA States and Singapore*, hereinafter referred to as *EFTA-Singapore agreement*, [online: web] visited 5 July 2017, URL: http://www.commonlii.org/sg/other/treaties/2003/2/ESFTA_Agreement.html. The fact that such TRIPS Plus provisions have been included within the agreement has also been acknowledged by trading bodies of Singapore. See 'Singapore Exporters 2014 Europe (ESFTA)', URL: http://insis.com/free-trade-agreements/ESFTA.pdf. Also see, text of the *EU-Korea FTA*, see *infra* at 82.

3.5.2.1 EU-Korea FTA:

The free trade agreement (FTA) between the EU and Korea[82] bears significance for being the first FTA entered by the EU with any Asian country. The EU free trade agreement with Korea has enough TRIPS Plus provisions, the most noteworthy of them being the detailed provisions on criminal IP enforcement which is probably the first of its kind provided for in any FTA[83]. It has also been observed that some of the measures on IP enforcement in this agreement have been drawn from the Anti Counterfeiting Trade Agreement (ACTA) that the South Koreans and Europeans had been negotiating together and at around the same time (Araujo 2013: 462). Particularly, the rules on criminal IP enforcement that were initially proposed in ACTA seem to be similar to the ones in EU-Korea FTA[84]. It obliges the parties to commit to both the WIPO internet treaties of 1996[85].

3.5.2.2 Singapore-EFTA FTA:

The Singapore-EFTA free trade agreement[86] was finalised and concluded in 2003. It overlays the set of Agreements governed by the WTO, including the TRIPS

---

[82] *FREE TRADE AGREEMENT between the European Union and its Member States, of the one part, and the Republic of Korea, of the other part*, OJ (2011) L 127; hereinafter, referred to as *EU-Korea FTA*.

[83] In the *EU-Korea FTA*, Section C deals with 'Enforcement of Intellectual Property Rights', of which, Subsection B (Articles 10.54 to 10.61) specifically provides for 'criminal enforcement' of intellectual property.

[84] Article 6.13.4 (g) commits the parties to 'strong and efficient intellectual property rights enforcement by customs authorities, regarding imports, exports, re-exports, transit, transhipments and other customs procedures, and in particular as regards counterfeit goods'. The inclusion of customs authorities' transit procedures is clearly beyond TRIPS requirements.

[85]Chapter Ten, Section B, Subsection A, Article 10.5 (c) and (d) of the treaty obliges the parties to comply with WCT 1996 and WPPT 1996 respectively.

[86] See, *Agreement Between the EFTA States and Singapore*, hereinafter referred to as *EFTA-Singapore agreement, supra* at fn. 81

Agreement, and any other international agreement[87]. This agreement clearly includes provisions that are essentially beyond what the TRIPS Agreement provides for. It requires the parties to provide for IP enforcement measures for counterfeiting and piracy in accordance with Article 54, that provides for 'Protection of Intellectual Property', along with Annexe XII that includes most of those aspects that exceed the TRIPS mandate. Singapore is also required to become a party to the WIPO internet treaties, namely the WIPO Copyright Treaty 1996 and WIPO Performances and Phonograms Treaty 1996, by January 1, 2005[88]. Membership to both these treaties is not mandatory till date; they provide for online protection and enforcement of IPRs and the use of technological protection measures for protection and enforcement of IPRs- something that was not included within the TRIPS. Singapore, by dint of this agreement, is also obliged to become a signatory to an international trademark resolution that had been adopted by the WIPO in September 1999[89]. One of the most interesting features of this FTA is its apparent resolve for the initiation of negotiations, mutual or otherwise, for setting newer IP standards in prospective international agreements[90].

It visibly obliges the country parties to join in forums for negotiating bilateral, plurilateral or any other international arrangement, besides prominent international organisations like WTO or WIPO, on matters concerning harmonisation and enforcement of IP. This seemingly is vital to build up a consensual process in drawing

[87] Article 4, that covers 'Relationship to Other Agreements', states: 'The provisions of this Agreement shall be without prejudice to the rights and obligations of the Parties under the Marrakesh Agreement Establishing the World Trade Organization and the other agreements negotiated thereunder (hereinafter referred to as "the WTO Agreement") to which they are a party and any other international agreement to which they are a party.

[88] See Annex XII, Article 2(2), *EFTA– Singapore agreement*.

[89] As under Annexe XII, Article 6, parties are required to undertake that they shall give effect to the 'WIPO Joint Resolution on Well -Known Marks' by January 1, 2005.

[90] Annex XII, Article 2.3, that relates to IP, states:

'The *Parties agree* to hold, without undue delay, expert consultations, *upon request of any Party*, on activities relating to the *identified or to future international conventions on harmonisation, administration and enforcement of intellectual property rights and on activities in international organizations*, such as the WTO and the World Intellectual Property Organization (WIPO), *as well as on relations of the Parties with third countries* on matters concerning intellectual property.' (emphasis added)

such developing countries onto an understandably continuous futuristic IPR negotiation process. Therefore by dint of this FTA Singapore, in some ways, had been imposed with a number of additional commitments on IPRs by the EFTA that are much beyond those in TRIPS.

The negotiations to one of the most recent plurilateral accords, the Anti Counterfeiting Trade Agreement (ACTA), had been initiated a few years after this agreement took shape and Singapore became one of its negotiating partners. It had been effectively abandoned by the EU consequently though, after it failed overwhelmingly to obtain assent by the EU Parliament owing to its negotiating secretiveness. Apart from Japan, it also failed to obtain ratification in almost all the countries that were parties to its negotiation process. Nevertheless Singapore, being one of its original negotiating partners, is understood to have had to alter its IP enforcement laws especially around or after the period of its formal conclusion.

3.5.2.3 EU-Singapore FTA:

The European Union has entered into negotiations for a free trade agreement with Singapore in 2009; it was concluded in late 2014[91]. This is said to be the first FTA that the EU has entered into with any member of the ASEAN group of countries in Asia. The EU-Singapore FTA or the EUSFTA contains various provisions that violate the TRIPS principles and exceed the standards of TRIPS Agreement.

Firstly, it obliges Singapore to become a signatory to the WIPO internet treaties, namely WIPO Copyright Treaty 1996 and the WIPO Performances and Phonograms Treaty 1996[92]. Further, there is an obligation to "provide adequate legal protection and effective legal remedies against the circumvention of any effective technological measures" employed by the right holders[93]. Among the TRIPS Plus provisions, one

[91] See, *Free Trade Agreement between the European Union and the Republic of Singapore* or *EUSFTA* [online: web] accessed 5 July 2017, URL: http://trade.ec.europa.eu/doclib/press/index.cfm?id=961

[92] See Chapter Eleven, Section B, Article 11.4 of the *EUSFTA* (as on May 2015) [online: web], visited 5 July 2017, URL: http://trade.ec.europa.eu/doclib/docs/2013/september/tradoc_151761.pdf

[93] See Chapter Eleven, Article 11.9.1 of the *EUSFTA*, *Ibid*

worrisome element is the minimum requirement of protection against unauthorised circumvention by those that have 'reasonable grounds to know'[94], or 'offering to the public by marketing of a device or product, including computer programs, or a service, as a means of circumventing an effective technological measure'[95]. Although apparently certain minimum standards of anti-circumvention laws have been laid down, nothing as such has been defined or illustrated in this regard as to what would constitute any of such reasonable grounds. Another problematic feature in these detailed stipulations is its provision for the protection of electronic rights management information. It requires the parties to provide adequate and effective remedies against unauthorised removal or alteration of any stored digital rights management information or make available copies of such works in which such unauthorised removal had occurred[96]. It includes counterfeit geographical indication goods and pirated design goods in 'border measures'[97]. Another provision that transgresses the TRIPS Agreement is that on border measures. It provides a clear mandate to the customs authorities to act *ex officio* upon any suspicion of counterfeit goods or pirated products including counterfeit geographical indication goods[98].

3.6 TRIPS Plus in Plurilateral Agreements:

Over a period of more than a decade, there has been an increasing trend of negotiating plurilateral and regional agreements that serve the trade and business interests of the developed countries. The United States, Japan and Members of the European Union who have similar trade interests take the leading role in setting off negotiations for these agreements before taking on board certain other countries that often include some developing countries as well. These treaties contain a number of provisions on

[94] Article 11.9.1 paragraph 2(a) (i), *Ibid*

[95] Article 11.9.1 paragraph 2(a) (ii), *Ibid*

[96] Article 11.10.1, *Ibid*

[97] Article 11.48 (a) defines counterfeit geographical indication goods, and Article 11.48 (d) defines pirated design goods. Among these, there is a provision for review of the procedures for pirated design goods only and not for counterfeit geographical indication goods.

[98] Article 11.49.2, *Ibid*

intellectual property that snap the legal confines set by the TRIPS Agreement[99]. Under the current context, two such plurilateral treaties – the Anti Counterfeiting Trade Agreement (ACTA) and the Trans Pacific Partnership Agreement (TPP or TPPA) will be discussed, followed by another similar predominantly Asian regional agreement – the Regional Comprehensive Economic Partnership (RCEP) Agreement.

3.6.1 The Anti Counterfeiting Trade Agreement:

The Anti Counterfeiting Trade Agreement[100] (ACTA) had been initiated to be an international IP enforcement treaty. It had been specifically aimed at raising the intellectual property enforcement standards that had been laid down in the TRIPS Agreement. An agreement governed by a multilateral system of the World Trade Organisation (WTO), the TRIPS has been able to set the minimum standards for IP protection and enforcement, thus making way for interested parties to raise the standards further in their respective countries or in mutual legal arrangements. The negotiations for ACTA hence provided the platform for concluding a plurilateral agreement that would have a particular set of such like-minded parties aiming to redefine global IP enforcement thresholds.

3.6.1.1. Genesis of ACTA:

The process of forum shifting and creating separate international legal frameworks to compliment the unfinished agenda of the technologically superior, demander countries has been continuing ever since the TRIPS agreement set the 'minimum standards' of IP protection and enforcement. Multiple reports on IP infringement across the globe were published, and most of these had held the developing countries

[99] The developed countries led by the United States have negotiated a large number of bilateral treaties or Free Trade Agreements (FTAs) with the developing countries till recently. Currently they are pursuing regional and plurilateral agreements, all of which are mainly aimed at consolidating the technological edge that they have traditionally enjoyed, by pursuing an international IP regime that exceeds the TRIPS standards.

[100] *Anti-Counterfeiting Trade Agreement,* May 2011, [online: web], accessed 5 July 2017, URL: http://www.mofa.go.jp/policy/economy/i_property/pdfs/acta1105_en.pdf

responsible for gross IPR violation owing to lack of proper IP enforcement procedures or laws in force (OECD 2008, 2009).

The history of the ACTA goes into the persuasions of the International Anti Counterfeiting Coalition which had held meetings at different places on the world each year. The 'First Global Congress on Combating Counterfeiting' took place in Brussels in May 2004. This event had been dubbed as 'unique' and was hosted by the World Customs Organization (WCO) at its Brussels headquarters in association with the Interpol and supported by the World Intellectual Property Organization (WIPO). Besides, certain private business groups representing some of the world's biggest trademark and copyright owners such as International Trademark Association (INTA), Global Business Leaders Alliance Against Counterfeiting (GBLAAC), and the International Security Management Association (ISMA) cosponsored the event (Daudpota 2004). The following year, Japan expressed its desire for negotiation of a treaty that would comprehensively deal with counterfeiting and piracy. The Japanese representative stated this at the 'Second Global Congress on Combating Counterfeiting' in 2005 at the Interpol headquarters in Lyon, France. It would not only be aimed to deal with such counterfeit and pirated products at the borders during imports or exports, but also during the transit of such goods as well as those that would exist on the internet. Although there were developed country representatives who were not averse to it, the proposal initially met with mixed reactions (Gerhardsen 2005). Interestingly however, it was officially reciprocated by the United States only after a couple of years, by the US Ambassador at the WIPO, just about a month after the Doha Development Agenda, 2007 was adopted (Viana 2007). Finally, the same year, the European Union sought to negotiate a new IP enforcement treaty that would be called the Anti Counterfeiting Trade Agreement (ACTA). In addition, the EU wanted to introduce 'strong IPR chapters in all its new generation of Free Trade Agreements with India, Korea, ASEAN and Latin America' (European Commission Press Release Database 2007). The common thread that was clearly visible in this official proposal is dealing with counterfeiting and piracy not only physically as a border measure or otherwise, but also over the internet. Such a proposal did not augur well with those who were aware of its consequences.

3.6.1.2. Problems about the ACTA:

The initial text of the ACTA, which was leaked on the internet portal Wikileaks, resembled the rationale for negotiating the treaty later provided officially by the US. This had left the world with little doubt about the genuineness of the document that was leaked online[101]. Thus, the main concerns expressed in some of the literatures initially were the following:

Firstly, that the treaty was being negotiated clandestinely and none else, even from the participating countries, other than the negotiators had any information about it. It had no space for public enquiry or public accountability thereby leaving such a potential international treaty at the behest of the negotiators or their pursuer business associations to an extent. Secondly, it sought to 'ratchet up' the intellectual property enforcement mechanisms by superseding the standards agreed upon in the TRIPS Agreement by including mandatory criminal liabilities and employing additional state resources for such enforcement. Thirdly, the treaty was being pursued chiefly by a select group of developed countries where IP enforcement standards were already higher than those of their developing counterparts and mostly comparable to the ACTA proposals, thus making way for a global harmonisation of IP enforcement laws. Fourthly, it would have provided unchecked power to the border or customs officials to act against particular IP rights infringers on the basis of mere suspicion, and without the requirement of any formal complaint whatsoever. Fifthly, such kinds of extraordinary IP enforcement, that would have stood atop the existing TRIPS IP enforcement levels, may well have been followed in the online environment as well, allowing the concerned authorities to control or regulate personal data online, thus raising concerns about privacy of individuals (Sell 2008; Kaminski 2009).

[101] The US officially stated its intent to negotiate an international anti-counterfeiting treaty on October 23, 2007, along with other industrialised countries like Japan, Switzerland and New Zealand, the country-bloc of the European Union as well as Republic of Korea and Mexico (Viana 2007). Later, they were joined by Australia, Jordan, Morocco, Singapore, and Canada. The main areas for negotiation of the ACTA were - international cooperation, enforcement practices and legal framework (ACTA Leaked Proposal 2007). These had almost concurred with those in the official USTR document expressing the US's intent to initiate negotiations - cooperation, best practices and a strong legal framework on IP enforcement (USTR 2007a).

The ACTA not only had been criticised for its lack of transparency during the negotiation process but also for attempting to take away the flexibilities that developing countries, chiefly the technology importers, had toiled hard to obtain during the TRIPS negotiations. Indeed, Susan Sell had rightly remarked:

> "Its one-size fits all policy exacerbates the problems that even the far more forgiving and flexible TRIPS revealed. It sharply reduces policy space for developing countries to design appropriate policies for their public policy for innovation and economic development. It also would create an additional international intellectual property governance layer atop an already remarkably complex and increasingly incoherent intellectual property regime" (Sell 2008: 9).

In the midst of this build up to ACTA, there was a significant episode that may have had some impact on the ongoing negotiations. Consignments of lawful Indian generic medicines were confiscated and detained in at least two ports at different locations in Europe, based upon a particular legislation within the EU that mandated such actions by concerned officials. These medicines were destined for use by governments or other voluntary organisations in developing countries to be distributed among the underprivileged population. India and Brazil lodged protest at the WTO TRIPS Council, cautioned the EU and later went on to lodge a trade dispute consultation at the WTO Dispute Settlement Body (ICTSD 2009; Ravi Kanth 2010).

Later however, there were persistent protests and campaigns in countries and organisations across the globe. The focus of their concern were upon access to medicines, access to education or knowledge, considerable lowering of TRIPS thresholds for criminality in alleged infringements, privacy concerns, etc. Besides, the demand for access to different ACTA negotiating texts became the central public objection, owing to which there was a significant setback to the global legislative overpowering agenda of the rights holders. There were widespread protests across countries and cities in the European Union over the guarded negotiations, the overextension of stringency in IP enforcement mechanisms as well as privacy worries. Demands were also made in Australia for rejecting the agreement[102]. The EU Parliament that was earlier presented with a petition demanding rejection of ACTA

[102] The demands were led by a political outfit by the name 'Pirate Party'. See, LeMay, Renal (2012), 'Pirate Party demands Australia reject ACTA treaty', [online: web] accessed 5 July 2017, URL: https://delimiter.com.au/2012/01/30/pirate-party-demands-australia-reject-acta-treaty/

signed by about two and a half million people worldwide (European Parliament 2012a), eventually rejected the ACTA by a vote of 478 to 39 (European Parliament 2012b), thereby marking its virtual death worldwide; it was hardly possible for the ACTA to move any further without approval or ratification in the EU.

However the ACTA, other than just the substantive provisions, in particular its negotiation process, shall remain significant for more at least two reasons. Firstly, it had successfully set the trend of looking for alternative forums outside the WTO TRIPS for international IP rulemaking. Secondly, it sets forth a new trend in international IP governance by seeking cooperation on IP enforcement norms from signatory States. Thirdly, by specifically including IP enforcement as the thrust area for negotiations, it had opened up a new movement by international interest groups to seek such agreements in near future.

3.6.1.3 Current status of ACTA:

The ACTA had made enough progress before it came to a sudden halt upon rejection by the European Parliament in 2012. Although it had been concluded and signed by the partner countries in 2011, until this date, Japan remains as the only country reported to have ratified the treaty in 2012 amidst domestic protests[103].

3.6.2 The Trans Pacific Partnership Agreement:

The Trans Pacific Partnership (TPP) Agreement[104] has not been perceived to be just a regular trade agreement; it has been considered as something of a completely different nature. As one author had shed light on its enormous possibilities:

[103] There had been protests in Japan both on the streets of Tokyo as well as over the internet, immediately after reports of ratification by the Japanese government were published online (Neal 2012).

[104] See, *Trans-Pacific Partnership,* Text of the Trans-Pacific Partnership, [online: web] accessed 5 July 2017, URL: http://tpp.mfat.govt.nz/text

> "The TPP is a new type of trade agreement. It does not fit into the more common molds of bilateral free trade agreements or plurilateral customs unions. Rather, the TPP represents an unprecedented free trade agreement (FTA) comprising eight or more members, including the United States, and has implications for regionalism—particularly in the Pacific Rim—and the World Trade Organization (WTO), and for the power dynamics between major trading blocs. The TPP has the potential both to harmonize and to fragment. It reflects both a convergence of economies seeking to form a broader alliance, and a divergence from the multilateral trading system. …" (Lewis 2011: 28).

Even though after conclusion of negotiations the treaty has come to a halt currently, the manner of its negotiations signify a departure from the multilateral trading system as under the GATT-WTO. The region and the partners involved are also indicative of a strategic deal, as discussed later in this subsection.

3.6.2.1. Genesis:

The Trans Pacific Partnership Agreement or the TPPA has been initially negotiated by the Asia Pacific Economic Cooperation (APEC) group of countries from Asia. At later times, countries like the US, Mexico and even Japan joined the negotiations. Originally known as the Trans Pacific Strategic Economic Partnership, it was being negotiated among Brunei, Chile, New Zealand and Singapore in 2005. The TPPA thereafter went underway as a regional free trade agreement- negotiated in secrecy between Australia, Brunei Darussalam, Canada, Chile, Japan, Malaysia, Mexico, New Zealand, Peru, Singapore, the United States and Vietnam. This had been widely publicized as one of the biggest in the history of free trade agreements that would achieve a broad Asia-Pacific regional economic integration.

In late 2013, the online portal 'Wikileaks' released a leaked draft of the Intellectual Property Chapter of the Trans Pacific Partnership Agreement[105]. Consequent to this, there were two successive leaks in 2014[106] and 2015[107]. All these available leaks

[105] 'Secret Trans-Pacific Partnership Agreement (TPP) - IP Chapter', *Wikileaks*, November 13, 2013, [online: web] accessed 5 July 2017, URL: https://wikileaks.org/tpp/pressrelease.html

[106] See, 'Updated Secret Trans-Pacific Partnership Agreement (TPP) - IP Chapter (second publication) *Wikileaks Press Release*, 2014-10-16, [online: web] accessed 7 June 2017, URL: https://wikileaks.org/tpp-ip2/pressrelease/

included provisions that went ahead of TRIPS by far. Even the final text of the agreement that was concluded in February 2016 seemingly contains many provisions on IP enforcement that exceed the TRIPS standards.

3.6.2.2. Problematic Areas on IP Enforcement:

The TPP has enough to be alarmed about regarding intellectual property enforcement provisions that exceed the TRIPS standards by far. It authorises injunctions that can prevent the sale of medicines when asked for, it has sanctioned an increase in the award of damages and has also widened the scope of confiscation of medicines at the borders (Baker 2016: 2). In certain cases, it also exceeds the standards of countries like the US; as Prof Baker explains:

> "It contains provisions requiring deterrent remedies, compelling the use of the right holder's retail price as a measure of damages, mandating injunctive relief, and banning reasonable royalties as an infringement remedy. Several of these proposals exceed US law. TPP governments will also be required to adopt border control measures like those that interrupted lawful passage of generic medicines through Europe in 2008 and 2009. Fear of excess liability, injunctions, and border seizures can deter generics from marketing competing equivalents when there is even a slight risk of patent infringement enforcement" (Baker 2016: 4).

According to a white paper released in September 2011 that focuses on access to medicines, the US had proposed provisions for IP enforcement by customs authorities on medicines bearing counterfeit trademark and also criminal IP enforcement for trademark violations in TPP countries[108]. In the latest factsheet released on TPP[109] before the Trump administration took over, the United States Trade Representative (USTR) had identified a set of newer TRIPS Plus norms that have been included in

---

[107] See, the so-called 'final negotiated text', Press Release, *WikiLeaks*, 'TPP Treaty: Intellectual Property Rights Chapter 5 October 2015', 2015-10-9, [online: web] accessed 5 July 2017, URL https://wikileaks.org/tpp-ip3/press.html

[108] See 'Trans-Pacific Partnership Trade Goals To Enhance Access to Medicines', [online: web] visited 5 July 2017, URL: https://www.keionline.org/sites/default/files/USTR_11sep2011_TPP_Trade_Goals_Medicines.pdf

[109] See USTR factsheet, 'Promoting Innovation & Creativity', [online: web] visited 5 July 2017, URL: https://ustr.gov/sites/default/files/TPP-Promoting-Innovation-and-Creativity-Fact-Sheet.pdf

the final TPP text. While it claims that it 'aligns with the Doha Declaration on TRIPS and Public Health,'(WTO 2001) it also aims to 'close loopholes used by counterfeiters' by enhanced penalties in case of 'trafficking in counterfeit trademark products that threaten health and safety', as also 'effectively enforce intellectual property rights' by including criminal enforcement among a host of other measures[110].

Among the provisions that have been included within the text of the final TPP Agreement, some including those for IP enforcement online, have indeed been found to include TRIPS Plus standards. The stipulation on 'technological protection measures', for example, mandates civil and administrative liability on any person who circumvents such measures knowingly[111]. In also authorises criminal liability for 'significant acts' that do not involve any 'commercial advantage or financial gain'[112]; such acts being evaluated merely by the 'volume and value' of the concerned infringing items in the marketplace[113]. Apart from criminal liabilities, the TPP also contains TRIPS Plus IP enforcement measures in general, that relate to 'border measures'. It contains mandatory *ex officio* border measures by the customs authorities of parties in respect of goods during their export and transit, besides imports[114], which is beyond the TRIPS requirement. Under the TRIPS provisions, such procedures are mandatory only in case of imports[115], and have been completely

[110] See USTR factsheet, *Ibid*

[111] See Technological Protection Measures (TPMs), Article 18.68:1(a), of TPPA in Chapter 18 of the Trans Pacific Partnership Agreement (TPP or TPPA, simultaneously) [online: web] accessed 7 July 2017, URL: http://dfat.gov.au/trade/agreements/tpp/official-documents/Documents/18-intellectual-property.pdf

[112] Any act, which has 'substantial prejudicial impact on the interests of the copyright or related rights holder in relation to the marketplace', is required to call for criminal liability. [Article 18.77: 1(b), TPPA, *Ibid*]

[113] See, fn. 127, Article 18.77: 1(b), TPPA, *Ibid*

[114] See, 'Special Requirements related to Border Measures', in the chapter on intellectual property, Chapter 18, Article 18.76:5 (a), (b) and (c) of TPPA, *Ibid.*

[115] Art. 51, TRIPS Agreement specifies such measures to be mandatorily applicable only during importation of goods; some States may require it during their exportations, however, that is not a binding requirement under the treaty.

done away with in case of goods in transit[116]. As discussed earlier in this chapter as well as in Chapter V, such kinds of customs legislations currently in practice in the European Union, have been found to be an impediment not only for trade in legitimate generic drugs, but also for the cause of access to medicines by the economically vulnerable among the international community.

3.6.2.3 IP included as 'investment':

The TPP also has enough to be concerned about as regards its direct as well as oblique reference to IP within the chapter on investment. It provides protection against appropriation to IP owners, as IP has been treated as a distinct form of 'investment'[117]; thereby, their expropriation shall be subject to challenges at international arbitral tribunals, disregarding the national judicial systems. The circumstances that constitute "investment" seem unrestrained and widens up to "every asset that an investor owns or controls, directly or indirectly".[118] It has "such characteristics as the commitment of capital or other resources, the expectation of gain or profit, or the assumption of risk"[119]. An interesting feature happens to be, that although a list of such assets provided includes intellectual property, it does not mention what would be the nature or kind of such intellectual property – whether patents or copyrights for example, thus making the subject of IP ownership wide open to interpretations. Concerns also exist regarding certain other issues as regards IP as a form of investment. For example, certain limitations or exceptions could be shown to adversely impact copyright owners' business interests and thus could be met with as expropriations of indirect nature at arbitral tribunals. This can adversely impact a

[116] Art. 51, fn. 13 of TRIPS states: "It is understood that *there shall be no obligation* to apply such procedures to imports of goods put on the market in another country by or with the consent of the right holder, or *to goods in transit*." (emphasis added)

[117] See TPP Chapter on investment, Chapter 9, Section A, Article 9.1 (f), including intellectual property within the definition of investment. See Chapter 9, [online: web] Visited 5 July 2017, URL:https://mfat.govt.nz/assets/_securedfiles/Trans-Pacific-Partnership/Text/9.-Investment-Chapter.pdf

[118] *Ibid*.

[119] *Ibid*.

state's ability to introduce exceptions and limitations to intellectual property, thus inhibiting many public interest objectives like access to affordable medicines, access to educational materials, the protection of consumer rights or promotion of competition, etc.

This has become all the more relevant in light of at least three major litigations that had been brought against as many countries by transnational corporations recently, and some of these lawsuits have similar elements in them. One of the most important cases of international arbitration in recent times had been brought against the government of Uruguay by multinational tobacco corporation Philip Morris in 2009, for mandatory warnings that had to be issued on tobacco packages[120]. Another case that has drawn global public attention is on an investment arbitration brought by the same tobacco major against the Australian government for its regulations for protecting and promoting public health[121]. Yet another one was brought by one of the largest US pharmaceutical corporations, Eli Lilly, against the Canadian government in 2013. It alleged that Canada was violating its obligations under the North American Free Trade Agreement (NAFTA) when its courts refused to grant patent to a couple of medicinal drugs it claims to have developed[122]. It is possibly the only case of its kind in which intellectual property has been downrightly included as a form of 'investment', in which refusal of granting a patent by any state or judicial authority has been alleged to have resulted into a loss of profits for the corporation. However, the large pharmaceutical firm has not been eventually successful in its international arbitral pursuit[123]. The arbitral panel dismissed the case 'in its entirety', and awarded

---

[120] See 'Philip Morris sues Uruguay over anti tobacco legislation'**,** Buenos Aires Herald.Com, 25 May, 2011, [online: web] visited 5 July 2017, URL: http://www.buenosairesherald.com/article/68152/philip-morris-sues-uruguay-over-anti-tobacco-legislation

[121] Philip Morris used a 1993 bilateral investment agreement between Australia and Hong Kong to challenge the government's regulations for tobacco packaging in apparently the first ever investor-state dispute brought against Australia. See, *Philip Morris Asia Limited (Hong Kong) v. The Commonwealth of Australia at the Permanent Court of Arbitration*, Case no. 2012-12, [online: web], visited 5 July 2017, URL: http://www.pcacases.com/web/view/5

[122] See 'Eli Lilly Files $500M NAFTA Suit Against Canada Over Drug Patents' Huffington Post Business, 13 Sep 2013, Canada, [online: web] visited 5 July 2017, URL: http://www.huffingtonpost.ca/2013/09/14/eli-lilly-nafta-lawsuit_n_3924140.html

[123] See, 'AWARD', in **INTERNATIONAL CENTRE FOR SETTLEMENT OF INVESTMENT DISPUTES** *IN AN ARBITRATION UNDER CHAPTER ELEVEN OF THE NAFTA AND THE*

millions of dollars towards costs of arbitration, legal representation and assistance to be paid to the Canadian government[124].

These cases bear utmost significance considering the fact that such action of transnational corporations, in challenging decisions of national public authorities, ostensibly puts the governments of sovereign nations at stake. Philip Morris though, had as well, lost both of the abovementioned arbitration cases that related to state regulations on tobacco control owing to their lack of merits[125]. As a result, in having to yield now to sovereign state decisions or policies in the aftermath of the adversarial arbitral awards, the possibility of future corporate indignations that may follow in any form cannot be ruled out[126]. These kinds of cases of international arbitration involving nation states as parties may not only affect the process of sovereign policymaking or framing rules and regulations of the state. It may eventually induce countries into making such policies and rules that are effectively favourable to the corporations even when those may have to come at the cost of issues of essential public interest like health[127].

UNCITRAL ARBITRATION RULES, 1976 between ***ELI LILLY AND COMPANY*** *Claimant and* ***GOVERNMENT OF CANADA*** *Respondent*, Case No. UNCT/14/2, FINAL AWARD, Date of dispatch to the Parties 16 March 2017, p 148, [online: web] accessed 5 July 2017, URL: http://icsidfiles.worldbank.org/icsid/ICSIDBLOBS/OnlineAwards/C3544/DC10133_En.pdf

[124] See, *Ibid*

[125] For Uruguay arbitration case, see Castaldi, Malena and Anthony Esposito (2016), 'Phillip Morris loses tough-on-tobacco lawsuit in Uruguay', Reuters US Edition, Health News, July 8, 2016**,** Montevideo, [online: web], visited 5 July 2017, URL: http://www.reuters.com/article/us-pmi-uruguay-lawsuit-idUSKCN0ZO2LZ. On arbitration involving Australia, see Hurst, Daniel (2015) "Australia wins international legal battle with Philip Morris over plain packaging", *The Guardian*, 18 December 2015, [online: web] accessed 5 July 2017, URL: https://www.theguardian.com/australia-news/2015/dec/18/australia-wins-international-legal-battle-with-philip-morris-over-plain-packaging

[126] See Armitage (2014), *infra*, reporting how Philip Morris not only pressurised Uruguay for its plain packaging rules on tobacco by dragging it to international arbitration, but also by closure of its factory there that had left at least forty workers unemployed.

[127] There are apprehensions that the entire purpose of taking the route of international arbitral tribunals is to intimidate such governments of countries which may consider themselves as not being strong enough to take on large corporations, and thus may make decisions or policies on such issues easier for corporations. See, Armitage, Jim (2014), 'Big Tobacco put countries on trial as concerns over TTIP deals mount', *The Independent* 21 October 2014, [online: web] visited 5 July 2017, URL: http://www.independent.co.uk/news/business/analysis-and-features/big-tobacco-puts-countries-on-trial-as-concerns-over-ttip-deals-mount-9807478.html

3.6.2.4 Current status:

The treaty, although finalised and signed by twelve countries in 2016, is presently undergoing a disorderly situation owing to a change in the US administration. In January 2017, after Donald Trump took over as the US President, the United States formally pulled out of the agreement (Chakraborty 2017). However, Japan[128] and New Zealand[129] have respectively ratified the agreement, little before and after the withdrawal by the US. A completely adversative move by arguably the most important partner[130], therefore, does not seem to have quietened the eagerness of the eleven other signatories to the pact, many of which are industrialised and have considerable stakes in the treaty. These countries recently came together and released a joint statement[131] to reiterate their pledge for the treaty. In fact, this statement seems to demonstrate their commitment to enforce the treaty among themselves, and even any other country that may be interested[132].

3.6.3 Regional Comprehensive Economic Partnership (RCEP) Agreement:

Free trade and regional agreements have been pursued in various parts of the world including Asia, Africa and the Americas. However, there is hardly any such trade arrangement that had witnessed either the shape or the nature of parties to the

---

[128] See, Kaneko, Kaori and Yoshifumi Takemotov (2016), "Japan ratifies TPP trade pact to fly the flag for free trade", *Reuters*, Dec 9, 2016, [online: web] accessed 5 July 2017, URL: http://www.reuters.com/article/us-japan-tpp-idUSKBN13Y0CU

[129] See, "New Zealand ratifies Pacific trade deal after US withdrawal", *Associated Press*, May. 11, 2017, Wellington, New Zealand, [online" web], accessed 5 July 2017, URL: https://www.apnews.com/81b57a440db64d0887215699718352ad/New-Zealand-ratifies-Pacific-trade-deal-after-US-withdrawal

[130] As per the present form of the TPP Agreement, the presence of the US stands as a mandatory requirement for it to enter into force. See the Associated Press report, *Ibid.*

[131] See, 'Trans-Pacific Partnership (TPP) Agreement Ministerial Statement', by Todd McClay, Trade Minister, New Zealand, 21 May 2017, Ha Noi Viet Nam, [online:web] accessed 5 July 2017, URL: https://www.beehive.govt.nz/release/trans-pacific-partnership-tpp-agreement-ministerial-statement

[132] See, the 'Ministerial Statement', *Ibid.*

negotiations for a mega Asian pact, the Regional Comprehensive Economic Partnership Agreement[133] (RCEP). This agreement is currently in the midst of consultations among State negotiators and no negotiating text has been released until date. It has been discussed below.

3.6.3.1 Origins:

Negotiations for a Regional Comprehensive Economic Partnership Agreement (RCEP) started in May 2013. However, there appears to be a 'shroud of secrecy and intense speculation' about the negotiations for this agreement. There had been proposals by countries like Japan and Korea that are pushing for stronger IP provisions that are in line with the TPP Agreement. This has already raised cautious apprehensions in India among civil society groups, farmers groups, patient groups and health activists over issues such as access to affordable generic medicines, farmers' rights on seeds, civil rights and other developmental concerns of developing nations. They have advocated for making the negotiating texts of the RCEP public (Chatterjee: 2015).

This negotiation brought on board countries with varied economic conditions and interests onto a single platform. The countries that are parties to the negotiations are the ten nations that make the ASEAN group, namely Brunei, Myanmar, Cambodia, Indonesia, Laos, Malaysia, the Philippines, Singapore, Thailand, Vietnam, and their current FTA partners- Australia, China, India, Japan, South Korea and New Zealand. This negotiation has brought into limelight some of the worrisome concerns that the TPP would otherwise have included if not faced with popular resentment, besides those that form the actual text of the recently signed TPP Agreement as well (Chatterjee: 2015).

[133] See, *Joint Declaration on the Launch of Negotiations for the Regional Comprehensive Economic Partnership*, 20 November 2012, [online: web] accessed 5 July 2017, URL: http://dfat.gov.au/trade/agreements/rcep/news/Documents/joint-declaration-on-the-launch-of-negotiations-for-the-regional-comprehensive-economic-partnership.pdf

3.6.3.2. Significance:

Although pursed at a regional level, the RCEP is being perceived to be one among the most important regional FTAs that are being negotiated which, in due course, may have a global impact. Peter Yu has highlighted a minimum of three reasons for this. Firstly, as he cites, that even though the TPP makes for almost 40 percent of global GDP, the participating countries of the RCEP negotiations account for almost half of the global population, almost 30 per cent of global GDP and over a quarter of world exports. The next issue, as he reasons, is about its importance within the Asia-Pacific region. He expects that it would potentially take on board the two most prevailing economies among the BRIC[134] group of countries, namely China and India, the two Asian majors- Japan and South Korea, alongside seven of the twelve TPP partners, namely Australia, Brunei Darussalam, Japan, Malaysia, New Zealand, Singapore and Vietnam. Thirdly, he points out that the RCEP could serve as a potential substitute to the TPP agreement since the latter has failed to obtain any generous support from any of the presidential candidates in the US during run up to the latest elections, thereby blurring its destiny after the term of Obama administration gets over. He further cites the ACTA as a failed agreement, owing to its failure to get ratification in the US or any other major partner country other than Japan (Yu 2016: 1-2).

The latest leaked draft of IP chapter of the RCEP agreement indicates that there will be a separate section on IP enforcement[135]. Although most of the planned enforcement provisions have been kept in tandem with the TRIPS, some of those that have been proposed by a few countries in the latest leaked draft seem relatively demanding and beyond TRIPS[136]. The proposed investment chapter within the RCEP is also raising some amount of concern about whether it would include IP within its ambit, given the

---

[134] The BRIC group of nations consists of Brazil, Russia India and China.

[135] See draft IP Chapter (leaked), 'SINGLE WORKING DOCUMENT ON THE INTELLECTUAL PROPERTY CHAPTER REGIONAL COMPREHENSIVE ECONOMIC PARTNERSHIP (RCEP) FREE TRADE AGREEMENT' [online: web] visited 5 July 2017, URL: https://assets.documentcloud.org/documents/2806177/RCEP-IP-Chapter-15October2015.pdf

[136] Countries like South Korea and Japan have been found to be seeking for slightly extensive enforcement provisions. For example, they have proposed statutory damages for infringement taking retail price as a measure (proposed Art 9 bis.2), *ex officio* actions by law enforcement authorities (proposed Art 9.2). See, *Ibid*.

mention of an investor-state dispute settlement mechanism among the proposals (Yu 2016: 4).

3.6.3.3 Current Status:

Consultations for the treaty are currently being continued behind a veil of secretiveness. The nineteenth round of discussion was held at Hyderabad, India under absolute secrecy and the next, i.e. twentieth round is scheduled to be held in Korea in October 2017[137]. The Indian government, which estimates the country to be losing out on revenues if it becomes a party to the current version of the pact[138], may soon become a hardliner during the negotiations[139]. This may, nonetheless, lead to some tough days for the agreement to come to any comprehensible conclusion.

3.7 'Digital' TRIPS Plus:

The developed countries seem to have come together to initiate a move that has been distended in the name of curbing online piracy. In this direction, a few major strides have already been taken by them at their respective national and international levels. They have made moves at certain international institutions and took on board certain other countries that could be at any level of economic development, and this has resulted in certain legislative advances being made at these institutions. Some such steps may often make it difficult for users to avail of certain legitimate uses of the digital contents.

---

[137] See 'Forward work program scheduled meetings 2017' in "Regional Comprehensive Economic Partnership" [online: web] accessed 5 July 2017, URL: http://dfat.gov.au/trade/agreements/rcep/Pages/regional-comprehensive-economic-partnership.aspx

[138] India's is expected to lose out on revenues by as much as 1.6% of its GDP, if it becomes a signatory to the RCEP, according to a recent internal estimate by India's commerce ministry (Mishra 2017).

[139] For the reason mentioned above, India may thus rigidly demand greater market access for its services – its chief revenue earner (Mishra 2017).

The TRIPS Agreement effectively set the 'minimum standards' of intellectual property protection[140] and therefore, ever since TRIPS was concluded, the developed world has been on a lookout to enhance such international legal standards by various means. A major such legal development after the TRIPS Agreement came into force is the conclusion of a couple of treaties for regulating IP over the internet or online environment- the WIPO Internet Treaties of 1996. These treaties may be perceived to have formed the basis of certain standards with higher benchmarks on IP in some future international pacts being pursued by the developed world at bilateral, regional and plurilateral levels.

3.7.1 The WIPO Internet Treaties

The current international treaties on digital contents are the WIPO Internet Treaties[141] of 1996 that have set rules that have not been laid down in the TRIPS Agreement. Until the time when the TRIPS came into being, the Berne Convention that had been revised at least four times[142] was the set standard for international copyright legislation. At the time when TRIPS was being negotiated, there were unfruitful negotiations for revision of the Berne Convention towards accommodating the new age technologies. The WTO-TRIPS was concluded in 1994 but the process of revision of Berne could not, and neither could the Rome Convention. This may have resulted in the perception of an absence of any online regulation of IP till that time. Therefore, there was a push for raising the norms further than the TRIPS, particularly in the area concerning IP enforcement in the online context. The WIPO Copyright Treaty (WCT) 1996[143], and the WIPO Performances and Phonograms Treaty (WPPT) 1996[144] are the

[140] Article 1.1 of the TRIPS Agreement states that —"Members may, but shall not be obliged to, implement in their law more extensive protection than is required by this Agreement". This implies that there is space for setting higher benchmarks of IP protection.

[141] See, *WIPO Copyright Treaty (WCT)(1996)* of December 20, 1996, entry into force March 6, 2002, [online: web] accessed 5 July 2017, URL: http://www.wipo.int/treaties/en/ip/wct/; and *WIPO Performances and Phonograms Treaty(WPPT)(1996)*, of December 20, 1996, entry into force May 20, 2002, [online: web], visited 5 July 2017, URL: http://www.wipo.int/treaties/en/ip/wppt/

[142] The revisions to the Berne Convention were held in Berlin (1908), Rome (1928), Brussels (1948), Stockholm (1967) and Paris (1971).

[143] See Ibid, fn. 141

first set of international treaties for the regulation of overall IP protection and enforcement over the internet. It is no wonder, in guise of covering a different and unconstrained domain, both of these treaties stretched little more than those set by the TRIPS Agreement. Thus, Kariyawasam opines:

> The WCT and WPPT are self-standing treaties which build on the *Berne* and *Rome* Conventions, and the TRIPS Agreement, but in certain areas go further, for example in the area of enforcement of copyright, digital rights management, and anti-circumvention measures (Kariyawasam 2007: 139).

These are what consists of major elements of the WIPO's Digital Agenda[145], and are the first set of treaties that legalised the use of technological measures for the protection of intellectual property rights on the internet. Commentators though are of the opinion, that in actuality, they reflect a virtual superimposition of a specific 'digital agenda' of the United States (Samuelson 1996). The treaties built up protection and enforcement of copyright in the digital environment and established newer obligations that were not otherwise addressed by the TRIPS Agreement. Both the treaties entered into force in 2002[146].

3.7.1.1 WIPO Copyright Treaty 1996

The WIPO Copyright Treaty (WCT) 1996[147] is the first internationally negotiated treaty on protection and enforcement of any form of intellectual property on the internet. The TRIPS Agreement did not have such stipulation that deals with online IP affairs, and most of it also happens to be obligatory in nature. This was the main reason for the whole schema of internet treaties to be pushed by the developed

---

[144] Ibid

[145] The 'WIPO Digital Agenda' presented by the WIPO Director General encourages adherence to these treaties for tackling the challenge posed to conventional copyright system by the present day electronic commerce aided by digital technologies. See WIPO Digital Agenda, WO/GA/24/11 Rev. ANNEX, [online: web], visited 5 July 2017, URL: http://www.wipo.int/edocs/mdocs/govbody/en/wo_ga_24/wo_ga_24_11_rev-annex1.pdf

[146] See *supra*, fn. 141

[147] *WIPO Copyright Treaty (WCT)(1996)* of December 20, 1996, entry into force March 6, 2002, [online: web] accessed 5 July 2017, URL: http://www.wipo.int/treaties/en/ip/wct/

nations[148], who legibly had a formidable stake in the production of mainly copyrighted as well as other materials, numerous of which are online today, to put forward such international legal accords.

The WCT was adopted on December 20, 1996 in Geneva; it entered into force in 2002[149]. As of today, it had been acceded by 93 countries and one intergovernmental organisation- the European Union[150]. The provision on enforcement is rather generalised; it warrants countries to take required measures for execution of the Treaty 'in accordance with their legal systems', and make sure that enforcement procedures 'permit effective action' against infringement including 'expeditious remedies to prevent infringements and remedies' as deterrence[151]. However for the first time, mandatory provisions, for providing 'effective legal remedies against the circumvention of effective technological measures that are used by authors in connection with the exercise of their rights' in the digital environment, have been included[152]. These measures as a whole may be termed as technological protection measures (TPMs). In addition, compulsory provision has been introduced for 'adequate and effective legal remedies' against unauthorised modification of electronic rights management information[153], or the further usage of such tampered works or copies[154]. The definition, as to what constitutes "rights management information" in the digital context, has also been provided[155]. Such measures together may be termed as Digital Rights Management (DRM). Thus, the WCT brought into the international legal arena an entirely new set of hi-tech measures in the form of

[148] See, Janssens 2009: 320.

[149] See, 'Summary of the WIPO Copyright Treaty (WCT) (1996)', [online: web] visited 5 July 2017, URL: http://www.wipo.int/treaties/en/ip/wct/summary_wct.html

[150] See, 'WIPO Administered Treaties', [online: web], visited 5 July 2017, URL: http://www.wipo.int/treaties/en/ShowResults.jsp?lang=en&search_what=B&bo_id=17

[151] See 'Provisions on Enforcement of Rights', Art 14, WCT.

[152] See 'Obligations concerning Technological Measures', Art 11, WCT.

[153] See 'Obligations concerning Rights Management Information', Art 12 (1) (i), WCT.

[154] See *Ibid*, Art 12 (1) (ii), WCT

[155] See *Ibid*, Art 12 (2), WCT

TPMs and DRM that are solely aimed at enforcing copyright over the internet across national territories.

3.7.1.2 WIPO Performances and Phonograms Treaty (WPPT) 1996

The WIPO Performances and Phonograms Treaty (WPPT) 1996[156] has for the first time introduced performers and producers of phonograms in the digital environment[157].

The WPPT was adopted on December 20, 1996 in Geneva along with the WCT and also entered into force in 2002. It had also been acceded by 93 countries and the European Union. Digital copyright enforcement in this treaty has been integrated on similar lines with the WCT. TPMs have been provided which stipulate 'effective legal remedies' against unauthorised 'circumvention of effective technological measures that are used by performers or producers of phonograms'[158]. DRM measures have been also been laid down both for unauthorised alteration[159] as well as further use of such altered works or copies[160].

Both the WCT and the WPPT recognise the significance of certain associated public interest areas, 'particularly education, research and access to information'[161]. This is particularly important for national legislators while framing their respective domestic laws and regulations. There is nothing particularly defined in any of the two pacts as regards what comprises of the 'effective technological measures' or 'effective legal

---

[156] See Ibid, fn. 141, *WIPO Performances and Phonograms Treaty*, [online: web], visited 5 July 2017, URL: http://www.wipo.int/treaties/en/ip/wppt/

[157] WPPT provides for 'rights of two kinds of beneficiaries, particularly in the digital environment: (i) performers (actors, singers, musicians, etc.); and (ii) producers of phonograms (persons or legal entities that take the initiative and have the responsibility for the fixation of sounds)'. See *WIPO Performances and Phonograms Treaty*, [online: web], visited 5 July 2017, URL: http://www.wipo.int/treaties/en/ip/wppt/

[158] See Art 18, WPPT

[159] See Art 19 (1) (i), WPPT

[160] See Art 19 (1)(ii), WPPT

[161] See the Preamble, WCT as well as Preamble, WPPT.

remedies'. In effect though, this leaves space for developing countries to adjust the new technological measures that matches their developmental levels or addresses other concerns like access to knowledge and education.

3.7.2 Extraterritoriality of legislations in the developed world

One of the most controversial bearings that the newer contemplations of IPR norms have triggered is regarding the extraterritoriality of laws and distinctive legislative characteristics that essentially originate in the developed countries. It is not just that some similar provisions have only been incorporated from within the WIPO Internet Treaties of 1996; there are also apprehensions that the newer legislations of the developed world would have a direct bearing on global lawmaking, including those in the developing nations. This seems not only important in terms of their scope but seemingly also goes against the principle that intellectual property rights are effectively territorial in nature. Legislations like the DMCA and regulations like the European Information Society Directive, have been brought in the US and the EU respectively, in order to incorporate the changes brought in the WIPO internet treaties. Besides, some other laws and regulations had also been considered, whose stipulations aim to go even beyond those in the WIPO treaties.

3.7.2.1 The Digital Millennium Copyright Act 1998:

The Digital Millennium Copyright Act (DMCA), 1998 ushered in an extremely broad legal protection within the digital rights management systems with the support of the US copyright industry. The United States was apparently the first to execute the commitment made in the WIPO internet treaties, in the form of its own domestic legislation in 1998. US laws on copyright at that time, nevertheless, were already complying with the requisite provisions in the internet treaties before those needed to be incorporated via the route of this legislation. Title I of the Digital Millennium DMCA prohibits tampering with or circumventing these systems as also the manufacture, distribution, and importation of circumvention tools." Kuanpoth suggests:

> While TRIPS is absent on obligations concerning technological protection measures (TPMs), all FTAs proposed by the US stipulate that parties must provide adequate legal protection and effective legal remedies against acts of circumventing TPMs and against devices which could be used for circumvention, regardless of the intended use of the device. It also limits the scope of exceptions in which TPMs may be used and extends the scope of criminal offences relating to the manufacture, distribution and use of circumvention devices. This means in effect that the US is now creating a new concept of copyright protection by extending the conventional economic rights of the author to the right to use and distribute circumvention devices (Kuanpoth 2007: 43).

He adds that:

> The provisions on prohibition of circumventing TPMs and devices will enable the owners to extend greater control over access to and distribution of works that copyright law expressly leaves unprotected in order to stimulate further creativity (ie works which have fallen into the public domain). The TPM circumvention prohibition will prevent the circumvention for non-infringing usage, and interfere with the rights of consumers to deal with the goods that they have legitimately purchased. In addition, the scope of fair use online will be narrowed down, as the owners can require payment for any use or excerption of a digital work, regardless of the user's purpose. The use of the internet and digital works for educational or private non-commercial purposes, or the use by educational and library organisation will be increasingly hindered because of this prohibition (Kuanpoth 2007: 43).

He further fears that, the inclusion of TPMs within national copyright laws of countries with which US signs FTAs is going to result in reduction of fair use restrictions. He reasons this as:

> While consumers in the US have a constitutional guarantee of free speech and are protected by broad fair use provisions, users of information in countries that sign an FTA with the US will have more restricted access to copyright material than users in the US due to the lack of the same aspects of consumer protection in those countries (Kuanpoth 2007: 43).

The US, in negotiating international treaties, is said to have sometimes gone beyond the mandate of the WCT or WPPT, or even the DMCA, as in the case of its FTA with Australia.

The US has been instrumental in exporting its own set of legal framework on digital copyright enforcement while negotiating with its FTA partners. This could be mostly comparable with the DMCA, but goes beyond that as well, in certain cases like the one found in the text of the FTA that it has entered into with Australia. In the chapter

on intellectual property in this FTA, the relevant 'takedown' provision sets no time limit for restoration of the alleged infringing material that has to be subsequently done upon a counter notice from the other end[162], whereas in the US a clear period of ten to fourteen business days has been laid down for that same[163]. Rather, it just exempts them from liability so long as they take reasonable steps to restore material online in response to an effective counter-notification. The abovementioned FTA is between two developed countries; however, the overreach of the takedown provision seems to be an example of how major copyright producing countries like the US tactfully induct provisions that that exceed their own standards. Such provisions could prove too costly in case of developing countries' concerns like access to education or knowledge.

3.7.2.2 Recent legal contemplations in US:

The recent contemplations in the United States for combating counterfeiting and piracy globally, form part of the Strategy Targeting Organised Piracy (STOP)[164] initiative by International Trade Administration (ITA) under the US State Department of Commerce. It was anticipated to be "the most comprehensive initiative ever advanced to smash the criminal networks that traffic counterfeit and pirated goods,

[162]The relevant Para 29(b) (x) of Art 17.11. says, "… the service provider shall be exempted from liability for any resulting claims, provided that, in the case of material residing on its system or network, it takes reasonable steps promptly to notify the person making the material available on its system or network that it has done so and, if such person makes an effective counter notification and is subject to jurisdiction in an infringement suit, to restore the material online unless the person giving the original effective notification seeks judicial relief within a reasonable time." See U.S.-Australia FTA, [online: web] visited 5 July 2017, URL: https://www.ustr.gov/sites/default/files/uploads/agreements/fta/australia/asset_upload_file469_5141.pdf

[163] It states, "replaces the removed material and ceases disabling access to it not less than 10, nor more than 14, business days following receipt of the counter notice, unless its designated agent first receives notice from the person who submitted the notification under subsection (c)(1)(C) that such person has filed an action seeking a court order to restrain the subscriber from engaging in infringing activity relating to the material on the service provider's system or network." See, 17 United States Code § 512(g)(2)(C) of Digital Millennium Copyright Act, 1998.

[164] See, *Strategy for Targeting Organized Piracy* (STOP) [online:web] visited 5 July 2017, URL: https://www.uspto.gov/learning-and-resources/ip-policy/enforcement/strategy-targeting-organized-piracy-stop

stop trade in these goods at America's borders, block these goods around the world."[165] Another initiative includes the creation of the Office of Intellectual Property Rights (OIPR).

i. Stop Online Piracy Act/ SOPA:

The WIPO Internet Treaties are said to have provided the impetus for the concerned legislation on the digital world, the Digital Millennium Copyright Act of 1998[166]. Even so, just a few years ago, the US Congress saw the introduction of a Bill that sought to prevent piracy in the internet. The Stop Online Piracy Act[167] or SOPA, as it was supposed to be called, was brought in as a Bill to tame online intellectual property piracy by websites that are overseas, hosting or providing links to perceivably 'pirated' contents. It would have provided the concerned authority with the power to seek a court order requiring service providers to block access to any site outside the US that infringes intellectual property[168]. Further, it also aims to provide rights holders the ability to seek court orders that would require payment providers, advertisers, and search engines to stop doing business with such a website that infringes copyright, thus making way for cutting off such site's funding besides removing search links to those sites. The SOPA however, attracted quite a lot of concerns over a brief period that it had been in the news as bill proposed to be made into a law. Security experts had raised concerns that its provisions may affect the

[165] See STOP, Ibid

[166] The US Congress had passed the Digital Millennium Copyright Act, 1998 in order to adhere to its international treaty obligations with the World Intellectual Property Organisation (WIPO) and for the development of electronic commerce. It was also said to have aimed at "providing copyright owners with legal tools to prevent widespread piracy". See 'Executive Summary: Digital Millennium Copyright Act, Section 104 Report', [online: web], visited 5 July 2017, URL: https://www.copyright.gov/reports/studies/dmca/dmca_executive.html

[167] See, *Stop Online Piracy Act*, H.R. 3261, 112th Cong. (2011) [here and hereinafter SOPA]

[168] It was being said that SOPA would have enabled the U.S. Attorney General seek a court order that requires "a service provider (to) take technically feasible and reasonable measures designed to prevent access by its subscribers located within the United States to the foreign infringing site."

general architecture of the internet[169]. Concerns have also been raised that many a websites may be affected as a whole, as a result of providing or hosting any link that may be suspected of being 'dedicated in the theft of US property'. The situation had been compared with that of "… requiring the manager of a flea market to shut down the entire market because some of the merchants were selling counterfeit goods" (Magid 2012). There were extensive protests all across the United States. It had attained a global scale when thousands of websites including the major ones like Wikipedia, WordPress, Reddit, etc. browsers like Mozilla Firefox and the giant search engine Google went for total or partial blackouts over the internet.

ii. Protect Intellectual Property Act (PIPA):

In 2011, another Bill of a similar nature as that of the SOPA was supposed to be introduced before the Senate. This bill, called the Protect Intellectual Property Act[170] or PIPA, was introduced on May 12, 2011 and was reported to have been approved by the Senate Committee. The PIPA along with the SOPA were tabled before the Congress on January 20, 2012 (Pepitone 2012). This Bill has two versions, both of which are available with the library of the Congress[171].

At the end of all these efforts however, those representing the industry majors like Motion Picture Association of America (MPAA), admitted that both the SOPA and PIPA had been clearly abandoned[172].

---

[169] It was reported that some companies dealing against malwares, besides security experts, had raised concerns that the SOPA may meddle with the architecture of the internet as a whole, something that had been shared by the US administration of the day as well.

[170] See text, *PROTECT IP Act of 2011* , 112th Congress (2011-2012) [online: web] accessed 5 July 2017, URL: https://www.congress.gov/bill/112th-congress/senate-bill/968/text

[171] See Ibid, for both the versions.

[172] The underlying concepts of SOPA and PIPA may see a return in the future, but the two bills in their contemporary formats are unlikely to see any further progress. Senator Chris Dodd, who headed the MPAA at that time, thus appeared to have conceded 'defeat' in this particular matter. See Lee, Timothy B (2012), *Internet wins: SOPA and PIPA both shelved* , Jan 20, 2012, [online: web], visited 5 July 2017, URL: https://arstechnica.com/tech-policy/2012/01/internet-wins-sopa-and-pipa-both-shelved/

iii. Online Protection and Enforcement of Digital Trade Act/ OPEN Act:

The Online Protection and Enforcement of Digital Trade Act[173] (OPEN Act) was introduced on the same day when the SOPA and PIPA met with widespread protests and partial or complete website blackouts[174]. It is said to provide more protection to the 'accused' sites than the former two bills. Besides strengthening enforcement of IP, it is supposed to allow the right holders to bring their cases before the US International Trade Commission that surprisingly looks into international trade disputes that involve US trading entities[175]. Thus, such disputes on copyright or trademark enforcement need not have to be moved through the judicial system or the federal courts. However those who backed the SOPA were of the opinion that the commission does not contain enough teeth for the enforcement functions and can even worsen the problem (Magid 2012).

3.7.2.3 Recent European Legislations

Towards the end of the last century European legislators have not only been deliberating to move towards higher levels of enforcement in the online environment but also wanted to make sure such laws are not bound by territorial limits. Some of these contemplations until now, that have been discussed here are the Information Society Directive, the IP Enforcement Directive, the Medicrime Convention of the Council of Europe and the EU Falsified Medicines Directive.

---

[173] See, H.R. 3782 (112th): *Online Protection and Enforcement of Digital Trade Act*, Jan 18, 2012 112th Congress, 2011–2013, [online: web], accessed 5 July 2017, URL: https://www.govtrack.us/congress/bills/112/hr3782

[174] Republican Darrell Issa from California introduced OPEN, and Democrat Ron Wyden from Oregon introduced it to the Senate. See Ibid, and also Gross Grant (2012) *SOPA Alternative Bill Introduced in the U.S. House of Representatives*, IDG News Service, Jan 18 2012, [online: web] visited 5 July 2017, URL: http://www.pcworld.com/article/248389/issa_introduces_sopa_alternative_in_the_house.html

[175] The United States International Trade Commission is said to be 'an independent, quasijudicial Federal agency with broad investigative responsibilities on matters of trade.' It 'also adjudicates cases involving imports that allegedly infringe intellectual property rights. Through such proceedings, the agency facilitates a rules-based international trading system.' See the website of the United States International Trade Commission, [online: web] visited 5 July 2017, URL: https://www.usitc.gov/press_room/about_usitc.htm

i. The European Information Society Directive 2001:

The European Union Information Society Directive 2001[176] has been introduced to implement the WIPO Internet Treaties. The directive had been primarily aimed at harmonising the three rights of reproduction, communication to the public (making available) and distribution over the information society.[177] This directive is not only extra-TRIPS but even surpasses the internet treaties. It does not end at prohibiting the act of circumvention of technological protection measures (TPMs), but is said to have gone further to outlaw the manufacture and trade in the devices that could be used for the purpose of circumvention[178]. There have been apprehensions that right holders using TPMs to prevent copying might well be doing so even for certain exceptions allowed, such as after expiry of the term of copyright or prevent it from entering the public domain[179]. Although apparently ambiguous, it does provide for national authorities to take 'appropriate measures' in such situations[180].

ii. The IP Enforcement Directive 2004:

In 2004, the IP Enforcement Directive[181] was passed by the European Community. The Intellectual Property Rights Enforcement Directive or IPRED aimed at synchronizing the procedures and remedies for dealing with intellectual property

---

[176] *Directive 2001/29 on Copyright and related rights in the Information Society, OJ (2001) L1767/10*

[177] Articles 2, 3 and 4, *Ibid*

[178] Art. 6.2.of the Information Society Directive seeks mandatory prohibition against 'the manufacture, import, distribution, sale, rental, advertisement for sale or rental, or possession for commercial purposes of devices, products or components or the provision of services which: (a) are promoted, advertised or marketed for the purpose of circumvention of, or (b) have only a limited commercially significant purpose or use other than to circumvent, or (c) are primarily designed, produced, adapted or performed for the purpose of enabling or facilitating the circumvention of, any effective technological measures'.

[179] An entire range of such activities have been pointed out with illustrations by the Electronic Frontier Foundation (EFF). See 'Unintended Consequences Archive', a year-wise series [online: web] visited 5 July 2017, URL: https://www.eff.org/wp/unintended-consequences-under-dmca/archive

[180] Art 6.4.1

[181] *Directive 2004/48/EC of the European Parliament and of the Council of 29 April 2004 on the enforcement of intellectual property rights;* hereinafter, to be called as EU Enforcement Directive

infringements. The standards of implementation of IP in this instrument had been raised enormously in comparison to those set in the TRIPS Agreement, in so far as their scope is concerned[182]. The level of unfairness involved in drafting and finalisation of this instrument had been a subject of criticism[183]. It had originally been said that it aims to bring in line IP enforcement measures in different EU countries while maintaining a 'balance' between the rights of owners and those of the users of IP, by protecting users from unfair litigation.[184] However, the broad coverage provided within the ambit of 'any intellectual property right' in the final document seems to be markedly different from what it was initially proposed for; it seemingly covers every kind of intellectual property violation[185]. It sought to amplify the level of penal compensation available for infringements of IP but was not successful in making it into the final document.[186] The European Commission also wanted to introduce elevated standards of criminal IP enforcement measures[187], but even that

[182] The scope of the Directive is stated to cover 'any infringement of intellectual property rights' [Art 2(1)], which seems to be much beyond the standard of TRIPS that limits the infringement actions to be applied only in commercial cases or those with a motive of profiting.

[183] See Hinze, Gwen 'Proposed E.U. Directive on Intellectual Property Enforcement', [online: web], accessed 5 July 2017, URL: https://www.eff.org/files/filenode/effeurope/eu_ipred_analysis.pdf. A large number of concerned citizens apparently also went against the legislation. See also Ernesto (2011), 'ISPs, Academics and Citizens Oppose EU Anti-Piracy Legislation', July 11 2011, [online: web], accessed 5 July 2017, URL: https://torrentfreak.com/isps-academics-and-citizens-oppose-eu-anti-piracy-legislation-110711/

[184] See European Commission Press Release, MEMO/03/20, Brussels, 30th January 2003, [online: web], accessed 5 July 2017, URL: http://europa.eu/rapid/press-release_MEMO-03-20_en.htm

[185] Article 2 (1) of the EU Enforcement Directive

[186] An effort to enhance the compensation was made via the European Union Enforcement Directive, Chapter 1, n. 83. A rephrasing of the Directive (Recital 26) was lastly done insisting that no one of Directive's provisions was aimed at introducing punitive damages. The original proposal for damages in the Directive (Ibid at 124) left it to the discretion of the court to award either compensatory damages or "damages set at double the royalties or fees which would have been due if the infringer had requested authorisation to use the intellectual property right in question" (as in Article 17.1 of the initial proposal). Members state representatives in the working group on the proposal opposed this, hence, it was eventually changed for courts to set damages either by considering "appropriate aspects", "elements other than economic factors, such as moral prejudice caused to the rightholder" or calculating a "lump sum on the basis of elements such as at least the amount of royalties or fees" (Article 13.1 of the Directive).

[187] European Commission intended to elevate IP enforcement standards by introducing higher criminal sanctions, but certain Member states raised questions on the legislative competence of the European Union to adopt such a directive concerning criminal law. In March 2009 the framework proposal was

attempt was as much a failure. A separate proposal for a directive concerning criminal enforcement of intellectual property rights was submitted in 2005 and amended in 2006, but ultimately withdrawn in September 2010[188]. Nevertheless, the IP Enforcement Directive was adopted days before as many as ten new member states entered into the European Union (Trimble 2012: 25).

iii. The Council of Europe: Medicrime Convention:

The Council of Europe adopted the Medicrime Convention[189] in December 2010. It is a binding international legal instrument (Saez 2015). The convention has been counted as being "the first binding international treaty in the criminal law field on counterfeiting of medical products and similar crimes involving threats to public health" (Fayzrakhmanov: 2012: 59). The scope of the Convention under Article 3 applies explicitly to:

"medical products whether they are protected under intellectual property rights or not, or whether they are generic or not, including accessories designated to be used together with medical devices, as well as the active substances, excipients, parts and materials designated to be used in the production of medical products" (Art 3, COE 2011).

The convention, which has generally entered into force on the first date of January 2016, allows even non Members of the Council of Europe to be signatories. The Preamble addresses "member States of the Council of Europe" as well as "other

withdrawn. See, *Proposal for a Council Framework Decision to Strengthen the Criminal Law Framework to Combat Intellectual Property Offences*, COM (2005) 276–2 (July 12, 2005).

[188] See, *Proposal for a European Parliament and Council Directive on Criminal Measures Aimed at Ensuring the Enforcement of Intellectual Property Rights* , COM (2005) 276-1 (July 12, 2005); *Amended Proposal for a Directive of the European Parliament and of the Council on Criminal Measures Aimed at Ensuring the Enforcement of Intellectual Property Rights, COM(2006) 168 final (April 26, 2006).*

[189] *Council of Europe Convention on the counterfeiting of medical products and similar crimes involving threats to public health*, Moscow 28.X.2011, Council of Europe Treaty Series No- 211, accessed 5 July 2017, URL: https://rm.coe.int/CoERMPublicCommonSearchServices/DisplayDCTMContent?documentId=090000168008482f

signatories to this Convention". Those non Members which have taken part "in its elaboration or enjoy observer status with the Council of Europe" shall be able to sign it automatically. The other non Members, who could be anyone around the globe, shall be able to do it simply "upon invitation by the Committee of Ministers"[190]. Nevertheless, the provision for inclusion of non Members of the Council of Europe having little to do with the organisation is one of the widest in lawmaking at organisational levels. It bestows the treaty with a potentially global sway even when it happens to have been proposed, negotiated and adopted within a European continental organisation. At present, 26 states have signed and 9 among them have already ratified the Convention[191]. Among the ratifying states so far, there are eight Members and only one among the three signatory non-Members of the Council of Europe[192].

Under Chapter II, this Convention makes the following as criminal offences- manufacturing of counterfeit medical products (*Article 5*), supplying, offering to supply and trafficking in counterfeit medical products (*Article 6*); falsification of documents (*Article 7*), certain 'similar crimes' (*Article 8*); and aiding and abetting the commission of crimes under the Convention (*Article 9*). It defines the term 'counterfeit' under Article 4 (j) as "a false representation as regards identity and/or source", as opposed to the TRIPS that defines "counterfeit trademark goods" as:

> any goods, including packaging, bearing without authorization a trademark which is identical to the trademark validly registered in respect of such goods, or which cannot be distinguished in its essential aspects from such a trademark, and which thereby infringes the rights of the owner of the trademark in question under the law of the country of importation[193].

In addition, in Article 8 it defines 'similar crimes involving threats to public health' if medicinal products are intentionally manufactured, kept in stock for supply, imported, exported, supplied, offered to supply, or are placed on the market without authorisation or if medical devices are not in compliance with the necessary

[190] Article 28, COE (2011)

[191] See 'Chart of signatures and ratifications of Treaty 211' [online: web] accessed 5 July 2017, URL: http://www.coe.int/en/web/conventions/full-list/-/conventions/treaty/211/signatures

[192] The only non-Member signatory ratifying the Convention so far has been Guinea; the other signatories being Israel and Morocco. See, Ibid.

[193] As provided in Article 51, footnote 14 of TRIPS.

conformity requirements. Article 9 also criminalises the intentional aiding or abetting of any of the included prohibited acts.

The Convention obliges signatories to allocate sufficient public resources meant only for counterfeit medical products and similar crimes which shall have to be specialised, and hence separated from other resources. Article 16.1 obliges states to undertake that there are "persons, units or services in charge of criminal investigations" who "are specialised in the field of combating counterfeiting of medical products and similar crimes involving threats to public health ..." Such persons shall have to be trained not only for this purpose but also "financial investigations" and such specialised units or services should also have "adequate resources". Additionally, there is requirement for states to make laws authorising such authorities to investigate with special techniques including financial or covert investigations. Thus, Article 16.2 further obliges signatory states to take "necessary legislative and other measures" for "effective criminal investigation and prosecution of offences" that allows its competent authorities to carry out "financial investigations, of covert operations, controlled delivery and other special investigative techniques" (COE 2011).

Although Member states of the Council of Europe had participated in the making of the treaty, the criminality of the acts incorporated within it has been praised by international law enforcement authorities as well. A recent publication of the Interpol points out the fact that every treaty does not require States to "… specifically criminalize the prohibited conduct. Those choosing to do so include the Medicrime Convention …", et al. (Interpol 2014: 155).

iv. The EU Falsified Medicines Directive:

In July 2011, the European Parliament and European Council adopted one of the broadest regulations that aims to deal with the issue of 'falsified medicines'[194]. It has

[194] See, *Directive 2011/62/EU Of The European Parliament And Of The Council Of 8 June 2011 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use, as regards the prevention of the entry into the legal supply chain of falsified medicinal products, L 174/74, 1.7.2011*, [online: web] accessed 5 July 2017 URL: https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-1/dir_2011_62/dir_2011_62_en.pdf

entered into force on 21st July, 2011[195]. It includes the term 'falsified medicinal product', and defines the same as:

> Any medicinal product with a false representation of:
>
> (a) its identity, including its packaging and labelling, its name or its composition as regards any of the ingredients including excipients and the strength of those ingredients;
>
> (b) its source, including its manufacturer, its country of manufacturing, its country of origin or its marketing authorisation holder; or
>
> (c) its history, including the records and documents relating to the distribution channels used[196].

The regulation has been coupled with a 'Delegated Regulation[197]. This was legislated to ensure the mandate of the Directive is implemented across the European Union, maintaining the same level of consistency in technicalities adopted[198] and a relative uniformity of timeline across the EU countries, even though a few of them may have little more leverage owing to their own national peculiarities[199]. The EU apparently does a distinction between what constitutes 'falsified medicine' as compared with that of 'counterfeit medicine'. The European Medicines Agency (EMA), an agency for evaluation of medicinal products in the EU[200], has distinguished the two kinds of faulty medicinal products. According to this specialised EU agency for medicines, while falsified medicines "are fake medicines that are designed to mimic real

---

[195] It states that the directive shall enter into force on the 20th day following its publication in the official journal. See, Article 5 of the Directive, *Ibid*.

[196] Art. 1(1) (c)

[197] See, *COMMISSION DELEGATED REGULATION (EU) 2016/161 of 2 October 2015* (European Commission (2016b)).

[198] See, paragraph 33 of Preamble to the Delegated Regulation, *Ibid*.

[199] See, paragraph 44 of Preamble to the Delegated Regulation, *Ibid*.

[200] The European Medicines Agency states itself as, 'a decentralised agency of the European Union (EU) responsible for the scientific evaluation, supervision and safety monitoring of medicines developed by pharmaceutical companies for use in the EU.' See 'who we are' [online: web], accessed 5 July 2017, URL: http://www.ema.europa.eu/ema/index.jsp?curl=pages/about_us/general/general_content_000112.jsp&mid=WC0b01ac0580028a43

medicines", counterfeit medicines are those "that do not comply with intellectual-property rights or that infringe trademark law"[201].

This regulation is primarily intended for European nations. It is not a criminal legislation and asserts that it aims "… to safeguard the functioning of the internal market for medicinal products, whilst ensuring a high level of protection of public health against falsified medicinal products …"[202] However, the directive has drawn criticism even from those who support the cause of having such a legislation in place.

3.8 Indian Law on IP enforcement

The Indian legal measures on counterfeiting and piracy of intellectual property include the legislations that were in place since independence of India. These cover areas such as trademark, copyright, designs, geographical indications, etc. However, there has been a change in India's customs regulation a few years ago in keeping with its commitments under the WTO TRIPS Agreement.

3.8.1 Border measures under Indian law:

The Customs Act 1962[203] contains the measures that are to be taken by the customs officials to check importation of counterfeit goods at the national borders. Under Section 11 of the Customs Act the Government of India may prohibit importation of goods under various circumstances. Section 11(2) of the Customs Act empowers the customs officials to prohibit the importation and exportation of goods in order to protect trademarks. In exercise of the powers conferred on it by sub-section (1) of section 156 of the Act, the Central Government has made a new set of rules, known as Intellectual Property Rights (Imported Goods) Enforcement Rules, 2007 to strengthen

[201] See 'Falsified medicines' on the EMA website [online: web], accessed 7 June 2017, URL: http://www.ema.europa.eu/ema/index.jsp?curl=pages/special_topics/general/general_content_000186.jsp

[202] See paragraph 33 of Preamble, *Directive 2011/ 62/ EU*

[203] *The Customs Act 1962 [No. 52 of 1962],* December 13, 1962, entry into force February 1, 1963

border enforcement with the objective of preventing the entry of counterfeit goods into the country.

Goods bearing false Trade Marks or false descriptions are prohibited from being imported into India under the Customs Act, 1962. If such goods are imported, they are liable to detention or confiscation. In respect of any such goods imported into India, if the Chief Customs Officer, upon representation made to him, has reasons to believe that the goods bear a false Trade Mark, he may require the importer of goods or his agent to produce any documents in his possession relating to the goods and also to furnish information as to the name and address of the person by whom the goods are consigned to India and the name and address of the person to whom the goods were sent in India. Non-compliance of this requirement is punishable with fine. Though the statute refers only to registered trademarks, the Customs Office is not prohibited from taking action against counterfeit of unregistered trademarks as well. However India, being a party to the TRIPS Agreement in the GATT-WTO regime, was under an obligation to bring in new rules that conform to the minimum standards set by the international IP treaty. The following subsection deals with the new rules.

3.8.2 Intellectual Property Rights (Imported Goods) Enforcement Rules 2007:

The new Intellectual Property Rights (Imported Goods) Enforcement Rules 2007 that the government has set up includes all the kinds of IP infringements namely, trademark, copyright, patent and geographical indication, among others. The circular[204] issued for this purpose expressly mentions that the current set of rules has been issued in keeping with the obligations of the government under the TRIPS Agreement of the WTO. It adds that it has also been done in response to request from trade bodies to include all kinds of IPRs within the ambit of customs procedures.

India, being a signatory to the Trade Related Aspects and Intellectual Property Rights (TRIPs) Agreement, has an obligation to provide effective remedies against unlawful import through the Customs authorities in accordance with the border measures

[204]Circular No. 41 /2007Customs, F. No. 305/96/2004FTT (Pt I) Government of India, Ministry of Finance, Department of Revenue, Central Board of Excise & Customs, Dated the 29th October, 2007.

provided by the TRIPS Agreement. Indian Customs rules albeit, prohibited import of goods infringing trademarks and designs, under the Trade and Merchandise Marks Act 1958 and Indian Patents and Designs Act 1911 respectively, much before the TRIPS Agreement came into being[205].

The Government of India has now put in place "Intellectual Property Rights (Imported Goods) Enforcement Rules 2007" (or Border Measure Rules)[206] which were notified by the central government on May 8 2007, exercising its powers conferred under Section 156(1) of the Customs Act 1962 read with Section 11 of the said Act. These rules, which have been presently inducted within the Customs Act 1962, provide an interface between the conventional Customs provisions and various IP enactments in India and at the global level. These rules have been put in force with effect from October 29, 2007. The distinctive feature of these rules is that, in contrast to the previous Customs provisions, these rules prohibit import of not only goods bearing false trademarks or false trade descriptions under the Trademark Act 1999 or infringement under the Designs Act 2000 but also prohibit import of goods that violate the Copyright Act 1957, Patents Act 1970 and the Geographical Indications of Goods (Registration and Protection) Act 1999.

The new Border Measures Rules provide for, *inter alia*, the following:

(i) the filing of a notice by the right holder;

(ii) registration of said notice by the Customs;

(iii) a time limit for right holders to join proceedings;

(iv) a single point for registration of the notice filed by the right holder;

(v) adequate protection to the rightful importer;

---

[205]Prior to 8.5.2007, when the present rules had been issued, Indian customs had in place vide notification no. 1/64-Cus, dated 18.1.64, the power and procedures for prohibiting import of goods infringing trademarks and designs under the Trade and Merchandise Marks Act 1958 and Indian Patents and Designs Act, 1911 respectively.

[206] The prohibition of the import of infringing goods has been issued vide Notification No. 49/2007, Customs, dated 8.5.2007. The detailed procedures to be followed by the Customs have been issued under Notification no. 47/2007-Customs (N.T.) dated the 8th May, 2007.

(vi) adequate protection by the Customs for bona fide act;

(vii) suo motu action by the Customs in certain specified circumstances;

(viii) disposal of the confiscated goods.

(ix) no action against goods of non-commercial nature contained in personal baggage or sent in small consignments intended for personal use of the importer.

Guidelines have been issued to the Customs authorities providing for a minimum standard to be followed by the government of India in implementing special border measures for the IPR infringements. The Indian Customs authority had to be upgraded to meet the TRIPS obligations against counterfeiting and yet to allow and not to intervene or hinder the fair trade in genuine goods. The authority needed to incorporate mechanisms and rules that did not create barriers to international trade. The Rules further recognizes and highlights preventive measures considering that the holders of the IP rights have the primary responsibility to take effective steps to protect their rights. Such measures include the registration of trademarks as prescribed by the trade mark law, and submission of enforcement applications to the Customs Authority in order to protect and establish IP rights.

It was also deemed necessary that the Customs authority be concurrently conferred with *suo motu* power, in appropriate cases, to assume an active role and take action on its own initiative in cases involving counterfeiting. But this power is to be exercised with utmost caution, since the liability shall ensue upon them, except when in good faith or under specific circumstances like prima facie evidences of IPR infringement. The Rules also provides that the Customs establish a smooth system for managing IP rights applications like establishment of IP cells. Under such a system, recordation by the right is not possible without showing *prima facie* evidence of counterfeiting, piracy or infringement of any of the IPRs.

3.8.3 India and the Internet treaties:

India is not a signatory to either of the 'internet treaties' – the WIPO Copyright Treaty 1996, or the WIPO Performances and Phonograms Treaty 1996, as on the current

date. However, provisions on online copyright enforcement have been recently incorporated within the Indian law. The latest amendment to the Indian Copyright Act, 1957[207], although provides for 'fair uses' for educational purposes[208], also authorises criminal measure and monetary fine for the circumvention of TPMs and DRM system[209]. India has been consistently placed in the Special 301 Watch List of the USTR for not having 'effective' IPR protection and enforcement. The USTR defines the Special 301 Report as:

> …the result of an annual review of the state of IP protection and enforcement in U.S. trading partners around the world, which the Office of the United States Trade Representative (USTR) conducts pursuant to Section 182 of the Trade Act of 1974, as amended by the Omnibus Trade and Competitiveness Act of 1988, the Uruguay Round Agreements Act, and the Trade Facilitation and Trade Enforcement Act of 2015 (19 U.S.C. § 2242)[210].

Further, that it reflects the Administration's decision "to call out foreign countries and expose the laws, policies, and practices that fail to provide adequate and effective IP protection and enforcement for U.S. inventors, creators, brands, manufacturers, and service providers"[211]. India has been placed in the most notorious, 'Priority Watch List' category, in the latest report prepared and released by the USTR[212]. Lobbying by US businesses has become a regular affair and has gained attention at the moment owing to significant expenditure involved[213]. Most of the studies for highlighting copyright piracy in India have been sponsored by the industry itself; hence, these cite

---

[207] The latest *Copyright (Amendment) Act 2012 [No 27 of 2012]* of India has been passed on 22 May 2012 and has been brought into force on 7 June 2012.

[208] See Sec 52, Ibid

[209] See, Sec. 65A and Sec. 65B, Ibid

[210] See, USTR '2017 Special 301 Report', in 'Executive Summary', at p.1, [online: web], accessed 5 July 2017, URL: https://ustr.gov/sites/default/files/301/2017%20Special%20301%20Report%20FINAL.PDF

[211] Ibid

[212] Ibid

[213] US firms, across industries, have been lobbying the Indian government for years by spending hundreds of millions of US dollars. See, "India-focussed US entities' lobby bill reach $212 mn in 2012", Indian Express Feb 10, 2013, PTI, PTI Washington, [online: web] accessed 5 July 2017, URL: http://archive.indianexpress.com/news/indiafocu.../1072173/

questionable figures without proper supportive evidence[214]. Often, international agencies and trade associations are associated with these exercises. Such pressure from abroad coupled with the domestic film and television industry also created enough pressure on the government to bring in such legislation incorporating the internet treaties that India is not bound to implement, for at least two reasons. Firstly, that India is not a party to the WIPO internet treaties, and secondly, the country may not be able to cope with concerns like lack of access to information or education, that go with its current stage of economic development. The National IPR Policy of India[215] released in May 2016 somewhat carries forward the approach taken in latest amended copyright enforcement provisions by considering state level IP cells and separate IP Courts. These are bound to incur further expenditure on additional resources that a developing nation like India can hardly afford at the moment. However, this noticeably sends a rather optimistic signal for India's industrialised FTA partners like Japan, Korea or Singapore, who maintain their own respective TRIPS Plus enforcement rules; these countries are also parties to the TRIPS Plus RCEP Agreement of which India is a negotiating partner[216]. There are possibilities that it may also favour those like the EU who are negotiating with the Indian government for an FTA by including stark amendments to India's national IPR laws. The government has been recently accused of advocating for multinational pharmaceutical firms and resorting to policies that favour them[217]. As discussed next, these may potentially be suitable to their business interests, while at the same time being adversarial to our own developmental or other serious concerns.

---

[214] See, "Piracy Studies in India", *The Centre for Internet and Society*, [online: web] accessed 5 July 2017, URL: https://cis-india.org/a2k/blogs/piracy-studies-india

[215] See, 'National IPR Policy', [online: web] accessed 5 July 2017, URL: http://dipp.gov.in/policies-rules-and-acts/policies/national-ipr-policy

[216] India is one of the negotiating countries with a host of others including some developed ones, for a Regional Comprehensive Economic Partnership (RCEP) Agreement in Asia since 2012 (Chatterjee: 2015).

[217] See, "Govt arms lobbying for pharma companies: Swadeshi Jagran Manch", *The Times of India*, May 2 2017, accessed 5 July 2017, URL: http://timesofindia.indiatimes.com/india/govt-arms-lobbying-for-pharma-companies-rss-organ/articleshow/58468172.cms

3.8.4 Negotiations for an EU-India FTA

The negotiation for a free trade agreement (FTA) between India and the European Union had been launched in 2007. The European Union and India has been participating in summits since 2000. In one such summit held in Helsinki in 2006, they agreed to initiate negotiations for a free trade agreement in 2007, for which the deadline was set to be the year 2009 (De Castro 2011: 28). Concerned officials belonging to both the parties have been carrying on trade talks and setting deadlines for conclusion of the agreement ever since. However, till date the treaty could not be finalised.

India happens to be the world's largest exporter of generic medicines. It caters to four-fifth of the drugs used for treatment of HIV-AIDS, besides those for heart diseases and cancer. Most of the AIDS patients who are from Africa rely on Indian generic medicines for their treatment. The export of Indian generics has been on the rise, and in recent times, it has exceeded that of developed countries (De Castro 2011: 31). India has indeed been hailed as the pharmacy of the developing world.

The European negotiators have apparently demanded a number of TRIPS Plus provisions in the FTA. These range from patent term extension, data exclusivity and limitation on the grounds of compulsory licenses. On the face of it however, the negotiators do not seem to have solicited for any additional stipulation on IP enforcement mechanism as such. However, in light of the recent seizure of Indian medicines shipments in the EU customs jurisdictions citing an EU border regulation, and considering the TRIPS Plus tendencies in EU negotiators' scheme of demands, any proposal on strict IP enforcements would arguably be just a matter of time. Any commitment on TRIPS Plus enforcement mechanisms by India would be highly detrimental not only for its generic pharmaceutical industry but also for the overwhelming majority of patients in the developing countries that depend on affordable yet efficacious Indian generic medicines.

3.9 Conclusion:

Most of the agreements outside the WTO TRIPS Agreement seem to be detrimental to the interest of developing countries. In this context, it is important to note the various disadvantages that the FTAs carry with them, in comparison with the multilateral trade agreements:

1. In an FTA between a developed and a developing country, the developing country is generally in a weaker bargaining position due to lack of effective negotiating skills or resources and delicate economic or political situations. This may be advantageous for the developed countries as it allows them to lay down measures that go beyond TRIPS.

2. The principle of special and differential treatment for States due to their socio-economic conditions is recognised in the World Trade Organization (WTO). The developing countries are thereby able to negotiate on the basis of non-reciprocity and for nonreciprocal outcomes. Therefore, they are not obliged to undertake obligations to the same degree as developed countries. However, these leverages are usually absent in FTAs which are negotiated on the basis of full reciprocity, as often such negotiations fall outside the GATT-WTO system. Consequently, there occurs an equal treatment of all parties representing a departure from TRIPS mandate.

3. Many a times, FTAs contain items that do not form part of the WTO rules. The developing countries have so far discarded these topics as subjects for WTO negotiations. However, items are creeping in through the FTA route and are taking the shape of binding obligations. Many binding border measures that form part of FTAs are thus TRIP Plus.

4. In WTO, the developing countries succeeded to obtain many flexibilities and options for implementation of TRIPS Agreement. But currently there are attempts by developed countries to take away these flexibilities. These attempts, if successful, would significantly reduce the policy space for developing countries to pursue development and socioeconomic goals.

5. There may be items in such FTAs which require a lot of technical expertise which may be not adequately available, given the large number of agreements and the limited resources. Such arrangements put pressure on the personnel and financial resources at various levels in the developing countries.

Thus the FTAs generally confine the policy space, that is, the options and instruments available to a country to institute certain social, economic and development policies suitable to its needs.

The plurilateral agreements like the ACTA, TPP or the RCEP firmly show the intent of countries to initiate negotiations at virtually every level. Although US has pulled out of the TPP, powerful nations may take advantage of that model. Weaker, smaller states hardly have much leverage at their disposal. Therefore, it is imperative for them to form coalitions among themselves in dealing with the industrialised countries. Such coalitions should be among developing and least developed nations whose interests mostly match with theirs.

The chief proponents of the plurilateral ACTA themselves have not been able to take home most of the strictures that they had initially asked for. No matter what the final text had contained, it was ultimately rejected by the European Parliament and therefore had their influence, over the individual FTAs with the partner countries of ACTA, significantly reduced. However, such a decision of the EU Parliament may also increase the probability on their part, to propose the inclusion of TRIPS Plus provisions abroad, so as to create a permeating effect within and amongst their own member countries.

The controversy and the resultant campaigns surrounding the plurilateral agreements like the ACTA or TPP negotiations are not uncommon. Developed countries like the US or economic blocs like the European Free Trade Association (EFTA) had often presented certain provisions in the FTA proposals that are not only TRIPS Plus, but also are indicative of a ‘one size fits all’ approach that are more suitable for their own conditions as opposed to those prevailing in developing countries. Developing countries faced with soaring public health crises, as in Thailand or in the instance of

states constituting the Southern African Customs Union had little option but to resort to outright rejection of such FTA proposals. FTA negotiations initiated by the advanced nations in these regions had thus come to a standstill (Lindstrom 2010: 972-973, 977).

It may also be worth mentioning that the WIPO Copyright Treaty 1996 in its 'agreed statements'[218] refers to the fact that its standard qualifies with that of TRIPS vis-à-vis certain aspects, in spite of their clear uncertainty. The idea apparently is to help interpret that these rules adopted at the WIPO are in concurrence with those of the TRIPS. However, the language used to express this consistency not only serves in a meagre way to resolve the ambiguity, but also potentially undermines the TRIPS at some places. Each of Article 4 of WCT and Article 10.1 of TRIPS, for example, state that computer software is protected by copyright. However, the subject matter of "computer programs" is dealt with differently in the two agreements. While TRIPS includes "whether in source or object code", the WIPO treaty provides for a broader definition for the same as, "whatever may be the mode or form of their expression", thus apparently providing a relatively generous range. This may, in the near future, make the more specific TRIPS definition outdated, following the advent and accommodation of newer technologies. There are other aspects though, wherein the WTO has to be consulted to resolve any definitional ambiguity (UNCTAD-ICTSD 2005: 55-56).

IPR infringements are not criminal offences *per se*. Yet a number of FTAs and in some cases, plurilateral agreements have either attempted or actually included criminal IPR infringement provisions that exceed the TRIPS norms. The inclusion of criminal enforcement provisions that ignore the essential factor of 'intention' in determining criminality[219] is a major flaw and represents an overreach. Thus,

[218] The 'agreed statements' of the *WIPO Copyright Treaty 1996* say, in reference to Article 4 and 5 that relate to computer programs and databases respectively and read with Article 2, that their scope of protection is consistent with both the Berne Convention and the complimentary provisions of the TRIPS Agreement. See 'agreed statements' in the endnotes, *WIPO Copyright Treaty 1996*.

[219] In criminal law jurisprudence, the element of '*mens rea*' (intention to commit a prohibited act) happens to be the main element, besides '*actus reas*' (a guilty act), in deciding whether a crime has at all been committed. The maxim, *actus reus non tacit reum nisi mens sit rea*, meaning 'an act does not make a person guilty of his crime unless his mind be also guilty' (Martin 2003: 10), is based on this very premise.

wilfulness and profit motive, that form the essentials of criminality as established under TRIPS, have often been found to be absent from these treaty provisions.

Finally, it may be mentioned that there has been a rapid emergence and push by developed countries or their stakeholders for inclusion of 'investor-state dispute settlement' (ISDS) mechanisms within the provisions of bilateral, regional or plurilateral agreements. Although few such proceedings have been rendered futile, such dispute redressal mechanisms may be aimed at placing non-state actors in private capacities to address ISDS cases that could attract public interest issues like health or education. This poses a major threat to the aspirations of the large chunk of population in the developing world and may prove to be too costly for their sustainability or developmental goals.

Chapter IV

International Institutions for Anti-Counterfeiting and Piracy

Chapter IV

International Institutions for Anti-Counterfeiting and Piracy

4.1 Introduction:

In recent times, the role played by International Organizations (IOs) in setting standards in international intellectual property protection and enforcement has assumed significance. Lately, there have been several efforts at the international organizational levels to raise the level of enforcement applicable to the various forms of IPRs. Whether it is creation of non-discretionary standards and norms for such purposes meant to be followed by their respective Member States, or taking action on the ground like actual seizure of counterfeit products; the range of these measures has been diverse.

A majority of these activities do not seem to fulfil the requirements of the TRIPS Agreement. In fact, till date, such standards considered or used, exceeded that of the TRIPS. That is why they have been referred to as extra TRIPS or TRIPS Plus.

The international institutions that primarily seem to be taking an active participation in such endeavours are the World Intellectual Property Organization (WIPO), the World Health Organization (WHO) the World Customs Organization (WCO), the International Criminal Police Organization (INTERPOL), Universal Postal Union (UPU), the International Telecommunication Union (ITU) and the UN Office on Drugs and Crime (UNODC).

In this chapter, it has been shown as to how these institutions have indulged in matters relating to counterfeiting and piracy, sometimes exceeding the standards set out in the TRIPS Agreement. Apart from organising events with selected stakeholders, there have also been efforts like the framing of model laws at international institutions such as the WHO, WCO and the UNODC. This indicates a paradigm shift in their very nature and functions. The aspect of unsolicited private funding in carrying out

programmes aimed at countering counterfeiting and piracy reflect the vulnerability of certain international institutions as well. As a consequence, not only are these institutions increasingly becoming susceptible to such external financial overreaches, but are also on the verge of losing their credibility. They also, in a sense, are aiding the international private corporations in carrying out their agenda to resist the developing countries' ability to realize their developmental goals.

In such a setting, Section 2 talks about the World Intellectual Property Organisation (WIPO) and its transformation from being a pro-developing country forum into an organisation being used today for favourable purposes of IP owners from developed States. An example shown is the programme on 'Building Respect for Intellectual Property'. Section 3 discusses about the World Customs Organisation (WCO) and its efforts in setting customs IP enforcement standards at a global level. It focuses on the instrument of such standardisation, the 'Provisional Global Customs Standards to Counter Intellectual Property Rights Infringements' (SECURE) and also considers the reasons for its withdrawal. Section 4 talks about the World Health Organisation (WHO) and the activities, including standardisation procedures initiated by pressure groups from pharmaceutical corporations, in line with the WIPO and the WCO. It puts forward the rationale as to why the WHO, being the plenary United Nations (UN) organisation on health, should not be used for making standards by means of lobbying efforts, including the creation of International Medicinal Products Anti-Counterfeiting Taskforce, or the IMPACT. It also analyses the recently disqualified working group on substandard/ spurious/ falsely-labelled/ falsified/ counterfeit (SSFFC) medical products. Section 5 deals with the efforts that were made indirectly at the Universal Postal Union (UPU), the international postal standards authority. It also mentions about the future plans of the organisation for the purposes of the same nature. Section 6 deals with the UN's International Criminal Police Organisation (INTERPOL). It looks at its 'Programme on Pharmaceutical Crime' and its measures on trafficking of illicit goods and counterfeiting. It further examines its publication initiatives, of late, and its closed doors meetings with representatives from private multinational corporations. Section 7 talks about the International Telecommunications Union (ITU), and its initiatives in organising meetings with other international organisations engaged in activities that aim at raising IP

enforcement standards. Section 8 brings up a rather unfamiliar UN organisation, the United Nations Interregional Crime and Justice Research Institute (UNICRI), that is being used to extend the range of activities that promote higher standards of IP enforcement. This UN unit mainly focuses on the issue by means of recent, one after the other, publications on organised and criminal breach of IPRs that have a bearing on Europe. Section 9 focuses on the United Nations Office on Drugs and Crime (UNODC) that engages in various activities concerning counterfeiting and piracy that have global connotations. It not only talks about the UNODC's campaigning and publications on product counterfeiting and efforts for a model legislation on counterfeiting of medicines, but also about joint exercises with other international organisations financed by private corporations. Section 10 analyses the entire chapter in light of a convergence of impending issues in all the organisations taken together, for demonstrating the future consequences of such efforts on developing countries.

4.2 World Intellectual Property Organisation (WIPO)

The World Intellectual Property Organization (WIPO) was established under the "Convention Establishing the World Intellectual Property Organization", July 14, 1967. The creation of the WIPO owes itself to the Stockholm Revision Conference of the Berne Convention in the same year. It could be realised owing to the eagerness of the less developed countries to establish an exception for themselves in the international intellectual property regime by the introduction of a new protocol in the Berne Convention. This protocol, however, has not been ratified until date (Yu 2004: 41).

The World Intellectual Property Organisation (WIPO) served as the chief international body on intellectual property rights until the end of the Uruguay Round of Trade Negotiations under GATT. After the introduction of the WTO-GATT system, the TRIPS Agreement and the WTO became the foremost authority for the creation, interpretation and adjudication of problems related to IPR.

On the issues regarding counterfeiting and piracy, the WIPO had conducted a number of meetings over the past few years. These meetings were hosted in collaboration with

some other international organisations like the World Customs Organisation (WCO) and the Interpol[1]. However, such meetings were conducted with the aim of setting newer, higher benchmarks of international IP enforcement standards that do not necessarily facilitate the interests of developing nations. On the other hand, existence of some such rules in the developed world had in recent times adversely affected legitimate trade and public health concerns, like access to affordable medicines, in developing countries[2].

4.2.1 WIPO Advisory Committee on Enforcement (ACE):

The WIPO Advisory Committee on Enforcement (ACE) is an advisory body of WIPO that had been formed in 2002. Recently at the World Intellectual Property Organisation (WIPO), an Advisory Committee on Enforcement (ACE) has been set up to deal with issues related to enforcement of IP[3]. The ACE's authority has been restricted to technical assistance and coordination on IP enforcement. Norm-setting has been expressly excluded from its mandate. It also has been entrusted to carry out the following functional objectives:

1. coordinating with certain organizations and the private sector to combat counterfeiting and piracy activities;
2. public education;
3. assistance;

[1] The WIPO alongside the WCO and the Interpol has been consistently involved in a number of meetings of the Global Congress Combating Counterfeiting and Piracy through the past decade or so. This initiative, in essence, is partnered and pushed by the private industry represented by business associations from the US, like the BASCAP and the INTA. See 'Global Congress on Combating Counterfeiting and Piracy', [online: web], accessed 5 July 2017, URL: http://www.wipo.int/enforcement/en/global_congress/

[2] IP enforcement regulations for customs authorities in the EU, for example the rules on transit, are higher than internationally accepted IP enforcement standards in the TRIPS Agreement. This has hampered access to essential medicines when generic drug consignments heading towards a couple of less developed South American nations were confiscated and detained by EU authorities during 2008 and 2009, for alleged violation of IPRs (Mara 2009b).

[3] See, Para 114 (i) of Report (WIPO 2002).

4. coordination to undertake national and regional training programs for all relevant stakeholders and
5. exchange of information on enforcement issues through the establishment of an Electronic Forum (WIPO 2002).

The ACE has been identified as an 'industry dominated' body that 'has devoted its efforts to discussing strengthening enforcement and problems that rights holders face in third countries' and 'has not devoted attention to public interest considerations' (Sell 2008). Besides this, the WIPO is also a member organisation of the IMPACT[4] group along with the WHO.

However, the WIPO does not opine by itself on such matters and relies mostly on the resources available with the WHO. It had been constituted by the mandate given under recommendation 45 of the WIPO Development Agenda. Thus, the WIPO's ACE has been somewhat able to limit the scope of lawmaking within the committee owing to restrictions laid down on norm-setting, which has nevertheless been assigned to technical assistance and coordination among member states. However, such programmes have often been taken over and in some cases, overshadowed by the involvement of the private industry or their associations in the name of funding them.

4.2.2 Building Respect for Intellectual Property:

A generous enforcement of IP is being endorsed and supported by a particular unit within the WIPO. It is called 'Building Respect for Intellectual Property'[5] – a project that had been approved by the 2008 WIPO General Assemblies[6]. This unit is collaborating with the private sector industry to set newer and higher IPR enforcement standards. In so doing, it has been actively participating and jointly organising events such as the Global Congress on Combating Counterfeiting and Piracy, together with

[4] An industry initiated taskforce or group consisting of industry associations and industry supported institutions, that also partners with the WHO and WIPO for campaigning on counterfeit medicines.

[5] See the WIPO's webpage on 'Building Respect for Intellectual Property' [online: web], accessed 5 July 2017, URL: http://www.wipo.int/enforcement/en/

[6] See, *Ibid*.

the Interpol and the WCO[7]. The most recent such event had been held in Shanghai, China in November 2016[8]. In addition, technical assistance under the new IPR enforcement agenda is also being provided. It is an initiative that is purely promoted, organised for and participated by private corporations with narrow participation from a majority of Member States. The varying conditions of different degrees of development among countries and their particular needs or implications seem hardly bearing any importance in such events. A report on the WIPO's overall technical assistance programs conducted by external reviewers in 2011 had found a number of lacunae according to the divisions in the report structure. The following are those:-

i) informational details of technical assistance programs provided by WIPO are neither transparent nor always available;

ii) specific requirements of countries are not always considered while providing assistance to the countries;

iii) no particular methodology has been followed while implementing the programs and findings or results are also patchy;

iv) substance and procedure of implementation of projects is also not properly brought together across the different areas covered by WIPO;

v) there is no clarity of information that is available to the public;

vi) recipient member states of the programs do not always participate in planning and deciding their objectives (Birkbeck and Roca 2011).

In addition to these, the report says that there was no common understanding or agreed definitions across the organization of terms such as 'technical assistance', capacity building, development activity or 'development cooperation activity'. It points out some significant shortcomings in WIPO's internal processes for defining, measuring and monitoring the distribution of its budget and expenditure. It refers to

[7] The Global Congress on Combating Counterfeiting and Piracy aims "to develop more effective solutions in pursuit of the common goal of building respect for IP and combating counterfeiting and piracy."

[8] See, 'International Conference for Building Respect for Intellectual Property', [online: web] accessed 5 July 2017, URL: http://www.wipo.int/meetings/en/2016/building_respect_conference.html

the fact that, the WIPO has devised an on-line database of its technical assistance activities which remains at the preliminary stage of implementation and suffers from numerous shortcomings (Birkbeck and Roca 2011).

4.3 World Customs Organization (WCO):

International Organisations are vital in identifying the infringements as well, hence easing out the determination of the counterfeit trademark goods and prated products. This was the mindset of the G-8 leaders while setting into motion the negotiations in establishing a new standard in IPR enforcement at the level of customs administrations (WCO: 2007a). Thus, the World Customs Organization (WCO) prepared a model legal framework for customs administration which deals with the border-related enforcement of IPRs.

4.3.1 WCO-SECURE:

In June 2006, the WCO Members established the "Provisional Standards to be Employed by Customs for Uniform Rights Enforcement (SECURE)". This document inflates the span of IPR enforcement radically. The WCO's Working Group on SECURE, after a three rounds of consultation, claimed to have formed a new standard for implementation.

The World Customs Organization (WCO) held the third meeting of the Working Group on the Provisional Standards Employed by Customs for Uniform Rights Enforcement (SECURE) in its Headquarters in Brussels 24-25 April 2008. The meeting, largely driven by some developed countries, was an attempt to promote their TRIPS Plus agenda on international border enforcement, i.e. deliberate universal standards and best practice that exceed those established by the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS), in the absence of the scrutiny of the international community. The WCO Secretariat appeared to have been targeting the adoption of this standard at its June, 2008 meet. It could not do so, and in the subsequent meeting of the WCO Policy Commission in December, 2008, it was

decided that the SECURE would be withdrawn. In June 2009, at the body's annual assembly it was the WCO replaced it with a dialogue mechanism (New 2009).

Nevertheless, the proposition and deliberations over the SECURE bear immense significance considering the future initiatives that are contemplated by the WCO in the area of international intellectual property enforcement. Hence, the document has been discussed briefly as hereunder.

4.3.2 Analysis of SECURE:-

The SECURE is referred to as the "Provisional Global Customs Standards to Counter Intellectual Property Rights Infringements". The SECURE enshrines enforcement rules and procedures for right-holders on one critical aspect of intellectual property rights enforcement, namely, border measures.

The SECURE draft is composed of an Introduction and four Sections. Section I of SECURE Working Draft, "IPR legislative and Enforcement Regime Development", lists 12 standards as the key component of the Working draft. The proposed scope and the level of enforcement of the 12 standards are much higher than that of any previous international agreements, especially the TRIPS Agreement, which is widely recognized as the most significant milestone in the development of intellectual property in the 20th Century, and the WIPO Development Agenda adopted in September 2007, which is a landmark achievement by developing countries to integrate development into IP policies.

This document, at its very inception (introduction) acknowledges the idea that the G-8 had in at least the preceding three of its meets, the agenda of combating IPR infringements. It explains the rationale for adopting such standard as being in the interest of the governments as they lose tax revenues that might be utilised for citizen welfare (Para 1 of SECURE).

In an apparent aim to validate the idea of bringing into play the customs (WCO), the document puts the customs administration as being "perfectly positioned" in putting

an embargo and thus upsetting the unlawful business in goods infringing the IPRs (Para 2, SECURE).

It lays down that the provisional standards, procedure and best practices offered in the document "will" be effective in controlling the global trade in counterfeit goods (Para 3, SECURE).

It mandates the WCO to co-ordinate with organizations like the Interpol, Organization for Economic Co-operation and Development (OECD), World Health Organization (WHO) and even the World Intellectual Property Organization (WIPO) besides the regional and other international organizations that have IPR "responsibilities". It advocates in favour of the global customs administration, which is essentially an assembly of public or governmental bodies, to 'interface' with the private entities to counter the problem. It lays down the three pillars on which the provisional IPR enforcement standards are resting, namely-

i. Customs-to customs cooperation (dealt in Section I);

ii. Customs/Right holder partnerships (dealt in Section II); and

iii. Customs interface with other private entities engaged in the fight against counterfeiting (dealt in Section III) [Para5, SECURE].

It further authorizes the Secretary General of the WCO to institute a working group of SECURE which will surpass all other intellectual property rights and such-related groups at the WCO (Para 9, SECURE).

Section I deals with "IPR Legislative and Enforcement Regime Development". It proposes to legally authorise the customs administrations to enforce IPR Laws in cases of goods that are under import, export, transit, warehouses, transhipments, free zones, free ports, portal shipments or even goods that are ordered via the internet. It proposes for national customs authorities to stretch the customs' IPR enforcements beyond the domain of trademarks and copyright to the "other" IPR areas (Standard 3). It also intends to audit the goods that have already been cleared at the border, hence being authorised for carrying out 'post-clearance audits' of imports (Standard 5). It

calls for the individual customs authorities to have a single authority delegated as the point of contact for catering to the matters of IPR enforcements.

Section II of the document deals with "Risk Analysis and Intelligence Sharing". Here, the customs authorities are empowered to not only create, but also apply those standards that specifically counter counterfeiting (Standard 2). This seems to be a quasi-judicial power to somehow decide on infringements clearly proposed to be conferred on the customs for countering the local, national and international unlawful trafficking. The different national customs authorities are proposed to set up 'Specialized teams" in order to combat counterfeiting (Standard 5).

Sec III deals with "Capacity Building for IPR Enforcement and International Cooperation". This section mainly focuses on training in collaboration with the private sector for the promotion of the 'legislative' and 'operational' best practices, and strangely enough, such private sector entities are also proposed to be part of taking into account the socio-economic 'realities' of each Member State (Standard 16 ii). This will obviously include the developing States as well. It also proposes to develop curricula that jointly cover the business and customs procedures at the same time (Standard 17).

This shows, undoubtedly, to what extent, the WCO had been sought to be manoeuvred by the transnational entities that have a very keen interest to come up with such standards. However, very recently, the organization appears to have altered its position on the issue.

4.3.3 Withdrawal of SECURE:

The customs supervisory body had been under sharp criticism from non-governmental entities and developing country members since when it created the SECURE. In the wake of sharp controversy as regards the authority and expertise of the customs to decide upon issues of intellectual property, the agency reportedly has decided to withdraw the SECURE (New 2009). In its meeting of the Directors General of 174 nations held between 25 and 27 June, the customs supervisory authority decided to put an end to the SECURE and in its place created a new dialogue-based

'Counterfeiting and Piracy' (CAP) group which would look after health issues taking into account the legal and enforcement typicality of each of its member nations (New 2009).

The proposed SECURE under WCO, if were adopted, would have had far reaching consequences. If compared with WTO TRIPS Agreement, the proposed SECURE standards on IP enforcement border measures are indicative of a significant departure from TRIPS provisions in terms of scope and strength of the border measures and obligations of the member states. The delicate balance under TRIPS would have been broken, thus affecting the flexibilities contained in TRIPS. From the standpoint of the WIPO Development Agenda, the proposed SECURE standards lean in favour of the right holders of IPRs, thus upsetting the balance between the right holders and other stakeholders, such as importers, manufacturers, consumers, (for example in respect of generic pharmaceutical products), etc. As of now, the SECURE seems to have faded away. But the enduring CAP group formation is still a formidable issue since the WCO, as earlier mentioned, does not have the expertise or required international legal mandate to deal in issues relating to intellectual property that are supposed to be dealt by specialised agencies like WIPO.

At present, the WCO clearly seems to be an equivalent partner alongside the WIPO and Interpol in organising and hosting meetings of the 'Global Congress on Combating Counterfeiting and Piracy'. In fact, it has chaired the latest meet in Istanbul, Turkey in 2013[9]. Therefore, the WCO being a law enforcement authority has not been spared of the cooption tactics adopted by the associations of multinational corporations who have deep interest in protecting their brands. However, the implicit overreach in matters concerning IP cannot be ignored in any of such initiatives, and

[9] The 7th Global Congress on Combating Counterfeiting & Piracy was held in Istanbul, Turkey, 24-26 April 2013. The Wold Customs Organisation (WCO) chaired the meet while World Intellectual Property Organisation (WIPO) and International Criminal Police Organisation (INTERPOL) were among other participating international organisations. Besides, business lobbies like Business Action to Stop Software Counterfeiting and Piracy (BASCAP) group of International Chamber of Commerce (ICC) and International Trademark Association (INTA) co-sponsored the event. See, '7th Global Congress on Combating Counterfeiting and Piracy (Istanbul, April 24-26, 2013): Evolving Challenges – Innovative Responses', [online: web] accessed 5 July 2017, URL: http://www.wipo.int/enforcement/en/global_congress/

still seems to be a matter of profound concern for the developing country stakeholders.

4.4 World Health Organization (WHO):

The World Health Organization is a specialized organ of the United Nations that oversees issues that concern the health of the world population. In such a pursuit, it seeks to ensure that the world's poor, who are the most vulnerable to any health risk, are well taken care of. The organization however, is taking into consideration plans to combat the menace of counterfeiting of medicinal drugs on a global scale since 1999 (WHO 1999). But those strategies tended to be materialized only as later as in 2006.

Recently, it had pondered upon and formed an international taskforce, with multifarious functions, to combat counterfeiting of medicines around the globe. This taskforce consisted of parties from almost all spheres like the industry, international organizations, organization of States and even the international financial institutions.

4.4.1 WHO International Medicinal Products Anti-Counterfeiting Taskforce (IMPACT):

On 15th November 2006, the World Health Organization (WHO) fashioned and founded the International Medicinal Products Anti-Counterfeiting Taskforce, or the IMPACT in Bonn, Germany. The main aim of this taskforce was to build synchronized networks across and among countries for bringing to an end to the manufacture, business and sale of fake medicines around the globe (WHO 2006).

The taskforce is composed of *inter alia,* the representatives from the WHO, Interpol, Organization for Economic Co-operation and Development(OECD), World Customs Organization(WCO), World Intellectual Property Organization(WIPO), World Trade Organization(WTO), International Federation of Pharmaceutical and Manufacturers' Associations(IFPMA), International Generic Pharmaceuticals Alliance, World Self-

medication Industry, *Asociación Latinoamericana de Industrias Farmacéuticas*, World Bank(WB), European Commission(EC), Council of Europe, Commonwealth Secretariat, ASEAN Secretariat, International Federation of Pharmaceutical Wholesalers, European Association of Pharmaceutical Full-line Wholesalers, International Pharmaceutical Federation, International Council of Nurses, World Medical Association, and *Pharmaciens sans frontières*. The Interpol has dedicated one of its officers on a full-time basis for carrying out the programmes of this taskforce. The involvement of the national government representatives, however, is not mandatory (IMPACT 2008).

IMPACT sought to comprehend five concerns, namely as follows –

i. Legislative and regulatory infrastructure;

ii. Regulatory implementation;

iii. Enforcement

iv. Technology; and

v. Communication.

i. Legislative and regulatory infrastructure: This issue is indicative of developing tougher laws that can empower the police, customs and the judiciary. The existing laws in different countries is said to have been looked into by the taskforce as also the models that are said to be presently successful and have come up with a set of principles so as to instigate countries to reproduce and adopt them according to their own requirements[10]. It will also focus on developing principles for the

[10] The IMPACT (2008) document refers to the fact that 'stakeholders' in the taskforce had already 'reviewed' the existing legislations in concerned countries and had thus come up with the 'Principles and Elements for National Legislation against Counterfeit Medical Products' (IMPACT 2008: 5).

establishment of appropriate legislation and penal sanctions, including a definition of "counterfeit medicines" under the law.

ii. Regulatory implementation: This indicates identifying the modes by which the regulators may take action and implement legislative measures taken on counterfeit medicines. It includes modified approaches to their quality, safety and efficacy so that some prescribed standards are implemented as regards the detection, regulation, control, investigation, prosecution of such products and the supply networks are well bridled.

iii. Enforcement: This signifies facilitating the identification and synchronized actions between customs officials, the police and the judiciary of different countries so as to keep an eye on the borders, tracing such counterfeits and thence, grabbing hold of the counterfeiters. In so doing, some advice may be taken from the regional groups or other groups which are familiar in dealing with counterfeiting.

iv. Technology: This aims to help aid the applicable technology pass on to countries across the levels of their development, for the authentication of any such products, by utilizing the broad partnership among the health agencies, pharmaceutical manufacturers and distributors.

v. Communication: This is intended to help make out and devise the corresponding potent mechanisms to counter and alert key receptors, stakeholders and the general society about counterfeits in communities and across all the nations (IMPACT 2008: 5-6).

In the following section, an analysis of the IMPACT document described above, has been made.

4.4.2 Analysis of IMPACT:

The WHO IMPACT has attempted to harmonize the anti-counterfeiting initiatives at the WHO. The document goes beyond the mandate of the WHO to deal solely in health and health-related issues, and prescribes IPR standards for countries across the board, irrespective of their levels of development. But the main problem that transpired from this document is regarding the definition of counterfeit which said that counterfeit drugs are:

> … medicines which are deliberately and fraudulently mislabelled with respect to identity or source. Counterfeiting occurs both with branded and generic products and counterfeit medicines include products with the correct ingredients but fake packaging, with the wrong ingredients, without active ingredients or with insufficient active ingredients (IMPACT 2008: 1).

Here it appears that the definition proposed by IMPACT removed the clause "deliberately and fraudulently" and replaces it with "a medical product … when there is a false representation in relation to its identity, history, or source". It further said that "this applies to the product, its container, packaging or other labelling information". IMPACT also wanted to see that WHO definition on counterfeiting "can apply to both branded and generic products and include products with correct ingredients/ components, with wrong ingredients/ components, without active ingredients, with incorrect amounts of active ingredients, or with fake packaging." Problems would have likely taken place with the phrases like, "….. It has been found that counterfeiters copy or imitate existing products, but they also manufacture products which they have invented, and are not normally available" (IMPACT 2008: 1).

IMPACT has been a controversial document right from the time of its inception, largely because it is perceived to be an agenda to pursue overreaching intellectual property enforcements by the industry groups belonging to the developed nations

(Sell 2008). One of the reasons for such an occurrence may be that the so-called 'originator' drug firms that are doing roaring businesses around the world are mostly, if not all, belonging to or incorporated with the developed nations. The developed nations are not only technologically more advanced than the developing countries, but are also aware of the fact that the developing countries or most of the pharmaceutical companies originating there, cannot afford to resort to such highly developed technologies for countering counterfeiting due to their domestic economic constraints. The people of developing, transitional or less developed countries may just not have enough economic capacity to have access to certain crucial medicines of Western origin, and which do not, nevertheless, come at a very cheap price.

It is inferable that the IMPACT document has been stimulated by the interests of the multinational pharmaceutical firms. It is also no surprise that these firms face stiff competition in the developing countries in the sales volumes of their products. This happens due to the enormous presence in these markets of the generic versions of the medicines that they themselves claim to have produced and invented. Such generic versions help cater to the huge demand for crucial medicines in these countries where the common people do not have enough means to buy the expensive medicines produced by such transnational pharmaceutical companies. Presence or production of such cheaper, generic versions of medicines is not at all contrary to the spirit of international IPR regime endorsed by the TRIPS. Articles 7 and 8 of TRIPS have categorically mentioned about the public health considerations that come parallel along with the implementation of any IPR legislation, hence indicating that the IPRs should not impede the rights of the people to have access to essential medicines.[11] This has also been reiterated in the successive ministerial meeting of the World Trade Organization (WTO). The developed countries, or at least some of them by promoting such a document, are believed to be breaching the tenets of the Doha (Ministerial)

[11] The principle, that the IPRs should balance between the rights and obligations of both the right holder and the users (read, consumers here) and should not form an obstacle to matters of socio-economic welfare including public health, has been embodied in Articles 7 and 8 of the TRIPS Agreement.

Declaration of 2001 that they had themselves resolved to (World Trade Organization 2001, Médecins Sans Frontières 2003: 2).[12]

On the other hand, the developing countries have much to be worried about in the whole affair. They (or their pharmaceutical and medicinal product markets) have not been shown in a good light as against their developed counterparts[13] (IMPACT 2008: 3), indicating that their governments have not been able to have an effective control over such markets. It is true that some such developing nations are at present not in a position to face such a challenge posed by the menace of counterfeiting, but saying that this concern has not been largely taken care of, perhaps, may not be the correct assumption. The main cause of botheration for the industrialised countries or their pharmaceutical trading entities is the threat posed by the size of the generic medicines market in these developing and less developed nations. The very inclusion of generic medicines within the ambit of counterfeits[14] might well give rise to conjectures such as the generic market for which such generic pharmaceutical companies are being targeted; it is well founded that the giant multinational drug firms are behind these developments (Shankar 2008). There appeared to be a deliberate attempt to create confusion whereby the large multinational drug manufacturers could benefit.[15] While it is true that the generic versions may also become victims of counterfeiting, but portraying their entire category in the way it has been done in the document was certainly not appropriate, especially when the document itself admits that the data provided therein is only suggestive and an merely an approximation, rather than being

[12]The Medecins Sans Frontieres Briefing (MSF 2003) also mentions, "At the 2001 Ministerial Conference in Doha, Qatar, Members of the World Trade Organization (WTO) adopted the groundbreaking 'Declaration on the TRIPS Agreement and Public Health', which unequivocally recognised that access to medicines should have primacy over commercial interests."

[13] IMPACT (2008) states that, "Most industrialized countries with effective regulatory systems and market control (e.g. USA, most of EU, Australia, Canada, Japan, New Zealand) have an extremely low proportion, i.e. significantly less than 1% of the market value;" And also, "Many countries in Africa and parts of Asia and Latin America have areas where more than 30% of the medicines on sale can be counterfeit".

[14] IMPACT (2008) mentions, "Counterfeiting of medicines occurs both with branded and generic products."

[15] The IMPACT (2008) document also says, "It has been found that counterfeiters copy or imitate existing products, but they also manufacture products which they have invented, and are not normally available."

substantiated data as such (IMPACT 2008: 3).[16] In addition, it may be mentioned here, that an earlier WHO survey is indicative of the fact that albeit the situation had been worse in the developing countries, yet, the percentages of counterfeit drugs had not been much different in many of the developed countries as well (WHO 2003). Hence, the argument that only the not so well-to-do countries are not in a position to take action themselves against the counterfeiters (IMPACT 2008: 2, 3) may not be fully sustainable.

The issue that is perhaps one of the most alarming in this context is the applicability or scope of the document. Apprehensions have already been expressed regarding the span of the content that pertains to counterfeiting as under the IMPACT document. As some of the literatures suggest, the document makes certain reference that purports to make patent infringement as counterfeiting[17]. These infringements are also suggested to be made as criminal offences. This is not at all an acceptable proposition, as TRIPS does not permit the offence of counterfeiting being a criminal offence unless it is (1) wilful and, (2) meant for profits. Unless both these conditions are together met, the offender cannot be treated to have committed any criminal offence.[18] Such fear articulated as to the cutting off of the supply of generic medicines has not been unfounded at all. Recently, a whole consignment of generic medicines has been left at the mercy of the European authorities as the Dutch customs held to their custody at least three shipments of Indian generic drugs that were officially meant for the same number of South American States (BRIDGES Weekly 2009 13(3)). A number of raids

[16] It has been said in the IMPACT (2008) document clearly, that, "These estimated ranges do not aim at providing an exact figure but rather an indication of the different possible levels of prevalence in different parts of the world."

[17] The Medicins Sans Frontieres report also states, "Counterfeiting and piracy are different from patent infringement." It also adds, "The TRIPS Agreement does not require that patent infringement be made a criminal offence—it only requires that the patent holder be able to take legal action against the infringement. Where people cannot afford the patented version of a life-saving medicine they may try to import or use a less expensive generic version; the patent holder may then choose to sue to cut off the supply of generic medicines. Legal provisions that criminalize patent infringement… could result in sending doctors and patients to prison for trying to get access to affordable medicines. Such provisions are harsh, extreme, and certainly not required by TRIPS" (MSF 2003).

[18] This stipulation comes under TRIPS Article 61 that reads as, "Members shall provide for criminal procedures and penalties to be applied at least in cases of wilful trademark counterfeiting …….. on a commercial scale."

have already been carried out, and are also currently being executed in developing countries across the world by the IMPACT taskforce in the name of ending the organized counterfeiting[19].

The continuation of activities of the IMPACT taskforce, in spite of bearing grossly biased terms favouring the MNCs in its very generic document (IMPACT 2008), is quite acutely problematic under international law. Such continuation of activities in the name of curbing counterfeit medicines indicates a complete breach of international law when it had not at all been accepted by the international community, especially the developing countries, owing to it being adversarial to their vital national and other interests, at the very forum from where it had been intended to be launched, the World Health Organization.

The next issue, which is of no less concern, is the data provided by the IMPACT document. The document presents a data on counterfeit medicinal/ medical products, published on an intergovernmental organization's official website, which was not made available to them by any governmental, intergovernmental or other authorized agency of the same kind. This document refers to the data on counterfeiting as being provided by the Pharmaceutical Security Institute (PSI). This institute is a trade body that comprises of the security directors of 14 major transnational pharmaceutical companies, and the body itself presently comprises of 33 such companies in all.[20] The credentials of the data provided by such a trade organization moulded by such private corporations are, however, not beyond doubts. While the WHO itself provides different data in different documents, the fact that the United States Federal Drug Agency (USFDA) and the European Commission (EC) data also differ from each other, clarifies the blurry picture of the data resources regarding the problem of drug counterfeiting[21]. Some authors have already expressed their reservation over the

[19] For example, 'Operation Mamba' of 2008 in Tanzania and Uganda; the INTERPOL has also made similar operations like 'Operation Storm' in Southeast Asia, 'Operation Jupiter' and 'Operation Pangea'; Data on these are available at INTERPOL official website, URL: http://www.interpol.int

[20] See, the official webpage of Pharmaceutical Security Institute (PSI), [online: web] accessed 5 July 2017, URL: http://www.psi-inc.org/index.cfm.

[21] In one of its studies, the WHO says that counterfeit medicines make up for more than ten percent of medicines in the world today (ICN 2005a), while in another, the same WHO says that the percentage of counterfeit or substandard medicines is as high as twenty-five percent in some developing countries

authenticity and numerical estimates about such data (Outterson and Smith 2006: 527). Notwithstanding this, the developing countries, irrespectively, have been implicated much more than their developed counterparts[22] for reasons which are by far more similar in both the kinds of economies.

4.4.3 Change in WHO policy on IMPACT:

Amidst widespread protests and grievances on part of large number of developing countries, nongovernmental organisations (NGOs), the industry and other stakeholders, the WHO had, in its World Health Assembly held in May 2008, reportedly decided that it would not further take up the issue of counterfeits (Mara 2009a). A lot of criticism and complaints by the civil society groups and developing countries ultimately seems to have frustrated such efforts carry upon under the aegis of the UN's health agency. The continuation of functioning of such a force which was essentially comprised of private multinational companies from the developed nations had been put on hold as the health supervisory body soon appeared to be disinclined to focus on the issue of counterfeits (Mara 2009a). Nonetheless, this was a positive development in favour of the developing countries that was to be expected to go a long way in making sure that such unwarranted impositions by private interest groups are not repeated any further.

4.4.4 WHO Working Group on SSFFC medicines:

At the 63rd World Health Assembly held in May 2010, a debate ensued between the developing countries and their developed counterparts on the issue of continuation of

(ICN 2005b). Again, the then Deputy Secretary General of the European Council stated that WHO accounts says that counterfeit medicines comprise eight to ten percent of the European pharmaceutical market, and in some countries it extends up to twelve percent (Liang 2006: 292). Whereas the USFDA, while reiterating the WHO figure in case of international pharmaceutical counterfeiting, brings down their home figure to as low as only around one percent of the their domestic pharmaceutical market (IMPACT 2008); (Liang 2006: 283).

[22] In one of the literatures, the 'WHO figures' suggest that the developing countries account for around 60 percent of all reported cases of counterfeit and substandard drugs (ICN 2005a), wherein an "Action Tool Kit" for International Nurses Day 2005 has been provided.

the IMPACT taskforce within the WHO. The developing countries led by India and Brazil stated that IMPACT was nothing but a 'hidden agenda' of the large drug manufacturers from developed countries to prevent the competition posed by generic medicines that are mainly produced in developing nations. The representative of Brazil even questioned the WHO's mandate for policing as was being done under the IMPACT programmes. Developing countries added that the WHO was intentionally being used by developed country firms to confuse the issue of spurious, substandard and falsified medicines with that of counterfeiting in order to pursue their agenda. There were questions raised not only on the functioning of IMPACT outside the legal sanction of the WHO, but also its apparent effect in influencing certain developing countries (like Kenya, for example) to bring legislations that are based on similar concerns (Mara 2010).

Finally, the WHO's primary 'role' in ensuring the safety, efficacy and quality of medical products was acknowledged and a "time-limited and results-oriented working group" was established "on substandard/spurious/falsely-labelled/falsified/counterfeit medical products comprised of and open to all Member States" (WHO 2010: 67). Thus the currently functioning working group on SSFFC medical products at the WHO was formed.

It was decided categorically that this new working group shall exclude trade and IP matters; it shall report and make recommendations to the WHA on the following:-

- WHO's role in measures to endure the availability of quality, safe, efficacious and affordable medical products;
- WHO's relationship with IMPACT
- WHO's role in the prevention and control of medical products of compromised quality, safety and efficacy such as substandard/spurious/false-labelled/falsified/counterfeit medical products from a public health perspective, excluding trade and intellectual property considerations (WHO 2010: 68).

In November 2011, there was a consensus reached between the parties on the WHO's working group on "substandard/ spurious/ falsely-labelled/ falsified/ counterfeit" (SSFFC) medical products. The working group agreed upon a draft resolution with an annex, mechanism, goals, objectives and the terms of reference. It was also agreed

that the term 'SSFFC' was not easy to define, and that any such mechanism proposed in the WHO should focus on the quality, safety and efficacy of medicines rather than merely on counterfeit drugs (Hermann 2011).

4.4.5 Member-State mechanism on SSFFC medical products:

In the 65th World Health Assembly (WHA) of the WHO in 2012, the Member-State mechanism on SSFFC medical products was instituted. The WHA in resolution 65.19 recognised the reality that "many people in the world lack access to quality, safe, efficacious and affordable medicines and that such access is an important part of a health system" and also the fight against SSFFC medical products "does not result in hindering the availability of legitimate generic medicines" (WHO 2012: 29). This system mainly aimed for three things besides looking into the various aspects concerning the SSFFC medical products. They are the following:–

i. "international collaboration among Member States",
ii. that will act "from a public health perspective" and
iii. that will be "excluding trade and intellectual property considerations …."(WHO 2012: 30).

It also asks Members States to join the mechanism voluntarily (WHO 2012: 30). It clarifies that the term "substandard/spurious/falsely-labelled/falsified/counterfeit medical products" shall remain in use until a definition has been approved by the WHO governing bodies. Endorsement of the mechanism to look at the issue from the viewpoint of public health exclusive of any intellectual property consideration and promoting "access to affordable, safe, efficacious and quality medical products" as a 'general goal' (WHO 2010: 31), expectedly comprise a lot of significance for the developing Member States.

4.4.6 Working Group proposal and removal of the term 'counterfeit':

The informal technical working group (SSFFC) medical products had a meeting on the 22nd of November, 2016, wherein they recommended a change in the term on

substandard/ spurious/ falsely-labelled/ falsified/ counterfeit. It was advised that the term 'counterfeit' should be dropped and instead, be changed to 'substandard and falsified'. It recommended three distinct categories of 'authorised medical products' that are mutually exclusive of each other (WHO 2016: 3). Since, including the term 'counterfeit' usually brings in intellectual property elements that indeed had led to seizures of lawful generic medicines from India destined for poorer countries, this recommendation was anticipated to simplify the confusion and help in preventing such arbitrary detentions and help access to medicines for those in need globally (Saez 2016). The WHO Executive Board approved the terms 'substandard and falsified' in January 2017. The term 'counterfeit' with reference to poor quality and fake medicines, was in use at the WHO for a period of around three decades (New 2017).

A common, globally accepted terminology for the previously used term, 'SSFFC' medical product, was thus brought into being at the WHO. In March 2017, the official report of the Director General of the Member-State mechanism on SSFFC medical products, mentioned the new terminology to be used as "substandard and falsified medical products" (WHO 2017a). The new definition for the two terms 'substandard' and 'falsified' as established in the group's November 2016 meeting, is stated in the report as:

a. substandard: "Also called "out of specification", these are authorized medical products that fail to meet either their quality standards or their specifications, or both" (WHO 2017a: 34).

b. falsified: "Medical products that deliberately/fraudulently misrepresent their identity, composition or source" (WHO 2017a: 34).

   It adds that "When the authorized manufacturer deliberately fails to meet these quality standards or specifications due to misrepresentation of identity, composition, or source, then the medical product should be considered "falsified"[23]. It also resulted in the addition of another category by the name

[23] This is inserted as a footnote under the definition. See, fn. 1, WHO 2017a: 34.

"unregistered or unlicensed medical products". These have been defined as those:

> … which have not undergone evaluation and/or approval by the NRRA[24] for the market in which they are marketed/distributed or used, subject to permitted conditions under national or regional regulation and legislation.
>
> These medical products may or may not have obtained the relevant authorization from the national/regional regulatory authority of its geographical origin (WHO 2017a: 35).

It further appends a clarification, originating from the mandate given to the SSFFC working group that, "Any consideration related to intellectual property rights *does not fall* within this definition" (WHO 2017a: 34-35).

The latest World Health Assembly in May 2017, therefore, saw delegates reaching an agreement on this entire subject matter (WHO 2017b). In so doing, it took the ultimate step in removing arguably some of the most complicated terminologies and thereby deciding on one of the most testing debates over a prolonged period.

4.5 Universal Postal Union (UPU):

The global postal authority had also been considered as another element of the interest group[25] at the international level to pursue, negotiate and foment a new generation of enforcement of intellectual property rights. Besides the WCO and the WHO, the international postal coordinating authority, the Universal Postal Union (UPU) has also come out with a well-drafted plan to cooperate and thwart the problem of counterfeiting.

The Universal Postal Union, headquartered in Berne, Germany, happens to be one of the oldest international organizations, second only to the International Telecommunication Union (ITU). According to the latest figures provided by the

[24] NRRA here stands for national and/or regional regulatory authorities (WHO 2017a: 16).

[25] The other members of this interest group are negotiating partners of the Anti-Counterfeiting Trade Agreement (ACTA) and few international organisation namely, World Customs Organization (WCO), World Health Organization (WHO), Universal Postal Union (UPU), the G8 and the (See 'Executive Summary' in Li 2008)

organization itself, the UPU has 192 Member States party to it. The Universal Postal Congress is the highest (supreme) authority of the international postal body (UPU) and meets every four years (UPU 2015). At no time until recently, the issue of counterfeiting did ever feature on the list of issues for discussion on the floor of the Congress. Even in its coordination with other organizations which it had been doing since quite a long time, the issue of countering counterfeiting has gathered momentum of late (WCO 2007b).

4.5.1 Deliberations on Resolution 40:

At its 24th Congress on 1st August, 2008, the Universal Postal Union adopted Resolution 40 on "counterfeit and pirated items sent through the post" (Fattahi 2008). This resolution "urges member countries in the context of national legislation to encourage their postal administrations to:

- take all reasonable and practical measures to support Customs in their role of identifying counterfeit and pirated items in the postal network; and
- cooperate with the relevant national and international authorities to the maximum possible extent in awareness-raising initiatives aimed at preventing the illegal circulation of counterfeit goods, particularly through postal services" (Fattahi 2008).

The 24th Congress saw three proposals being laid on its floor. These were as follows:

i. Resolution 40 on "Counterfeit and pirated items sent through the post".

ii. an amendment to the UPU Convention on the list of articles prohibited through the post; and,

iii. an amendment to the Convention on sender's liability (Shashikant and Tayob 2008).

Resolution 40, in its preamble, notes that the postal service is being used along with the other means of circulation, in the sending of counterfeit and pirated items. It further says that from a study by Postal Operations Council (POC) 3 Customs Support Project Group customs and security-related issues on matters concerning intellectual property, it has come to be known that the UPU has neither the expertise nor legal competence to deal with such issues. Besides acknowledging that the customs authorities are proficient enough in dealing with counterfeit items, it admits that operational and legal complications at the national level remain a problem. Hence, in order to address this, some "performance indicators" such as assisting designated operators for building up strategies at national level together with national customs authorities and other learning and cooperation in logistical, educational and operational techniques had been proposed (Shashikant and Tayob 2008).[26]

The resolution was introduced by France saying that postal avenues are being used for the dispatch of counterfeit items and adding that it was the global customs body which raised the issue. Germany, while favouring the resolution, also pointed out that since the postal authorities were not in a proper position to deal in such issue, this should rest with the customs. The US said that though the postal bodies are not in a position to implement matters concerning intellectual property enforcement, the postal bodies do cooperate and help in such issues. The Malaysian representative objected over the usage of the term "reasonable and practical measures" in assisting the customs as it is nowhere clear as to what this term actually means. It also expressed concern over the need to raise maximum awareness to prevent illegal circulation of counterfeit goods particularly through postal services adding that it also hints to indictment of the postal authorities for the movement of counterfeit items, albeit there are nations where the detection of counterfeit items rest solely with the other specialised departments rather than the posts, hence the language used calls for further refinement. When Saudi Arabian delegate said that in his country the issue is dealt with by the culture

[26] The article adds, that the "performance indicators" include, "assistance given to designated operators to develop strategies at a national level in cooperation with national customs authorities; enabling postal administrations to learn risk-assessment techniques on how to identify counterfeit and pirated items in the postal network; reading materials developed in cooperation with the WCO; participation of the UPU at international forums to study/follow postal-related issues concerning IP infringements; developing an e-learning module in cooperation with the WCO" (Shashikant and Tayob 2008).

department, France clarified that “reasonable” measures mean that it was up to each country to implement the regulations according to its own specific interpretation. Brazil suggested an addition to the proposal as, “in the context of the national legislation”. In the voting that took place since the chair terminating the deliberations for voting, notwithstanding various other nations wanting to issue statements, 95 voted in favour and 22 voted against it while 20 abstained from voting. These results prompted a group of nations co-sponsored by Egypt, India, Jordan, Libya, Malaysia, Pakistan, Saudi Arabia, South Africa, Syria, China and Turkey to file an appeal for amendment in the plenary session of the Congress where it comes up for the final adoption (Shashikant and Tayob 2008).[27] An amendment to Article 15 of the 2004 Bucharest Convention which pertains to the list of articles prohibited (to be sent by post) was also sought by France and Italy supported by Great Britain and Netherlands. They proposed to include in the list of prohibited articles: (1) a new paragraph 2.1.2bis on "counterfeit and pirated articles"; (2) the word "other" in front of "articles the importation or circulation of which is prohibited in the country of destination"; and (3) a new paragraph 2.1.5bis on "where prohibited articles are identified, they shall be treated in accordance with the national legislation" (Shashikant and Tayob 2008). The third and final proposal moved by France and supported by Britain and Italy was the amendment of Article 23 of the Convention and inclusion of a new paragraph 4 bis on sender's liability. It read: "The sender of a pirated or counterfeit good shall be fully liable, under the legislation of the country of origin as well as that of the country of destination". Apprehensions were expressed by Canada, US and China *et al* saying that this creates “extraterritoriality in terms of application, as also being unclear in terms of its civil or criminal enforcement or measures. This proposal,

[27] According to the article, the exact areas where amendments have been sought are:

PP 1 (bis) -- "Without prejudice to the ongoing IP related work in other competent international organizations"

PP 4 (alt) -- "Understanding that determination of counterfeit items is the responsibility of relevant national authorities, in accordance with national legislation".

(PP here signifies proposals)

on being put to vote, was rejected since 42 nations favoured it, 53 opposed and 36 abstained from voting (Shashikant and Tayob 2008).

4.5.2 Some Initiatives on Counterfeiting as planned by UPU:

So far, the global postal authority has already set a great deal of gravity on the issue of counterfeiting or, in postal parlance, the sending of counterfeit goods and products. Some of the measures that have already been undertaken by the body are:

a. Inclusion of counterfeit items in the list of prohibited items that are to be sent through the post.

The inclusion of the subject in the list of prohibited articles to be sent through the post appears to be a clear signal as to the importance UPU is giving to the issue. It has already passed the resolution 40 that deals with "Counterfeit and pirated items sent through the post". It is now to be brought about in the plenary session of the institution so that it gets a final go-ahead. It has already cooperated with the customs authorities on a large number of remedial measures that may be taken to counter the problem of counterfeiting (UPU 2008).

b. Develop electronic messaging with the customs.

The UPU, admitting that superior electronic data is likely to enable the customs to have a better say on the counterfeit items, intends to cooperate more on the issue. In so doing, it has already submitted the design of the electronic message to the WCO, and a new device is being developed for the detection of the multiple offenders.

c. Raising awareness of postal employees about counterfeit products

UPU is said to have developed a new course for educating its employees and in it a 'security module' has all the necessary information about the counterfeit items. Along with the WCO, the UPU had also planned to set up 'an e-learning module on IPR infringements being committed through postal traffic' (UPU 2008).

d. Developing a checklist so as to improve the compliance with the customs declarations.

The senders shall be informed on a prior basis about the fact that the counterfeit items (goods and products) are not allowed to be sent by the post. Among others, the senders shall also be warned about the potential liabilities and consequences upon sending of such counterfeit items through the mail.

e. The Union (UPU) plans to have a study on counterfeit products.

The postal authority also had a plan to have a vivid study conducted on the issue of counterfeit products sent through the post. The study was planned to be done between 2009 and 2012. It was said that a proposal to this extent had been sent to the Postal Congress for approval (UPU 2008).

4.6 International Criminal Police Organization (INTERPOL):

The international police organization has of late shown a lot of interest in enforcement of IPRs. The organization has recently declared to have established a permanent, full-fledged unit on intellectual property. It claimed to have found a link between terrorist financing and intellectual property 'crimes' around the world in 2003 (INTERPOL 2003). The Interpol seems to have connected the issue of counterfeiting with several alleged terrorist groups operating across the world (Foxnews.com 2004).

The global law enforcement organisation has got a number of crimes enlisted on its website, out of which 'Trafficking in illicit goods and counterfeiting' and 'Pharmaceutical crime' are relevant to the topic of this thesis.

4.6.1 Trafficking in illicit goods and counterfeiting:

The Interpol has a dedicated webpage on 'Trafficking in illicit goods and counterfeiting' that comes with a number of links that relate the visitor to the following:

'Operations', 'Capacity building and training', 'Legal assistance', 'Raising awareness', 'Events', 'Partnerships', 'IP Crime Investigators College' and 'Resources'[28].

This website clearly refers to the act of counterfeiting as a trademark infringement and that of piracy as copyright infringement. It states that trafficking of illicit goods is a generic term and "includes such practices as counterfeiting (trademark infringements), piracy (copyright infringements), smuggling of legitimate products and tax evasion"[29]. It stresses on the link between counterfeiting an organised criminals, who "are attracted by the lucrative profits involved in trading counterfeit or fake goods, or in trading legitimate goods through illicit channels". It further refers that criminal networks "exploit new technology, differences among national regulatory regimes and links between the global economic, finance and transportation systems for their own gain"[30]. The policing agency states that it responds to this problem in four ways, i.e., by means of operations, capacity building and training, raising awareness and legal assistance[31].

It states to have partnerships with the WCO, WIPO and Europol among the major international organisations, and a host of industry sponsored institutes and associations like Underwriter Laboratories, International Trademark Association (INTA), Business Software Alliance (BSA), Motion Picture Association (MPA), Business Action to Stop Counterfeiting and Piracy (BASCAP), Entertainment Software Association, etc. It also enlists a number of national IP and other regulating authorities like that from the US, Kenya, Zambia, etc[32]. It is important to mention that both Kenya and Zambia have participated in national legislative mechanisms involving anti-counterfeiting measures only recently.

---

[28] See, INTERPOL webpage, 'Trafficking in illicit goods and counterfeiting' [online: web] accessed 5 July 2017, URL: https://www.interpol.int/Crime-areas/Trafficking-in-illicit-goods-and-counterfeiting/Trafficking-in-illicit-goods-and-counterfeiting

[29] Ibid

[30] Ibid

[31] Ibid

[32] See 'Partnerships', Ibid

There is an online 'interactive training facility', IP Crime Investigator's College (IPCIC) that is "aimed at the law enforcement community as well as judicial authorities, regulatory bodies and government officials"[33]. It provides online certified courses at introductory, intermediate and advanced levels. The legal advice provided "may include specific criminal cases and offences to be charged, advice on legal processes, legislative updates, implementation of international treaties, the role of the private sector in a criminal trial, and any other legal advice sought"[34].

4.6.2 Interpol Programme on Pharmaceutical Crime

The Interpol in 2013 had entered into a partnership with the international pharmaceutical industry for a programme that aims to fight pharmaceutical crime. The programme entails substantial funding by 29 of the multinational pharmaceutical majors. According to a press release, it is:

> … a three-year deal, worth EUR 4.5 million, will see the creation of INTERPOL's Pharmaceutical Crime Programme to further build on the work of its Medical Product Counterfeiting and Pharmaceutical Crime (MPCPC) unit. This will enhance the law enforcement community's response to pharmaceutical crime through stronger partnership development (INTERPOL 2013).

The programme is stated to "focus on the prevention of all types of pharmaceutical crime including branded and generic drug counterfeiting as well as the identification and dismantling of organized crime networks linked to this illegal activity." The release even refers to the World Health Organisation to have estimated "that in more than 50 per cent of cases, medicines purchased over the Internet from illegal sites that conceal their physical address have been found to be counterfeit" (INTERPOL 2013). Thus this announcement also seemed to set out a strong message on the ensuing partnership arising out of the funding being provided.

The programme is felt by many as a repeat of a failed attempt to introduce similarly fused issues on IP and public health, via a group or taskforce, some years back at the

[33] See, 'IP Crime Investigator's College', Ibid

[34] See, 'Legal Assistance', ibid

WHO. The particular media release also cited incidents, at least on one of which has never been established as that of drug counterfeiting at all (Saez 2013).

In concerned circles, there is a feeling that it is actually intended to further the agenda of the large pharmaceutical manufacturers[35] conflating matters of intellectual property infringement with that of organised crimes in general. It is also making the generic manufacturers apprehensive of the intended consequences as not a single generic firm seems to be among the funders. There also seems to be a case of conflict of interest when such funding for a specific programme involving their own interest is being provided to the international policing authority by the drug firms themselves. This seems to be more pertinent in light of the fact that 16 out of 17 instances of seizures of Indian generic drug shipments were made by Dutch authorities citing allegation of counterfeit medicines (Datta 2013).

The international drug majors have funded the programme adequately, and hence, any outcome that may result from this programme is unlikely to escape the vested interests of these large drug corporations.

The programme at present: A complete webpage[36] has been dedicated by the Interpol to the issue of 'pharmaceutical crime' on which it currently maintains a sub-directorate. This site takes the visitor to a number of links that relate to the following:

'Pharmaceutical crimes', 'The dangers', 'Operations', 'Skills and knowledge', 'Partnerships', 'Pharmaceutical Industry Initiative to Combat Crime', and 'Resources'.

The Interpol, in this website, claims that the act of 'pharmaceutical crime' is associated with a number of other crimes[37]. It defines the same as:

[35] The 29 funding firms include some of the largest pharmaceutical manufacturers from developed countries, like Pfizer, Abbott, Bayer, Lilly, Bristol-Myers Squibb, Merck, Novartis, Roche AstraZeneca, and Sanofi. See, 'Participating companies' in INTERPOL (2013).

[36] See, Interpol webpage 'Pharmaceutical crime' [online: web] accessed 5 July 2017, URL: https://www.interpol.int/Crime-areas/Pharmaceutical-crime/Pharmaceutical-crime

[37] Ibid

> Pharmaceutical crime involves the manufacture, trade and distribution of fake, stolen or illicit medicines and medical devices. It encompasses the counterfeiting and falsification of medical products, their packaging and associated documentation, as well as theft, fraud, illicit diversion, smuggling, trafficking, the illegal trade of medical products and the money laundering associated with it[38].

Thus, the policing agency clearly seems to link general kinds of criminal activities with that of IP, and in particular, trademark violation.

The programme declares that it has 'partnership' with a number of UN organisations like the WHO, WIPO and UNODC, international organisations like the European Commission and the Council of Europe, and a number of institutes and associations representing the private pharmaceutical industry[39].

The link on 'resources' is perhaps the most detailed among all the links hosted by the programme website. It provides continent specific recommendations for Africa, the Americas and Europe. It also provides factsheets, analytical reports, speeches, news, etc. as well as information on the related international conferences and the UN resolutions that are thought to be relevant[40].

4.6.3 Interpol publications:

The Interpol has published a rather comprehensive 'Legal Handbook' that deals with a number of crimes that are essentially referred to as 'illicit trade'. The handbook has been divided into four parts, namely, understanding the problem, the different sectors of illicit trade, legal counter to the problem, and developing national strategy against illicit trade. Interestingly, it includes both 'Intellectual Property (IP) crime' as well as 'pharmaceutical crimes' as separate sectors. A notable feature of this handbook is, it generally relies upon unsubstantiated data published by private associations or sponsored institutes in establishing the trend of the offences regarding IP or pharmaceuticals (INTERPOL 2014a).

[38] Ibid

[39] Ibid

[40] Ibid

The organisation has also associated itself with publications that essentially connect offences relating to pharmaceuticals with a number of organised crimes in general. In July 2014, the Interpol has recently published a report on pharmaceutical crimes. This publication puts out various facts based on inputs from multinational pharmaceuticals companies and their developed country counterparts. It mainly says about this 'crime' that: criminals involved operate in both supply chains well as informal networks, that it has increased recently, that a substantial amount of money is involved in this, that the main types of such 'illicit' medicines are those for treatment of erectile dysfunction medication; slimming pills; as well as pain and anxiety relief medication and that online trading in such medicines has increased over the past (INTERPOL 2014b: 2).

4.6.4 Interpol and private corporations:

In October 2014, the Interpol had organised a two-day conference that was co-hosted by the An Garda Siochána (the national police service of Ireland) and Ireland's Health Products Regulatory Authority. The conference was called 'Ten Years of Combating Pharmaceutical Crime: Review and Prospects', and was held on 19 and 20 November 2014 in Dublin, Ireland. Besides the international police agency, it saw at least two Irish state authorities participating. The 'objectives' of the conference were:

- … to discuss experiences, lessons learned, opportunities and constraints of international action aimed at combating pharmaceutical crime;
- … recommend ways forward for strengthening international collaboration in this area (INTERPOL News 2014).

The press invite stated, "Media are invited to attend the opening of the conference …," followed by a press conference. It categorically added, "The remainder of the conference proceedings are closed to journalists; …" Thus, the proceeds of the conference were a closed door event that did not provide access to journalists or anyone else other than those authorised (INTERPOL News 2014).

4.7 International Telecommunications Union (ITU):

The International Telecommunications Union (ITU) is the oldest intergovernmental organisation in the world. It was founded on 17 May 1865 in Paris, and was originally known as the International Telegraph Union. It was initially headquartered in Berne and thereafter shifted to Geneva, Switzerland. It is the United Nations special agency for information and communications technology (ICT)[41].

The functions of the ITU focuses entirely on the standardisation, rationalised distribution of frequency and services, development of infrastructure and capacity building in developing countries and promotion, knowledge sharing and networking in the field of ICT. [42] In recent times, however, the ITU has been involved in a number of issues and measures that pertain to counterfeiting and piracy. Most of these programmes are jointly executed in coordination with the private sector entities.

The ITU has recently started publication of articles and pieces relating to anti-counterfeiting and piracy on its website. One such piece, 'Intellectual property rights in Today's digital economy' appeared in 2011. It refers to 'estimates' done for the International Chambers of Commerce (ICC) that 'suggest that digital piracy accounted for about USD 75 billion in 2008, and project that it will reach USD 215 billion by 2015'. The article justifies the involvement of 'telecommunication and internet communities' within the discussion on IPRs owing to 'endemic copyright infringement facilitated by broadband infrastructure'. It further points at the 'pressure' that the 'film, music, publishing and television industries are putting' on internet service providers 'to play a more active role in addressing not only 'commercial copyright infringement' but also 'infringement by consumers'. It adds that, the telecommunication regulators 'are increasingly being looked to as the authority to implement rules that protect copyright ...' It notes down the problems owing to piracy faced by the industry in the areas of film, music, television, publishing and software. Not only does it point towards commercial piracy as a significant hazard, it indicates

[41] See website of the ITU, 'Overview of ITU's History', [online: web] accessed 5 July 2017, URL: https://www.itu.int/en/history/Pages/ITUsHistory.aspx

[42] See, 'Focus on ITU's Areas of Work', [online: web] accessed 5 July 2017, URL: https://www.itu.int/en/history/Pages/FocusOnITUAreasOfWork.aspx

that activities even at a personal level like sharing of music files, films, software, etc. has led to considerable losses for the industry. It has even referred to certain figures to back up the claims for losses that have been provided by private business alliances like Business Software Alliance (BSA), Publishers Association, International Federation of the Phonographic Industry, etc. While noting European Commissioner's statement that regulatory moves on curbing digital copyright piracy are often challenged by issues of privacy, data protection and net neutrality, the article concludes unto 'finding a delicate balance that both stimulates and protects all the different stakeholders' (ITU News 2011).

In November 2014, it organised an international event titled, 'Combating counterfeit and substandard ICT devices' that virtually marked the entry of this UN organisation into the area of counterfeiting and piracy. This meeting was organised in accordance with the mandate of a resolution[43] adopted at the World Telecommunication Development Conference in Dubai and reinforced at the ITU Plenipotentiary Conference in Busan, Korea in the same year. It was the first meet on the issues of counterfeiting and piracy hosted by the ITU (ITU 2014b). The event, organised in collaboration with other international bodies like the WIPO, WTO and WCO, saw attendance from a large number of private industry associations. These were mainly traditional anti-counterfeiting and piracy lobbying groups like the International Chamber of Commerce (ICC), Business Action to Stop Counterfeiting and Piracy (BASCAP), International Federation of Pharmaceutical Manufacturers & Associations (IFPMA), etc. country groups like the European Commission and OECD, as well as others like the Audiovisual Anti-Piracy Alliance, Mobile Manufacturers Forum (MMF), etc. . The event saw participation from some of the largest multinational business houses having stakes in the field of ICT like Apple, Hewlett-Packard (HP), Microsoft, Cisco Systems Inc., Invigo, Qualcomm, etc. A large number of ministries or concerned ICT agencies of countries- developed, less developed and developing, participated in the event (ITU 2014a).

The event stated to have three objectives, namely:

[43] Resolution 79, World Telecommunication Development Conference, Dubai 2014 is on, "The role of telecommunications/information and communication technologies in combating and dealing with counterfeit telecommunication/information and communication devices" (ITU 2014a).

(1) discuss the global scope and impact of counterfeiting and substandard ICT products on various stakeholders;

(2) highlight the common concerns, challenges, initiatives, practices and opportunities of the various stakeholders in their fight against counterfeiting and substandard ICT products; and

(3) examine the possible role of ICT standards development organizations (SDOs) and in particular the ITU, as part of the global strategy and solution to curtail counterfeiting and substandard ICT products as well as to assist members in addressing their concerns regarding counterfeit devices (ITU 2014a).

Very recently, in June 2016, the ITU organised a workshop "Combating Counterfeit Using Conformance and Interoperability Solutions" at its headquarters in Geneva. The objectives of this workshop included creating awareness and developing a framework to counter counterfeit ICT devices, studying newer trends in device counterfeiting, supply chain management for greater transparency and to seek views from experts within and outside ITU for further studies on the issue in future (ITU: 2016a). It has relied upon studies and data provided by the OECD and BASCAP to make a case on the various kinds of impacts of counterfeit and pirated goods (ITU 2016b).

The ITU as an international organisation is supposed to act as the UN special agency for standard setting, rational distribution of frequency and services, knowledge sharing, capacity building, etc. on information and communications technology. The objectives as laid out above for the 2014 meeting, the activities like publications and workshops on counterfeiting and piracy relate either to international IPR legislations or their infringements. These activities do not seem to be within the mandate of the functions of a specialised agency like the ITU. Nevertheless, it now appears to be seeking to "refine" its role "in assisting members address their concerns regarding counterfeiting ..."[44] Recently, a few other UN agencies and organisations have also been unusually found to be involved in affairs relating to counterfeiting and piracy.

[44] See, the statement of Mr Brahima Sanou, Director of the ITU Telecommunication Development Bureau, at the meeting hosted by ITU (ITU 2014b).

4.8 United Nations Interregional Crime and Justice Research Institute (UNICRI)

The United Nations Interregional Crime and Justice Research Institute (UNICRI) is a crime research institute of the United Nations, located in Turin, Italy. It has conducted studies in counterfeiting and piracy in collaboration with a host of national authorities of Italy such as Italian Ministry for Economic Development, Italian National Anti-Counterfeiting Council, Italian Pharmaceutical Agency, etc. The location of this institute in Italy may have been the reason why it had chosen to coordinate with this particular Member state of both the European Commission and OECD. At least two studies on counterfeiting, conducted in 2007 and 2012, had relied upon the assistance provided by a number of Italian state agencies.

In 2007 this UN institute had prepared its first report on the subject of counterfeiting named, 'Counterfeiting, a global spread, a global threat', wherein it had noted counterfeiting as a growing phenomenon that affects both consumers and economies (UNICRI News 2007). A recent study by UNICRI and Agenzia Italiana del Farmaco (AIFA) or the Italian Pharmaceutical Agency has referred to the hazard of falsified medicines that are being sold worldwide. The study, titled 'Counterfeit Medicines and Organised Crime', connects the issue of spurious or falsified medicine to that of organised crime. In this connection, it has counted on the role of the ITU to regulate the menace of 'spam advertising' by organised groups that are allegedly involved in this alleged offence carried out on a global scale via the medium of internet (UNICRI 2012: 66). The report says:

> Medicines and drugs are at the top of this list. Their production, distribution and availability for public consumption are not only extremely sensitive issues but also an appealing lucrative market for counterfeiters and spammers. It is for this reason that counterfeit medicines are among those products that are commonly advertised through spam (UNICRI 2012: 68).

Studies and projects that have been recently carried out in other UN organisations and agencies in other UN organisations have not been much different from such a contention.

4.9 United Nations Office on Drugs and Crime (UNODC):

The United Nations Office on Drugs and Crime (UNDOC) has been one of the foremost international organisations that has been involved in activities that pertain to counterfeiting. Among the areas that it has taken initiatives to work upon, a perceivable thrust has been seen in the endeavour to associate the issue of counterfeit drugs to organised crime. It has been apparently published articles on such a linkage from time to time.

4.9.1 Publications on Counterfeit products

In 2010, it had published one 'report' on transnational organised crime wherein it had a separate chapter dedicated to counterfeit goods[45]. According to this report, the primary reason for counterfeiting to be an act of organised crime is the requirement of manpower and time. It says, "Product counterfeiting is typically an organized group activity, because the manufacturing of goods takes people and time, and the goal is invariably profit" (UNODC 2010: 173). This report is highly problematic. For example, while defining the term 'counterfeit', the report has even equated pharmaceutical counterfeiting to mass manslaughter. It says:

> For the purposes of this discussion, "counterfeit" means any product that does not contain what the packaging indicates. This applies equally to branding as to chemical content, freshness and potency. Defined in this way, pharmaceutical counterfeiting is a form of health fraud that often amounts to mass manslaughter (UNODC 2010: 173).

The study has even pointed at counterfeit pharmaceuticals being substandard ones and that may potentially result in antimicrobial resistance in humans. In another place, it bluntly refers to Indian counterfeit pharmaceuticals destined for Europe and North America, contributing to more than half of a large consignment of counterfeit drugs seized (UNODC 2010: 184). However, this appears to be completely unsubstantiated, fabricated and false[46]. The report principally refers to figures and data provided by

[45] See Chapter 8, 'Counterfeit Products', UNODC 2010.

[46] The official press release on the results of the concerned operation 'MEDI-FAKE' nowhere states either the origin of the products as India, or their destinations as North America or Europe. See,

industrialised country organisations like OECD or EU and private institutes like Pharmaceutical Security Institute (PSI). The UNDOC concedes at the very beginning that the document had not been formally edited (UNODC 2010). This UN agency had recently been curiously continuing to make similar publications online[47].

4.9.2 Joint exercise with other International Organisations with private financing:

In 2012, the organisation had coordinated with the World Customs Organisation for an initiative called The Container Control Programme (CCP). The CCP has been stated to be "a joint UNODC/ World Customs Organization project working to boost the inspection of containers and detect illicit goods ..." This CCP project has been stated to have begun as a counter to drug trafficking that had fast turned out to be an instrument to deal with fraudulent goods. The organisation has formally endorsed donation for the project from a particular apparel brand over a press release. It also conspicuously asked for further financial help from the private sector in general which, it said, "… represents a key step in involving businesses with a vested interest in countering this …" and "offers a win-win situation for the private sector whose revenues and brands rely on tackling counterfeit goods." The agency said that global trade is done almost ninety percent through the sea routes and therefore, "smuggling via containers is an attractive avenue for criminals." It added that only two per cent of the containers used in the sea are inspected and for this reason, "identifying illegal goods is a challenging task with criminal networks exploiting legitimate shipping routes to move illegal goods" (UNODC 2012).

In February 2013, the UNODC had organised a key event on trafficking of fraudulent medicines with participation from a host of international organisations, countries and

---

European Commission Press release database, IP/08/1980, Brussels, 16 December 2008, [online: web] accessed 5 July 2017, URL: http://europa.eu/rapid/press-release_IP-08-1980_en.htm

[47] For example, another separate chapter has also been published on its website. See, 'Chapter 11: Counterfeit consumer goods from East Asia to the United States and the European Union', [online: web] accessed 5 July 2017, URL: http://www.unodc.org/documents/toc/Reports/TOCTA-EA-Pacific/TOCTA_EAP_c11.pdf

their blocs, drug manufacturing corporations and their association and certain establishments specialising in fraudulent drugs. The event involved contribution from other international organisations like the WHO, WCO and INTERPOL. It saw representatives from concerned departments of developed countries like the US, France, Italy, Belgium and developing countries such as Argentina, China, Russian Federation, Mongolia, Nigeria, etc. There were country unions as well, like the European Union and Economic Community of West African States (ECOWAS). The largest association of drug manufacturers of industrialised nations, the International Federation of Pharmaceutical Manufacturers & Associations (IFPMA) also participated along with a host of privately funded institutes like International Institute against Counterfeit Medicine (IRACAM) and Pharmaceutical Security Institute (PSI). Incidentally, as per the agenda, the only international civil society organisation that was to participate was the Third World Network (TWN) (UNODC 2013). The participation from the private companies along with their associations is notable for the fact that it shows the importance and position which these entities have started to enjoy of late at a UN agency. The apparent invite to countries and country unions across developmental levels, international organisations, industry bodies and an extremely limited section of the civil society seems to be an endeavour to provide legitimacy to the entire exercise at the cost of the voice of the general public.

4.9.3 UNODC Campaign on Counterfeiting:

In 2014, following the event, the UNODC launched a major campaign to raise awareness to counter trafficking in counterfeit goods (WIPR 2014). The campaign which comes in the form of a dedicated online webpage, linking counterfeiting to organised crime, is being called as "Counterfeit: Don't Buy into Organised Crime"[48]. It states that "as a global, multi-billion dollar concern, there is a strong link between counterfeiting and transnational organized crime"[49]. The webpage so far includes the following contents-

[48] UNODC webpage, 'Counterfeit: Don't Buy into Organised Crime' [online: web] accessed 5 July 2017, URL: http://www.unodc.org/counterfeit/

[49] *Ibid*

- An unsigned, unedited online article named 'Focus On: The Illicit Trafficking of Counterfeit Goods and Transnational Organized Crime"[50].

- A graphically illustrative brochure that mentions the scale of the hazard, the various kinds of counterfeit products and the different aspects of counterfeiting that are really and potentially damaging[51].

- A link to another webpage linking the various other campaigns and awareness programmes on counterfeiting mainly carried out by private corporations[52].

- Two graphic posters on the counterfeit consumer electronic and luxury goods, that point towards them as 'unethically produced' by exploiting labour and environment standards, and a source of 'funding organised crime'[53]. It has also published a 'factsheet' on counterfeit goods. It has been named as 'Counterfeit Goods – A bargain or a costly mistake?', and is devoid of anyone taking responsibility for the contents of the publication[54]. The peculiarity in this campaign is the usage of the symbol of the United Nations on each such unspecified document that has been prepared. The contents themselves mention that they are unedited and no person or authority, including the UNODC, has taken responsibility for their authenticity. Such kinds of questionable usage, though may appear to provide authority for the campaign in the public eye, seems to be neither appropriate and hence, not in the interest of such an international organisation that is under the aegis of the UN.

---

[50] See, 'Focus On: The Illicit Trafficking of Counterfeit Goods and Transnational Organized Crime', [online: web], accessed 5 July 2017, URL: http://www.unodc.org/documents/counterfeit/FocusSheet/Counterfeit_focussheet_EN_HIRES.pdf

[51] See, UNDOC document [online: web] accessed 5 July 2017, URL: http://www.unodc.org/documents/counterfeit/Leaflet/Counterfeit_Brochure_2014_-_EN_-_WEB.pdf

[52] See UNDOC webpage [online: web] accessed 5 July 2017, URL: http://www.unodc.org/counterfeit/en/other-campaigns.html

[53] See the UNODC documents, [online: web], accessed 5 July 2017, URLs: http://www.unodc.org/documents/counterfeit/Posters/Counterfeit_posterA2_phone_EN_HIRES.pdf, and http://www.unodc.org/documents/counterfeit/Posters/Counterfeit_posterA2_watch_EN_HIRES.pdf

[54] See 'Counterfeit Goods – A bargain or a costly mistake?', [online: web] accessed 5 July 2017, URL:http://www.unodc.org/documents/toc/factsheets/TOC12_fs_counterfeit_EN_HIRES.pdf

4.9.4 UNDOC Model Legislation:

The modest organisation had lately become so much involved in affairs regarding counterfeiting of medicines that it had lately taken to drafting model legislation on fraudulent medicines as well. The mandate for framing such legislation however, came from a resolution passed by its member states in the year 2011[55]. Therefore, the UNDOC began the drafting of a legislation that would include IPR as the distinctive factor.

> The latest draft available included "medical products", which apparently goes outside the mandate of the 2011 resolution that was aimed at fraudulent "medicinal" products. The draft apparently acknowledges that "fraudulent medical product" has been similarly defined as in the Medicrime Convention and the Falsified Medicines Directive, but it leaves to the preference of each member state to define and implement the measure. There was a heavy presence of European, especially French authorities in the informal drafting group that left out major stakeholders from across the globe including developing nations and the civil society (New 2014). A few years ago a similar attempt to secure IP enforcement standards at the WCO and WHO suffered defeats to the developing countries' resilient resistance. Explaining the reason why developing countries were left out, a civil society organisation remarked:
>
> > It is very clear that the developing countries would not agree to a resolution which promotes IP enforcement; therefore the Secretariat did not want to consult the whole membership of States and instead chose a selective approach of consultation (Third World Network 2014).
>
> It also says that the second expert consultation meeting agenda "clearly shows a selective pick of like-minded experts who support the IP enforcement initiatives" (Third World Network 2014).

[55] The mandate comes particularly from paragraph 2 and 3 of Resolution 20/ 6. While Para 2 asks Member States 'to prevent trafficking in fraudulent medicines by introducing legislation, as appropriate, covering, in particular, all offences related to fraudulent medicines,..', Para 3 directly 'Invites Member States to review their legal and regulatory frameworks in order to provide effective legislation and improved regulatory mechanisms,..'. See, UNDOC (2011).

Some of the chief persuaders in the drafting process include the French government, the Interpol and the Council of Europe. The drafting process was initiated by the Paris-based Institute for Research Against Counterfeit Medicines (IRACM) that acknowledges to be funded by Sanofi- a French multinational pharmaceutical firm. Many European pharmaceutical manufacturing associations like European Federation of Pharmaceutical Industries and Associations (EFPIA), and the European Generic medicines Association (EGA) expressed willingness to join the European Stakeholders Model, which was established for the implementation of the EU Falsified Medicines Directive. In face of a defeat to developing countries' opposition to set such standards at WCO few years ago, the UNODC initiative is also being seen as another case of forum shopping (New 2014). However, such attempts at legislation of IP enforcement standards at international organisations by wielding influences is nothing new. Thus, it has also been noted that:

> UNODC is one of the organisations that public health circles say is 'captured' by the pharmaceutical TNCs to further IP enforcement standards. Earlier similar organisational capture was seen at the World Customs Organisation (WCO), INTERPOL, Universal Postal Union (UPU) and World Health Organisation (WHO) (Third World Network 2014).

In a letter dated 10 December 2014, the union of leading emerging economies among developing states, the BRICS[56], questioned the UNDOC authorities on various grounds. These included, mainly the following:

i. the basis of selection of participants in the informal drafting group,

ii. whether the relevant UNDOC resolution 20/6 does provide the mandate for initiation of drafting of the model legislation, and,

iii. the funding source of the expert drafting group meeting (Gopakumar 2015).

The letter also asked the UNODC for a review of any future initiative for model law on fraudulent medicine, until it consults Member States who, in reality, had not given any express mandate. The UNODC answered that since the model legislation forms part of its technical assistance program, the Member states' mandate was not

[56] The BRICS group of nations include Brazil, Russia, India, China and South Africa.

necessary for it. In June 2015, the UNODC sent emails to embassies of BRICS countries, that it is suspending its activities regarding fraudulent medicines in light of the absence of an internationally established definition for the same under the WHO (Gopakumar 2015).

4.10 Conclusion:

The international institutions of the twenty first century have a wide role to play in the any issue that affects the international society. Counterfeiting and piracy are issues that are essentially linked to IPRs. The mandate to deliberate or decide on issues pertaining to IPRs lies only with the World Intellectual Property Organization (WIPO) and the TRIPS Council within the WTO system.

Most of the abovementioned organizations have served well enough in realizing and advancing the areas that they usually deal in. However, in matters concerning IPRs these organizations are neither technically equipped nor authorized by the international community of States and other entities. This is precisely why the WCO had to do away with the SECURE standards or the WHO had to deviate from its plans on IMPACT.

The withdrawal of the term ‘counterfeit’ from the WHO vocabulary of classification of medicines, very lately, should be realisation enough to move the collective conscience of the combination of developed States and their transnational pharmaceutical corporations. It is not only a victory for the hundreds of IP academics, nongovernmental organisations and health activists who have been insisting on its removal, but also likely to go a long way in ensuring that such conflation of IP issues with those on public health do not recur in near future. The developed world like the US, EU and Japan, who have maintained the inclusion of this term within their domestic laws and regulations, should now act accordingly by respecting the mandate of WHA.

However, the continued participation of the WCO in events pertaining to counterfeiting and piracy in collaboration with the large private corporations is still a matter of concern. Each such organization has an important role to play in the

respective area that it has been mandated with. Incursion into the area exclusively dealt by other international organization shall only result in disagreements. If at all such a requirement arises that the organizations have to deliberate on issues pertaining to another's domain, it should be done in coordination with that IO in order to avoid any future conflict.

The recent involvement of the International Telecommunications Union (ITU) in matters pertaining to counterfeiting is a subject of concern. The participation and association of a large number of multinational corporations and private business bodies that make the traditional anti-counterfeiting lobby gives rise to reasonable apprehension as to what might be their future course of action. For such purpose, it may be worthy to note, that some of these corporations and bodies were the ones who lobbied not only for materialising the first internationally binding IPR agreement – the TRIPS, but also in a concerted and persistent demand for higher, TRIPS Plus standards for IPRs in a number of organisations and agreements around the globe.

The involvement and subsequent pursuance of the UN organisations in so many IP enforcement programs aimed at heightened and unprecedented standards signifies their susceptibility to powerful international actors like Western nations and their prominent transnational corporations. This may erode their credibility as international institutions with specific functionalities and orientations.

In reference to one such case that had transpired as having happened with the INTERPOL, the Third World Network[57] notes:

> The INTERPOL Secretariat went to the extent of accepting Euro 4.9 million from 29 pharmaceutical TNCs to further IP enforcement activities known as 'pharma crime' (Third World Network 2014).
>
> It therefore adds:
>
> … According to UN observers this is a classic case of vulnerability of UN organisations, which can be captured with financial resources … (Third World Network 2014).

[57] The Third World Network (TWN) is a leading international alternative policy group consisting of a network of organizations stationed around the world. It often participates in debates and discussions at major international organizations like the WHO and WIPO.

Such attempts by multinational corporations to intrude into so many UN and other organisations conferred with specialised functions in the semblance of dealing with counterfeiting and piracy must be resisted with every effort that may be required. It is still a part of their age old tactics and a clear-cut agenda of resisting the technological and other developmental aspirations of the developing countries.

Chapter V

Implications of IP Enforcement Laws for Public Health

Chapter V

Implications of IP Enforcement Laws for Public Health

5.1 Introduction:

The developed world, led by the US and the EU, is leading a number of ongoing negotiations at the bilateral, regional and multilateral levels to create international legal norms on intellectual property enforcement. In respect of public health, the IP enforcement specifically purports to deal with alleged counterfeit or spurious medicines. The WTO TRIPS Agreement is presently the international legal standard for protection and enforcement of intellectual property. It has been viewed as the "de facto norm" for deciding IP laws and practices at every level – multilateral, regional, bilateral and even national. Thus, it forms the basis for standard-setting of IPRs (Sanders: 2007: 6). However, standard of the stipulations that are currently being negotiated has reached far above that provided under the TRIPS Agreement, potentially including a number of legitimate lifesaving medicines within its purview. Such demand of norms sought under these agreements, has led to opposition by the developing countries participating in the negotiations; counter arguments, however, have also followed from certain developed nations as well. It has been argued that the various proposed stipulations would limit their space for policymaking that facilitates their citizens for accessing various lifesaving medicines at affordable costs. A certain group of industrialized countries, driven by the some of their determined industry lobbies, have always sought an upward push for breaking even the limits of private IP protection and enforcement that are provided by the TRIPS- the only concluded international intellectual property agreement that had been multilaterally negotiated, as part of the General Agreement on Tariffs and Trade, 1994. In the current scenario, however, certain developing countries have also been taken on board as negotiating members.

There were continuing efforts by developed counties aiming for higher standards of IPRs internationally ever since negotiations for the TRIPS Agreement concluded, as

they felt that TRIPS could not fetch them with what they had aimed for. The recent surge in the push for negotiating international agreements to increase IP enforcement standards at various levels globally started off almost a decade after the TRIPS Agreement entered into force, when the developed countries grouped together for negotiating the Anti Counterfeiting Trade Agreement (ACTA), citing a large scale increase in counterfeiting around the globe. Owing to complaints and oppositions on its nature and content from various countries including some of the negotiating members themselves, nongovernmental organisations as well as certain international authorities, the negotiations for the ACTA had been rendered almost inconclusive. In response to the stalled negotiations on ACTA, the developed countries started looking for alternative forums at other multilateral, bilateral and regional levels to push for raising the bar on IP enforcement standards that would help their industrial bodies to monopolistically market their medicinal products. In some of these negotiations, wherein a few developing countries have again been co-opted alongside mainly developed ones, certain stipulations on IP enforcement that have been proposed, by far exceed the TRIPS standards. Such draft proposals by the developed nations are currently threatening to upset the balance of interests, that had been somewhat achieved at the conclusion of the TRIPS, and which have thus far been able to fairly take care of the healthcare needs of millions of underprivileged population across the developing world. In the name of countering the menace of medicine counterfeiting, the developed world led by the US, EU, Japan, etc. are putting every effort to raise the standards of IPR enforcement across the globe that sometimes seem to be exceeding even those that are followed in their own respective countries.

In this chapter, the various attempts by the developed world to create as well as enforce certain problematically elevated standards of IPR enforcement around the world have been shown. These efforts nonetheless have been relatively successful as well until this date. Hence, there is a growing necessity on part of the developing countries to challenge such endeavours that are thus far perceived to act inimically to the issue of affordability and accessibility interests of an overwhelming majority of their citizens. Section 2 talks about public health, access to medicines and international IP enforcement regime. It denotes the importance of health under international law and refers to international public health regulations in light of

internationally recognised provisions on human rights and the relevant TRIPS provisions. Section 3 deals with counterfeiting of medicines and public health in relation to the various international legal measures and attempts on raising IP enforcement standards at a multitude of international organisations. Section 4 details the IP enforcement 'agenda' of a global coalition of actors, who are mainly the developed nations alongside their industrial and trading leagues. It shows in separate subsections, a combination of legal, institutional and political modes in different parts of the world that are working to pursue the broader goals of the agenda. It articulates an analysis of a range of developing country specific push for legal changes and a host of institutional and political events aimed at the same. Section 5 summarises the chapter and mentions the various implications of the global IP enforcement agenda on access to medicines worldwide.

5.2 Public Health, Access to Medicines and present global IP regime:

The WTO Trade Related Aspects of Intellectual Property Rights (TRIPS) has clearly recognized the importance of protecting public health. It has provided for the protection and maintenance of the public health requirements of a country as against the international intellectual property norms. It is universally acknowledged that the right to health of human kind is their fundamental right, and therefore, the rules laid down on IPRs should not prevail over them. There is established international law on public health besides the relevant provisions of the WTO TRIPS Agreement. This entire set of international jurisprudence suggests public health occupying a prime position.

5.2.1 The Primacy of Public Health in International Law:

International law has provided ample space in recognition of the significance of public health. There are quite a few conventions that are meant to address public health, besides inclusion of provision in many international treaties and agreements.

The TRIPS Agreement is an international accord on intellectual property that was proposed, negotiated and concluded at the behest of the owners of IP, who are mostly from the developed world. So much so that, this treaty almost entirely looks after the rights owners' interests. The Doha Declaration on TRIPS and Public Health has categorically recognised that issues concerning public health may be more important as compared to the core provisions of TRIPS. As Dutfield and Suthersanen have stated:

> The Doha Declaration clarified the ambit of both Articles 7 and 8 by stating that these provisions may be of more importance in interpreting the Agreement than other provisions, including the Preamble (which is biased towards rights owners) (Dutfield& Suthersanen: 2008: 224).

5.2.2 International Public Health Regulations:

The responsibility to deal with public health usually rests with the States. However, with the passage of time, countries have realised that there are overarching situations in cases of certain diseases that go beyond the limits of a country's boundaries. Infectious diseases, for example, can hardly be prevented by attempting to halt them at the borders. It may, however, be prevented by trying to identify the diseases and controlling them by various means that are based on developing and maintaining a system and infrastructure for public health.

5.2.2.1 General International Law:

The International Health Regulations is the internationally accepted legal standard for dealing with public health. It is a set of international legislations, stated to be "an international legal instrument that is binding on 196 countries across the globe, including all the Member States of WHO". Its aim is "to help the international community prevent and respond to acute public health risks that have the potential to cross borders and threaten people worldwide."[1] Having entered into force on 15 June

[1] Please see, webpage of the World Health Organisation, 'International Health Regulations' [online: web], accessed 5 July 2017, URL: http://www.who.int/topics/international_health_regulations/en/

2007, it obliges countries "to report certain disease outbreaks and public health events to WHO"[2]. The regulations "define the rights and obligations of countries to report public health events, and establish a number of procedures that WHO must follow in its work to uphold global public health security"[3].

The WHO Constitution also contains a few important provisions. The Preamble states:

> The enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social condition (WHO 2005: 1).

The 'Objective' of the WHO has been stated to achieve the highest possible levels of health for everyone (WHO 2005: 2).

Article 22 states that, the regulations adopted at the World Health Assembly, the lawmaking authority of the WHO, shall be automatically binding on all the Member States of the WHO unless they notify the Director General within a specified time of their intention otherwise (WHO 2005: 7).

5.2.2.2 Human Rights provisions:

The Universal Declaration of Human Rights (UDHR) is the leading international instrument on the various types of human rights. It refers to health and healthcare as being basic human rights of human beings. It thus says that, '[e]veryone has the right to a standard of living adequate for [their] health and well-being … including food, clothing, housing and medical care and necessary social services'[4].

The International Covenant on Economic, Social and Cultural Rights (ICESCR) of 1966 has identified the physical and mental of human beings as a matter of universal

[2] *Ibid*

[3] *Ibid*

[4] Universal Declaration of Human Rights, G.A. Res. 217A (III) A, U.N. Doc. A/RES/217(III), art. 25 (Dec. 10, 1948)

right. It asserts 'the right of everyone to the enjoyment of the highest attainable standard of physical and mental health'[5].

The UDHR also provides for balancing out the innovators' business interests as well as ethical obligations concerning human beings. Thus, it provides for a wider right of access to the produces of such scientific developments as well as engaging in the legible material interests in any kind of progress in science.

Article 27 of the Universal Declaration of Human Rights (UDHR) reads as follows:

> 1. Everyone has the right freely to participate in the cultural life of the community, to enjoy the arts and to share in scientific advancement and its benefits.
>
> 2. Everyone has the right to the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author[6].

The idea recommended here in the UDHR has been codified into the International Covenant on Social and Economic Rights (ICESCR) as follows:

> 1. The States Parties to the present Covenant recognize the right of everyone:
>
> a. To take part in cultural life;
>
> b. To enjoy the benefits of scientific progress and its applications;
>
> c. To benefit from the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author.
>
> 2. The steps to be taken by the States Parties to the present Covenant to achieve the full realization of this right shall include those necessary for the conservation, the development and the diffusion of science and culture.
>
> 3. The States Parties to the present Covenant undertake to respect the freedom indispensable for scientific research and creative activity.

[5] International Covenant on Economic, Social and Cultural Rights, opened for signature 16 December 1966, 993 UNTS 3 (entered into force 3 January 1976), article 12(1).

[6] *Ibid*, art. 27 (Dec. 10, 1948)

> 4. The States Parties to the present Covenant recognize the benefits to be derived from the encouragement and development of international contacts and co-operation in the scientific and cultural fields[7].

5.2.3 TRIPS provisions on Public Health:

Ever since the WTO TRIPS Agreement came into force, developing countries have been expressing their disapproval of the increasing monopoly over intellectual property at the hands of only some rights holders from the global North. The rights owners from developed countries in tandem with their respective state agencies interpreted the TRIPS in a way that only favoured their corporations, ignoring the space that it leaves for developing states to make up for their lag in technological capabilities. The manufacturing of generic pharmaceuticals is one such area that they rightfully demanded as their right. The developing countries' objection was aimed at appraisal of the apprehensions about this kind of a monopolistic supremacy that may affect their populations in accessing pharmaceutical products at affordable rates (Lanozska 2003: 182, 189, 193).

The TRIPS Agreement has addressed the issue of public health both directly as well as indirectly. While it has express provisions that apparently deal with the issue, it also has further addendums in the form declarations that add to their significance. It contains provisions that enable Members of the WTO to enjoy certain policymaking steps for meeting national interests or for pursuing steps that are beneficial for their citizens.

Noting the 'Objectives' of the Agreement, Article 7 TRIPS states that,

> The protection and enforcement of intellectual property rights *should contribute* to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations. (emphasis added)

This implies that although IPRs do serve as one of the main incentives for the innovation and development of products for protection and maintenance of public

[7] International Covenant on Economic, Social and Cultural Rights, G.A. Res. 2200A (XXI) A, U.N. Doc. A/6316, art. 15 (Dec. 16, 1966)

health, the protection and enforcement measures concerning IPRs have been mandated to balance the interests of the right holders as well as those of the consumers.

Also noting the 'principles' of the Agreement, Article 8.1 TRIPS states:

> Members *may*, in formulating or amending their laws and regulations, *adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development*, provided that such measures are consistent with the provisions of this Agreement. (emphasis added)

Article 8.2 further states,

> Appropriate measures, provided that they are consistent with the provisions of this Agreement, may be needed to *prevent the abuse* of intellectual property rights by right holders or the resort to practices which *unreasonably* restrain trade or adversely affect the international transfer of technology. (emphasis added)

Article 8 refers to practices that "unreasonably" hold back legitimate trade. In cases of preventing trade in goods that are merely suspected to be infringing intellectual property, such legislation that authorises random procedures that do not require a formal complaint, cannot be seen as part of any public policy that could be in compliance with the TRIPS Agreement. TRIPS provisions are also meant to be read holistically in the context of one of the main aims of the Agreement, which is to 'reduce distortions and impediments to international trade'[8].

In addition, TRIPS also provides for certain leeway by means of exemptions. However, such exemptions are not always exclusive in themselves. For example, Article 30 of TRIPS provides for '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 into account the interests of third parties'. Such provisions have perceivably been inducted to provide alternatives to proprietary medicines that may have to be made available at a much lesser price in times of national emergencies and situations when their use becomes necessary.

[8] As stated in the very Preamble to the TRIPS Agreement.

5.2.3.1 The Doha Declaration on TRIPS and Public Health:

The conditions, under which the provisions of flexibilities could be used, remained controversial however, until resolved at the Doha Ministerial Conference in 2001. The Declaration on the TRIPS Agreement and Public Health[9] (generally known as the Doha Declaration) states that:

> . . . the TRIPS Agreement does not and should not prevent members from taking measures to protect public health (and) . . . . We affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all (Paragraph 4).

and

> . . . each provision of the TRIPS Agreement shall be read in the light of the object and purpose of the Agreement as expressed, in particular, in its objectives and principles (Paragraph 5(a)).

The Doha Declaration also affirms each member's right to determine its own grounds to make use of the flexibilities. The Declaration also allows members freedom to define what constitutes a national emergency. Useful as they are for countries with a reasonably developed pharmaceutical industry, these flexibilities are no great help for a large number of the LDCs that have no pharmaceutical industry or insufficient manufacturing capacity to meet their health needs. That this latter group of countries could not make use of these flexibilities is recognised by the Declaration in stating that:

> . . . 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 2002 (Paragraph 6).

---

[9] *Declaration on the TRIPS Agreement and Public Health, WT/MIN (01)/DEC/2 of 14 November 2001*, [online: web] accessed 5 July 2017, URL: https://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.pdf. Here and hereinafter, to be referred to as 'Doha Declaration'.

5.3 Medicine counterfeiting and Public Health

Counterfeiting, as an issue is not a new one and, has been dealt with in the WTO TRIPS Agreement. In fact the entire TRIPS Agreement has been the resultant outcome of a proposal by a few developed countries to negotiate on an anti-counterfeiting code, during the Tokyo Round of multilateral trade negotiations (Matthews 2002: 8-9). Pharmaceuticals, especially therapeutic medicines, are indispensable for sustenance of human life and health and may be required on a daily basis. The United States' pharmaceutical and copyright business entities were the most influential lobbies in the US government's trading arm, the United States Trade Representative (USTR), which had pushed for an intellectual property agreement within the GATT framework during the pre-TRIPS negotiations. Their actions had been attributed to the reason that these sectors were perceived to be prone to replication of intellectual property and hence the need for a universal protection of their proprietary (pharmaceutical and copyright) industries (Matthews 2002: 18).

The association of US pharmaceutical manufacturers, one of the largest such bodies around the globe, allege that their drug industry has been time and again suffering massive losses owing to rampant counterfeiting both within and outside the US, the latter taking place at even more considerable scales. A number of initiatives have been taken up recently, most of which have been pushed by originator drug companies having a global presence, fearing that their businesses are being hampered by considerable production and sale of counterfeit drugs worldwide.

The World Health Organization (WHO), the global plenary institution on public health had recently witnessed the pharmaceutical industry pushing for a specialised mechanism to deal with counterfeit medicines[10]. These corporations not only

[10] At the WHO, the issue of counterfeit medicines initiated in 1992 with a definition for the same, approved by a significant number of WHO Member States, the INTERPOL, the Customs Cooperation Council (presently, the World Customs Organisation), the International Narcotics Control Board, the International Federation of Pharmaceutical Manufacturers' Associations, the International Organisation of Consumer Unions and the International Pharmaceutical Federation. Thereafter, a 'satellite conference' in Madrid, Spain in February 2004, that was followed after two years by another, in which the participants announced the Declaration of Rome, 18 February 2006. See, 'Declaration of Rome (2006)'. Most of these latter meets saw participation from alliances of large pharmaceutical companies and organizations such as Pharmaceutical Security Institute that are funded by the same multinational pharmaceutical corporations.

participated in the meets but also set off a global body, supposed to function under the WHO, for overseeing the issue of counterfeit medicines, having much more stringent standards for the same[11]. At a later point in time however, the WHO stated that it is going to focus on its core mandated function of public health. In so doing, the World Health Assembly (WHA) decided to form a time bound and result oriented intergovernmental working group to look into those aspects of the WHO's role that can ensure availability of quality, safe, efficacious, and affordable medical products, its relationship with IMPACT, and its role in the "prevention and control of medical products of compromised quality, safety and efficacy such as substandard/ spurious/ falsely labelled/ falsified/ counterfeit medical products from a public health perspective, excluding trade and intellectual property considerations" (WHO: 2010: 67-68).

The Council of Europe has also negotiated over an international convention that deals with the act of medicine counterfeiting[12]. It is purported to treat the act of counterfeiting of pharmaceuticals as a crime and seeks to promote national and international cooperation, besides devising certain specific mechanisms to tackle the issue[13]. Globally, this draft Convention aiming to deal with the subject of medicine counterfeiting, is possibly the only one of its kind.

Efforts have been made by the UN Office on Drugs and Crime (UNODC) to collaborate with private actors and other international institutions to coordinate technical training sessions and arranging multi-stakeholder meetings on counterfeiting and piracy. However, these meetings had hardly shown any appropriate representation

[11] In recent times, the International Medical Products Anti-Counterfeiting Taskforce (IMPACT), a taskforce comprising of various stakeholders, including pharmaceutical industry associations, drug regulatory authorities, international agencies and non-governmental agencies and enforcement bodies was formed within the WHO, that defined counterfeit medicines in a way that included patent infringement as a form of medicine counterfeiting, raising doubts and concerns from developing countries and stakeholders like the generic pharmaceutical industry. However at a later period, a corrigendum, to this effect, had been issued that said, patent infringements are not to be treated as counterfeiting, while trademark infringements should be (WHO 2008).

[12] See 'Draft Council of Europe Convention on Counterfeiting of Medical Products and Similar Crimes Involving Threats to Public Health' (European Committee on Crime Problems), [online: web], accessed 5 July 2017, URL: https://rm.coe.int/16806a9574

[13] Ibid at Article 1

from developing countries or their concerned stakeholders. The most worrying aspect is the framing of model legislation on the same, recently. Of late, it has even entered into agreement with a group of multinational corporations to obtain substantial funds for carrying out programmes on counterfeiting and piracy that suits the latter's IPR ownership interests. In spite of criticism and opposition by the civil society globally as well as developing country stakeholders, the programme seems very much on track.

5.4 IP Enforcement Agenda: legal, institutional and political modes:

International actors, led by some of the industrially advanced nations and their industry associations, have continually attempted to increase the levels of IP protection and enforcement to help their industries to flourish and maintain an edge over their counterparts in developing nations. Ever since the two distinct areas of industrial trade and intellectual property have been interlinked, shrinkages in flexible policymaking that takes care of core welfare concerns like public health has been felt by the developing nations[14]. Sanders has thus opined against business entities, while critiquing the growing demand by large business and industry for upward revision of intellectual property rights, alleging 'piracy'. In his opinion:

> Flexibility is, however, something that sits uneasy with the current trend in intellectual property policy. This trend has been one of maximizing rights to stamp out piracy and one of harmonization to provide a one-size fits all level playing field of rights. Flexibility to curb the full exercise of the intellectual property monopoly to accommodate the interests of users, competitors or developing countries is not popular among industrialists (Sanders: 2007: 5).

The TRIPS Agreement was conclusively negotiated taking into consideration the several representations from the developing and least developed countries that spoke

[14] Explaining this context, Muzaka states:

> .. the linkage established between IP protection and trade rules in the WTO TRIPs agreement has had the effect of limiting the space available to governments in dealing with certain public health responsibilities. This has certainly been the case for the majority of developing and least developed (WTO) members, who, already struggling to deliver on the public health front, are required to make substantial changes to their IP laws, especially with regard to pharmaceutical IPRs, in order to comply with TRIPs provisions (Muzaka 2009: 183).

of their legitimate concerns like education, public health as also catching up on their own industrial aspirations. The entering into force of the TRIPS Agreement forced many less developed nations to accept the 'minimum standards' in IPR enforcement across the globe. Some of them are now finding it even harder to withstand the pressure created on them essentially by business and trade bodies from the industrially advanced nations- legally, institutionally as well as politically.

5.4.1 Legal modes – TRIPS Plus and Access to Medicines:

A host of bilateral treaties have been negotiated from a period preceding the conclusions of the TRIPS Agreement. Some of them like the North American Free Trade Agreement (NAFTA) had even been entered into by parties before the entry into force of TRIPS. Recently, a large number of bilateral, regional and plurilateral agreements are being negotiated at the behest of developed countries in order to achieve their aim of consistently increasing the levels of IP enforcement much ahead of what was laid down in TRIPS. Developing countries are lured into agreeing to strict enforcement provisions in these treaties that binds them, with the promise of foreign investment besides technology. This, in essence, had already made some less developed countries to lose the essential policy space available to them for meeting fundamental public interests matching their levels of socioeconomic development.

Sanders has indicated that:

> … combination of multilateral and bilateral agreements is widening the scope of IPR even more. These BITs or FTAs permit developed countries to use their considerable economic leverage comprising foreign direct investment or market access to influence the domestic economy of developing countries (Sanders: 2007: 7).

He explains: "When IPR provisions are included, these agreements are referred to as TRIPS-plus agreements and they can have serious adverse effects on the public interests in developing countries" (Sanders: 2007: 7).

5.4.1.1 Free Trade Agreements: Bilateral and Regional Arrangements

Developed countries, chiefly the US and the European Union have been gradually entering into treaty arrangements with countries in Latin America, Africa and Asia. These agreements may have been entered into bilaterally or signed by a group of countries with the developed country- the United States for example, or a group like the European Union. Such deals were negotiated in order to limit the legroom for policymaking on their own developmental requirements, won by the developing countries during the course of the negotiations leading up to the TRIPS Agreement.

Prof Correa had shown more than a decade ago how developed countries like the US stand to gain in the entire design of TRIPS Plus treaties. He states, in the context of bilateral treaties:

> Interestingly, the countries involved in bilateral negotiations with the United States account for a minor share of U.S. exports. FTAs are attractive to governments of developing countries as they may gain political credit for greater access (generally for agricultural products, raw materials and low value added manufactures) to the large U.S. market. The less tangible but equally or more important effects on development policies appear as matters of secondary concern (Correa: 2004: 81).

Thus, he insightfully explained, that there would be little 'commercial gains' for the less developed nations whereas "the dramatic increase in the level of protection of IPRs is likely to have a direct and significant impact on the capacity to design and implement development policies, particularly in the area of public health" (Correa: 2004: 81).

For example, the EU has recently concluded a partnership agreement with CARIFORUM group of countries[15] with provision containing detailed description on IP enforcement measures that are extra TRIPS[16]. The issue at hand in this treaty is the

[15] It is a subgroup of the African, Caribbean and Pacific group of states. The CARIFORM Member States constitute of Antigua and Barbuda, The Bahamas, Barbados Belize, Dominica, Grenada, Guyana, Haiti, Jamaica, Montserrat, Saint Lucia, St. Kitts and Nevis, St. Vincent and the Grenadines, Suriname, and Trinidad and Tobago. The Associate Member States are Anguilla, Bermuda, British Virgin Islands, Cayman Islands, and Turks and Caicos Islands.

[16] The EPA was signed on October 15, 2008. See, 'Economic Partnership Agreement between the CARIFORUM States, of the one part, and the European Community and its Member States, of the other part', OJ [30 October 2008] L 289, [online: web] accessed 5 July 2017, URL:

inclusion of border enforcement measures for all forms of IPRs. This is otherwise permissible only for trademarked and copyrighted goods under TRIPS. Further, it extends such measures to those goods that are in transit. The aforementioned border measure in the concerned EU initiated treaty is carrying the essence of the EU's own border measures regulation. Thus, not only does it clearly amount to an export and resultant imposition of high standards of EU legislations in developing countries, but it comes at the cost of flexibilities that they otherwise lawfully benefit from under the TRIPS Agreement.

There are a number of FTAs either negotiated or concluded by the US that have enhanced features on enforcement procedures and criminalisation of IP infringements. For example, each of the US-Morocco or the US-Peru free trade agreements has provision that requires *ex officio* border measures over suspected infringing goods[17]. Such measures stand authorised even in the absence of any formal complaint by the right holder or any other private party and extend even to the situation while the suspected goods or items are in transit, besides during importation and exportation[18].

There are currently many such provisions within several treaties across the globe that challenging the flexibilities in the TRIPS. Most of the people in need of essential drugs for treatment of HIV-AIDS, tuberculosis, etc. reside in the developing countries, but they mostly lack the means to afford them owing to their very high costs. This had in the past led to many cases of deaths, often in thousands, simply because they were unaffordable. The global AIDS crisis of the new millennium is one such prominent example. Some developing countries including India and China, who have manufacturing capacity of generic medicines, export these drugs to voluntary international agencies or governments of less developed nations, at a small fraction of their original prices. Thus, they ensure that many essential medicines reach such needy population of less developed economies.

---

http://ec.europa.eu/world/agreements/prepareCreateTreatiesWorkspace/treatiesGeneralData.do?redirect=true&treatyId=7407. See, particularly, measures in transit, in 'Border measures' Article 163.

[17] See Art 15: 11: 23 of US- Morocco FTA and Art. 16: 11: 23 of US- Peru FTA

[18] Ibid

TRIPS plus border measures enforced by the European Union has resulted in seizure and detention of consignments of these vital medicines at multiple locations or ports within the EU, mostly in a particular Member country of the bloc, only a few years ago. These were destined for less developed nations and were meant for the economically vulnerable. This had resulted in protests across a spectrum of those concerned in the civil society, academia and the developing countries. Developing states such as Brazil and India initially cautioned the EU and later brought the issue before the WTO dispute settlement process (Ravi Kanth 2010). Thus, legal standards of IPR enforcement in international treaties stands as an essential factor in ensuring or blocking access to essential medicines to the poor and vulnerable across the globe.

5.4.2 Legislative overtures in developed, developing and least developed nations:

Legislative measures adopted by a number of countries and blocs of nations recently exceed the TRIPS standards. Some of these legislations include the term ‘counterfeit medicine’, while others use the terms ‘falsified’ or ‘false’. A debate on the issue of all kinds of spurious, falsifies, substandard or counterfeit medicines had ensued upon the introduction of a taskforce within the WHO, which is chiefly concerned about public health. There were concerted attempts to make model legislation for use by the Member states. It conflated the trademark violation of counterfeiting with those pertaining to quality or active ingredients, and included generic medicines while defining ‘counterfeit’ drugs. This had virtually put the entire gamut of generic medicines at peril. However, protracted efforts in making reasonable interventions by the developing country representatives and civil society organisations hampered the taskforce’s onward march. Thus, any such legislation anywhere, is a potential peril for the cause of access to medicines. A few such are being discussed here.

5.4.2.1 The EC Regulation 1383/2003:

The EU Regulation 1383/ 2003[19] mandates that, customs authorities have the discretion to take action either based on an application by any right holder or *ex officio* in suspending goods that infringe an intellectual property right based on the idea of local rights. This implies that, even though this Regulation does apply to every EU Member State, whether there is violation of any intellectual property right is a function of national law. For example, French customs authorities ought to apply patent laws of France for determining whether any goods in-transit actually infringes the patent laws[20]. Additionally, recital 8 of the Regulation implies that any violation of intellectual property rights has to be determined on the basis of whether the goods in question would have infringed the same when manufactured in the EU Member State[21]. In recent times, this Regulation has been used to apprehend a number of shipments of legitimate generic drugs that have been manufactured in and shipped from India. Although a mechanism has been set out for the release of the suspended goods[22], it may result in inordinate delay for such low cost generic medicines to reach their intended markets. The time for the said mechanism becomes all the more important when such essential and lifesaving drugs are meant for the underprivileged sections of several developing nations that are suffering from alarming diseases of various types like HIV-AIDS, Tuberculosis, Hepatitis, etc. that call for the earliest possible and sustained medication.

---

[19] Council Regulation (EC) No. 1383/2003 of 22 July 2003 concerns customs action against goods suspected of infringing certain intellectual property rights and the measures to be taken against goods found to have infringed such rights.

[20] See EU Regulation 1383/ 2003, Chapter 3, Article 10

[21] EU Regulation 1383/ 2003, recital 8 says: "Proceedings initiated to determine whether an intellectual property right has been infringed under national law will be conducted with reference to the criteria used to establish whether goods produced in that Member State infringe intellectual property rights."

[22] The owner of the good in transit may apply for obtaining their release either by putting forth his objection to a patent owner's request to destroy the goods, or by notifying the customs office that legal procedures have been initiated to evaluate whether patent infringement has occurred (Articles. 13–14, EC Regulation 1383/2003).

5.4.2.2 The Medicrime Convention (2010) in Europe

In April 2010, a meeting was organized in Basel aiming for a realistic execution of the Council of Europe's convention on counterfeiting of medical products and similar crimes involving threats to public health. It has been opined that this convention sets the first global standard for criminalisation of the manufacture and distribution of counterfeited medicine that compromises public health. The draft text of the convention was ready to be signed by the Committee of Ministers in May and was open for signature in November, 2010 (Ermert 2010). The Council of Europe's Convention on the Counterfeiting of Medical Products and Similar Crimes involving threats to Public Health (Medicrime Convention[23]) was adopted in December 2010.

The Convention by and large proposes to barricade safeguard public health through punitive methods that supposedly tackle criminal behaviour, protect victims, promote cooperation at national and international levels, and take certain preventive measures. The convention is independent of any other existing national or international treaty or framework and its sole intention seems to be criminalisation of acts of counterfeiting of medical products. It is said to be the outcome of a perception by the Council of Europe that the act of counterfeiting of medical products had taken the shape of large illicit industry worth multi billion euro and international sanctions for addressing these acts are inadequate (Ermert 2010). Till date, this convention has been signed by 24 countries within and outside the European Union, and finally ratified by 5, of whom 3 are Members of the Council of Europe[24]. It is stated to be a binding agreement and is set to enter into force on January 1, 2016. The civil society and national governments had already expressed their reservations in treating the issue of 'counterfeiting', a matter of intellectual property infringement, as being the same with that of quality of a medicine that may affect patients. They insist that they are different issues and hence, cannot be conflated into one (Saez 2015).

[23] Since inception, the convention has been widely known as Medicrime Convention in business as well as academic circles.

[24] The official webpage of the convention on the Council of Europe website mentions about this fact. Please see 'Council of Europe Convention on the counterfeiting of medical products and similar crimes involving threats to public health', accessed 5 July 2017, URL: http://www.coe.int/en/web/conventions/full-list/-/conventions/treaty/211

5.4.2.3 The EU Falsified Medicines Directive 2011:

Further Amendment- The European Parliament Directive 2011:

The European Parliament adopted a Directive in February 2011 to amend the codifying Directive incorporating provisions for the detection of counterfeit medicines.[25] The new Directive introduces newer tools for tackling counterfeit pharmaceuticals. It is aimed at improving border measures and regulating the sale of drugs by the medium of Internet. All the Member States of the EU had a period of two years to include these methods to deal with counterfeiting within their legislation[26]. In 2011, the European Union issued the Falsified Medicines Directive[27].

5.4.2.4 Kenya:

Kenya, a developing country, has been one of the first in the African continent to introduce anti-counterfeiting legislation. In 2008, the Anti Counterfeit Bill[28] was proposed and the very same year the Kenyan Parliament hurriedly passed the Anti Counterfeit Act, 2008[29]. This legislation has not been seen as a positive development vis-à-vis the interest of its poor citizens in accessing affordable medicines. This law

---

[25] See 'Proposal for DIRECTIVE OF THE EUROPEAN PARLIAMENT AND THE COUNCIL amending Directive 2001/83/ EC as regards the prevention of the en try into the legal supply chain of medicinal products which are falsified in relation to their identity, history or source', [online: web] accessed 5 July 2017 URL: http://www.europarl.europa.eu/sides/getDoc.do?type=REPORT&reference=A7-2010-0148&language=EN#title2

[26] Ibid

[27] See *DIRECTIVE 2011/62/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL*

[28] See *The Anti-Counterfeit Bill, 2008,* [online: web], accessed 5 July 2017, URL: http://infojustice.org/wp-content/uploads/2012/04/Kenya-AC2008.pdf

[29] *THE ANTI-COUNTERFEIT ACT No.13 of 2008*, Date of Assent: 24th December. 2008, [online: web], accessed 5 July 2017, URL: http://www.industrialization.go.ke/images/downloads/policies/Anti_Counterfeit_Act_2008.pdf

had not only provided for the inclusion of all forms of IPRs within the definition of counterfeiting but also made it a criminal offence. Such definition and strict penal measures would not have otherwise qualified under the TRIPS Agreement[30]. The passage of the Bill has been criticised as an action that had been carried out under pressure from global pharmaceutical companies from developed countries who had deceitfully inducted themselves as members of local manufacturing associations (Mbatiah: 2010).

5.4.2.5 Uganda:

Uganda is one among the many least developed countries of East Africa. Enforcement of intellectual property rights has been taken up very keenly by the Ugandan government at the legislative level. At least two versions of an anti-counterfeiting legislation were initiated by the Ugandan administration to deal with the problem of counterfeiting of goods. The first one, the Counterfeit Goods Bill 2008[31], defined 'counterfeiting' in a manner that went beyond what the TRIPS Agreement mandates. This definition had indeed made a mention about the infringement of 'all intellectual property rights' and therefore, included patents besides trademark and copyright infringements[32]. Criminal penalties had been mentioned for goods that have been found to be counterfeit, which is, five times the market price of the genuine goods or imprisonment of a minimum of five years, or both. However, the Ugandan government had to yield owing to pressure from the civil society organisations who pointed out at many such sweeping provisions that exceeded the mandate of the TRIPS Agreement[33]. Indeed, in the final version of this in The Counterfeit Goods Bill

[30] The TRIPS Agreement relates the issue of counterfeit goods with trademarked items and pirated goods with copyrighted items (See footnote, Art. 51, TRIPS Agreement). Criminal measures under TRIPS can only be applied when the alleged infringement occurs wilfully and for pecuniary gains (Art 61, TRIPS Agreement).

[31] See, The Counterfeit Goods Bill 2008 [online: web], accessed 5 July 2017, URL: https://www.wcl.american.edu/pijip/download.cfm?downloadfile=B966F531-D8C4-1111-3B1065F2C799BF40&typename=dmFile&fieldname=filename

[32] See The Counterfeit Goods Bill 2008, Part 1 Section 1, *Ibid*.

[33] Such criminal sanctions mentioned in the 2008 Bill had indeed exceeded the 'minimum requirements' as under Article 61 of the TRIPS Agreement.

2010[34] certain notable changes had been made. The definitions of 'counterfeiting' and 'piracy' had done away with the universal term 'any intellectual property right' and included only trademark and copyright.

5.4.2.6 East African Community:

Five countries from eastern Africa, namely Kenya, which is a developing country and four least developed countries Rwanda, Burundi, Uganda and Tanzania, have come together under one umbrella for harmonise of their laws on intellectual property rights. They have framed a policy document that is aimed at curbing counterfeiting and piracy[35]. As mentioned in the document, the objective of this policy brief is to present, 'a policy basis for a robust legal framework for the protection and enforcement of Intellectual Property Rights in the Region with specific focus on combating counterfeits and pirated products." The goal of this draft policy has been stated as, 'To lay the foundation for the establishment of an effective regional mechanism to combat and if possible, eliminate counterfeiting and piracy trade in the region and thereby create a conducive investment climate as a prerequisite to industrialization and economic growth'. The definition of piracy in this document explicitly includes patents[36], and such is the case when it comes to the definition of 'counterfeiting'[37]. Piracy and counterfeiting, as provided under the TRIPS Agreement,

[34] See, The Counterfeit Goods Bill 2010 [online: web], accessed 5 July 2017, URL: https://www.wcl.american.edu/pijip/download.cfm?downloadfile=916DA7FE-B94E-491D-A737C1279E31C2DE&typename=dmFile&fieldname=filename

[35] See 'The East African Community Policy On Anti-Counterfeiting, Anti-Piracy And Other Intellectual Property Rights Violations, September 2009', [online: web], accessed 5 July 2017, URL: http://documents.jdsupra.com/01d012c0-95c9-48c4-8f8c-5d4704332a2d.pdf

[36] In this policy brief, piracy has been defined as 'the illicit, unauthorized and illegal reproduction of works/ materials protected by copyright, patent or trade mark law or any other intellectual property law and applying to the unlawful reproduction or distribution of copyright works for purposes of trade'. (paragraph 4.1.6)

[37] See paragraph 4.1.5 of ibid, at p 31

have been restricted only to goods that come within the purview of copyright and trademark protection respectively[38].

These countries have different standards for the protection and enforcement of IPRs that they have essentially inherited since colonial times. While Rwanda and Burundi provide for flexibilities under TRIPS that are available for the least developing countries, Tanzania and Uganda have provisions in their respective IP laws that have potential to hinder access to affordable lifesaving medicines for their peoples (Muheebwa: 2014).

5.4.3 Political advances

It has been observed that there have even been some political moves adopted by developed countries led by the US while collaborating among themselves in matters concerning IP enforcement in general. Some of these, had in recent times, raised some amount of concern in certain circles.

5.4.3.1 Security and Prosperity Partnership (Canada, Mexico and the United States)

On March 23, 2005 the leaders of United States, Canada and Mexico met in Waco, Texas, for discussing a number of issues including trade and economic collaboration. A core outcome of this meet that came about was the announcement of Security and Prosperity Partnership of North America or the SPP. Thereafter, in the summit of August, 2007 at Montebello, Canada, leaders of these three North American countries jointly announced their current achievements that included, among others, an Intellectual Property Action Strategy. (Villarreal& Lake: 2009: 4-5) The North American Competitiveness Council (NACC) is an 'official working group' under the SPP consisting of 'private sector representatives from North American corporations'. It had 'identified priorities' while listing its recommendations to the leaders that contained a 'trilateral Intellectual Property Action Strategy for more rigorous

[38] See footnote 14 to Art. 51 of the TRIPS Agreement

protection' of IPRs (Villarreal& Lake: 2009: 7). Diplomatic cables leaked on the international whistleblower website Wikileaks, show that the US officially intended to introduce USPTO IP Enforcement Programs during the course of communications with the Canadian state authorities[39]. The US Department of Homeland Security had in fact, formally proposed to 'host' the Canadian state officials at the USPTO office, in order to train them in IPR enforcement since the US had considered their IP enforcement to be inadequate[40].

The SPP is an official programme being carried out by governments of the three North American states although it does not serve as a treaty. However, a corollary of initiating this schema may be assessed as being the demand by the private corporations for an enhanced IPR protection even when the North American Free Trade Agreement or NAFTA, which itself contains certain far-reaching IPR provisions, was in place. This might eventually have a complementary effect on the general standards of intellectual property while negotiating a futuristic treaty involving IPRs at any bilateral, regional or international level.

5.4.3.2 The G-8 Initiative

In the summit of 2008, the G-8 or Group of Eight developed countries announced the intensification of intellectual property anti counterfeiting and piracy initiatives[41]. It declared creation of a set of enforcement standards on intellectual property to be followed at the World Customs Organization[42]. Further, it committed to acceleration

---

[39] Please see 'IPR Enforcement: Training and Technical Consultations' in the concerned partially leaked cable on the various official communications over the Security PP, [online: web] accessed 5 July 2017, URL: https://wikileaks.org/plusd/cables/05OTTAWA1725_a.html

[40] *Ibid.*

[41] Please see Para 17, Protection of Intellectual Property Rights, in '*G8 Declaration on the World Economy*' [Online: Web] accessed 5 July 2017, URL: https://www.eff.org/files/filenode/EFF_PK_v_USTR/foia-ustr-acta-response1-doc51.pdf

[42] It is supposedly a non-binding institutional scheme at the World Customs Organisation (WCO), named 'Standards to be Employed by Customs for Uniform Rights Enforcement or SECURE. The WCO being an international apex authority on customs issues, this set of IPR enforcement standards may have set a benchmark to be followed by the customs authorities worldwide. See WCO earlier in this Chapter and also in Chapter IV.

and thereby conclusion of ongoing negotiations for the new international treaty called Anti Counterfeiting Trade Agreement or ACTA[43].

In April 2012, the G-8 countries announced another rather mellow 'initiative' for responding to the problem of counterfeit products and medicines- the 'Non-Paper on Intellectual property Rights Protection'[44]. This 'non paper' contained specific references to measures on how to deal with the issue of global counterfeiting and piracy[45]. Therefore, even if there is a temporary slowdown on anti counterfeiting and piracy schemes at various institutional levels, it surely has not died down and is visible as items within various treaties concerning international trade.

5.4.4 Institutional modes:

The issue of public health had so far been dealt with only at the World Health Organisation (WHO). Over the last decade or so, a number of international institutions ranging from specialised international organizations dealing in international trade to those that deal in customs or crimes, seem to have taken up the cause of public health as a corollary of IPR infringements. Thus internationally, IPRs and health currently seem to be governed by several international institutions other than the WHO, like the World Trade Organization, the World Intellectual Property Organization, the World Customs Organization, the INTERPOL, etc. In each of these organizations, IP enforcement standards are being focussed upon and had been

[43] The ACTA was supposedly a very stringent international treaty on intellectual property enforcement aimed specifically at countering counterfeiting and piracy globally. After several rounds of negotiations for a few years, it could not fructify owing mostly to secrecy on the various substantive aspects of its negotiation during the various stages, by the negotiating countries. Besides this, sustained opposition to the inclusion of extra TRIPS provisions, by the civil society and various international organisations at almost every part of the world also had an important role to play. The European Union Parliament rejected this treaty as one that cannot be implemented. Therefore, since 2012, it went into quiescence and is currently not in course of negotiations.

[44] Officially, this document seems no longer available. But it can be accessed online elsewhere. Here, it can be accessed at this webpage of the European Digital Rights (EDRI): [online: web] accessed 5 July 2017, URL: https://edri.org/files/G8.pdf

[45] See *Ibid* Section 1, 'G-8 Initiative to Strengthen Enforcement against Cross-Border Counterfeiting and Piracy'

subjected to a sustained upward push. Stringency in enforcement standards ranges from introducing IP enforcement units to framing model legislations for countries to adopt at institutions that have almost nothing to do with IP. This subsection shall focus on the issue of access to medicines aspect of public health.

5.4.4.1 WTO:

The WTO has been one of the main actors as regards access to medicines and IPRs in general are concerned. The various cases brought before the WTO Dispute Settlement Mechanism have, from time to time, helped established the jurisprudence to be carried forward on issues related to intellectual property. Most of these case studies do not have a direct bearing on the issue of IPR enforcement as such, barring one. In recent times, only the *US-China* case[46] has brought in many issues concerning enforcement of IPRs at the international level. An important corollary in the Panel's decision in this case was that it agreed that many of China's IP standards did not violate the TRIPS provision.

The TRIPS Council under the aegis of the WTO is the platform where debates over various issues concerning IPRs take place among the Members of WTO. It was mainly the discussions at the TRIPS Council that finally resulted in the Doha Declaration on the TRIPS Agreement and Public Health in November 2001. It did not introduce any new obligation or rights, but merely acknowledged the flexibilities already provided within the TRIPS Agreement. This effectuated in the reinforcement of the right to their usage by the WTO Members, stating that these flexibilities should be interpreted in a way which is considerate of public health.

The supervisory function of the TRIPs Council[47], however, aims at effective execution and enforcement of TRIPs was central in the dissemination of a narrow

[46] *China-Measures affecting the protection and enforcement of intellectual property rights—Report of the panel (26 January 2009) WT/DS362.* See, discussions on this case in Chapter II.

[47] The Council for Trade Related Aspects of Intellectual Property or the TRIPS Council is a body constituting of all the WTO Member States that is mandated to oversee the implementation of the TRIPS Agreement within their respective States. Commentators have complained on the fact that the Council, while monitors and ensures the full implementation of TRIPS within domestic laws of

version of TRIPs provisions which restricted the flexibilities provided for governments of developing nations. Thus, during the late nineties of the last century the developing and least developed countries, where TRIPs was still not entirely in force, found themselves strained through tacit pressurisation by the United States Trade Representative (USTR). The USTR in reality acted at the behest of the US business and corporations, and voluntarily took up the job to 'educate' them in these meetings at the TRIPS Council as to how TRIPs should be put into practice. (Sell 2003: 123) In the same manner, for the sake of 'technical assistance' to such countries chiefly offered by the WTO and WIPO as also authorised under Article 67 of TRIPS, the USTR has been principally considerate by providing conveniently tailor-made texts of IPR laws, a few of which were 'TRIPs plus' or exceeded the TRIPS standards. These were not intended to advance the best interests of developing countries in the use of TRIPs flexibilities, but to discourage them from pursuing any dispute settlement case related to the enforcement of IPRs (Drahos 2002: 194-195). In so doing, the WIPO had even gone on to the extent of favouring the private IP right holders' interests over that of the developing countries in setting TRIPS Plus standards[48].

5.4.4.2 WCO:

The World Customs Organisation has In June 2006 the WCO Members established the ―Provisional Standards to be Employed by Customs for Uniform Rights Enforcement (SECURE). This document inflates the span of IPR enforcement radically. The WCO's Working Group on SECURE, after a three rounds of consultation, claimed to have formed a new standard for implementation. The World Customs Organization (WCO) held the third meeting of the Working Group on the

---

countries, does not have the mandate to review the financial statements of global pharmaceutical firms or where their research is standing (Lanoszka: 2003: 185).

[48] Dutfield and Suthersanen have pointed out this feature concerning the WIPO. They say, " WIPO's favouritism … is manifested in several ways including the provision of technical assistance to developing countries, which is believed by some to deliberately overlook the flexibilities of TRIPS and other multilateral intellectual property agreements, and promote what are effectively TRIPS plus standards" (Dutfield and Suthersanen 2008: 276).

Provisional Standards Employed by Customs for Uniform Rights Enforcement (SECURE) in its headquarters in Brussels 24-25 April 2008. The meeting, largely driven by some developed countries, was an attempt to promote their TRIPS-Plus-Plus agenda on international border enforcement, i.e. deliberate universal standards and best practice that exceed those established by the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS), in the absence of the scrutiny of the international community. The WCO Secretariat appeared to have been targeting the adoption of this standard at its June, 2008 meet. It could not do so, and in the subsequent meeting of the WCO Policy Commission in December, 2008, it was decided that the SECURE would be withdrawn (New 2009).

Nevertheless, the proposition and deliberations over the SECURE bear immense significance considering the future initiatives that are contemplated by the WCO in the area of international intellectual property enforcement.

5.4.4.3 The World Health Organisation (WHO):

The World Health Organization (WHO), under the auspices of the United Nations, is the nodal international agency for the protection and safeguarding of public health. The plenary organisation responsible for the execution of functions that essentially relate to public health around the globe and especially in developing countries is the WHO. It had discussions over the issue of spurious and fake drugs that affect human health since quite a long time. Very recently however, there had been efforts at this institution to define counterfeit medicine.

The issue of dealing with counterfeiting of medicine was actually part of a concerted effort to bring together a large number of organisations under one umbrella that would cooperate and coordinate amongst each other[49]. This was a 'taskforce', called the

[49] The taskforce's link on the WHO website states that it "aims to build coordinated networks across and between countries in order to halt the production, trading and selling of fake medicines around the globe. IMPACT is a partnership comprised of all the major anti-counterfeiting players, including: international organizations, non-governmental organizations, enforcement agencies, pharmaceutical manufacturers associations and drug and regulatory authorities." Thus, it attempts to bring together multifarious bodies under one roof.

International Medicinal Products Anti-Counterfeiting Taskforce or IMPACT, which was supposed to deal with the manufacture, business and sale of fake medicines. It conflated the trademark violation of counterfeiting by including issues relating to quality, safety and efficacy of medicines. It further went on to include generics within the definition of counterfeit medicines (IMPACT 2007). This posed a direct challenge to the generic manufacturers in developing countries like India, who are the major exporters to the developing as well as the developed world. Most of the generics exported by these producers stood the risk of their produces to be termed as counterfeits. The IMPACT sought to engage in five concerns, namely legislative and regulatory infrastructure, regulatory implementation, enforcement, technology and communication. It also had the mandate to set model legislation that would be adopted by Member countries of the WHO.

WHO being the plenary public health institution, is not the suitable forum for discussing issues concerning IPR or IP enforcement. Therefore, it was challenged and ultimately the IMPACT's existence and moves were thwarted by rational interventions made by developing country governments and international civil society at its highest decision-making body, the World Health Assembly. The IMPACT Secretariat, which was earlier hosted by the WHO, had been shifted outside the organisation. A working group on similar issues of spurious, substandard, falsified, counterfeit medicines has been established with a clear mandate to focus on public health objectives before making recommendations (WHO 2010: 67-68).

5.4.4.4 World Intellectual Property Organisation (WIPO):

Prior to the TRIPS Agreement, the World Intellectual Property Organisation was the plenary forum where issues concerning intellectual property were dealt with. TRIPS resulted in a shift of forum and thenceforth intellectual property issues, which currently are mostly related to international trade, are being essentially dealt at the WTO's TRIPS Council.

Recently at the World Intellectual Property Organisation (WIPO), an Advisory Committee on Enforcement (ACE) has been set up to counter problems arising out of

lack of enforcement of IP[50], including those related with pharmaceutical counterfeiting. Besides, the WIPO is also a member organisation of the IMPACT group of the WHO. However, the WIPO does not opine by itself on such matters and relies mostly on the resources available with the WHO. The WIPO declares that:

'The Advisory Committee on Enforcement (ACE) was established by the 2002 WIPO General Assemblies' and it is authorised to execute 'technical assistance and coordination in the field of enforcement'[51]. However, it also asserts that such mandate does not allow it to indulge in any kind of norm setting. It says:

> Within the framework of recommendation 45 of the WIPO Development Agenda, the ACE focuses on:
>
> - coordinating with public and private organizations to combat counterfeiting and piracy;
> - public education;
> - assistance;
> - coordination to undertake national and regional training programs for all relevant stakeholders; and
> - exchange of information on enforcement issues.
>
> Membership of the ACE (which emerged from various previous committees and meetings) is open to all member states of WIPO and/or of the Paris Union and/or of the Berne Union[52].

Conventionally, the WHO has long been considered as a promoter of public health. The World Intellectual Property Organization (WIPO), which generally functioned only as a forum for negotiating international agreements to protect intellectual property rights, has had a limited responsibility in matters concerning international policies, more so, in matters concerning development. However, of late, there have been a few instances of creation of newer laws that contained elements of both- those that set a new dimension to the TRIPS standards as well as those exceeding it. In

[50] See 'Advisory Committee on Enforcement', [online: web] accessed 5 July 2017, URL: http://www.wipo.int/enforcement/en/ace/

[51] See Report of the WIPO General Assembly Twenty-Eighth (13th Extraordinary) Session, Geneva, September 23 to October 1, 2002, WO/ GA/ 28/ 7, [online: web] accessed 5 July 2017, URL: http://www.wipo.int/edocs/mdocs/govbody/en/wo_ga_28/wo_ga_28_7.pdf,

[52] Ibid

2004, it engaged in taking up the interests of developing countries at the request of Argentina and Brazil in the form of a "Development Agenda"[53]. The resultant impact was instantaneous and within the WIPO a Substantive Patent Law Treaty (SPLT), which was sought by industrialised nations in order to raise the standards of protection and enforcement of patents globally, could be averted. Following this, in 2007 the WIPO adopted the Development Agenda that constituted a paradigm shift in the overall approach as to how intellectual property could and should also be utilised for the benefit of mankind[54].

However, the WIPO has also been involved in coordinating events that are not necessarily pursued by nations or their representatives. In recent times it has been hosting events on IP, along with other international bodies like International Criminal Police Organisation (INTERPOL) and World Customs Organisation (WCO). These were mainly organised by private entities from developed world with converging interests in advocating TRIPS Plus international IP enforcement rules that aimed at heightening stringency and criminality in cases of infringement (Sell 2008). Such rules, though existing in certain parts of the developed world, nonetheless, have already affected legitimate international trade and access to affordable medicines in the developing world.

5.4.4.5 International Criminal Police Organisation- INTERPOL:

The Interpol has been involved in a number of raids and confiscations of pharmaceutical products in the developing countries, especially in Africa, where certain frivolous companies have been manufacturing spurious pills and medication. The organization had, not long ago, declared to have established a full-fledged unit on intellectual property. It claimed to have found a link between terrorist financing and

[53] See *Proposal by Argentina and Brazil for the Establishment of a Development Agenda for WIPO*, WIPO doc. no. WO/GA/31/11 at the WIPO General Assembly, 27 August 2004, [online: web] accessed 5 July 2017, URL: http://www.wipo.int/edocs/mdocs/govbody/en/wo_ga_31/wo_ga_31_11.pdf

[54] The WIPO Development Agenda talks of IP or its harmonization not to be regarded as an 'end in itself', as this may lead to 'higher protection standards in all countries, irrespective of their levels of development.'

intellectual property crimes around the world in 2003 (INTERPOL 2003). The Interpol had even connected the issue of drug counterfeiting with several alleged terrorist groups operating across the world (Foxnews.com 2004).

The international police organization has of late shown a lot of interest for the implementation of IPRs, and currently maintains a dedicated webpage for the subject of 'Pharmaceutical Crime'[55]. The organisation has entered into an agreement with 29 of the world's biggest pharmaceutical companies in obtaining a fund of 4.5 million Euros to develop the current activities and boost law enforcement on pharmaceutical crime.[56] Not only that, it has associated with these pharmaceutical majors to create a Pharmaceutical Crime Programme, to deal with what is being termed as 'pharmaceutical crime' in both generic as well as branded version of drugs. Further, it will help identify and dismantle organised crime networks linked to such activity that, according to Interpol, threatens the life of millions (Saez: 2013).

Meanwhile, the Interpol has published an 'analytical report' that examines the relation between pharmaceutical crime and organised crime. This report has defined pharmaceutical crime as, 'manufacturing and distribution of counterfeit or falsified (spurious/fake/falsely labelled) pharmaceuticals or medical devices, through licit and illicit supply chains', that involves theft, fraud, diversion, smuggling, illegal trade, money laundering or corruption. In addition, it has been predefined that such crimes are to remain within the ambit of this definition irrespective of whatever the national legislation of the country concerned provides for such offences (Interpol 2014). This feature is potentially problematic when it comes to the implementation of the laws by the various national law enforcement authorities concerned.

On the other hand, however, generic drug companies from India have raised concerns over such an arrangement citing the fact that they have to regularly resist both open as well as secretive efforts in the global marketplace to vilify them, and tag them as

[55] The topic of 'Pharmaceutical Crime' has been discussed by the Interpol authorities in the following webpage [online: web] accessed 5 July 2017, URL: https://www.interpol.int/Crime-areas/Pharmaceutical-crime/Pharmaceutical-crime

[56] Information on this exercise and pharmaceutical companies that are funding this, may be accessed on an Interpol webpage, [online: web] accessed 5 July 2017, URL: https://www.interpol.int/Crime-areas/Pharmaceutical-crime/Pharmaceutical-Industry-Initiative-to-Combat-Crime

'counterfeit'. As a matter of fact, apparently controversial incidents of seizure and detention of shipments of generic Indian medicines by various customs authorities had indeed taken place between October and December 2008 at different points within the European Union, most of which were held in transit. It was found that most of them were en route to the African and Latin American nations for the treatment of poor patients who cannot afford to buy expensive branded drugs; none of these consignments either originated from or destined for any of the EU nations. The WHO has even disapproved of this undue action by the customs authorities in the EU, terming it as 'misuse of rules' (Mehdudia: 2010). At a later point in time, Brazil and India took the dispute with the EU to the consultative process of dispute settlement at the WTO, while Indian generics and other shipments chose to opt for alternatives to European carriers and routes. Only after realising that they were losing business owing to such counteractive measures, the EU relented and assured that such overreaches would not recur (Mathew 2011). The Indian Pharmaceutical Alliance has thus recently expressed dismay at this collaborative scheme of the Interpol and the global pharmaceutical majors, and termed it as "a continuation of the efforts by branded companies to use such agencies as Customs and Universal Postal Union to target generics as counterfeits" (Saez 2013).

5.4.4.6 UNDOC:

Lately, the UN Office on Drugs and Crime (UNODC) has been taking active part in matters concerning intellectual property enforcement, precisely, counterfeiting and piracy. A considerable thrust has been put in linking counterfeiting and piracy to organised crimes. It has resorted to publication of reports on these issues that directly points fingers at generic medicines exported from developing countries like India[57]. However, these have been found to be merely unsubstantiated allegations.

It has participated in joint initiative with the World Customs Organisation recently in inspection of container vessels in the seas and detection of illicit counterfeit goods. It

[57] An example of pharmaceutical drugs originating from India forming about half of the counterfeit drugs seized from consignments destined for Europe and North America has been included in this report (UNODC 2010: 184). Nonetheless, the data seems to be devoid of any evidentiary support.

had even received donations to carry out the exercise (UNODC 2012). In 2013, it had been the organiser of an event on trafficking of fraudulent medicines with participation from WHO, WCO and INTERPOL (UNODC 2013). In 2014, it launched a major campaign for countering trafficking in counterfeit medicines, which it unequivocally links up with organised crime (UNODC 2014).

The most worrying aspect of all its efforts is its recent drafting of model legislation on fraudulent medicines. It had obtained the authorisation for engaging in similar objectives via a resolution in 2011. However, it went beyond that mandate by defining fraudulent 'medical products' in place of permitted 'medicinal products'. Such a move was found to be very similar to those that were thwarted at the WHO and WCO few years ago. Questions have been raised not only about selection method of the drafters or their mandate to do so, but also the funding source of their meetings (Gopakumar 2015). The outcome of these exercises is very much predictable, and specifically targeted at developing country generics that are inimical to the interests of so called originator drug companies from the developed world. Such moves apparently have a direct impact on the export of legitimate generic medicines from India and other developing nations to their respective destinations around the world.

Broadly seen as another case of forum shopping, an otherwise mellow UN organisation with a different functional orientation is being used by multinational drug corporations for pursuing their IP enforcement agenda. However, being an UN organisation, any resultant success of such moves is likely to have at least some impact in influencing legislative standards in many countries, thereby threatening the cause of access to essential medicines and treatment.

5.4.5 Modes of 'technical assistance' and 'training':

TRIPS comes with several promises made to the developing and least developed countries in order to draw them into signing the agreement, one of which is that of providing 'technical assistance'. Technical assistance is thus legally mandated, and is to be provided by developed countries under Article 67 of the TRIPS Agreement[58],

[58] Article 67 of TRIPS lays down that:

upon the request of any developing or least developed country. The subject of technical assistance, among many others, not only featured in the 'Development Agenda[59]' presented by Brazil and Argentina at the WIPO, but also among the recommendations proposed by the Provisional Committee on Development and Intellectual Property (CDIP)[60] formed subsequently for its implementation.

The United States Patent and Trademark Office (USPTO) has established the Global Intellectual Property Academy (GIPA) in 2006 that 'offers programs on enforcement, patents, trademarks, copyrights'[61]. In September 2009, it came together with multinational pharmaceutical company Pfizer, to present a seminar in India. It was themed on various aspects of India's intellectual property legislation that favour India's role as a manufacturer and supplier of generic medicines, but are perceivably adversative to the desires of the various international pharmaceutical majors. The George Washington University of the US since 2003, has started initiatives that range from funding for the setting up of intellectual property law schools and shaping their course curriculums, forming bodies that would specifically train patent attorneys in line with those in the US, training judges in the higher judiciary of India in IP related matters[62].

The United States' nodal international trading agency, the United States Trade Representative (USTR) has been involved in providing technical assistance to

---

> In order to facilitate the implementation of this Agreement, developed country Members shall provide, on request and on mutually agreed terms and conditions, technical and financial cooperation in favour of developing and least-developed country Members. Such cooperation shall include assistance in the preparation of laws and regulations on the protection and enforcement of intellectual property rights as well as on the prevention of their abuse, and shall include support regarding the establishment or reinforcement of domestic offices and agencies relevant to these matters, including the training of personnel.

[59] See 'Development Agenda for WIPO' [online: web], accessed 5 July 2017, URL: http://www.wipo.int/ip-development/en/agenda/

[60] The Committee initially suggested 111 proposals that were finally tailored down to 45 recommendations.

[61] See 'Global Intellectual Property Academy' [online: web] accessed 5 July 2017, URL : https://www.uspto.gov/learning-and-resources/global-intellectual-property-academy

[62] Please refer to the following webpage of George Washington University, [online: web] accessed 5 July 2017, URL: https://www2.gwu.edu/~magazine/archive/2006_sept/docs/feature_lawindia.html

developing and least developed countries around the world. Some other organs and agencies of the US administration also take part or help in such exercises which are mainly aimed at countries it has trading relations with. Some of these are the U.S. Patent and Trademark Office, the U.S. Copyright Office[63], the Department of State, the U.S. Agency for International Development[64], U.S. Customs and Border Protection[65], the Department of Justice[66], and the Department of Commerce.

On similar lines as that of the US, the European Union has also initiated certain collaborative programs at the international level to train developing and least developed nations[67]. These include 'assistance in the preparation of draft laws on the protection and enforcement of intellectual property rights, exchange of information, awareness raising and support for the establishment or reinforcement of intellectual property rights domestic offices and agencies, including the general and specialised training of personnel'. Countries with which the EU has been involved in such exercise are the African Caribbean Pacific (ACP) countries, the Balkans, China,

[63] See 'International Activities' in the US Copyright Office webpage, [online: web] accessed 5 July 2017, URL: https://www.copyright.gov/docs/regstat72398.html

[64] Nisha Desai Biswal, assistant administrator for Asia bureau, USAID, informed the US Congress about pilot training on intellectual property being given by the USAID to Chinese supreme court justices as part of the 'USAID Rule of Law program in China', 'Statement Of Nisha Desai Biswal, Assistant Administrator, Bureau For Asia, Before The House Subcommittee On Asia And The Pacific - Bilateral Assistance Programs In China' on 15 November 2011, [online: web] accessed 10 February 2016, URL: https://www.usaid.gov/news-information/congressional-testimony/statement-nisha-desai-biswal-assistant-administrator-bure-0

[65] The US and EU customs authorities have jointly developed a 'brochure and Web toolkit to assist intellectual property owners in working with Customs to enforce their rights and to prepare information to help U.S. and E.U. Customs Agencies determine whether goods are counterfeit or pirated'. Please see 'US Customs and Border Protection (CBP)' [online: web] accessed 5 July 2017, URL: https://www.dhs.gov/xlibrary/assets/pso_cat_cbp.pdf

[66] See 'International Outreach and Training' in '*United States Department of Justice: Pro-IP Act Annual Report 2013*' at p 25, [online: web] accessed 5 July 2017, URL: https://www.justice.gov/sites/default/files/dag/pages/attachments/2014/10/31/pro_ip_act_report_fy2013_doj_final.pdf

[67] See 'EU technical assistance programmes in the field of intellectual property', [online: web] accessed 12 February 2016, URL: http://trade.ec.europa.eu/doclib/docs/2013/april/tradoc_150990.pdf

Indonesia, Mexico, Pakistan, Philippines, ASEAN, Cambodia, Central Asia, India, Laos, Thailand, Ukraine, Moldova and Vietnam among others[68].

Certain joint programs between developed economies have also come up in recent times. For example, the EU and the US had come up with a strategy to deal with concerns in significant developing economies such as China and Russia through closer coordination and information exchange, alongside enhanced customs cooperation and technical assistance to third countries[69]. By means of a combined working group, they have established regular information sharing on the endeavours to improve the overall IP enforcement environment in China and Russia[70]. Thus, they continue to pursue these kinds of efforts in almost every part of the world.

5.4.6 IP Enforcements by overseas pharmaceutical firms:

It has been observed in recent times, that searches and raids are being periodically conducted in a country by large drug firms that are headquartered abroad[71]. These firms take the help of the local law enforcement authority[72], and tend to apply legal standards that may overreach those that exist in that particular country. In addition, the main argument based on which such raids are conducted may be utterly improper and since there are private entities involved, there is always a probability that these claims may even be unfounded or misleading.

---

[68] *Ibid*.

[69] See 'EU–US Action Strategy for the Enforcement of Intellectual Property Rights', Brussels, 20 June 2006, [online: web] accessed 5 July 2017, URL: http://trade.ec.europa.eu/doclib/docs/2006/june/tradoc_129013.pdf

[70] *Ibid.*

[71] In 2011, joint raids by Pfizer and Peruvian police were conducted in localities in Peru. There were searches and raids to detect and seize 'counterfeit medicines' that were being sold locally. See, 'The Difficult Fight Against Counterfeit Drugs', accessed 5 July 2017, URL: http://www.cbsnews.com/news/the-difficult-fight-against-counterfeit-drugs/

[72] Firms may often become 'informers' for the local law enforcement, who are persuaded to make such searches and raids. See *Ibid*.

Multinational pharmaceutical majors have recently donated a substantial amount of money to the Interpol and UNDOC for carrying out programmes that suit their interests. They also regularly collaborate with similar international institutions for funding and organising events on counterfeit medicine. They had even funded a programme with the UNODC to detect counterfeit drugs in container vessels in the seas (UNODC 2012).

5.5 Conclusion:

As we have seen in this chapter how the international laws and institutions have played their respective roles both in ensuring as well as restricting healthcare requirements for the needy population throughout the globe. Specialised institutions belonging to the UN family have been recently used to pursue an overarching agenda of IP enforcement by the corporations from the developed world. All these institutions have a specific functioning mandate that seems to be breached by the imposition of the role that is chiefly the function of the WIPO, other than the WTO TRIPS. Wrongful moves adopted by UN organisations like the WHO, WIPO or the UNODC may in due course restrict the route to ensure access to medicines for the world's poor and needy.

In many countries and blocs there are laws and regulations that are aimed at dealing with the issue of counterfeit medicines. While ensuring the quality and safety of medicines is a noble criterion, the conflation of a trademark issue with so many other matters like quality, safety, efficacy, etc. raises concerns. Conflated definition may result in lawfully manufactured medicines not conforming to safety or quality standards. Thus internationally, such moves must be continued to be thwarted even at lesser known forums like the UNODC, as had been done earlier at the WHO or the WCO.

Many treaties of whatsoever nature that have TRIPS plus IP enforcement measures in them, like broad and ex officio powers for border officials, criminal sanctions for non wilful or materially gainful IP infringements, are threatening to block access to medicines as explained in this chapter.

Authors, such as Kuanpoth explain the phenomena. He says:

> The TRIPS-plus treaties increase the monopolistic power of large companies by demanding for harsh penalties, criminal enforcement for IP violations, and imposing obstacles to the use of compulsory licensing and revocation of patents, restricting the leverage that has helped the patent-granting country to achieve monopoly control (Kuanpoth 2007: 36).

Therefore, the developed world must be sensitised and if required and feasible, politically coerced at international forums like the WIPO or TRIPS Council, to have such treaties or their worrisome provisions rescinded. Rightful access to medicines by the human kind is too precious a cause to be ignored at the cost of exponential gains by multinational drug majors.

Plan an alternative IP system ensuring access to medications for all:

Article 61 TRIPS obliges Member countries to provide for criminal procedures at least in case of wilful counterfeiting and copyright piracy. In line with this provision, the TRIPS should also include provisions that deter patent owners to indulge in undue or frivolous patenting. Patents have been found to have been granted, mostly in the US and some other developed nations, for products that may not merit a patent due to lack of certain basic criteria for patenting. Patents should therefore be granted by the developed countries only in case of those applications that call for genuine innovation, and those parties who resort to too much of erratic application, should be reprimanded or punished by the concerned authorities.

Sanders thus points the relevance of WIPO Development Agenda as:

> The mandate of the Development Agenda is to come up with a humane policy that takes into account the needs of developing nations. The recognition of access to medicine as a human right was seen as a first step in formulating this humane policy. Yet, the adoption by the UN Commission of Human Rights of a declaration on the right of access to medicine remains merely symbolic if the IPR system remains unclear on the appropriate balance of rights and interests. Rather than looking to other or higher legal principles like human rights to forge humane IPR policy, the IPR system needs to internalise the recognition of the interests of all stakeholders. The recognition of interests of both developed and developing nations is therefore part of a wider concern on the fundamentals of the IPR system. Individual right holders, consumers, citizens and society at large all share a common interest in innovation and development of and access to industrial and intellectual creativity (Sanders 2007: 19-20).

Raise the issue of increasing budgets by developed countries for A2M:

A number of initiatives have been taken up by various international organisations to help the population in the developing and least developed countries to access essential and lifesaving medicines. One of the most significant among these is the Global Fund AIDS, Tuberculosis and Malaria, etc. which is mostly funded by the developed world. However, recent years have seen a reduction in the quantum of donations expected for the fund[73], while the global burden of diseases that it aims to cover takes an upward leap. There is likelihood that such a problem may result into gradual shortage of medicines that are required to be accessed by a large section of underprivileged population of the underdeveloped world. Therefore, allocation of such funds should be enhanced to such extents so that it is able to meet the accessibility requirements of a large chunk of patients in the third world who have limited, or no affordability for essential medicines.

Limit access and IPR enforceability on results of publicly funded research:

It is well known fact that a majority of fundamental research is carried out in universities that are publicly funded. It takes years or decades to discover a single molecule that could ultimately prove effective in preventing a disease or in some cases, many more diseases. Private organisations often collect the results of such public funded university research, develop them and market them commercially. The fruits of such basic research often find themselves as medicinal products marketed by large private pharmaceutical corporations across the globe. Thus, one proposal that may be put across in this context is the limiting access to such results of publicly funded research, based on certain conditionality that would include reducing their IPR enforceability standards.

[73] The Global Fund officials had contended before the donor developed nations that they required a fund of US $ 15 billion for different purposes ranging from prevention of new cases of malaria, providing care for more patients with tuberculosis or multidrug-resistant tuberculosis, and increasing the availability of antiretroviral therapy by the year 2016. However, it turned out such, that the countries together ultimately pledged about US $ 12 billion only (Usher: 2013).

Chapter VI

Stringent IP Enforcement: Restricted Access to Knowledge

Chapter VI

Implications for Development: Restricted Access to Knowledge

6.1 Introduction:

> How we regulate and manage the production of knowledge and the right of access to knowledge is at the centre of how well this *new economy*, the knowledge economy, works and of who benefits. At stake are matters of both distribution and efficiency (Stiglitz 2008: 1695).

International legal measures on intellectual property rights (IPR) have thus far taken little care of the concerns and interests of the world's underdeveloped and developing populations. Historically, the international IPR rules had been made for and on behalf of economically powerful, industrialised countries in the West, most of who colonised a large number of nations across the world. In the sixties and seventies of the last century such colonised developing countries were gradually decolonising and were starting to make fine inroads into the processes of international rulemaking at various fronts. There were calls by the newly decolonised nations during the seventies for a New International Economic Order (NIEO)[1] or presenting a Charter Economic Rights and Duties of States[2] at the major international organisations like the United Nations. Negotiations, under the aegis of the General Agreement on Tariffs and Trade (GATT) 1947 for harmonised international trade norms however, went on throughout the late seventies and eighties. There were several rounds of negotiations[3] and at the end of the Uruguay round in the mid-nineties the TRIPS Agreement had been finally reached. The multilaterally concluded TRIPS Agreement comprises the current

[1] *Declaration on the Establishment of a New International* Economic *Order,* U.N.G.A. Res. A/3201 (1974)

[2] *Charter of Economic Rights and Duties of States,* U.N.G.A. Res. A/3281 (1974)

[3] Negotiations for a number of areas in the international trading system under the GATT are continuing even today. Some of the significant rounds of negotiations in the past were the Dillon round, the Kennedy round, the Tokyo round, the Uruguay round, etc. Today, trade talks continue under the Doha round of trade negotiations.

international norms and rules on intellectual property. In spite of the TRIPS not being such a perfect international legislation as being a resultant of aggressive persuasion by industrial lobbies from advanced industrialised nations, it has been at least able to accommodate many of the vital interests of the developing countries. This had been an end result of plenty of resistance and efforts for decades, against intense pressure and lobbying by countries and interest groups from the developed world. However, the current ratchet-up of international copyright rules has led to an era that is seemingly marked by growing restrictions on the use of books, periodicals, journals and other forms of gathering knowledge. The nature of these new international legal measures to control supposedly 'unauthorised access' to information or knowledge is such that it limits and jeopardises the basic idea of knowledge – to be shared among individuals and peers. Knowledge being shared, helps build upon itself so that it is developed towards creation of newer and higher forms of knowledge; regrettably, several forms of international legal restrictions are being applied today, in the process of accessing and sharing knowledge.

In such a setting, this Chapter will firstly highlight the current international intellectual property regime that impinges upon access to information and knowledge. Section 2 deals with the correlation between TRIPS provisions and access to knowledge. It notes the relevant provisions on copyright for databases, explains the so-called 'three-step test' for copyright exemptions and also compulsory licensing as stated in the Berne Convention appendices. Section 3 then turns to the role of World Intellectual Property Organisation (WIPO) in helping build upon the idea of access to knowledge. It narrates the backdrop of the proposal for a Development Agenda by Argentina and Brazil at the WIPO, the preparation of the Draft Treaty on Access to Knowledge and the adoption of The Agreement on a Development Agenda consisting of forty-five agreed proposals adopted in September 2007. Section 4 broaches the position of the World Summit on the Information Society (WSIS) within the debate on access to knowledge. It discusses the various proposals and recommendations made at the lone international forum on information society supported by the United Nations. Section 5 discusses the idea of knowledge vis-à-vis the concepts of 'commons' or the 'public domain'. Thereafter, Section 6 narrates the barriers to access the several forms of knowledge. It shows the difficulties in accessing

information, educational materials as well as scientific and technical knowledge and analyses their reasons. Finally, Section 7 summaries the chapter and makes recommendations to deal with the different kinds of obstacles faced in accessing various forms of knowledge.

It will then attempt to show how there is a growing imperious dominance over the various forms of knowledge in the name of controlling IPR piracy. It will demonstrate that this may not only help the cause of widening up of certain already existing fault lines in the developing world, but may also gradually lead them into an evolving set of elevated international legal norms that may, in due course, perpetually bind them. It will further try and show that such norms apparently not only fail to meet the fundamental requirement in their pursuit for access to knowledge but undermine their developmental compulsions as well in the long run.

6.2 TRIPS and Access to Knowledge:

The TRIPS Agreement has a number of provisions that have a bearing on the idea of access to knowledge and information. It also contains certain built-in provisions that act as safety valves for an ever increasing plethora of restrictions imposed by the IP rights holders. These are briefly discussed here.

While stating its *Objectives*, TRIPS clearly affirms that:

> The protection and enforcement of intellectual property rights should contribute to the *promotion of technological innovation* and to the *transfer and dissemination of technology*, to the *mutual advantage of producers and users of technological knowledge* and in a manner *conducive to social and economic welfare*, and to a *balance of rights and obligations*[4] (emphasis added).

Thus, Article 7 of the TRIPS Agreement in laying down the aims of the treaty, quite comprehensibly has one of the most important roles while we interpret of each of the substantive provisions within the Agreement.

As regards the scope of copyright protection, TRIPS also provides that, 'Copyright protection shall extend to expressions and not to ideas, procedures, methods of

[4] Article 7, TRIPS Agreement

operation or mathematical concepts as such'[5]. However when read together with Article 2 (8) of the Berne Convention, which WTO Members have to mandatorily comply by virtue of Article 9 (1) of TRIPS[6], a certain degree of inconsistency between the concepts of 'idea' with that of 'expression' becomes apparent. This eventually leads to a divergence between whatever that may be protected under copyright and those that are under the public domain. The exploitation and access to ideas, concepts as also information or bare facts should not be considered as any exclusive right. Even when a work is protected, this check upon the extent of copyright protection makes it possible for anyone else to develop the basic ideas, thoughts, information, etc. and use them in future for as many times as required. This fundamental imperative is generally recognised around the globe (UNCTAD-ICTSD 2005: 139).

Therefore, this abridged scope of copyright protection that facilitates others to work upon the core concepts or facts is apparently critical for accessing, and thereby widening the reach of, information and knowledge. The dichotomy of idea and expression seemingly takes care of the interest of economies that are catching-up so that they may also espouse the ability to build on existing information and knowledge, to develop newer, innovative products and services; hence making way for them to compete and challenge, thereby assuring a holistic progress of science and the arts. Further, it disallows any control on access to and distribution of the fundamental edifices of knowledge, which is vital from the perspective of educational necessities in society (Ruse-Khan: 2009: 583).

Article 9 (2) of TRIPS provides for a *mandatory* obligation for WTO Member countries, that they "shall protect expressions under copyright, but shall not allow the protection of ideas, concepts and procedures." Under the current trend of 'TRIPS Plus' or enhanced protection of copyrighted subject matter being incorporated within Free Trade Agreements (FTAs) pursued by industrialised countries, mostly comprising of developing countries at the receiving end over the last decade or more,

[5] Article 9 (2), TRIPS Agreement

[6] Article 9 (1) TRIPS integrates the Berne Convention with TRIPS. It mandatorily requires WTO Member countries "to comply with Articles 1 through 21 of the Berne Convention (1971) and the Appendix thereto. …"

this proviso holds particular significance. Firmly within the domain of WTO jurisprudence, Article 1 (1) of TRIPS Agreement provides that WTO Members 'may, but shall not be obliged to, implement in their law more extensive protection than is required by this Agreement, *provided that such protection does not contravene the provisions of this Agreement'* (emphasis added) . Accordingly, TRIPS Plus standards of copyright protection hindering access to and transfer of ideas, information or other forms of unprotectable knowledge subject matter may be considered as in disregard of the dichotomy of idea and expression. Ubiquitous protection simply based on the appearance and functionality of software, grant of copyright merely on the basis of sizeable costs incurred for compilations of data, texts or websites, etc. entails them into some kind of a *sui generis* right for non-original databases; this may well end up protecting plain data, or other incorporated elements, which could be seen to be at odds with the dichotomy existing between idea and expression and further with article 2 (8) of the Berne Convention. As Ruse-Khan points out, that the latter:

> … is also a mandatory provision and participates in the TRIPS acquis by virtue of article 9 (1) TRIPS so that FTA provisions contravening article 2 (8) Berne may equally be actionable under article 1 (1) TRIPS. Finding such conflicts is even more likely keeping in mind the balancing objectives of article 7 TRIPS which – by virtue of article 3 (2) DSU and article 31 (1) VCLT – should guide the interpretation of both article 1 (1) as well as article 9 (2) TRIPS (Ruse –Khan 2009: 583-584).

6.2.1 Copyright for database:

Article 10 (2) TRIPS Agreement provides for copyright protection of compilations of data (or databases). This is also a key provision from the perspective of access to knowledge. It says:

> Compilations of data or other material, whether in machine readable or other form, which *by reason of the selection or arrangement of their contents constitute intellectual creations* shall be protected as such. Such *protection, which shall not extend to the data or material itself*, shall be without prejudice to any copyright subsisting in the data or material itself (Art 10 (2), TRIPS).

This provision is based on Art 2 (5) of the Berne Convention. It is this provision that the international standard for copyright protection of assortment of information is founded upon. Due to the ever increasing importance of systems, tools or mechanisms

to store, manage, order and provide access to the vast amounts of information available in particular via open networks such as the internet, copyright protection for such collections of information or databases can have significant implications in the context of access to knowledge.

Members of the WTO have to afford protection to databases as soon as there is an intellectual creation either in the preference or in the order of the data or other material. This implies that the database creator either has to choose innovatively from the pool of data at hand the material which he wants to include in the body of his database, or has to sort that material inventively in a definite order. Interpreting this in accordance with Article 7 TRIPS and combined with the 'minimum standards' notion, it appears to assign the function of deciding upon the level of intellectual distinctiveness to the countries themselves. This leaves considerable policy space for countries that need to permit access to material within these databases in order to adopt a higher level for copyright protection[7], thus protecting innovative aspects alone and not the information concerned *per se*.

6.2.2 The 'three-step test' for copyright exemption:

Article 13 TRIPS has ample aptitude to protect and facilitate access and dissemination of knowledge and information. It reads as:

> "Members shall confine limitations or exceptions to exclusive rights to *certain special cases* which *do not conflict with a normal exploitation of the work* and *do not unreasonably prejudice the legitimate interests of the right holder*" (emphasis added).

Article 13 TRIPS, outlined upon Article 9 (2) of the Berne Convention[8], sets out three conditions that must be met in case any WTO Member enacts a law on exception to copyright. It does not define any minimum standard in the area of exceptions to

[7] Thus, anyone is general is free to use such material, which becomes clear and obvious under Article 10 (2) which states that copyright protection shall not 'extend to the material itself'.

[8] Art. 9 (2) of the Berne Convention is supposed to deal exclusively with the right of reproduction. It states: 'It shall be a matter for legislation in the countries of the Union to permit the reproduction of such works in certain special cases, provided that such reproduction does not conflict with a normal exploitation of the work and does not unreasonably prejudice the legitimate interests of the author.'

copyright. The right of access to information or knowledge for research, educational purposes or aiding disabled persons, etc. are time and again realized only by means of exemptions or restrictions to the explicit rights. This, as a consequence, tends to affect the broad restraint on the authority to legislate in such cases. In order to provide for such copyright exception under Article 13 TRIPS, it is apparent that three separate conditions of legality have to be met. They are:–

i. Confining limitations or exceptions to exclusive rights to 'certain special cases' alone:

Interpretation of the notion 'certain special cases' has been varying amongst different sections of commentators and jurists.

Ricketson had observed in this regard that the phrase should be interpreted as requiring an exception for a 'specific purpose' and that a broad exception that includes a multitude of subject matter or uses would not be consistent with the provision. He further adds that a specific public policy or other particular situations should ideally be a justification for its applicability (Ricketson 2003: 4).

The WTO Panel Report in *United States – Section 110(5) of US Copyright Act* [9] in this regard inferred however, that Article 13 precludes broad exceptions which may commonly apply as contrary to any understanding based on the subjective purpose of the legislation of a country (UNCTAD-ICTSD: 2005). If one has to sum up the analysis and interpretation of the Panel Report vis-à-vis the broad approach of Article 13 TRIPS, it indicates the overwhelming inconsistency the three-step test can have on the exceptions that favour a broader approach on access to and distribution of knowledge.

In this respect, Dutfield and Suthersanen construe it subject to clarity offered within the domestic regulations. They state:

> … a limitation or exception in national legislation should be clearly defined and should be narrow in its scope and reach; there is no need, however, to

[9] WTO Panel Report, Section 110 (5) of the U.S. Copyright Act, June 15, 2000, NT/DS160/R at para 6 in '*United States – Section 110(5) of US Copyright Act – Request for Consultations by the European Communities and their Member States*', WT/ DS160/1- a case brought against the United States' on account of a particular stipulation providing for copyright exception.

> identify explicitly each and every possible situation to which the exception could apply, provided that the scope of the exception is known and particularised. … (Dutfield and Suthersanen 2008: 95).

ii. Such exclusive rights should not conflict with normal exploitation of the work

Article 13 TRIPS maintains that such immunity, other than being limited to 'certain special cases' also may *not conflict with any normal exploitation* of the copyrighted work by the right holder (emphasis added). This condition in effect renders the interests served by exceptions and limitations as secondary to those of the right holders. The interpretation by the Panel in the aforementioned dispute between the EC and US[10] only persuades this kind of an understanding. Each time exploitations, that primarily fall within the ambit of exclusive rights, yet exempted under limitations, enter into a contest with the right holders' observation of a financial viability that denies them considerable trade benefit, it essentially results in an inconsistency with ordinary utilization of the work. Article 7 TRIPS demands a reasonable examination, whereas analysis of the three step test by this WTO Panel seemingly denies the endeavour afforded by an exemption to ever predominate over business interests of the right holders (Ruse-Khan 2009: 589).

Another view in this respect states that the 'second step should not pose too much of a burden to any development policy seeking to promote the dissemination of knowledge through the free availability of copyrighted material.' The rationale that is provided for this is that 'fair dealing provisions' or 'statutory exceptions' mostly contain a major characteristic feature- that they are limited to non-commercial uses. Hence, if documents are subject to reproduction for private, research or teaching purposes in less developed countries, such facsimiles (copies) will simply not come into competition in the manner that the right holders draw financial worth from that copyright, as has been expressed by the panel in some of its deductions. Since such facsimiles are not likely to be sold in the market, thus interrupting some trade prospects for the copyright holder, or that fair dealing provisions upset the right holder who is not able to sell the required material to those people or institutions that

[10] See *supra* n. 7 at 4.

make use of them for teaching or education purposes. However, such a contention overlooks the fact that the disadvantaged people who get some assistance from the free availability of restricted copies do not enjoy the financial means to pay for those. From the right holder's perspective, thus, the issue of loss of business does not arise (UNCTAD-ICTSD 2005: 192).

iii. Such rights should not unreasonably prejudice legitimate interest of the right holders:

Article 13 TRIPS does not allow realization of the benefits of swollen profit from the unrestricted utilization of copyrights. The benchmark incorporated in the law more or less rules out deciding on what makes a 'reasonable loss' of income, as also hardly allows unreasonable discrimination against the right holders' concerns. This is why the third criterion of the three-step test must be carefully verified, as it does authorize monetary compensation to right holders in certain copyright protected materials. This has particular consequence for the replication of resources acquired from documentation centres, collections, archives, libraries, etc. for purposes such as research, school, college or university usages, or any other mostly non-commercial educational purpose.

The WTO Panel Report[11] mentioned above suggests that the third step in Article 13 of TRIPS covers economic as well as non-economic benefit or deficit. This is indicative of some interests concerning matters of public policy that have a probability to add credence while analysing the interest of the right holder which is legitimate. For example, the free speech objectives that underlie copyright in many countries might suggest that a right holder who wants to use copyright to suppress the communication of certain works may not be exercising the right in a legitimate way. In other words, such an author may not have a "legitimate" right to suppress the communication of his works. Likewise, it could be argued that a right holder who wishes to prevent the free distribution of copies of his work for non-commercial purposes lacks any legitimacy in doing so. While in the case of non-commercial use, the right holder does not run

[11] See, *supra* n. 7

the risk of important economic losses, she/he would at the same time prevent the implementation of a policy that offers a promising potential for the development of a knowledge-based society in less advanced countries.

It has been indicated that this provision on exception and limitation in the TRIPS Agreement does respond to certain vital interests and stakes that have not been addressed earlier in international intellectual property law. The 'TRIPS version of the three-step test' has thus been pointed out as something distinctive:

> It should be noted ..... the TRIPS Agreement does refer to the competing and complementary objects and purposes of the agreement under Articles 7 and 8. This is not so under the Berne Convention where it is very clear that the object and purpose of the Berne Convention is solely concerned with the protection of the rights of authors, without reference to other kinds of competing objects and purposes, such as education and research or the promotion of public access to information (Dutfield & Suthersanen 2008: 96).

The provision concerns limitations and exceptions to copyright which very often serve the purpose of allowing the use and exploitation of copyrighted subject matter for a particular purpose (such as criticism, parody or illustration for teaching or research), by a particular group of beneficiaries or institutions (disabled persons, libraries, the press) and/or to a certain extent (limited to certain forms of use or to a specific portion of the protected work).

6.2.3 Compulsory licensing as under the Berne Appendix:

Another approach in international law that has implications for access to knowledge mostly in developing countries is by means of the Appendix to the Berne Convention. An Appendix, now part of the TRIPS Agreement, was included in the Paris Act of 1971 of the Convention, which allows compulsory licensing for educational uses corresponding to mass reproduction and translation of works. Article 9 (1) TRIPS binds all Members of WTO to abide by this set of provisions which seeks to ensure considerable and inexpensive access to works concerning technological and scientific advancement. The Berne Appendix method works on the basis of compulsory licences to be granted by the competent developing country authorities on the rights of translation and reproduction, seemingly dealing with one of the major concern over

access to knowledge in developing countries: the lack of cost-effective vernacular material.

The objective suggests that the mechanism should serve as a fundamental response in dealing with any apprehension regarding access to copyrighted material in developing countries. But on the contrary, it has been put through various restrictive precincts referred to in articles II and III of the Appendix itself as given here.

A nonexclusive and non-transferable compulsory license to translation right of a work may be authorized only under the following circumstances:–

i. after a minimum of three years from the date of its first publication

ii. when no publication of the work exists in any of the country's common languages, or

iii. in case an existing translation is not in print.

This licence is however put through several exclusive conditions, like its availability for nationals of the particular country; the translated work can merely be published in printed or analogous form and for nothing more than teaching, scholarship or research purposes alone.

Reproduction rights to a work may also be authorised for an additional compulsory licence upon meeting the following conditions:–

i. after a period of three years for the works in natural and physical sciences including mathematics and of technology;

ii. after seven years, for fictional works, poetry, drama and music and for books of art;

iii. for any other work for a period of five years from the date of first publication of the work and only if

iv. copies of the work have not been distributed to the general public in the country at a cost reasonably around that normally spent within that country for comparable works.

This licence is yet again subjected to additional conditions under article III of the Appendix.

On the whole, the Berne Appendix though is perceived to be an utter disappointment vis-à-vis the educational requirements of developing nations. Dutfield and Suthersanen opines that, although it came up as a post colonial project during the 'international crisis of copyright' of the 1960s and 1970s, it could do little to serve the purpose of advancing supply of affordable books to the developing countries. They feel, "it is highly doubtful that the Berne Appendix did anything to give practical effect to the notion that the educational needs of people in developing countries should have priority over intellectual property rights" (Dutfield and Suthersanen 2008: 288). They have also summarised the causes of its failure as being the following:-

Firstly that, its detailing and complication exceeds the original Berne Act in length.

Secondly, an extremely intricate provision seems to nullify the sanction for use of compulsory licence upon failure of voluntary negotiations for translation and reproduction rights of works.

Thirdly, the Appendix only relates to translation and reproduction rights, and not to broadcasting or other communication rights including online transmission of works.

Fourthly and finally, it does not include any requirement for free educational use or for any reduction in duration of copyright (Dutfield and Suthersanen 2008: 288).

Additionally, it has also been remarked that its complex and burdensome requirements and high transaction costs make it unaffordable for less developed countries. Its additional irrelevance lies in the digital context, particularly; the copyrighted material stored in electronic databases or provided upon demand make that system almost useless for electronic media. She compares the same with an exception provided for export of patented drugs under compulsory licence to less developed countries lacking in manufacturing capacity, terming both as being unyielding of any result (Ruse-Khan 2009: 59).

6.3 WIPO and Access to Knowledge: The Development Agenda:

Representing a group called the 'Friends of Development', Brazil and Argentina primarily presented a proposal for the establishment of a Development Agenda at the World Intellectual Property Organisation (WIPO) in favour of the developing countries[12]. There was a universal consensus at the WIPO General Assembly in its 2004 annual session to consider the proposal by the "Friends of Development"[13] and proposals by other Member States on the subject[14]; thus responding by initiating negotiations on a 'Development Agenda' in 2004 among the Members and relating to all of its features[15]. The success of the Argentinean and Brazilian proposal came about in September 2007 when the WIPO Development Agenda was adopted by the WIPO General Assembly[16]. Some of the main propositions that have been agreed upon concerning access to knowledge within the domain of the current international copyright system are being attempted to be discussed. In this setting, it has been divided into the following three sections:-

1. proposal on behalf of the 'Friends of Development',

---

[12] See *Proposal by Argentina and Brazil for the Establishment of a Development Agenda for WIPO*, WIPO doc. no. WO/GA/31/11 at the WIPO General Assembly, 27 August 2004, [online: web] Accessed July 18, 2015, URL: http://www.wipo.int/edocs/mdocs/govbody/en/wo_ga_31/wo_ga_31_11.pdf

[13] The countries that comprised of the 'Friends of Development' were Argentina, Bolivia, Brazil, Cuba, Dominican Republic, Ecuador, Egypt, Iran, Kenya, Peru, Sierra Leone, South Africa, Tanzania, and Venezuela. *See* WIPO, Inter-Sessional Intergovernmental Meeting on a Development Agenda for WIPO, 1st Sess., *Proposal to Establish a Development Agenda for WIPO: An Elaboration of Issues Raised in Document WO/GA/31/11*, Annex at 2, IIM/1/4 (Apr. 6, 2005)

[14] *Report of the WIPO General Assembly: Thirty-First (15th Extraordinary) Session, September 27–October 5, 2004* (October 5, 2004), WIPO doc. no. WO/GA/31/15, para. 128, [online: web] Accessed July 18, 2015, URL: http://www.wipo.int/edocs/mdocs/govbody/en/wo_ga_31/wo_ga_31_15.pdf

[15] An update on this issue was provided in, "Moving Forward The 'Development Agenda' In WIPO", *Bridges* Vol. 8 No. 33, 6 October 2004, [online: web] Accessed: 17 July 2015, URL: http://www.ictsd.org/bridges-news/bridges/news/moving-forward-the-development-agenda-in-wipo

[16] In all, forty-five recommendations were agreed upon for the WIPO Development Agenda, which included nineteen recommendations that were meant to be implemented immediately. All of these are contained in World Intellectual Property Organization, *Report of the Assemblies of the Member States of WIPO: Forty-Third Series of Meetings, September 24–October 3, 2007*, Annexes A and B, WIPO doc. no. A/43/16, [online: web] Accessed July 18, 2015, URL: http://www.wipo.int/edocs/mdocs/govbody/en/a_43/a_43_16-main1.pdf

2. Draft Treaty on Access to Knowledge, and

3. The Agreement on a Development Agenda:

6.3.1 The proposal on behalf of the 'Friends of Development':

This proposal recognized the inevitable necessity for incorporating the significant aspect of *development* within the domain of international intellectual property policymaking. It said, among others, that:

> "Intellectual property protection cannot be seen as an end in itself, nor can the harmonization of intellectual property laws leading to higher protection standards in all countries, irrespective of their levels of development."[17]

Such an affair also bears no less importance as far as WIPO's activities in general are concerned. It took care of the broad themes of the role of development in IP policymaking, and a need-based arrangement designed to accommodate individual countries' interests[18]. Besides, this proposal also dealt especially with, manners of norm setting, transfer of technology, IP enforcement, technical cooperation and assistance as well as member and civil society participation[19].

At a time when various kinds of IP rulemaking beyond that required under the TRIPS Agreement were in continuance, this proposal called for provisions that would safeguard public interest and policy space for the Member States[20] and that would be on the lines of Articles 7 and 8 of the TRIPS Agreement[21]. It expressly reflected upon

---

[17] Please see *supra* n. 12 at 2

[18] *Ibid*

[19] *Ibid.*

[20] 'WIPO is currently engaged in norm-setting activities in various technical Committees. Some of these activities would have developing countries and LDCs agree to IP protection standards that largely exceed existing obligations under the WTO's TRIPS Agreement, while these countries are still struggling with the costly process of implementing TRIPS itself' (*Ibid*, n.10 at 3) This indicates ongoing negotiations at the WIPO on IP norms that were aimed towards exceeding the standards laid down under TRIPS.

[21] 'Provisions on "objectives and principles", reflecting the content of Articles 7 and 8 of the TRIPS Agreement, should be included in the SPLT and other treaties under discussion in WIPO.' (*Ibid* n. 10 at 3-4) It signifies that the SPLT or Substantive Patent Law Treaty was well perceived as being one

the value of protecting and providing for access to knowledge in the overbearing legal framework of intellectual property and its impact on the digital landscape.[22] It also voiced concern over the use of newer forms of technological protection measures (TPMs) within the imminent international laws on IP under negotiations that inhibit access to knowledge.

Besides Brazil and Argentina, this proposal was further co-sponsored by several other countries and was robustly complimented by the patronage of a diverse group of non-governmental organisations (NGOs), lawyers, academics, artists, etc. A Provisional Committee on Proposals Related to a WIPO Development Agenda (PCDA) was set up in 2005. In a span of just two years, 111 individual suggestions were made by different Member States of WIPO to the PCDA. Finally, 45 proposals were generally agreed upon and these were presented for adoption to the 2007 WIPO General Assembly.

6.3.2 The Draft Treaty on Access to Knowledge:

One of the significant aspects of the proposal by the 'Friends of Development' was the section on development dimension and transfer of technology, that contained recommendation of a Treaty on Access to Knowledge and Technology[23]. It stated that even when intellectual property should encourage transfer of technology as mentioned under Articles 7 and 8 of TRIPS Agreement, many of the developing countries had by then already started adopting standards of IP that were higher than TRIPS. They had to do so in spite of the fact, that there were deficiencies in the necessary infrastructure and institutional capacity in such countries to be identified with such technology.

---

among a gamut of international regulatory norms that go beyond the TRIPS obligations that provided room for flexibilities in case of the developing countries.

[22] "While access to information and knowledge sharing are regarded as essential elements in fostering innovation and creativity in the information economy, adding new layers of intellectual property protection to the digital environment would obstruct the free flow of information and scuttle efforts to set up new arrangements for promoting innovation and creativity, through initiatives such as the 'Creative Commons'. …." (*Ibid*, n. 10 at 4)

[23] See in section V of 'The Development Dimension and The Transfer of Technology', *Ibid* n. 10 at 4

The Draft Treaty on Access to Knowledge[24] of May 9, 2005 is the only one of its kind across the globe. The idea behind this Treaty is “to protect and enhance [expand] access to knowledge, and to facilitate the transfer of technology to developing countries.”[25] It solicits "to enhance participation in cultural, civic and educational affairs" and share" the benefits of scientific advancement." It recognizes “the importance of knowledge resources in supporting innovation, development and social progress, and of the opportunities arising from technological progress particularly the Internet.”[26]

In order “to overcome disparities in wealth, development, and access to knowledge resources”, it undertakes to be firm “to create the broadest opportunities to participate in the development of knowledge resources.” It is apprehensive about “private misappropriation of social and public knowledge resources”, and thus recognises “the need to protect and expand the knowledge commons”, and is therefore firm “to protect, preserve and enhance the public domain.”[27]

It aims “to control anticompetitive practices, concerned technological measures that restrict access to knowledge goods” and “will harm authors, libraries, education institutions, archives, and persons with disabilities”. It thus suggests requirement of “new incentives to create and share knowledge resources without restrictions on access.” It is aware of “the importance of the global information networks in expanding access to knowledge”, while being attentive of “the benefits of open access to scientific research and data.” It recognizes “the benefits of greater transparency of knowledge resources and technologies, the need for global action to protect and enhance access to knowledge resources”, while pursuing “to promote the transfer of technology to developing countries.”[28]

---

[24] See, ‘Draft Treaty on Access to Knowledge’ [online: web], accessed 5 July 2017, URL: http://zoo.cs.yale.edu/classes/cs457/backup/A2K_Treaty_consolidatedtext_may9.pdf

[25] See Article 1-1, ‘Objectives’, *Ibid* at 21

[26] See ‘Preamble’ *Ibid* at 21

[27] *Ibid*

[28] *Ibid*

Further, the Treaty asserts certain important changes in international Copyright laws in order to make it more inclusive[29]. For instance, it proposes to allow fair use of works, as primary materials for educational instructions, whenever the price of such materials exceed beyond a reasonable point, though entitling the right holder to an 'equitable remuneration'[30]. It also asks for allowing such fair uses for purposes of reverse engineering[31] of justifiable nature and usages by persons with disabilities[32]. Such uses have been proposed to be deemed as 'special cases' that do not unduly discriminate against due interest of the right holder[33], but in doing so, the magnitude of its larger public interest ought to be considered[34]. A 'general exception' in special cases has also been proposed in cases where the social, cultural, educational or other developmental benefit of a use outweighs the costs imposed by it on private parties"[35]. Further, this Treaty asks for a "new protocol for access to copyrighted works in developing countries" through compulsory licenses[36]. Besides Copyrights, this treaty also proposes several broad modifications in international Patent laws that are generally of inclusive nature.

6.3.3 The Agreement on a Development Agenda:

The WIPO General Assembly adopted the 45 proposals on 28 September 2007, which the PCDA agreed upon during two key sessions in February and June that year. Of those proposals, 19 had been selected for implementation with immediate effect. It further approved the establishment of a Committee on Development and Intellectual Property which had the tasks of developing a work programme for the implementation

[29] See *Ibid* Article 3 -1 on " General Limitations and Exceptions to Copyright"

[30] *Ibid* Article 3-1(a)(iv)

[31] *Ibid* Article 3-1(a)(vi)

[32] *Ibid* Article 3-1(a)(vii)

[33] *Ibid* Article 3-1(b)

[34] *Ibid* Article 3-1(c)

[35] *Ibid* Article 3-1(d)

[36] *Ibid* Article 3-12

of the adopted recommendations and to monitor, assess, discuss and report on the implementation process. The Committee is supposed to meet twice a year, starting in 2008. It will replace WIPO's current body dealing with development issues, the Permanent Committee on Cooperation for Development Related to Intellectual Property (PCIPD).

The 45 agreed proposals are divided into six clusters: (A) technical assistance and capacity building; (B) norm-setting, flexibilities, public policy and public domain; (C) technology transfer, information and communication technologies (ICT) and access to knowledge; (D) assessment, evaluation and impact studies; (E) institutional matters including mandate and governance; (F) other issues. Of these clusters, (B) and (C) are of specific interest for the access to knowledge issues in the context of international copyright regulation. Within (B), proposal 15 stipulates that norm-setting activities shall 'take into account different levels of development' and consider a balance between the costs and benefits of the IP regulation at stake. Proposal 17 then requires WIPO to 'take into account the flexibilities in international IP agreements, especially those which are of interest to developing countries and LDCs'. Both the proposals are amongst the 19 which are to be implemented immediately.

6.4 The World Summit on the Information Society (WSIS):

Information and communication technology has enormous possibilities for access to knowledge if used effectively, and the international community had to deliberate upon it as a matter of common concern. One of the most remarkable advancements for Access to Knowledge in the area of information and communications technology (ICT) is undoubtedly the World Summit on the Information Society (WSIS) organised by the United Nations[37] in two phases. The first phase was held in Geneva in 2003 and the second one in Tunis was held in 2005 (WSIS 2003; WSIS 2005).

[37] A High-Level Summit Organizing Committee (HLSOC) established with the assistance and support of the UN Secretary-General at that time, Kofi Annan. This committee intended to bring together the endeavours of the 'international United Nations family in the preparation, organization and holding of WSIS'. Please see WSIS webpage [online: web], accessed 5 July 2017, URL: https://www.itu.int/net/wsis/basic/about.html

The foundational touchstone, the 'Declaration of Principles' of the WSIS, states:

> "We declare our common desire and commitment to build a people-centred, inclusive and development- oriented Information Society, where everyone can create, access, utilize and share information and knowledge, enabling individuals, communities and peoples to achieve their full potential in promoting their sustainable development and improving their quality of life …"[38]

The summit mainly highlights the best way to proficiently use the available technologies for sustainable development and improvement of livelihoods and to develop an enabling institutional and policy framework for the information society. The Tunis phase of WSIS saw the delegate States reiterate their pledge for supporting educational, scientific, and cultural institutions, including libraries, archives and museums, in their role of developing, providing equitable, open and affordable access to, and preserving diverse and varied content, including in digital form, to support informal and formal education, research and innovation; and in particular supporting libraries in their public-service role of providing free and equitable access to information and of improving ICT literacy and community connectivity, particularly in underserved communities (WSIS 2005). The WSIS fora take place on an annual basis with a 'leading role' played by the International Telecommunications Union (ITU) based at Geneva which also houses its permanent executive secretariat[39]. Executive secretariats have also been set up by the host countries of the first two phases - at Geneva (Switzerland) and Tunis (Tunisia)[40].

The WSIS has played a leading role in taking onboard, and hence overseeing, that not only governments but international organisations, UN agencies, non-governmental organisations, the press, etc.[41] had all participated and voiced their respective

---

[38] World Summit on Information Society, Declaration of Principles, Document WSIS-03/GENEVA/DOC/4-E, 12 December 2003, Para 1

[39] Please see the webpage of WSIS [online: web], accessed 5 July 2017, URL: https://www.itu.int/net/wsis/basic/about.html

[40] *Ibid*

[41] "WSIS, while recommending representation from governments at the highest level also invited participation of all relevant UN bodies and other international organizations, non-governmental organizations, private sector, civil society, and media to establish a truly multi-stakeholder process." See *Ibid*.

opinions. In so doing the necessary steps, towards ensuring that a major chunk of the underprivileged population worldwide could have access to the fruits of ICT, could be taken. The gateway to access knowledge, that includes information and education for the masses, forms a major outcome of such an initiative. Thus, recognizing the significance of the role being played by the summit for over a decade, the *Preamble* to the 'WSIS+10 Statement on the Implementation of WSIS Outcomes' had stated:

> The evolution of the information society over the past 10 years is contributing towards, inter alia, the development of knowledge societies around the world that are based on principles of freedom of expression, quality education for all, universal and non-discriminatory access to information and knowledge, and respect for cultural and linguistic diversity and cultural heritage. When mentioning the information society, we also refer to the above mentioned evolution and to the vision of inclusive knowledge societies (WSIS Outcomes 2014: 12).

6.5 Knowledge and the concept of Commons – the Public Domain:

Throughout the history of mankind there had always existed what is known in common discussions as the 'public domain'. In intellectual property parlance though, it is supposed to be construed as, all the resources that are free of any kind of private ownership. In the following subsections, attention is being drawn to both these concepts as emphasised by various scholars.

6.5.1 Definition of Public Domain Information:

The meaning and sense of 'public domain' may vary according to its utilities and applicability. In some situations this term may imply a legal connotation while in some others it may denote something of the nature of a social construct.

The United Nations Educational Social and Cultural Organization (UNESCO), almost a decade ago, had provided an idea of public domain information. This description is certainly purposeful in understanding the notion of public domain in the context of knowledge and information. It refers to 'public domain information' as:

> ….. publicly accessible information, the use of which does not infringe any legal right, or any obligation of confidentiality. It thus refers on the one hand to the realm of all works or objects of related rights, which can be exploited by everybody without any authorization, for instance because protection is not granted under national or international law, or because of the expiration of the term of protection. It refers on the other hand to public data and official information produced and voluntarily made available by governments or international organizations (UNESCO 2003: 6).

6.5.2 Public Domain information and Intellectual Property:

Intellectual property, precisely copyrights, may provide the concept of public domain information with a slightly different undertone. In keeping with his association with the UNESCO, Matsuura describes the information on public domain from the perspective of sanction or approval. He states:

> Public-domain information is publicly accessible information, the use of which does not infringe any legal right or any obligation of confidentiality. It thus refers to the realm of all works or objects of related rights that can be exploited by everybody without any authorization (Matsuura 2004: 8).

He adds that this information is devoid of copyright and "often not sufficiently well known to potential contributors and users". He explains that the growing restriction in some countries on the availability and use of public information and data may arise when information and data in the public domain are subjected to privatization or commercialization by what he refers to as "a process of re-packaging" (Matsuura 2004: 8).

Paul Uhlir asserts that he and Prof. Reichman have shown that public domain information as those "whose uses are not restricted by intellectual property or other statutory regimes and that are accordingly available to the public for use without authorization or restriction." They have analysed that data and information in the public domain can be divided into two major categories:

> 1. information that is not subject to protection under exclusive intellectual property rights or other statutory restriction; and
>
> 2. information that qualifies as protectible subject matter under some intellectual property regime, but that is contractually designated as unprotected (Uhlir 2003: 4).

They add that:

> The first major category of public-domain information can be further divided into three subcategories: (i) information that intellectual property rights cannot protect because of the nature of the source that produced it; (ii) otherwise protectible information that has lapsed into the public domain because its statutory term of protection has expired; and (iii) ineligible or unprotectible components of otherwise protectible subject matter (Uhlir 2003: 4).

From the standpoint of enforcement of intellectual property rights, however, Waelde and MacQeen's perspectives have indeed facilitated in surmising the value of public domain. They indicate that:

> If the public domain is so important, it becomes as important to identify what it is, and what its continued well-being requires, as it is to promote the development and enforcement of intellectual property rights (Waelde and MacQeen 2007: xi).

Thus, according to them:

> Public domain analysis in law really begins from the identification of whatever it is that lies unprotected by intellectual property rights and so is free for use by all engaged in intellectual endeavours of whatever kind, being incapable of that exclusivity which is the core of legal conceptualisations of ownership (Waelde and MacQeen 2007: xii).

6.6 Barriers to access the various forms of Knowledge:

Access to a diverse variety of human intellectual produces like medical and agricultural technologies, educational materials, software, musical records, photographic or cinematic films that are direct or indirect resultants of knowledge are currently facing a number of restrictions. These hindrances or barriers have been created via the extraordinary expansion in various kinds of intellectual property protection and enforcement.

Among all other forms of IPRs, patents and copyrights draw the major obstacles to gathering of knowledge as these are substantive in their nature, and probably that is why these are rapidly being amplified through various means at international, regional, plurilateral, bilateral and national levels. Since the days of the Paris and Berne Conventions, a number of restrictive provisions on intellectual property

enforcement have been incorporated within the national and international legislations. These seem to have been currently ratcheted up to result into a historically extraordinary stringency in international IPR enforcements.

The TRIPS Agreement also acts as the main impediment for access to the various forms of medical and agricultural technologies as well.

6.6.1 Access to Information:

Access to information is one of the primary precepts upon which the entire information society is founded. It is not only endorsed by the UN Charter but also the Universal Declaration of Human Rights (UDHR). The World Summit on Information Society thus states:

> We declare our common desire and commitment to build a people-centred, inclusive and development-oriented Information Society, where everyone can create, access, utilize and share information and knowledge, enabling individuals, communities and peoples to achieve their full potential in promoting their sustainable development and improving their quality of life, premised on the purposes and principles of the Charter of the United Nations and respecting fully and upholding the Universal Declaration of Human Rights…[42]

Matsuura however refers to an incongruous situation that has emerged with the advent and subsequent spread of the internet. He accordingly points out, that:

> We face a paradox, however. On the one hand the accelerating spread of the Internet and new opportunities for free or low-cost publishing are generating real benefits. On the other hand, the new economic and technological environment is raising concerns about the erosion of access to certain information and knowledge whose free sharing facilitated scientific research and education in past decades (Matsuura 2004: 7).

The TRIPS Agreement, as reminded by some scholars, makes reference to a number of competing elements as regards its object and purpose. This aspect of the treaty, as illustrated in Articles 7 and 8 of the agreement, distinguishes it from its predecessor,

---

[42] *World Summit on Information Society, Declaration of Principles, Document WSIS-03/GENEVA/DOC/4-E, 12 December 2003*, Para 1.

the Berne Convention, which merely concerns itself with the rights of the authors. Certain 'competing objects and purposes' like education, research or promotion of access to information by the public, etc. do not find any mention in it (Dutfield and Suthersanen: 2010: 20).

Internationally, IP regimes have strengthened by leaps and bounds. At the same time, movements and measures in opposition have also shown their global prominence. Koutras underscores these, by making a mention about "the open source software, the access to medicines lobby, the open access movement, the development of Creative Commons licenses and the European Orphan Works directive etc." He says that they "are strong signs of a possible turn towards a more balanced approach to intellectual property issues." He views access to information as:

> … a crucial factor for knowledge economies of the future and fortified if, inter alia, open access repositories (OARs) are given a fair chance of both survival and of development. The information revolution has given the open access movement the best chance it will get. Thus, the enlargement of information accessibility safeguards human rights for the future of developing and developed countries (Koutras 2015: 134).

6.6.2 Access to Educational Materials:

Education is essential for the human beings to gain in knowledge and develop their minds. Human development is almost impossible without a sound and systematic education. Under the current IPR system, many factors have arisen which inhibit the reach of education to people, especially in the developing world. Some of them are being discussed here.

6.6.2.1 Copyright:

The idea of Copyright law is to look for a balance between the incentives to create, and make best use of ways for accessing the information that had been created. The idea of Copyright is not just defining the rights of the copyright owner, but to characterize the precincts of information that is to be accessible privately and publicly. Copyright creates an immediate blockade for the access to the various kinds

of materials that may be essential to meet educational requirements. Educational materials that are restricted by copyright may even be purposeful in order to modernize essential utilities such as the medical science or healthcare. As Land points out "Increased copyright protections are perceived as limiting access to, among other things, educational materials such as textbooks and scientific publications necessary for the advancement of medical treatment" (Beutz Land 2009: 6). A monopoly of copyright is thought to encourage production of information by excluding those who would not pay and trade in such information at a commanding cost. Moreover, there is a necessity that copyright law must find a way to deal with the excesses that are currently being proposed with the cyberspace, multimedia, and computer software. It has also been noted, that an outsized population from the less developed countries are rather excluded from accessing some important literature that may play a vital role in improving their conditions in key areas like public health which are definitely one of their primary concerns (Yamey 2008: 21-22).

Margaret Chon has outlined the importance of the approach on education from the viewpoint of copyright policy in developing countries. She portrays the stance of those developing countries where there is an acute insufficiency of education, and the role that copyright policy might play. This kind of a developmental problem is about meeting "basic human capabilities", as she explains:

> From an "essential needs" standpoint, access to basic educational materials is as important as access to life-saving medicines. Education is fundamental to the capacity-building upon which all further progress is made. Although copyright is only one of many factors that go into the provision of basic education, it is an essential policy lever for educational development generally (Chon 2006: 2885).

6.6.2.2 High Cost of materials for education:

Developing and least developed countries have their own fundamental economic constraints that are markedly different from developed nations. Educational materials like books are knowledge goods whose exclusivity may set their prices at a higher range than what it should be for other goods that rather have to face market

competition; this often may affect developmental concerns like access to education in developing societies. Rizk and Shaver have thus observed:

> Intellectual property monopolies always impose a social cost, as knowledge goods are priced at higher than the price that would prevail in a competitive market. This leads to the accumulation of monopoly rents for the IP rightsholder, but limits the productive utilization of the knowledge good in the larger economy (Rizk and Shaver 2010: 3).

The problem of access to educational materials starts right at the level of primary schools. At this level, high prices of books apparently constitute the major reason for non accessibility of many good books that are otherwise accessible to the affluent sections in a developing society or to those in the developed nations in general. This problem continues even at higher levels for those who seek to pursue distance education. Many scholars have noted the problem of soaring cost of both text as well as non-text books hindering access to knowledge.

The state of abject poverty suffered by a major section of the population has been identified by scholars as being a major reason for the increase in piracy. They say that piracy provides the low-income groups in an underdeveloped country like Uganda with text books, the price of which would have been otherwise beyond the reach of the common people. They affirm the "intuitive assertion" that undeniably it is piracy that acts to bridge the breaches in basic educational goals created by the standard copyright-oriented industry of the land (Kawooya, Dick et al. 2010: 297).

Often, as in the case of distance education in Africa, most of the educational materials happen to be under copyright protection. The cost involved in their access from databases via the internet is quite high and it may become unaffordable for many. The subsequent distribution of the educational materials by the institution concerned takes place by means of reproducing, translating, adapting, or converting them into printable formats (Ncube 2011: 270). Cost 'overheads', as she terms it, in obtaining copyright permissions, reduces the quality of the study materials when such institutes are rendered incapable of purchasing the requisite copyright permissions for them (Ncube 2011: 274).

6.6.2.3 IPRs on educational software:

We are presently standing in an age of various technological progressions- the most important advancement being in the field of information and communication technology. It would not perhaps be an exaggeration to say that computers- its hardware and the allied software, have become as important as an essentiality in our daily life. Many basic works such as reading, writing, etc. that form part of educational curriculum are being done at a much faster pace via the medium of software. However, most of the software that are required for such day to day uses are copyrighted and come in the market at a cost that is beyond the reach of most of the population living in the developing countries. People in such countries have little option but to be left out, or avail themselves unauthorised copies of the original software from grey markets at a non-retail price which they could manage to afford. The most common reason for such unavailability is the non revelation of the source code[43] for such software. The source code is essential for the development of any software or computer program.

There are primarily two types of software or computer programs- 'proprietary software' and 'open source software'. A purposeful and informative website named 'opensource.com' has defined 'proprietary software' as one whose source code cannot be modified by anyone but the person, team, or organization that had created it and who maintain an exclusive control over it. It explains that since its source code is the property of its original authors, they are the only ones legally allowed to copy or modify it. Examples of proprietary software are Microsoft Word and Adobe Photoshop[44]. On the other hand however, it says that the authors of open source software make its source code available to others who would like to view that code, copy it, learn from it, alter it, or share it. It provides LibreOffice and GNU Image

[43] Source code, is that part of software that most computer users are not aware of, and has been defined as "… the code computer programmers can manipulate to change how a piece of software—a "program" or "application"—works. Programmers who have access to a computer program's source code can improve that program by adding features to it or fixing parts that don't always work correctly". See [online: web], accessed 5 July 2017, URL: https://opensource.com/resources/what-open-source

[44] Ibid

Manipulation Program as such examples[45]. Therefore apparently, the right to use such scientific data in software does not necessarily rest solely with any particular company that may enjoy its proprietorship, but continues to remain with the scientific community that is developing it.

However, currently there have been efforts, both at the governmental levels as well as collectively, to make such software available at almost free of cost. One such effort is the open source software[46] model or Open Content model. This has been started in South Africa, where the government has adopted a policy of Free and Open Source Software (FOSS) in public information technology systems[47].

Recently, a collective scholarly initiative based on software, the 'Public Knowledge Project'[48], has been started in which academics benefit from the opportunity to generously exchange their works of research and publication anywhere around the world. This is supposed to have greatly increased the general contribution to research and scholarship. Macgregor, et al, have identified some of the factors that provided for realization of the idea behind such a schema. They have attributed the success of the project in developing the software used by journals in different parts of the world to the 'collective wisdom' and 'trial and error' of the team involved, over the years. Such wisdom, as they add:

> … has found its expression in, for example, the early adoption of open source and community development models; the active development of the international PKP community; and the feedback of users in guiding software and workflow design decisions that reflected principles of simplicity,

[45] Ibid

[46] Open Source Software refers to any computer software, the source code of which is available via a licence that mostly relies on public domain and permits the users to learn and gain knowledge and then make alterations to improve the software, and which can be redistributed either in modified or in original form. Thus, it is developed mostly in an open and collaborative way.

[47] Republic of South Africa (2006). Policy on free and open source software use for South African government, 2006, http://www.doc.gov.za/index.php?option=com_docman&task=doc_view&gid=49, accessed 30 October 2009

[48] The website of the Public Knowledge Project or PKP states it to be 'a multi-university initiative developing (free) open source software and conducting research to improve the quality and reach of scholarly publishing'. See PKP [online: web], accessed 17 January 2016, URL: https://pkp.sfu.ca/

interoperability, accessibility, and openness, without sacrificing capability (Macgregor et al 2014: 166).

6.6.2.4 Technological Protection Measures or Anti Circumvention Measures:

There has been recently a number of measures legislated within certain international copyright treaties that aim to prevent copyright piracy by making countries commit to adopt certain technological protection measures (TPMs) mainly on the internet. TPMs mainly function as digital locks of copyrighted works. A couple of treaties concluded under the aegis of the WIPO[49] have provisions that direct contracting parties to provide for adequate legal protection and effective remedies against the circumvention of TPMs used by authors or other copyright owners like performers and sound recording companies, with the exercise of their rights and that restrict acts which they have not authorised and that are not permitted by law[50].

Digital world or the cyberspace has contributed immensely to the production and distribution of information and knowledge goods across the globe. However the access to these knowledge goods, a scholarly article or a book in electronic format for example, may be subjected to systematic digital anti-circumvention laws. Information online is currently easily subjected to digital control mechanisms by means of efficient tools assigned by copyright owners. The functions of these tools may range from blocking the access to any copyrighted work or preventing their copying and sharing in the digital form.

Technological protection measures may include Digital Rights Management (DRM) techniques like certain anti-circumvention tools. DRMs are techniques that "prevent individuals from lawful lending and sharing of creative works, or making "fair use" of them through commentary, parody, scholarship, or news reports." In the United States, the Digital Millennium Copyright Act (DMCA) of 1998 imposed criminal penalties for circumventing encryption and other technological protection measures,

[49] The two treaties are the WIPO Copyright Treaty 1996, and the WIPO Performances and Phonograms Treaty 1996

[50] See, Art 11 of WIPO Copyright Treaty 1996 and Art 18 WIPO Performances and Phonograms Treaty 1996, both providing for 'Obligations for Technological Measures'.

or even distributing circumvention tools, and the Sonny Bono Copyright Term Extension Act (CTEA), which extends the already lengthy duration of copyright for twenty years, thereby freezing the public domain where works are freely available to distribute, copy, and share. General apprehensions have been expressed at the possible fallouts of the DRMs (Rens et al: 2006).

Ronan Deazley has identified a couple of risks that the technological protection measures (TPMs) may hold for the public domain. They are:-

1. Those works whose copyright term had ended may also be put through a 'technological lock-up' by the content providers.

2. These measures may also constrain the 'lawful uses' of those that are within the terms of copyright. As he says, it could be "without permission, whether set out in the legislation or at common law (how do you make copies from a work, whether substantial or insubstantial, fair or unfair, in the public interest or not, whenever the medium itself is copy-protected?" (Deazley 2007: 29).

The interface between copyright's public domain and that of the law of contract could also be rendered problematic. Copyright owners nowadays are increasingly using contractual provisions to make users opt out of those which are otherwise freely available within the public domain. He explains:

> This can of course occur in a one-to-one contract negotiation, but is increasingly prevalent in relation to the delivery of copyright content online with the use of evermore generic click-wrap licensing agreements, the terms of which end users rarely ever read (Deazley 2007: 29).

He further illustrates as:

> …. if you access material on Westlaw or Lexis-Nexis (or any other information database) are you legally entitled to read that material on screen only? Or does the licence also authorise you to print a hard copy of the work? Or save it on your computer's hard drive? Moreover how do these various actions relate to your ability to deal fairly with that work for the purpose of private study? … (Deazley 2007: 29).

The US stands out as the foremost among the developed nations who had made it an agenda to pursue enforcement of IP norms in every possible area, including through the medium of the internet. The Digital Millennium Copyright Act (DMCA) of 1998

has provided for a wide range of coverage for copyright protection over the digital medium that by far exceeds the standards of the TRIPS Agreement. This legislation ushered in an extremely broad legal protection within the digital rights management systems with the support from the copyright industry of the US. However, the US maintains an approach of upholding legal obligations towards its own citizens while opting for higher digital norms with other countries with which it enters into FTAs.

Kuanpoth shows this in a clear, comprehensible manner. He refers to Title I of the DMCA that prohibits the tampering with or circumventing the systems, as also the manufacture, distribution, and importation of circumvention tools. He states:

> While TRIPS is absent on obligations concerning technological protection measures (TPMs), all FTAs proposed by the US stipulate that parties must provide adequate legal protection and effective legal remedies against acts of circumventing TPMs and against devices which could be used for circumvention, regardless of the intended use of the device. It also limits the scope of exceptions in which TPMs may be used and extends the scope of criminal offences relating to the manufacture, distribution and use of circumvention devices (Kuanpoth 2007: 43).

As a consequence, the author's conventional economic right is being stretched to include the users' right to use or distribute the devices that may be used for the circumvention. This creates a whole new concept of copyright protection. The access and distribution of works in public domain, which copyright law otherwise leaves unprotected to encourage creativity, shall now be controlled by owners by prohibition of both circumventing TPMs and devices. It will interfere with the rights of consumers to deal with their lawfully purchased goods by preventing the circumvention for non-infringing uses as well. Further, online fair uses shall be constricted by requiring users to pay for any use or quotation without considering the purpose. The obstruction of non-commercial uses of internet or digital works privately will swell as much as in educational institutions or libraries (Kuanpoth 2007: 43).

He further states that, the inclusion of TPMs within national copyright laws of countries with which US signs FTAs is going to result in reduction of fair use restrictions. He reasons this owing to the presence of wide fair use provisions and a guarantee of free speech by the US Constitution and the corresponding absence in the US's FTA partner countries (Kuanpoth 2007: 43).

The (European) Information Society Directive also contains very similar provisions. Article 6(1) and (2) of Directive mandates Member States for providing 'adequate' legal protection against the circumvention of effective TPMs and against trafficking in anti-circumvention devices or services.

Referring to the UK's 'Commission on Intellectual Property Rights' report 2002, Barton has also identified appropriate arrangements for digital material especially in relation to the internet, as one of the important issues on the international IPR negotiations. As he states, the "driving force" for such 'is the concern of the music and cinema industries that digital material can be readily copied, thus making impossible an adequate return on the investment in content production". But he insists that, the principles involved in such negotiations "will almost certainly affect computer programs and perhaps scientific information as well" (Barton 2003: 57). These concerns have led to a desire to provide 'technological protection,' such as encryption, for such material, and to seek international treaties and statutes, e.g. the 1996 World Intellectual Property Organization (WIPO) Copyright Treaty and the 1998 US Digital Millennium Copyright Act, to prohibit circumvention of such technological protection. Here, he points out, that it:

> … may interfere with fair use rights and thus not be in the interests of the developing world. There will certainly be an effort to extend such anti-circumvention legislation and treaties to the entire world, and the developing nations will need to consider how to respond (Barton 2003: 57-58).

The publishing industry, the major educational content suppliers, has both advantages and disadvantages from the most recent developments. While there has been significant technological development in the area of digital publications that facilitates access to certain contents that till today were not otherwise available to many, it has also been perceived to be a threat by many of them. The advent of the internet has been seen as something that encourages a potentially unrestricted entry into a domain of exclusive rights of authors and publishers. Therefore, the WIPO Internet Treaties[51] of 1996 seek to restrict access to copyrighted works as well as allow copyright owners

[51] The *WIPO Copyright Treaty 1996* and the *WIPO Performances and Phonograms Treaty 1996* are together referred as WIPO Internet Treaties.

to deny users, sometimes, their lawful usage rights under general educational exceptions, or that of fair use.

6.6.2.5 Language as a barrier:

Educational and literacy levels of individuals from developing countries constitute another major reason to hinder their access to knowledge. Most of the citizens in developing countries generally do not speak any major recognised language of international use like English, French or Spanish. While most of the books and other materials are published in these languages around the world, it would be little surprising as to why the commoners are more likely to be detached from what they should have been able to easily access.

A survey by a public spirited consumer group few years ago had indeed found language to be one of the barriers to access books, software, etc. This indicates that had those materials been available in local languages, it would have been far easier to reach for those who access the materials concerned (Consumers International 2010).

Art. 8 grants authors the exclusive right "of making and of authorizing the translation" of their works. The wording of the provision implies that this right is *unlimited* (emphasis added). Nevertheless, restrictions are conceivable even under the Convention itself, if legitimate user interests so require. There is widespread agreement that Arts 2*bis*.2, 9.2, 10.1, 2 and 10*bis* are to be taken into consideration for that purpose. In addition to the criteria set out in these provisions, restrictions on copyright including the right of translation within the framework of TRIPS must meet the three-step test which is embodied in Art. 13 of TRIPS. Minor exceptions outside this test, i.e. restrictions in connection with religious celebrations, military activities, education and folklore distribution of works are not permitted. This follows, according to Art. 31 VCLT, from the lack of agreement of the Union States on this point, as their extremely heterogeneous practice proves (Stoll, Busche and Arend: 2009).

Ever since the time of the world's first known formal copyright law, the 'Statute of Anne of 1710', as Ruth Okediji notes, "the encouragement of learning and the

dissemination of knowledge has been a focused objective of the grant of proprietary rights to authors" (Okediji: 2004: 1).

She also refers to the limitations granted to authors, established by the Statute of Anne for fulfilment of public purpose. The two limitations that she particularly considered noteworthy for encouragement of access to education, research and learning were that it did not preclude the "importation, vending, or selling" of books in foreign languages printed overseas and its system of price control on books." She further notes that it did not preclude the importation, vending, or selling of books in foreign languages printed overseas (Okediji: 2004: 1).

As under Article II, a developing country has to wait for three years after the first publication when it can issue compulsory license for translation. However, "if the original right owner has exercised the translation right in the language at issue" it cannot be issued. Any mass access required within those three years is subject to negotiations with the rights owner; hence putting timely relevance of scientific works into jeopardy. She also identifies another pertinent problem with the Appendix. In a developing country, after a person has filed for a license, there is a grace period of six months, during which the rights owner can exercise the translation right; compulsory license may only be issues when such translation right is not exercised by the owner. In addition, licenses under Article II are applicable only to teaching, scholarship and research (Okediji 2004: 10).

Article III license, the second major component, may be obtained to reproduce and publish only for use in connection with systematic instructional activities. Such licenses are generally issuable after five-years from the date of first publication, and after three years in case of scientific work. In case of fiction, poetry, drama, music and art, it could be issued only after seven years (Okediji 2004: 10).

In some developing countries like India, Pakistan or China, multiple languages are spoken. Some difficulty might arise in matters concerning translation rights in such situations. In an 'ICTSD-UNCTAD Policy Discussion Paper on Intellectual Property Rights and Development' Suthersanen has highlighted that translating from one language to another causes problems in these countries, and so the requisite permission normally has to be sought for all such translations (Suthersanen 2005).

Even in a continental setup like Africa, comprising cultural affluence and miscellany at the same time, major predicaments like illiteracy and people speaking only local languages are realities; integrating such individuals within the information society is indeed overwhelming task. It has been acknowledged that expanding the breadth of information and making it inclusive across societies, economies, cultures and geographies seem easier said than done (Samassékou 2006: ix).

In southern Africa, while documenting the various problems for access to knowledge it has been noticed that besides unavailability of materials, their unsuitability also forms one of the major blockades for accessing educational materials. It had been found that higher the level of education, lesser becomes the availability of materials in indigenous languages. Rens et al observe that:

> …. the majority population, though multilingual, is primarily fluent in one or more of the indigenous languages. Rural students ….receive their primary and secondary education in one of these indigenous languages, depending on the region the student is from, and the options available. Dominant languages (such as English and Afrikaans) are then only encountered upon entering tertiary education at which point the student is confronted with a near-total lack of learning materials in her preferred language of instruction, thus often having to grapple with learning in an unfamiliar language (Rens et al 2006: 15).

They note that learners in indigenous languages, those with sensory disabilities or availing distance learning – all belong to a group outside the mainstream, as educational materials have to be adapted from their original format accordingly to suit their respective requirements. The original one usually happens to be a book printed in the English language (Rens et al 2006: 15-16).

Major languages used internationally, can themselves act as barriers for non availability of materials or services in local languages. Chinna and Malcolm, while referring to a consumer survey report on software uses in various countries, highlights the reason why even in a relatively developed country, the use of open source software in services sector may be limited. “For example, it makes sense that the lowest awareness of open source software amongst developed countries is in South Korea, because until this year that country’s government mandated the use of Microsoft software for e-commerce applications such as Internet banking.” They add, that “… all of the countries that reported the availability of materials in their local

language to be a barrier to access, were from countries that did not speak one of the five major UN languages" (Chinna and Malcolm 2010: 45-46).

While addressing 'Literacy and Information Society', Raseroka contends that according to the United Nations, the world about a decade ago had 799 million adult illiterates, the majority of whom belong to the developing world. The author points out that:

> … language in which printed sources of information are written is a significant factor for successful access to information stored in libraries. The world's printed information is predominantly in English and other principal languages, since the nations in which those languages are used are the most prolific producers of scientific and technological information that influences the accumulation of capital commodities (Raseroka 2006: 92).

Since a fairly undersized population in the developing economies have proficiency of these languages, it has only led to an increase in the numbers of those who cannot comprehend the meaning via electronic information. It is in this manner as the author says, that "the vision of an inclusive information society is thwarted by the levels of literacy and the predominance of the principal world languages, such as English as the language of the Internet, which is the premier vehicle for global electronic transfer of information" (Raseroka 2006: 92).

In this framework, Suber also states that in order to reach the potential of a true universal access, even after that factors of cost and permissions are taken out, there could be a few other barriers as well. While pointing to the fact that language happens to be one such barrier, he mentions that most of the literature available online "are in English, or just one language, and machine translation is very weak" (Suber 2007: 183).

'Wikipedia' has been cited as an example while discussing possibilities of widening the scope of reaching out by breaking language barriers. It has been noted:

> Wikipedia, an online encyclopedia open to anyone who wishes to contribute, is now one of the most popular sites on the web, with 5.3 million unique visitors a month. It has amassed more than one million entries and inspired wikipedias in more than five dozen languages (Bollier 2007: 36).

Haupt also refers to Wikipedia and its sister projects that have helped in narrowing the gaps as far as language barrier is concerned. He says:

> ..*Wikipedia*'s sister projects include Wikitionary, Wikibooks, Wikispecies, Wikisource, Wikiquotes, Wikinews and Commons. The online projects are available in a wide number of languages, including Afrikaans, German, Spanish, Arabic, Swedish, Hebrew, French, Malay, Basque, Welsh, Croatian, Icelandic, Kurdish, Walloon, Indonesian, Persian, Japanese, Georgian and Italian. At a 2007 event hosted by iCommons in Observatory, Cape Town, *Wikipedia* founder Jimmy Wales pledged to support African initiatives that generate knowledge in indigenous African languages. Wales is thus interested in broadening access to knowledge production and dissemination in ways that undermine cultural imperialism. … (Haupt: 2008: 109).

It is therefore owing to the "newer mandatory requirements" and "lower thresholds of protection" as far as translation rights is concerned – reasons noted by Dutfield and Suthersanen, that the UNESCO's Universal Copyright Convention had won more acceptability in the developing world. They explain:

> …The Convention was also perceived as being more developing country friendly with its extensive restrictions on the right of translation; thus, for example the Convention declared that if there was no translation of a work into the local language of a country after seven years from the publication of a work, then any national person could obtain a non-exclusive compulsory licence to translate the work, subject to certain formalities" (Dutfield & Suthersanen 2010: 17).

6.6.3 Access to Scientific and Technological Knowledge:

There had been considerable criticism of the TRIPS Agreement vis-à-vis the need for the vital technologies that developing countries were promised but were delivered in peanuts. Evelyn Su pointed out that the broad international IPR legislation "… provides the protection that industries and developed countries have been seeking. However, the TRIPs Agreement simultaneously narrows the developing countries' access to technology, discouraging the rapid diffusion of new technology needed for economic growth" (Su: 2000: 171).

Technology brings changes in many aspects that are not merely bound to human development but also the common resources that they are used to enjoying. According to Hess and Ostrom, when new technologies are introduced, it can play a significant role in the strength as well as weakness of a commons by enabling their capture. Once free and open 'global commons' or public goods, like the deep seas, the atmosphere, the electromagnetic spectrum, and space, etc. had met with the same fate. They point

toward a ‘fundamental change in the nature of the resource’ that takes place owing to the ‘ability to capture the previously uncapturable’. The resource gets transformed “from a nonrivalrous, nonexclusionary public good into a common-pool resource that needs to be managed, monitored, and protected, to ensure sustainability and preservation” (Hess& Ostrom: 2007: 10).

Evelyn Su narrates the historical correlation between technology, IPRs and lopsided development. She says that in recent times, developing nations’ demand for access to Western technology has increased to the extent of complete elimination of IPR and other restrictive regimes that obstruct free flow of technology across the globe. Their argument, as she explains, issues a note of caution on the international IPR regime that favours powerful economies like US, European Union or Japan while ignoring their interests. She refers to the doctrine of "uneven development," cited by developing countries, whereby developed countries became wealthy and industrialised, denying the developing countries a chance of progress, hence owing them the technology earned at their expense. IPR is viewed by developing countries as a mechanism of making the developed countries richer through rent transfer. Thus, they view the prevailing order of international economic law as unfair as it is largely beneficial for developed nations alone (Su: 2000: 200).

Su strikes a chord in narrating how the developing countries fought back by pushing developed countries to change policies via The Declaration on the Establishment of a New International Economic Order[52] that proposes the principle of "[g]iving to the developing countries access to the achievements of modem science and technology, and promoting the transfer of technology and the creation of indigenous technology for the benefit of the developing countries in forms and in accordance with procedures which are suited to their economies." She also refers to its further expansion within the Charter of Economic Rights and Duties of States, stating:

1. Every State has the right to benefit from the advances and developments in science and technology for the acceleration of its economic and social development.

[52] See, UNGA (1974), United Nations General Assembly, Sixth Special Session Agenda Item 7, Resolution adopted by the General Assembly, 3201 (S-VI). *Declaration on the Establishment of a New International Economic Order,* A/ RES/ S-6/3201, 1 May 1974, [online: web] accessed 5 July 2017, URL: http://www.un-documents.net/s6r3201.htm

2. All States should promote international scientific and technological co-operation and the transfer of technology, with proper regard for all legitimate interests including, inter alia, the rights and duties of holders, suppliers and recipients of technology. She then points out, that the TRIPs Agreement increases IPR protection by restricting transfer of technology even though developing countries had asked for a new economic order for transfer of technology that fuels their economic growth (Su: 2000: 200).

6.7 Conclusion:

The governance of international intellectual property regime has been historically under the control of the owners of IP. This has led to a number of their propositions that have been deliberated upon, to be accepted, legislated and in due course bind the international community via international legal provisions. However in many cases, as has been shown in the chapter, the interests of economically weaker nations have been virtually ignored while making policies and legislations on the alleged piracy of IP. The access interests of developing countries, particularly concerning knowledge resources across a host of areas, thus called for a better relook in the recent past.

The Access to Knowledge (A2K) movement had played a significant role in shaping some of the norms of international copyright treaties that would have otherwise ignored their concerns to a large extent. As Madhavi Sunder notes:

> "A2K recognizes and responds to diverse concerns well beyond those of traditional intellectual property law. It acknowledges existing differences in power and incomes and the disparate social effects of intellectual property on local and global social relations."
>
> Thus, she explains: "A2K would restructure rights – not just through voluntary mechanisms, but by reforming default rules -to redress the maldistribution of resources and to re-strike the balance between intellectual property and the public domain that many of A2K's framers believe existed in earlier times" (Sunder 2006: 311).

Access to Knowledge being connected solely to human rights could be potentially problematic, as rights owners in the present day and time are corporations in an overwhelming majority of cases. These firms may speciously lay claim on intellectual

property rights through the mode of citing them as being human rights. However, in this respect, it may be pertinent to mention that human rights may not always ensure 'distributive justice', which ideally is the main aim of such an exercise. Distributive justice implies that every individual has a legitimate claim to their required resources but those who are by and large disadvantaged, have a better claim over social resources.

But human rights, in particular the principle of state accountability, could help where barriers to access are general or systemic. Many a times, educational materials are unavailable because of IP rights. But there are other reasons, inestimable or otherwise, why they may not be available. Some of these may be unavailability of authors on a particular subject, publishers or even a suitable market. Logistical problems like unavailability of any carrier to despatch them where they are more needed, absence of roads, schools, or even teachers may be others. In such cases, nevertheless, state action comes of help.

Countries have a strong rationale to maintain their educational goals firmly intact even if it requires them to opt for a relative compromise on intellectual property, as a matter of state policy. Thus, replication is more pertinent for areas in which the educational materials exist, in case of technical education for example, where it may just call for an apt circulation. In this context, Chon suggests that some "regulatory alternatives to intellectual property for increasing knowledge" should be chosen. She asserts:

> Innovation may simply not be at issue when fundamental texts are already available and require dissemination. But even at a technical education level, states may have a strong policy justification for prioritizing imitation and diffusion over protection of knowledge goods (Chon 2006: 2891).

Open Access Scholarly Publishers Association (OASPA) – Globally there could be publishing bodes that serve the interest of access. Koutras points out in this regard, about trade associations like the Open Access Scholarly Publishers Association (OASPA) that "represent the interests of open access journals and book publishers worldwide in all scientific, technical and scholarly disciplines" (Koutras 2015: 136). He explains thus:

> Its mission will be carried out through sharing information, setting standards, advancing shapes, assistance, education and the promotion of innovation. The OASPA blog will serve as a critical forum for communicating crucial issues in relation to open access publishing and will frequently present posts from guest authors (Koutras 2015: 136).

Legislation for Disabled and the Blind: In the age of the considerable and unbridled build up of intellectual property rights virtually leaving only few aspects of life untouched, one major achievement in standing against such policies and laws cannot be ignored. The recent international legislation for the benefit of the differently abled and the blind[53] has indeed been a tangible outcome of decades of negotiations by countries, international organisations, nongovernmental organisations, activists, academics, etc. It has surely benefitted millions of persons across the globe that had long deserved the limitations and exceptions on copyright. However, even after such a notable treaty was adopted, its ratification had been resisted by a group of European Union countries led by Germany and Italy pushed by their publishers association, igniting protest from the association of blind people in Europe (IPW 2015). Finally, even though it could be adopted by the EU Parliament most recently, the idea of compensating publishers for the accessible copies made has been dubbed as having failed the agreement's central objective of access (Ermert 2017).

Strict IP enforcement regimes, which emanate from the developed world, could be challenged in a number of ways. The idea of mutual affiliation and recognition among concerned people is one such that perhaps has the potential to form meaningful partnerships. These partnerships in the long run may help to reduce the barriers of access and information. Katz cites such an example in 'iCommons', an international organisation that had grown out of Creative Commons, translates the software and other licenses in the maximum possible number of languages. He states, that iCommons:

> … has created a network of information commons activists and experts all over the world. They meet at an annual summit and support A2K efforts such as open access, open education, free software, and free culture with collaborative projects across its network year round (Katz: 2010: 288).

[53] The treaty was adopted at the WIPO on 27 June, 2013. See, *Marrakesh Treaty to Facilitate Access to Published Works for Persons Who Are Blind, Visually Impaired or Otherwise Print Disabled* , [online: web] accessed 5 July 2017, URL: http://www.wipo.int/wipolex/en/treaties/text.jsp?file_id=301019

The current international standard on intellectual property as set by the TRIPS must be embraced and held onto; tougher laws might be challenging for ensuring compliance. Some of the world's most underdeveloped places, like those in Africa are already facing problems in complying with the current copyright laws; therefore, stronger laws would be unachievable. While it is a fact that a far-reaching incapacity, as opposed to hostility to abide by the laws, is the primary reason for failure of their enforcement, additional exceptions as suitable for accessing learning materials, for example, as present in many developed as well as developing countries, must be incorporated (Schonwetter et al. 2010: 50).

UNESCO has been an international platform traditionally used by national governments to generate and propagate the ideas and visions on global educational, social and cultural facets. It is apparent from the recent past however, that currently this forum is also being used by multinational corporations, lobbying trade associations and their counterpart developed country state agencies for purposes like IP training and workshop[54] in less developed countries. Many of these exercises carry the hidden agenda of superimposing the legal standards of developed nations in those countries while ignoring, in most cases, the special needs of these countries and hence, are not TRIPS compliant. Such moves must be resisted and in their place a just protocol should be worked out in keeping with the TRIPS flexibilities and also as referred to in the Doha Development Agenda and the Doha Declaration on TRIPS and Public Health.

[54] One such training workshop had been organised in Namibia, Africa in 2006. It had the support of (International Federation of Reproduction Rights Organization (IFFRO) and International Publishers Association (IPA), International Federation of the Phonographic Industry (IFPI), the Motion Picture Association (MPA), Business Software Alliance (BSA), and was funded by the Spanish Ministry of Foreign Affairs and Cooperation. See, UNESCO (2006)

Chapter VII

Conclusions

Chapter VII

Conclusions

Ever since inception, the international legal regime on counterfeiting and piracy is in a constant state of evolution. The escalation in the production of counterfeit goods in recent years has necessitated its regulation within the framework of the international trading system. The advent of the technology-based goods in the international market has led the manufacturers to take steps to protect their new technological innovations. These technology-based industries, situated mainly in the developed world, depend heavily on the protection of their product identity. The international community has exerted a lot of legislative and administrative efforts for tackling the nuisances of counterfeiting and piracy through the GATT/WTO system since the seventies of the last century.

The present international legal regime on counterfeiting and piracy is primarily based on the TRIPS Agreement as discussed in Chapter II of this study. TRIPS incorporates provisions pertaining to 'border enforcement of IPR' in order to keep in check counterfeiting and piracy. There had been several junctures when propositions for radical IP enforcement measures were made during the course of the negotiations on TRIPS, but were prevented by developing and least developed countries like India and Brazil.

Developing countries also managed to obtain exceptions to some of the norms laid down in the TRIPS Agreement. These form the vital flexibilities in their favour. However, as has been discussed in the course of this study, it is apparent that the developed countries are not content with the current scheme of things. The industry groups within the developed world are even today the principal players in making demands whenever they feel the necessity for it.

As explained in Chapter III of this study, there are many risks involved for the developing countries in the emerging regime on counterfeiting and piracy. The border measures included in the TRIPS Agreement and as applied by the customs authorities

is essentially a domestic issue. It should predominantly be treated domestically keeping in mind the domestic peculiarities, ranging from lopsided development to barriers in accessing essential medicines, and certainly not by any prescribed global standards.

This study has shown certain apparent aberrations from the IP enforcement measures provided by the TRIPS Agreement. The European Union, as illustrated in the study, has certain regulations on border measures that far exceed the mandate of TRIPS. The recent seizure of the Indian medicine shipments in Netherlands bears testimony to the fact that developing economies are continuing to remain at the receiving end of the global trading system. Such seizure of goods, the Indian generic medicine consignments in this case, may certainly be said to have violated the WTO mandate by obstructing legitimate trade by a Member State. The EU has since reduced seizures and responded by inserting a qualification clause within their current regulation. However, as it comes out from the study, the language of the clause does not suffice for its potential misuses in future.

The Anti Counterfeiting Trade Agreement (ACTA) or the Trans Pacific Partnership Agreement (TPP) negotiations have been mooted, deliberated and concluded at the behest of the developed countries. Only a negligible number of developing nations, who again are parties to FTAs with either the US or the EU, were invited for these secret discussions. Any secret discussion in the making of international treaties is in violation of basic principles of international law. A recent opinion by an independent expert appointed by the UN Human Rights Council[1] buttresses this fact. He states:

> Trade is not an end in itself, but must be seen in the context of the international human rights regime, which imposes binding legal obligations on States. Trade agreements are not 'stand-alone' legal regimes, but must conform with fundamental principles of international law, including transparency and accountability. … . (UNOHCHR News 2016).

The United States and the European Union have managed to enter into free trade agreements (FTAs) with several countries in strategically important regions. The

[1] Prof. Alfred de Zayas from United States of America is the first Independent Expert on the promotion of a democratic and equitable international order, appointed by the UN Human Rights Council, since May 2012.

FTAs are a mode of bypassing TRIPS in order to create new standards for IP enforcement and strict criminal measures for infringement. These standards, once in force, oblige countries to abide by them in spite of the TRIPS Agreement, thereby creating higher benchmarks outside the existing multilaterally accepted standards. These provisions substantially restrict the policy objectives that the developing country governments are known to practice in view of their socio-economic conditions.

Most of the FTAs entered into by the US or the EU with developing nations makes little mention about public health, access and affordability concerns or similar educational objectives. The inclusion of such provisions within the legal text of trade agreements helps formulate national objectives that may be of essential public interest. Thus consumer welfare, which is paramount in any trading system, finds a small place in these documents that may run into scores of pages. This noticeable departure from the TRIPS may not be favourable for the millions of consumers around the globe.

At the organizational level also, as discussed in Chapter IV, there are ongoing efforts to set similar aims in place. The World Health Organization (WHO), a UN agency that is supposed to supervise health aspects of the global population, has been lately used by such industry groups to set substantive standards on pharmaceutical counterfeiting. The consistent effort that has been noticed on part of national governments of economically powerful countries is to influence the international health body. It is enough indication of the rapidity with which their industry wants to capture the international medical and pharmaceutical market in its entirety. By doing so, they have hardly left any space for the developing countries. The provisions in documents like those in International Medicinal Products Anti-Counterfeiting Taskforce (IMPACT) document may have rendered legally manufactured generic medicines to be deemed as ‘counterfeits’ in near future. This would not have been beneficial for the economically poor countries. Thus, IMPACT was withdrawn and a different committee formed to look into the quality, safety and efficacy of drugs, explicitly mandating it to refrain from touching upon IP matters. The steady and unremitting advocacy, activism and health diplomacy led by the nongovernmental organisations, academia and developing States forced the banning of the word

'counterfeit' from the WHO vocabulary on medicines. The eventual removal of this three decades-old term is certainly a decisive achievement in recent times, and should serve as the leading motivating factor for those working on similar issues.

The World Customs Organization, the global customs body, had come out with a set of standards concerning IPRs. Some of these standards are not TRIPS compliant and are too intrusive. In recent times, the INTERPOL has been also creating programmes and perspectives on intellectual property. The international police body has opened a unit on IP crime. It has also related the problem of counterfeiting with international terrorism. This seems to have been done deliberately to artificially project the seriousness of the problem of IPR infringements. It is apparent that many initiatives on IP violations including counterfeiting are now being taken by the international policing organization. Nevertheless, there are specialised international bodies that are responsible for IP subject matters as well as their enforcements, and the global police body may be naïve enough to be proceeding according to its current plans on intellectual property infringements.

The international postal body, the Universal Postal Union (UPU), has also been lately working in tandem with the international customs authority, the WCO, to set higher benchmarks of IP enforcement. For the first time in 2008, the organization has come out with a resolution in its highest decision-making authority, the UPU Congress, to pay attention to the counterfeit items sent through the post. Apparently, it seems to be a good idea, but, the proliferation of international organisational pursuits and the trespassing into the area of intellectual property, which is supposed to be dealt by international bodies like WIPO, does not make it any better for developing countries.

Even a lesser known organisation like the United Nations Organisation on Drugs and Crime (UNODC) is being used in an effort to bypass the TRIPS standard. The most worrying matter about UNODC is that it has been able to initiate discussions on a model legislation based on an internal mandate. Crime being one of the focus areas of this UN body, it probably forms a fine evidence that IP infringement standards are increasingly being pushed upwards so as to straightforwardly criminalise them in more or less every other circumstance.

Thus, at an organizational level, the ongoing efforts are indicative of the attempt to set higher benchmarks of IP enforcement or even evade specialised international IP bodies like the World Intellectual Property Organization. This seems to be a disturbing trend considering the unsuitability of each of these organizations when it comes to adjudication or even the understanding of the substantive nature of offences in counterfeiting and piracy.

Internationally, efforts should be made by the developing countries at institutional levels such as the WIPO and the WTO TRIPS Council to oppose and prevent the current attempts to raise enforcement standards by the developed countries and their industry groups. This should not only include endeavours by the developing countries themselves, but should also take into account the contribution made by the civil society, the academia and the Non Governmental Organizations (NGOs).

Consumer products such as software, music, and movies do not pose any perceptible public health or safety concern even if they are counterfeits. The problematic area that may be of concern is of quality or that relating to substandard or spurious products, such as certain pharmaceuticals. Counterfeiting and piracy being trademark and copyright issues respectively have little to do with this problem. However, the infringement of IPRs relating to these products is increasingly being projected as a serious one. The manner in which the infringements relating to these products are professed to be criminalized requires further serious consideration.

It appears that the industry groups of multinational corporations have, for a significant time concentrated on the pharmaceutical sector. This is because, apparently, their persuasions may just hold up to the logic of the so-called ‘safety’ of such products when counterfeiting of such products indeed are found to have occurred in certain parts of the world. An additional reason for their focus on this sector may be that they realise, that this is one of those sectors that had historically provided them with some of the highest levels of profit. Nevertheless, this makes it more powerful a cause to be pursued by the developing countries to turn the tide to their favour considering the flexibilities as available under the TRIPS for each specific country as well as the success in achieving the Doha Declaration for serving the health of millions of third world peoples. This stands to be of vital significance also for the generic medicine

industry in countries like India, Brazil or China, which cater to the needs of millions of the poor and vulnerable with cheap, effective medicines. Indeed, India has been rightly referred to as the pharmacy to the developing world.

The study drew attention to a range of issues pertaining to international enforcement of intellectual property rights. The conclusions with respect to them, within the framework of the hypotheses of the study, are stated below.

A. The scope and range of the global IP enforcement framework is dependent on definitions of 'counterfeiting' and 'piracy':

1. A thicket of IP enforcement standards and laws favour IP maximalists

   An entire range of international legislations have been adopted and are being vigorously pursued at international treaty-making and institutional levels, making the international legal domain on counterfeiting and piracy broad and complex. This is clearly being done at the behest of large transnational private corporations who, through their trade associations, constantly refer to their products and brands as being faced with increasing counterfeiting and piracy overseas. However, in this exercise with an entire spectrum of legislations, scope of the definitions for counterfeiting and piracy is being deliberately and unrelentingly restricted by the private players from industrialised nations in their favour. This apparently seems to be done in order to consolidate international dominance. The relatively newer players from developing countries, e.g. generic drug firms, are likely to get caught up in such legal complexities abroad, negatively affecting their trading volumes and thus impacting development. Besides, vital humanitarian interests like access to medicines and treatment also get badly affected. This situation helps multinational corporations pursue their monopolistic trading goals. In the long run, it may even help them capture large emerging markets like India or Brazil, challenging their established firms in their own backyard. Developing nations must come together to ensure that their socioeconomic and developmental aspirations are not affected by any of these developments. Such

efforts to create legislative thickets should be prevented by insisting on the multilaterally negotiated TRIPS standards of IP enforcement as being the only yardstick to be followed.

2. Conflation of IP infringements

The definition of 'counterfeit' or 'piracy' in certain cases is intentionally being broadened or conflated to meet virtually any criteria proposed or pursued by the multinational corporations to meet their satisfaction. The term 'counterfeit' for example, has long been used to define spurious or substandard medicines in the name of combating medicine counterfeiting at the WHO. The most recent exclusion of this terminology from the aforesaid definition by the seventieth World Health Assembly (WHA), the highest authority of the WHO, and subsequent approval of the terms 'substandard and falsified' bears testimony to the fact that such terms do not deal with quality of an item which is its main concern. Further, it also clarified officially that IP considerations are beyond its mandate. There cannot be any single definition or a criterion that suffices for all, as it depends on the context and application, and therefore, the TRIPS standard must be adhered to. In light of the problems perceived owing to multiplicity of definitions at different fora, if the TRIPS definition of counterfeiting and piracy is not firmly stood by, the entire idea of policy space meant for developing countries may be lost soon in the thicket of the legislative jungle being created.

B. Stricter definitions within the IP enforcement regimes are inimical to the interest of developing countries:

3. Rigorous and persistent maximisation of enforcement standards

IP maximalists hardly bother about the forum or place, but they seem to be in continuous pursuit of the maximum IP enforcement levels anywhere in the world. Such very high enforcement standards could also be imposed

anywhere. It could range from inflicting the EU standards of IP enforcement measure on medicines, for example, by its customs authorities or even including it within the national legislative bills of less developed countries like Kenya or Uganda that would be otherwise barely informed even on the issue itself. Ignoring the TRIPS mandate that had been secured multilaterally, maximalists attempt to show these exceptionally elevated enforcement regimes as models to set them as global standard. Such efforts by the maximalists must be challenged and thwarted at appropriate forums like Brazil and India did against the EU at the TRIPS Council. Lesser developed nations should study such gestures adopted by the developing economies and attempt to include them in their own policies and rules.

4. IP infringement as general crimes- disregard for TRIPS

There is an increasing trend to correlate the offences of pharmaceutical manufacturing with those concerning organised crimes such as theft, smuggling, money laundering, etc. This places the matters concerning IP on the same platform as the others, thus resulting into juxtaposition of general crimes along with IP infringements like counterfeiting or piracy. This results into a general tendency to universally regard every case of IP infringement as a crime, disregarding the preconditions of wilfulness and commercial profit set in the TRIPS Agreement. In order to justify the push towards a general criminalisation, IP infringements have been rigorously pursued at organisations that specialise in crimes and criminality like the Interpol, UNODC or even the UNICRI. The aforesaid requirements as laid down under TRIPS must be properly followed in determining whether any such infringement falls within the definition of crime. Any unsolicited thrust on passing off IP infringements as cases of general crime must be resisted at the appropriate fora, besides clarifying that the last word for determining that lies with the WIPO and the TRIPS Agreement.

5. Development goals are greater than IP enforcement standards

While IP can be used to formulate policies and legislations that are beneficial for a nation's economic development, there appears to be little evidence till date that IP or stricter IP enforcement can ensure economic development by ushering in innovation or investment by overseas companies. The public domain is diminishing by the day through the high standards of IP protection and enforcement. Therefore any country, especially those in need of rapid development, while formulating its national IP policy, should also simultaneously broaden the nature and extent of public domain to the extent that it can reach out or is accessible to the maximum members of the general public.

C. Authority of the TRIPS Council and WIPO is being undermined by the FTAs:

6. *Three visible periods of IP enforcement*

International IP enforcement may be classified into three periods-

i. pre-TRIPS

ii. TRIPS, and

iii. post-TRIPS

There had been more or less of a consensus during the first two phases- one preceding and another during the build up to the TRIPS and its initial years, even though its demand was led by the developed countries. But the post-TRIPS phenomena are remarkable owing to consultations at multiple fora and forging FTAs at different parts of the world at various levels with virtually exponential ambitions. Any fair amount of global consensus-building under such circumstances is barely possible, resulting into a confusing situation, which the pursuers are likely to take advantage of. Such situations are more

likely to benefit the demanders of strong IP enforcement – the developed country industry and their lobbying business associations like the Business Action to Stop Counterfeiting and Piracy (BASCAP), the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA), etc. in this case. The developing countries, instead of allowing such forum shopping to go on unhindered, must insist upon the credence and authority of the TRIPS Council and the WIPO on any matter concerning intellectual property including enforcement.

7. *Developing country participation forced in setting higher enforcement standards*

There are clear, perceptible intentions either for influencing or coercing developing countries to take part in futuristic treaty-making process as negotiating partners. It had started to happen since the days of North American Free Trade Agreement (NAFTA) and is currently continuing with the Anti Counterfeiting Trade Agreement (ACTA), Transpacific Partnership Agreement (TPP) or Regional Comprehensive Economic Partnership (RCEP) Agreement. The outcomes of such kinds of treaties mostly result into newer, higher standards of IP enforcement. Therefore, becoming parties to the same automatically snatches away or at least reduces the bargaining capacity of the participating developing countries. Developing nations, upon being offered to become parties to any FTAs, should first understand every issue including IP enforcement. In any necessary situation, they should undertake proper consultation and guidance from concerned experts, the academia or international organisations like the South Centre, that specifically pay attention to their interests.

8. *Multiple UN bodies used to legislate on IP matters*

Many international organisations belonging to the United Nations family nowadays seem to be more often getting involved in framing IP legislations or

standards. These include specific areas like pharmaceutical counterfeiting or copyright piracy across various areas like music, films, etc. Apart from the prevailing institutions like the WTO TRIPS Council or the WIPO, that are suitably meant for such purposes, it now includes the WHO, WCO, UNODC, ITU, UPU, etc. and even certain UN funded institutes like the UNICRI. This is indicative of the vigorous and concerted efforts being made by the transnational corporations, already well-known by the name of 'forum shopping'. These UN organisations are being used to provide some degree of legitimacy to the persuasiveness being adopted. Therefore, instead of being allowed to be utilised for merely achieving private trade interests, they should rather concentrate on their respective areas of utility and specialisation. For example in case of illicit medicines, if at all initiatives have to be taken they should be made to combat substandard pharmaceutical products instead of concentrating on 'counterfeiting', which is an IP issue and only the WIPO or the TRIPS Council should have the mandate to deal with it. In case of discussions at the WIPO, quality of the product should have primacy over nature of the packaging or external appearance- an essential feature of counterfeiting. The WHO decision-making body has recently acknowledged this. After three decades, it has agreed to remove the word 'counterfeit' upon sustained persuasion by developing countries and the global civil society in usage of certain problematic features for unlawfully manufactured medicines. Nonetheless, the efforts at every other UN fora should also be thwarted in a similarly resolute manner.

D. Existing global regime does not provide policy space for developing countries:

9. Aggressive and speedy negotiation process

The developed countries had been sometimes successful in carrying out their IP treaty-making agenda in an extremely fast pace. For example, the US took

the lead in proposing and negotiating the WIPO Copyright Treaty. This international agreement probably took one of the shortest possible time-period for an IP treaty to go through the entire process of negotiations and finally conclude. This happens mainly owing to the imposition of certain standards or trends of IP enforcement regulations that happen to be already present in the developed nations, but are completely new to the developing countries. In these kinds of multilateral scenarios, an aggressive velocity of negotiations may disadvantage the developing countries, which might not even be able to grasp the pros and cons of the agreements in their entirety before they reach the stage of conclusion. Developing countries must resist any move to accelerate the negotiation process by insisting on being provided with the necessary time to comprehend the matters properly in order to negotiate for their own interests.

10. Consistent secretiveness adopted in setting enforcement standards

IP maximalists pursue negotiations for plurilateral treaties. It has happened with the likes of the agreements like the ACTA or TPP, and currently in progress at the RCEP negotiations regularly, concertedly and mostly in a secretive manner. The secretiveness involved, has become so regular now that it is gradually on the verge of becoming a standard norm. Secretive negotiation of any kind for the formulation of international treaties does not conform to the basic principle of international law. This threatens democratic processes like public participation, opinion-making or an open analysis. In this whole process, private interests take over larger public interests- and thus, business takes over people. The developing nations who participate in such negotiations should make sure that the drafts of these treaties at different stages of negotiation are publicly available. This would help them by ways of appropriate understanding of the texts, enhancing their bargaining position and thus keeping a check on the secretive tactics adopted especially by lobbyists from the IP-intensive industry.

11. *Developing countries are playing fairer, hence should be returned their due*

During those times when today's developed economies were catching up, they were consistently applying restrictive measures as policy, including no intellectual property protection or enforcement for foreign individuals or entities. This policy was met with success only a few decades ago in the US, Switzerland, Japan, etc. to support and empower their own domestic industry. At that time, there was hardly any uniformly applicable or binding multilateral regime. These kinds of isolated domestic regimes had helped them catch up, thereby protecting their own domestic industries while enjoying a free ride in putting or imposing all those measures. Today, the WTO Members, many among whom have not had such opportunity, are being made to abide by the rules of the international agreements through indirect coercion. The developing states are therefore, playing much fairer and hence, should not be denied their legitimate share of fairness in matters concerning international trade and intellectual property.

Mapping out each individual study chapter and their respective outcomes, this study has thus identified the issues that may explain the existence, nature and development of transnational interests in international IP enforcement.

Some additional issues and behaviour in the realm of international IP enforcement, however, have also been observed in this study. They are now being highlighted with the possible policy alternatives, as underneath:

On IP Enforcement Agenda:

While referring to IPR enforcement it may be pertinent to note certain other aspects that may also concern 'enforcement' as such. In framing laws and policies on intellectual property till date, merely 'rights' have always been the enforceable subject. However, there could be certain other aspects as well. In this context, Susan Sell suggests that:

> … it is important to emphasize that "enforcement" is not a one-sided concept. Enforcement means not only enforcing IP holders' rights, but it also means enforcing balance, exceptions and limitations, fair use, civil rights, privacy rights, and antitrust (or competition policy) (Sell 2008: 15).

Thus, these characteristics must also be taken into account while framing IP rules and policies and not be ignored as in most cases.

Recently, the United States had apparently succeeded to persuade Indian ministerial authorities to oblige to a number of enforcement obligations that are beyond TRIPS. The European Union is also hard bargaining on the augmentation of the Indian IPR standards on border measure that meets the EU model of IP enforcement. Indian lawmakers and policymakers should desire for and prioritise its own developmental essentialities before anything else; thus, it should maintain its current standards and not yield to any unsolicited pressure in formulating its IPR policy. Any substantial gain in the IPR enforcement agenda by the likes of the US or the EU would result in an equal weakening of policy space by countries like India in carrying forward their sustained long term goals towards development.

Development concerns amid harmonisation of IP:

Currently, there has been a growing trend of including the accession to legal instruments that are external to a certain treaty or agreement in question, as prerequisite to its signature. For example, many such treaties at bilateral, plurilateral or regional levels across the globe require accession to the WCT or WPPT. This apparently demonstrates a rather indirect coercion of those nations, which had earlier chosen not to be parties to treaties that contain elements that do not match with their contemporary national developmental concerns, into becoming signatories.

Okediji makes a workable suggestion in the context of addressing the variations in development concerns of the less developed countries. She concedes that every such development concern cannot be addressed for as many intellectual property treaties. Therefore, as she explains:

> An integral part of development strategy in the immediate future is to identify global-specific, region-specific and some countryspecific development

> priorities. Strategies should concentrate heavily on areas where these three converge. A working list of such areas of convergence, and relevant sectors implicated, should be used for preparations to negotiate common ground between developing countries (Okediji 2003: 97).

She further highlights the importance of forging association among nations in some cases, when interests merge, even if their levels of economic development vary. As she states:

> Some consideration should also be given to creating alliances with some developed countries in areas where those countries may share similar concerns. This was a strategy that worked very well during the TRIPS negotiations as well as during the WCT/WPPT negotiations (Okediji 2003: 97-98).

On lack of proper limitations in Internet treaties:

The WIPO internet treaties contains certain exemptions for copyright, but those are limited and only takes into account the interest of the content makers. In the backdrop of the European copyright system, Janssens has insightfully observed on the inadequacy of the standard of exceptions that need to be adopted while formulating legislations involving the digital environment. She draws attention to the fact that although the WIPO internet treaties do provide for exceptions and limitations on copyright online, it is not satisfactory. They are confined merely to the three-step test and an Agreed Statement permitting the Contracting Parties to 'to carry forward and appropriately extend into the digital environment limitations and exceptions in their national laws' as well as 'to devise new exceptions and limitations that are appropriate in the digital network environment'. However, as she insists, the last Preamble of both the treaties which she refers as the most 'interesting' could provide some alternative. These recognise the balance between the authors' rights with that of larger public interest, particularly education, research and access to information (Janssens 2009: 322-23). Thus, these issues that are of vital concern for development must be included within the limitations in the WIPO internet treaties.

On safeguards for TPMs:

In case of technological protection measures (TPMs) applied to copyrights, as has been shown here, the Digital Millennium Copyright Act (DMCA) in the US also contains important safeguards as balancing elements. It is important to note from the perspective of the developing countries, that they should ensure comparable, if not better safeguards while negotiating international treaties at any level. As a matter of fact, it must be borne in mind that the TPMs, by default, truly control the mechanism of accessing itself, in addition to controlling unauthorised copies and duplication. TPMs cannot distinguish between legitimate purposes like research and education while blocking the access to any material or file. The prohibition of the manufacture and sale of the devices that could be used for circumvention as in the US and European legislations further adds to the complexities. In effect, they render useless even the normal exceptions to copyright laws like private non-profit uses like research or education. The access interests of developing countries are vital for building certain pillars of their development concerns, like education for example. These should always find preference over TPMs and devising legal alternatives for the same is extremely important for them.

On Access to Knowledge- some possible solutions:

The Draft Treaty on Access to Knowledge emphasizes plausible changes in the international IPR regime as a whole to make it more inclusive. It is a comprehensive document, in whatsoever form, which in fact had brought together almost every section of the global population. Thus, Madhavi Sunder has commented that this draft agreement:

> …… brings to the table free culture advocates and indigenous peoples, representatives of the developed world and the developing world. Focused on freedom and equality, it promises to be a Universal Declaration of Human Rights for intellectual property in the Knowledge Age. (Sunder 2006: 310)

Alternative models of accessing copyrighted works must be given their due importance. Measures such as Open Educational Resources (OER), Free and Open Source Software (FOSS) and gradually more online open access libraries must be

provided a lot of impetus by governments. Such methods are likely to be most relevant in those countries the majority of whose consumers would find it hard to access contents and works due to circumstances or means pertaining to unaffordability. The question of affordability owing to high pricing mechanisms is one of the most important barriers not only to access general and creative works in most cases, but also adds further to the digital divide; this leads to a knowledge gap between developed and developing nations. Thus, it must be overcome in near future.

Internationally, the Access to Knowledge (A2K) movement has served the millions of people over the last decade or more. It has been making sincere efforts in bringing the fruits of research and creativity at the hands of those who would have been otherwise barred of such products and resources. However, there is still a lot to be achieved. In this context, as Madhavi Sunder observes, "A2K is both revolutionary and conservative at the same time." She explains that:

> … while it would redistribute knowledge products, in its current state A2K does little to address the need for enhancing poor people's capacity to produce knowledge themselves, which is considered increasingly important for realizing the developmental goals of the new millennium. A2K's lofty aspirations, I suggest, need to be grounded in a new theory …. (Sunder 2006: 312).

Thus, it is imperative on part of the governments, especially of developing countries, to improvise their respective IPR systems so that those at the bottom of the economic or social ladder do not continue to remain there as regards knowledge. Rather, IPR enforcement laws and policies in future should be structured in a manner that these sections are empowered enough to *contribute to the domain wherefrom they were able to gain*. Only this would eventually help in carrying the tenets of the A2K movement to its fulfilling end.

On India and its IP enforcement:

As discussed in this study, the Indian laws on border measures and enforcement of intellectual property as under the Customs Act 1962 could be regarded as adequate. In addition to these existing rules and regulations, the Central Government has decided to bring in new rules for the enforcement of IPRs at the country's borders –

Intellectual Property Rights (Imported Goods) Enforcement Rules 2007. These rules, although setting a higher benchmark than the previous ones, are essentially procedural in nature and also subject to certain safeguards. They have been brought into force for the Indian customs authorities and are fairly suitable for the country and its requirements under the current circumstances.

The government of India has recently put out a national IP policy; this is something India has never seen before. The merits, or otherwise, in such a move are yet to be ascertained. On substantive terms though, India has kept the policy of adhering to the TRIPS standards. But policies for setting up separate commercial IP courts, IP cells at the state levels are surely worrisome features as these are likely to involve a separate allocation of manpower as well as administrative mechanisms that is expected to come from the public exchequer. India at this point cannot afford to allocate separate budgetary expenditure for such efforts when it has pressing concerns for its underprivileged like public health priorities and education still figuring prominently. In addition, India's commitment to resort to technology-based measures in combating online as well as offline piracy stands outside the domain of TRIPS. The only multilateral agreements that include such measures are the WIPO internet treaties, to which India is not a signatory till date. Such measures, as demonstrated in this study, also pose a potential threat to concerns on access to knowledge for developing countries in general.

The steady broadening and complicating of the definitions of trademark counterfeiting and copyright piracy beyond what is necessary to keep up with the technological advancements are avoidable, but are perceivably aimed at hampering developing countries' interests. Industrialised countries and their IP intensive industry are likely to make every move to make sure their business interests are pursued in the most vigorous manner and oppose the developmental aspirations of developing countries while setting rules of international IP enforcement.

The WTO administers a broad set of agreements that are binding in nature; the TRIPS Agreement happens to be just one among them. The numerous trade agreements including stringent IP enforcement mechanisms that are constantly being negotiated at various levels are not compliant of general international legal standards, as pointed

out by the independent legal expert appointed by the UN Human Rights Council. In such a scenario, developing countries may come together and strive for a different international legal order on IP that prioritises and keeps their aspirations and concerns together. This could be in consonance with the general international law principles as Daniel Gervais has suggested for the developing countries. As he suggests, in preference to a maximum enforcement of every kind of intellectual property, developing countries should earnestly mull over a *minimum compliance* domestic regime depending on the category of IPR, of course subject to TRIPS (Gervais 2005). In addition, while framing regulations, the outlays in conformity and the ensuing returns must be harmonious with the peculiarities of each economy.

In sum, international legal regime on IP enforcement may be said to be in a state of emergent and continuous development in light of the numerous treaties being steadily negotiated and concluded. It is yet to consolidate in form and contents. The way in which this regime evolves would be of key significance for the developing world to see how it accommodates their interests.

REFERENCES
(*indicates a primary source)

*ACTA Leaked Proposal (2007), "*Discussion Paper on a Possible Anti-Counterfeiting Trade Agreement*", [online: web] accessed 5 July 2017, URL: https://file.wikileaks.org/file/acta-proposal-2007.pdf

**Agreement between the EFTA States and Singapore*, [online: web] visited 5 July 2017, URL: http://www.commonlii.org/sg/other/treaties/2003/2/ESFTA_Agreement.html

**Agreement Between The United States Of America And The Hashemite Kingdom Of Jordan On The Establishment Of A Free Trade Area*, [online: web] accessed 5 July 2017, URL: https://ustr.gov/trade-agreements/free-trade-agreements/jordan-fta/final-text

**AGREEMENT establishing an association between the European Community and its Member States, of the one part, and the Republic of Chile, of the other part*', 30.12.2002, [online: web], accessed 5 July 2017, URL: http://eur-lex.europa.eu/resource.html?uri=cellar:f83a503c-fa20-4b3a-9535-f1074175eaf0.0004.02/DOC_2&format=PDF

**Agreement Establishing the World Trade Organization*, 15 April 1994 (entered into force 1 January, 1995) [online: web], accessed 5 July 2017, URL: https://www.wto.org/english/docs_e/legal_e/04-wto_e.htm

**Agreement on Measures to Discourage the Importation of Counterfeit Goods*, (GATT Doc. L/5382, October 1982)

**Agreement on Measures to Discourage the Importation of Counterfeit Goods* (GATT Doc. No. 1/4817 (31 July 1979).

**Agreement on Trade-Related Aspects of Intellectual Property Rights*, Apr. 15, 1994, *Marrakesh Agreement Establishing the World Trade Organization*, Annex 1C, THE LEGAL TEXTS: THE RESULTS OF THE URUGUAY ROUND OF MULTILATERAL TRADE NEGOTIATIONS 320 (1999), 1869 U.N.T.S. 299, 33 I.L.M. 1197 (1994)

Alliance against Counterfeiting and Piracy (2009), "Proving the Connection: Links between Intellectual Property Theft and Organised Crime", [Online: Web] Accessed 5 July 2017, URL: http://www.allianceforip.co.uk/downloads/reports/Proving-the-Connection.pdf

Anghie, Antony (2006), "The evolution of international law: Colonial and postcolonial realities", *Third World Quarterly*, 27(5): 739 – 753.

**Anti-Counterfeiting Trade Agreement,* May 2011, [online: web], accessed 5 July 2017, URL: http://www.mofa.go.jp/policy/economy/i_property/pdfs/acta1105_en.pdf

Attaran, Amir et al. (2015), "Europe and the United Nations: Clinical Trials, Not Criminal Trials," *Harvard Public Health Review* Special Commentary- Clinical Trials, February 2015

Australian Government (2017), '*Eighteenth Round of Negotiations – 2 to 12 May 2017, Manila, Phillippines*', Department of Foreign Affairs, 16 March 2017, [online: web] accessed 5 July 2017, URL: http://dfat.gov.au/trade/agreements/rcep/news/Pages/eighteenth-round-of-negotiations-2-to-12-may-2017-manila-philippines.aspx

Baker, Brook K. (2016), 'Trans-Pacific Partnership Provisions in Intellectual Property, Transparency, and Investment Chapters Threaten Access to Medicines in the US and Elsewhere', *13(3) PLoS Med: e1001970. doi:10.1371/journal.pmed.1001970*

Barton, John (2003), "Integrating IPR Policies in Development Strategies" in Bellmann, Christophe et al. (eds.), *Trading in Knowledge -Development Perspectives on TRIPS, Trade and Sustainability*, London, Sterling VA: ICTSD-Earthscan Publications

BASCAP- INTA (2017), *The Economic Impacts of Counterfeiting and Piracy*, Report prepared for BASCAP and INTA, Frontier Economics: Brussels. Accessed 7 February 2017, URL: http://www.inta.org/Communications/Documents/2017_Frontier_Report.pdf

Beutz Land, Molly (2009), 'Protecting Rights Online', *34: 1 Yale Journal of International Law: 1-46*

Biadgleng, Ermias Tekeste and Viviana Munoz Tellez (2008), "The Changing Structure and Governance of Intellectual Property Enforcement", Research Paper 15, South Centre, Geneva, [Online: Web] Accessed 5 July 2017, URL: https://www.southcentre.int/wp-content/uploads/2013/05/RP15_Structure-and-Governance-of-IP-Enforcement_EN.pdf

Birkbeck, Carolyn Deere and Santiago Roca (2011), *An External Review of WIPO Technical Assistance in the Area of Cooperation for Development*, Final Report submitted on 31 August 2011.

Blair, Roger D. and Thomas F. Cottier (2005), *Intellectual Property- Economic and Legal Dimensions of Rights and Remedies*, Cambridge and New York: Cambridge University Press

Boer-Buquicchio, Maud de (2005), Deputy Secretary General of the Council of Europe, 'Limiting the Risks of Counterfeit Medicines to Public Health in Europe by Adequate Measures and Mechanisms' Opening Speech of Seminar on "Counteract the Counterfeiters!", (Sep. 21-23, 2005) select portions of transcript [online: web] accessed 12 September 2016, URL: http://lib.znate.ru/docs/index-17715.html?page=11

Boldrin, Michele and David K. Levine (2008), *Against Intellectual Monopoly*, Cambridge, New York: Cambridge University Press

Bollier, David (2007), 'The Growth of the Commons Paradigm', in Charlotte Hess and Elinor Ostrom (eds.), *Understanding Knowledge as a Commons: From Theory to Practice*, Cambridge, Massachusetts London, England: The MIT Press: pp 27-40

Braithwaite J. and Drahos P. (2000), *Global Business Regulation*, Cambridge: Cambridge University Press.

Braithwaite J. and Drahos, P. (2002) *Information Feudalism: Who Owns the Knowledge Economy?* Oxford: Oxford University Press.

Bruce, Margaret (2009), "Combating counterfeiting and piracy: the Commonwealth initiative", *35 (4) Commonwealth Law Bulletin*: 703-711

**CAFTA-DR (Dominican Republic-Central America Free Trade Agreement)*, or *CAFTA*, [online: web] accessed 5 July 2017, URL: https://ustr.gov/trade-agreements/free-trade-agreements/cafta-dr-dominican-republic-central-america-fta/final-text

Cava, Camelie et al. (2015), "Man claims exploding iPhone left him with severe leg burns", *CNN International Edition*, March 5, accessed 5 July 2017, URL: http://edition.cnn.com/2015/03/02/us/new-york-iphone-explosion/index.html

Chakraborty, Barnini (2017), "Trump signs executive order withdrawing US from TPP trade deal", *Fox News*, January 23 2017, [online: web] accessed 5 July 2017, URL: http://www.foxnews.com/politics/2017/01/23/trump-signs-executive-order-withdrawing-us-from-tpp-trade-deal.html

Chang, Ha-Joon (2003), Kicking Away the Ladder: The "Real" History of Free Trade, *Foreign Policy in Focus (FPIF),* December, FPIF Special Report

Chatterjee, Patralekha (2010), 'India combats confusion over counterfeit drugs', The Lancet (375), February 13 [online: web] accessed 5 July 2017 URL: http://www.thelancet.com/pdfs/journals/lancet/PIIS0140-6736%2810%2960214-0.pdf

Chatterjee, Patralekha (2015), 'Secret Regional Comprehensive Economic Partnership (RCEP) Takes Centre Stage In Asia', *Intellectual Property Watch* 24 June 2015, [online: web] accessed 5 July 2017, URL: https://www.ip-watch.org/2015/06/24/secret-regional-comprehensive-economic-partnership-rcep-takes-centre-stage-in-asia/

Chimni, B. S. (1992), "Political Economy of the Uruguay Round of Negotiations: A Perspective", *International Studies,* 29: 135.

Chimni, B.S. (2007), 'A Just World Under Law: A View From the South', *American University International Law Review 22 (2): 199-220.*

Chimni, B.S (2010), 'Mapping Indian Foreign Economic Policy', *International Studies: 47(2–4):163–185*

**China—Measures Affecting the Protection and Enforcement of Intellectual Property Rights*, WT/DS362/R

Chinna, Karuthan and Jeremy Malcolm (2010), 'Second Phase: global questionnaire' in *Access to Knowledge for Consumers: Reports of Campaigns and Research 2008–2010* Jeremy Malcolm (ed.), Kuala Lumpur, Malaysia: Consumers International Regional Office for Asia Pacific and the Middle East

Chon, Margaret (2006), "Intellectual Property and the Development Divide", *Cardozo Law Review 27: 6: 2813*

CIPR (2002), 'Integrating Intellectual Property Rights and Development Policy' Report of the Commission on Intellectual Property Rights, September 2002, Commission on Intellectual Property Rights: London

*Court of Justice of the European Union (2011), JUDGMENT OF THE COURT (First Chamber) 1 December 2011 (*), In Joined Cases C-446/09 and C-495/09 *Koninklijke Philips Electronics NV v Lucheng Meijing Industrial Company Ltd, Far East Sourcing Ltd, Röhlig Hong Kong Ltd, Röhlig Belgium NV, (C-446/09)* and *Nokia Corporation v Her Majesty's Commissioners of Revenue and Customs (C-495/09)*, ECLI:EU:C:2011:796, [online: web] accessed 5 July 2017, URL: http://curia.europa.eu/juris/document/document.jsf;jsessionid=9ea7d2dc30d616fffd7c09f94b40b514ef96336eb08b.e34KaxiLc3qMb40Rch0SaxyLbN50?text=&docid=115783&pageIndex=0&doclang=EN&mode=lst&dir=&occ=first&part=1&cid=565979

* *Council Regulation (EC) No 1383/2003 of 22 July 2003 concerning customs action against goods suspected of infringing certain intellectual property rights and the measures to be taken against goods found to have infringed such rights*', Official Journal L 196, 02 08 2003 P 0007 – 0014, [Online: Web] Accessed 5 July 2017, URL: http://euromedaudiovisuel.net/Files/2010/03/26/1269563837256.pdf

*COE (2011), *Council of Europe Convention on the counterfeiting of medical products and similar crimes involving threats to public health*, Moscow 28.X.2011, Council of Europe Treaty Series No- 211, accessed 5 July 2017, URL: https://rm.coe.int/CoERMPublicCommonSearchServices/DisplayDCTMContent?documentId=090000168008482f

**Convention Establishing the World Intellectual Property Organization*, July 14, 1967, 21 U.S.T. 1749, T.I.A.S. No. 6932, 828 U.N.T.S. 3

Consumers International (2010), *Access to Knowledge for Consumers: Reports of Campaigns and Research 2008–2010* Jeremy Malcolm (ed.), Kuala Lumpur, Malaysia: Consumers International Regional Office for Asia Pacific and the Middle East

Correa, Carlos (2004), 'Bilateralism In Intellectual Property: Defeating The WTO System for Access to Medicines', *Case Western Reserve Journal of International Law 36:79-94*.

Cottier, Thomas (2005), "The Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPs) in *The World Trade Organization: Legal, Economic and Political Analysis*, vol. I p. 1041, P.F.J. Macrory, A. E. Appleton, M.G. Plummer (eds.), Springer 2005

Council of the European Union (2009), *COUNCIL RESOLUTION of 16 March 2009 on the EU Customs Action Plan to combat IPR infringements for the years 2009 to 2012*, Official Journal 2009/C 71/01, 23.3.2009, [online: web] accessed 5 July 2017, URL: http://ec.europa.eu/taxation_customs/sites/taxation/files/resources/documents/customs/customs_controls/counterfeit_piracy/commission_initiatives/council_resolution_en.pdf

Council of the European Union (2012), *Resolution on the EU Customs Action Plan to combat intellectual property rights infringements (2013 to 2017)* , 3208th COMPETITIVENESS (Internal Market, Industry, Research and Space) Council meeting Brussels, 10 December 2012, [online: web] accessed 5 July 2017, URL: https://www.consilium.europa.eu/uedocs/cms_data/docs/pressdata/en/intm/134125.pdf

Cullet, P (2006), 'Intellectual Property Rights, Plant Genetic Resources and Traditional Knowledge' in *Susette Biber-Klemm, Thomas Cottier (eds.) Rights to Plant Genetic Resources and Traditional Knowledge Basic Issues and Perspectives, Oxfordshire, UK: CABI*

Datta, P T Jyothi (2013), 'Generic-makers wary about Interpol pact with drug majors', *The Hindu Business Line*, Mumbai, March 14, [online: web], accessed 5 July 2017, URL: http://www.thehindubusinessline.com/companies/genericmakers-wary-about-interpol-pact-with-drug-majors/article4509263.ece

Daudpota, Faisal (2004), 'Congress on Counterfeiting Raises Public Awareness', *59:12 INTA Bulletin*, July 1, 2004, New York [online: web], accessed 5 July 2017 URL: http://www.inta.org/INTABulletin/Pages/CongressonCounterfeitingRaisesPublicAwareness.aspx

Day, Gregory (2017), 'Competition and Piracy', *32: 2 Berkeley Technology Law Journal*, at SSRN, [online: web] accessed 7 June 2017, URL: https://ssrn.com/abstract=2904373

De Castro, Tereza (2011), 'EU-India TRIPS-plus Agreement: A Real Threat for the Developing World?' *Contemporary European Studies 2011 (1)*

Dearden, Lizzie (2014), "iPhone 6 'catches on fire and burns man's leg after bending in his pocket'", *The Independent*, 20th October, accessed 5 July 2017, URL: http://www.independent.co.uk/life-style/gadgets-and-tech/news/iphone-6-catches-on-fire-and-burns-mans-leg-after-being-bending-in-pocket-9806524.html

Deazley, Ronan (2007), 'Copyright's public domain', in Charlotte Waelde and Hector MacQueen (eds.) *Intellectual Property The Many Faces of the Public Domain*, Cheltenham, UK& Northampton MA, USA: Edward Elgar

DeLauro, Rosa L. (2003) "Imported Drugs: FDA Suddenly Gets 'Concerned'," *L.A. Times*, 5 November, [online: web] Accessed 5 July 2017, URL: http://articles.latimes.com/2003/nov/05/opinion/oe-delauro5

* *Declaration of Rome* (2006) "*Conclusions and Recommendations of the WHO International Conference on Combating Counterfeit Medicines: Declaration of Rome*", 18 February 2006, Rome, Italy, [online: web] accessed 5 July 2017, URL: http://www.who.int/medicines/services/counterfeit/RomeDeclaration.pdf

Department of Foreign Affairs and Trade (1990), "Intellectual Property Rights, A Guide to the GATT Uruguay Round", March 1990, Canberra, as quoted in Evans GE (2000): 124, *Lawmaking under the Trade Constitution: A Study in Legislating by the World Trade Organization, Studies in Transnational Economic Law*, Kluwer Law International: The Hague

* *Digital Millennium Copyright Act, 1998, 17 United States Code.*

**Directive 2004/48/EC of the European Parliament and of the Council of 29 April 2004 on the enforcement of intellectual property rights*, 2004 O.J. (L 157)

**Directive 2011/62/EU Of The European Parliament And Of The Council Of 8 June 2011 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use, as regards the prevention of the entry into the legal supply chain of falsified medicinal products, L 174/74, 1.7.2011*

*DIRECTIVE 2011/62/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 8 June 2011 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use, as regards the prevention of the entry into the legal supply chain of falsified medicinal products, 2011 O.J. (L 174/ 74), 1.7.2011.

**Draft Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations, Revision, Trade-Related Aspects of Intellectual Property Rights, Including Trade in Counterfeit Goods*, MTN.TNC/W/35/Rev. 1, 3 Dec. 1990.

*Draft SECURE Text (2007), in the July 2005 G-8 meet, June, [Online: Web] Accessed 24 May 2009, URL: http://www.keionline.org/misc-docs/SECURE_text.pdf

Drahos, Peter (1995), "Global Property Rights in Information: The story of TRIPS at the GATT", *Prometheus*, 13 (5): 6-19.

Drahos, Peter (2001), "BITs and BIPs – Bilateralism in Intellectual Property", *Journal of World Intellectual Property*, 4 (6): 791—807.

Drahos, Peter (2002), "Developing Countries and International Intellectual Property Standard-Setting", *Journal of World Intellectual Property*, 5 (5): 765-789.

Drahos, Peter (2005), "*An Alternative Framework for the Global Regulation of Intellectual Property Rights*", Australian National University, Centre for Governance of Knowledge and Development, Working Paper, October, [online: web] accessed 5 July 2017, URL: https://www.anu.edu.au/fellows/pdrahos/articles/pdfs/2005analternativeframework.pdf

Drahos, Peter and John Braithwaite (2002), '*Information Feudalism*', London, Sterling, VA: Earthscan Publications

Dutfield, Graham and Uma Suthersanen (2008), *Global Intellectual Property Law*, Cheltenham, UK & Northampton, MA, USA: Edward Elgar

Dutfield, Graham and Uma Suthersanen (2010), 'Global Intellectual Property Law and Policy', *The Global Community Yearbook of International Law & Jurisprudence 2010 (I): 7-34*

**ECONOMIC PARTNERSHIP AGREEMENT between the CARIFORUM States, of the one part, and the European Community and its Member States, of the other part*, OJ (2008) L 289/I/3

**Economic Partnership Agreements Between The European Union And Its Member States, Of The One Part, And The SADC EPA States, Of The Other Part*', [online: web] accessed 5 July 2017, URL: http://trade.ec.europa.eu/doclib/docs/2015/october/tradoc_153915.pdf

Ermert, Monica (2010), 'Medicrime: Another Anti-Counterfeiting Convention Emerges In Europe', *Intellectual Property Watch*, 24 April, [online: web] Accessed 5 July 2017, URL: https://www.ip-watch.org/2010/04/24/medicrime-another-anti-counterfeiting-convention-emerges-in-europe/

Ermert, Monica (2017), "EU Parliament Adopts Marrakesh Treaty; Blind Union Prepared To Fight Publisher 'Compensation'", *Intellectual Property Watch*, 6 July 2017, [online: web] accessed 6 July 2017, URL: https://www.ip-watch.org/2017/07/06/eu-parliament-adopts-marrakesh-treaty-blind-union-prepared-fight-publisher-compensation/

**EU Council Regulation EEC No 2641/84* O.J 1984, L 252/1

European Commission Press Release Database (2007), 'European Commission seeks mandate to negotiate major new international anti- counterfeiting pact', IP/07/1573 Brussels, 23 October 2007, [online: web], accessed 5 July 2017, URL: http://europa.eu/rapid/press-release_IP-07-1573_en.htm

European Commission Press Release database (2009), 'Internal Market: Commission launches European Observatory on Counterfeiting and Piracy', IP/09/497, Brussels, 30 March 2009, [online: web] accessed 5 July 2017, URL: http://europa.eu/rapid/press-release_IP-09-497_en.htm

European Commission (2015), Register of the Data Protection Officer, "DPO-3670.2 Processing in the COPIS database of data contained in application for action for the enforcement of intellectual property rights by customs authorities in the Member States", Directorate-General: DG Taxation and Customs Union , Controller: LARRIEU Pierre-Jacques, Publication: 2015-07-07, [online: web], accessed 5 July 2017, URL: http://ec.europa.eu/dpo-register/details.htm?id=39708

European Commission (2016a), 'Commission notice on the customs enforcement of Intellectual Property Rights concerning goods brought into the customs territory of the Union without being released for free circulation including goods in transit', 2016 O.J. (2016/C 244/03), 5.7.2016, [online: web] accessed 5 July 2017, URL: http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=OJ:C:2016:244:FULL&from=EN

*European Commission (2016b), *COMMISSION DELEGATED REGULATION (EU) 2016/161 of 2 October 2015 supplementing Directive 2001/83/EC of the European Parliament and of the Council by laying down detailed rules for the safety features appearing on the packaging of medicinal products for human use*, 2016 O.J (L32/1), 9.2.2016

European Commission (2017a), 'REPORT FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT AND THE COUNCIL on the implementation of Council Regulation (EU) No 608/2013', Brussels, 15.5.2017 COM(2017) 233 final, [online: web] accessed 5 July 2017, URL: http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52017DC0233&from=en

European Commission (2017b), 'OVERVIEW OF ECONOMIC PARTNERSHIP AGREEMENTS', updated June 2017, [online: web] accessed 5 July 2017, URL: trade.ec.europa.eu/doclib/docs/2009/september/tradoc_144912.pdf

European Parliament (2012a), *Parliament receives petition against ACTA*, European Parliament News, Committee on Petitions Press release - External/ international trade - 28-02-2012, [online: web] accessed 5 July 2017, URL: www.europarl.europa.eu/news/en/news-room/20120227IPR39337/Parliament-receives-petition-against-ACTA

European Parliament (2012b), *European Parliament rejects ACTA*, European Parliament News, Plenary Session Press release External/ international trade - 04-07-2012, [online: web] accessed 5 July 2017, URL: http://www.europarl.europa.eu/news/en/news-room/20120703IPR48247/european-parliament-rejects-acta

European Union Press Release (2007), *European Commission Seek Mandate to Negotiate Major New International Anti-counterfeit Pact* October 23, [Online: Web] accessed 5 July 2017, URL: https://www.eff.org/files/filenode/EFF_PK_v_USTR/foia-ustr-acta-response1-doc14.pdf

Europol (2017), 'European Union (EU) Serious and Organised Crime Threat Assessment 2017 (SOCTA 2017)', *Europol*, The Hague, Netherlands

Evans, Gail E. (1994), "Intellectual Property as a Trade Issue -The Making of the Trade-Related Aspects of Intellectual Property Rights", *World Competition*, 18 (2): 137-180.

Fattahi, Parva (2008), "The Unrolling Enforcement Agenda" in the Washington College of Law's Program on Information Justice and Intellectual Property(PIJIP) 19 August, [Online: Web] accessed 5 July 2017, URL: https://www.wcl.american.edu/pijip/go/blog-post/the-unrolling-enforcement-agenda

Fayzrakhmanov, Nail F. (2012), 'The Council of Europe Convention Medicrime and Its Role in the Fight Against International Crime', *Internal Security*, January-June 2012: 55

Foxnews.com (2004), 'Terrorists Eye Counterfeit Goods, Interpol Says', by Associated Press, published in *Foxnews.com* 25 May 2004, [online: web] accessed 5

July 2017, URL: http://www.foxnews.com/story/2004/05/25/terrorists-eye-counterfeit-goods-interpol-says.html

**FREE TRADE AGREEMENT between the European Union and its Member States, of the one part, and the Republic of Korea, of the other part*, OJ (2011) L 127

**Free Trade Agreement between the European Union and the Republic of Singapore* [online: web] accessed 5 July 2017, URL: http://trade.ec.europa.eu/doclib/press/index.cfm?id=961

Garner, Brian A et al. (ed.) (1999), *Black's Law Dictionary* Seventh edition, St. Paul: West

Gerhardsen, Tove Iren S. (2005), 'Japan Proposes New IP Enforcement Treaty', *Intellectual Property Watch, 15/11/2005* [online: web] accessed 5 July 2017, URL: https://www.ip-watch.org/2005/11/15/japan-proposes-new-ip-enforcement-treaty/

Gervais, Daniel (2007) 'The Changing Landscape of International Intellectual Property' in Christopher Heath and Anselm Kamperman Sanders (eds.), *'Intellectual Property and Free Trade Agreements',* Oxford and Portland, Oregon: Hart Publishing.

Gervais, Daniel J. (2005), 'Intellectual Property, Trade & Development: The State Of Play', *Fordham L. Rev 74: 505*

Gervais, Daniel J. (1999), "The TRIPS Agreement: Interpretation and Implementation", *European Intellectual Property Review,* 21(3): 156-162.

Gervais, Daniel (1998), "*The TRIPS Agreement: Drafting History and Analysis*", London, Sweet and Maxwell.

Geuze, Matthijs (1998), "Patent Rights in the Pharmaceutical Area and their Enforcement", *Journal of World Intellectual Property*, 1 (4): 585-683.

Gopakumar, K M (2015), 'Suspension of UNODC work program on model law on fraudulent medicines', TWN Info Service on Intellectual Property Issues (Oct15/04), Geneva, 1 October 2015, [online: web] accessed 5 July 2017, URL: http://twn.my/title2/intellectual_property/info.service/2015/ip151004.htm

*Government of India (2007), Ministry of Finance, Department of Revenue, New Delhi, dated the 8th May, 2007, *Notification no. 47/2007-customs (N.T.)*

*Government of India (2007), Ministry of Finance, Department of Revenue, New Delhi, dated the 8th May, 2007, *Notification no. 49/2007-customs (N.T.)*

Government of India (2016), '*National Intellectual Property Rights Policy*', Ministry of Commerce and Industry Department of Industrial Policy and Promotion, 12 May 2016, New Delhi

Grossman, Gene M. and Carl Shapiro (1988), "Foreign Counterfeiting of Status Goods", *The Quarterly Journal of Economics,* 103 (1): 79-100.

Hasik, Daniel and Anna Łapinska (2015), "The seizure by customs authorities of counterfeited goods: the ruling by the European Court of Justice in *Blomqvist v. Rolex* and the changes brought about by regulation (EU) No. 608/2013", *ERA Forum* 16: 73–87

Haupt, Adam (2008), *Stealing Empire: p2p, intellectual property and hip-hop subversion*, Cape Town, South Africa: HSRC Press

Hegde, V. G. (2005), "India and the International Patent System", in Bimal Patel (ed.) *India and International Law*: 93-116, Leiden/ Boston: Martinus Nijhoff

Hegde, V.G. (2007), "Intellectual Property Rights and Asian-African States", in *Fifty Years of AALCO: Commemorative Essays in International Law*: 124-147, Asian African Legal Consultative Organization (AALCO), New Delhi: AALCO.

Hegde, Venkatachala G. (1995), *Developing Countries and the Evolving Regime of Intellectual Property Rights*, Ph. D. Thesis, New Delhi: Jawaharlal Nehru University.

Helfer, Laurence R (2004), "Regime Shifting: The TRIPs Agreement and New Dynamics of International Intellectual Property Lawmaking", *Yale Journal of International Law*, 29 (1): 1-83.

Hermann, Rachel Marusak (2011), 'WHO Group Agrees On New Mechanism To Fight Poor-Quality Medicines', *Intellectual Property Watch* 01/11/2011, [online: web] accessed 5 July 2017, URL: https://www.ip-watch.org/2011/11/01/who-group-agrees-on-new-mechanism-to-fight-poor-quality-medicines/

Hess, Charlotte and Elinor Ostrom (2007), *Understanding Knowledge as a Commons: From Theory to Practice*, Cambridge, Massachusetts & London, England: The MIT Press

Higgins, Richard and Paul H. Rubin (1986), "Counterfeit Goods", *Journal of Law and Economics*, 29(2): 211-230.

ICN (2005a), International Council of Nurses, "Nurses for Patient Safety: Targeting Counterfeit and Substandard Medicines, [Online: Web] accessed 5 July 2017, URL: http://www.icn.ch/images/stories/documents/publications/ind/indkit2005.pdf

ICN (2005b), International Council of Nurses, International Perspectives, 'ICN Asks Nurses to Help Protect Patients from Counterfeit Medicines', *International Nursing Review,* 52 (85)

ICTSD (2008), International Centre for Trade and Sustainable Development (Geneva), "Secretive ACTA Negotiations under Scrutiny", *BRIDGES Weekly Trade News Digest*, 12(33), 9 October [online: web] accessed 5 July 2017, URL: http://www.ictsd.org/bridges-news/bridges/news/secretive-acta-negotiations-under-scrutiny

ICTSD (2009), *European Generic Drug Seizures Take Centre Stage at TRIPS Council Meeting*, Bridges 13 (21), 10 June 2009, ICTSD: Geneva, [online: web] accessed 5 July 2017, URL: http://www.ictsd.org/bridges-news/bridges/news/european-generic-drug-seizures-take-centre-stage-at-trips-council-meeting

IMPACT (2008), Final Brochure presented at the World Health Assembly (WHA), updated May 2008, [Online: Web] Accessed 5 July 2017, URL: https://www.gphf.org/images/downloads/library/whoimpact2008_counterfeit_drugs_kill.pdf

IPW (2015), "Brief: Germany, Italy Leading Resistance To EU Ratification Of Marrakesh Treaty, Blind Union Says", *Intellectual Property Watch*, 10/12/2015, [online: web] accessed 5 July 2017, URL: https://www.ip-watch.org/2015/12/10/germany-italy-leading-resistance-to-eu-ratification-of-marrakesh-treaty-blind-union-says/

**International Bureau of WIPO, Existence, Scope and Form of Generally Internationally Accepted and Applied Standards/ Norms for the Protection of Intellectual Property*, GATT Doc. MTN.GNG/NG11/W/24 Rev. 1; WIPO Doc. WO/INF/29, September 1988

**International Convention for the Protection of Performers, Producers of Phonograms and Broadcasting Organizations,* Done at Rome on October 26, 1961 [online: web], accessed 5 July 2017, URL: http://www.wipo.int/treaties/en/text.jsp?file_id=289757

INTERPOL (2003), '*The links between intellectual property crime and terrorist Financing*', Before the United States House Committee on International Relations, One hundred eighth Congress, 16 July, Text of public testimony of by Ronald K. Noble, Secretary General of INTERPOL, [online: web] Accessed 5 July 2017, URL: https://www.interpol.int/content/download/6058/49613/version/2/file/SG20030716.pdf

INTERPOL (2013), 'INTERPOL and pharmaceutical industry launch global initiative to combat fake medicines' 12 March 2013 Media release, [online: web] accessed 5 July 2017, URL: https://www.interpol.int/News-and-media/News/2013/PR031

Interpol (2014a), '*Countering Illicit Trade In Goods: A Guide For Policy-Makers*', Legal Handbook Series, June 2014, International Criminal Police Organization (ICPO) – INTERPOL: Lyon

INTERPOL (2014b), '*Pharmaceutical Crime and Organized Criminal Groups: An analysis of the involvement of organized criminal groups in pharmaceutical crime since 2008*', 17 July 2014, Interpol Pharmaceutical Crime Sub-Directorate, Interpol: Lyon

INTERPOL News (2014), 'Media invitation for Global INTERPOL Conference – Ten Years of Combating Pharmaceutical Crime: Review and Prospects', 29 October 2014, [online: web] accessed 5 July 2017, URL: https://www.interpol.int/News-and-media/News/2014/N2014-205

ITU (2014a), 'Combating counterfeit and substandard ICT devices (Geneva, Switzerland, 17-18 November 2014)' [online: web] accessed 5 July 2017, URL: https://www.itu.int/en/ITU-T/C-I/Pages/WSHP_counterfeit.aspx

ITU (2014b), ‘Counterfeit and substandard ICT products discussed at ITU’, Headlines, Geneva, Switzerland, 21 November, [online: web] accessed 5 July 2017, URL: https://www.itu.int/en/ITU-D/bdt-director/Pages/News.aspx?ItemID=82

ITU (2016a), *ITU Workshop on "Combating Counterfeit Using Conformance and Interoperability Solutions"*, Geneva, Switzerland, 28 (PM) June 2016 [online: web], accessed 5 July 2017, URL: https://www.itu.int/en/ITU-T/Workshops-and-Seminars/20160628/Pages/default.aspx

ITU (2016b), *Summary of Discussions at ITU’s Workshop on "Combating Counterfeit Using Conformance and Interoperability Solutions”*, ITU Headquarters, Geneva, Switzerland 28 June 2016, [online: web] accessed 5 July 2017, URL: https://www.itu.int/en/ITU-T/Workshops-and-Seminars/20160628/Documents/Summary/Summary_Workshop_Counterfeit.pdf

ITU News (2011), ‘Intellectual property rights in Today's digital economy’, September 2011 [online: web], accessed 5 July 2017, URL: https://www.itu.int/net/itunews/issues/2011/07/38.aspx

IViR (2006), *The Recasting of Copyright and Related Rights for the Knowledge Economy: final report*, Institute for Information Law, University of Amsterdam, The Netherlands, November 2006

Janssens, Marie-Christine (2009), ‘The issue of exceptions: reshaping the keys to the gates in the territory of literary, musical and artistic creation’, in *Research Handbook on the Future of EU Copyright*, Estelle Derclaye (ed.), Cheltenham, UK & Northampton, MA, USA: Edward Elgar

**Joint Declaration on the Launch of Negotiations for the Regional Comprehensive Economic Partnership*, 20 November 2012, [online: web] accessed 5 July 2017, URL: http://dfat.gov.au/trade/agreements/rcep/news/Documents/joint-declaration-on-the-launch-of-negotiations-for-the-regional-comprehensive-economic-partnership.pdf

Kaminski, Margot (2009), “The Origins and Potential Impact of the Anti-Counterfeiting Trade Agreement (ACTA)”, *Yale Journal of International Law*, 34 (1): 247-256.

Kaneko, Kaori and Yoshifumi Takemotov (2016), “Japan ratifies TPP trade pact to fly the flag for free trade”, *Reuters*, Dec 9, 2016, [online: web] accessed 5 July 2017, URL: http://www.reuters.com/article/us-japan-tpp-idUSKBN13Y0CU

Kariyawasam, Rohan (2007), ‘*International Economic Law and the Digital Divide: A New Silk Road?*’ Edward Elgar**:** Cheltenham, UK • Northampton, MA, USA

Katz, Eddan (2010), ‘Mapping A2K Advocacy’ in *Access to Knowledge for Consumers: Reports of Campaigns and Research 2008–2010* Jeremy Malcolm (ed.), Kuala Lumpur, Malaysia: Consumers International Regional Office for Asia Pacific and the Middle East

Kawooya, Dick et al. (2010), “Uganda”, in C. Armstrong, J. De Beer, D. Kawooya, A. Prabhala, T. Schonwetter (eds.) *Access to knowledge in Africa: The role of copyright*, Claremont, South Africa: UCT Press

Kuanpoth, Jakkrit (2007) 'TRIPS-Plus Rules under Free Trade Agreements: An Asian Perspective' in Christopher Heath and Anselm Kamperman Sanders (eds.), *'Intellectual Property and Free Trade Agreements',* Oxford and Portland, Oregon: Hart Publishing.

Lanoszka, Anna (2003), 'The Global Politics of Intellectual Property Rights and Pharmaceutical Drug Policies in Developing Countries', *24 (2) International Political Science Review, pp. 181-197*

Lee, Yong-Shik (2006), "*Reclaiming Development in the World Trading System*, Cambridge and New York: Cambridge University Press.

Lewis, Meredith Kolsky (2011), 'The Trans-Pacific Partnership: New Paradigm or Wolf in Sheep's Clothing?' *34 B.C. Int'l & Comp. L. Rev. 27*, [online: web] accessed 5 July 2017, URL: http://lawdigitalcommons.bc.edu/iclr/vol34/iss1/3/

Liang, Brian A (2006), 'Fade to Black: Importation and Counterfeit Drugs', *American Journal of Law & Medicine,* 32: 279-323

Li, Xuan (2008), "WCO SECURE: Lessons learnt from the abortion of the TRIPS-Plus-Plus IP Enforcement Initiative", Research Papers 19, December, *South Centre*: Geneva

Li, Xuan (2010), 'The Agreement on Trade-Related Aspects of Intellectual Property Rights Flexibilities on Intellectual Property Enforcement: The World Trade Organization Panel Interpretation of China- Intellectual Property Enforcement of Criminal Measures and Its Implications', *The Journal of World Intellectual Property 13(5): 639-659*

Lindstrom, Beatrice (2010), "Scaling Back Trips-Plus: An Analysis Of Intellectual Property Provisions In Trade Agreements And Implications For Asia And The Pacific", 42 *N.Y.U. Journal of International Law and Politics*.

MacGregor, James et al. (2014), "The Public Knowledge Project: Open Source Tools for Open Access to Scholarly Communication" in Sönke Bartling & Sascha Friesike (eds.) *Opening Science: The Evolving Guide on How the Internet is Changing Research, Collaboration and Scholarly Publishing*, Heidelberg, New York, Dordrecht, London: Springer Cham

Magid, Larry (2012), 'What are SOPA and PIPA and Why All the Fuss?' *FORBES,* Jan. 18, 2012, accessed 5 July 2017, URL: https://www.forbes.com/sites/larrymagid/2012/01/18/what-are-sopa-and-pipa-and-why-all-the-fuss/#5de9147d22dd

Mara, Kaitlin (2010), 'Debate Erupts Over WHO Police Work Against "Counterfeit" Drugs Trade', *Intellectual Property Watch* 20/05/2010, [online: web] accessed 5 July 2017, URL: https://www.ip-watch.org/2010/05/20/debate-erupts-over-who-police-work-against-counterfeit-drugs-trade/

Mara, Katlin (2009a), 'World Health Assembly Takes On R&D, Pandemics, Not Counterfeits', *IP Watch*, 18 May,[Online: Web], accessed 5 July 2017, URL:

https://www.ip-watch.org/2009/05/18/health-assembly-takes-on-rd-pandemics-not-counterfeits/

Mara, Katlin (2009b), 'Drug Seizures in Frankfurt Spark Fears of EU-Wide Pattern', *IP Watch* 5 June, [Online: Web], accessed 5 July, 2017, URL: https://www.ip-watch.org/2009/06/05/drug-seizures-in-frankfurt-spark-fears-of-eu-wide-pattern/

Martin, Elizabeth A (2003), *A Dictionary of Law*, Fifth Edition, Oxford: Oxford University Press

Maskus, Keith E (2006), 'Intellectual Property Rights', in *Trade Relations Between Columbia and the United States*, Jeffrey J. Schott (ed.), Peterson Institute for International Economics: Washington DC

Maskus, Keith E. (2004), 'The Globalization Of Private Knowledge Goods And The Privatization Of Global Public Goods', *Journal of International Economic Law 7(2), 279–320*

Mathew, Joe C. (2011), 'EU countries clear water for Indian pharma firms to anchor', *Business Standard*, New Delhi, March 31, 2011

Matsuura, Koichiro (2004), 'UNESCO's Approach to Open-Access and Public-Domain Information' in *Open Access and The Public Domain in Digital Data and Information for Science: Proceedings of an International Symposium*, Julie M Esanu and Paul F. Uhlir (eds.) Washington D.C., The National Academic Press.

Matthews, Duncan (2002), '*Globalizing Intellectual Property Rights- The TRIPS Agreement*', London and New York: Routledge

Mbatiah, Suleiman (2010), 'KENYA: Pharmaceutical Companies Pushing Anti-Counterfeit Law', Inter Press Service, [online: web], accessed 5 July 2017, URL: http://www.ipsnews.net/2010/06/kenya-pharmaceutical-companies-pushing-anti-counterfeit-law/

Mehdudia, Sujay (2010), 'EU seizure of Indian drugs improper: WHO', *The Hindu*, New Delhi, May 23, 2010

Mercurio, Bryan (2012), 'Beyond The Text: The Significance Of The Anti-Counterfeiting Trade Agreement,' *Journal of International Economic Law* 15(2), 361–390

*Ministerial Declaration, 20 September, 1986, BISD, 33S, 1987, 1987, 19

Mishra, Asit Ranjan (2017), 'RCEP negotiations: India likely to take a more aggressive stand', *Livemint*, April 18 2016, New Delhi, [online: web] accessed 7 July 2017, URL: http://www.livemint.com/Politics/37pnX4pjCINPeglF6d53HL/RCEP-negotiations-India-likely-to-take-a-more-aggressive-st.html

Moore, Adam (2001), '*Intellectual Property and Information Control: Philosophic Foundations and Contemporary Issues*,' New Brunswick, New Jersey: Transaction Publishers

MSF (2003) Médecins Sans Frontières, Fifth Informal Consultation between the OECD Trade Committee and Civil Society Organisations (CSOS), *Doha Derailed: A Progress Report on TRIPS and Access to Medicines,* Briefing for the 5th WTO Ministerial Conference, Cancun 2003, Paris, 20 October, OECD Doc. No. TD/TC/CSO/RD (2003)2 [Online: Web] Accessed 5 July 2017, URL: http://www.oecd.org/tad/xcred/16073275.pdf

Muheebwa, Hillary (2014), 'East African Community Moves To Harmonise IP Rights Regulation', *Intellectual Property Watch*, 11 April, [online: web] accessed 5 July 2017, URL: https://www.ip-watch.org/2014/04/11/east-african-community-moves-to-harmonise-ip-rights-regulation/

Musungu, Sisule F. (2007), *An Analysis of the EC Non-Paper on the Objectives and Possible Elements of an IP Section in the EC-Pacific EPA*, CAFOD, London, UK; and ICTSD Programme on Intellectual Property Rights and Sustainable Development, International Centre for Trade and Sustainable Development, Geneva, Switzerland.

Muzaka, Valbona (2009), 'Dealing with Public Health and Intellectual Property for Pharmaceuticals at the World Trade Organization' in MacLean, Sandra, J. et al. (eds.) '*Health for Some- The Political Economy of Global Health Governance'* UK& USA, Palgrave Macmillan.

Ncube, Caroline B (2011), "Key copyright issues in African distance education: a South African case study", *32(2) Distance Education*: 269-275

Ndirangu, Gichinga (2013), 'EAC gives nod to intellectual property law', May 18, *The East African*, [online: web] accessed 5 July 2017, URL: http://www.theeastafrican.co.ke/news/EAC-gives-nod-to-intellectual-property-law-/-/2558/1856346/-/8n4vvwz/-/index.html

Neal, Dave (2012), "Japan ratifies ACTA agreement", *The Inquirer*, Newsletter, 06 September 2012, [online: web] accessed 5 July 2017, URL: https://www.theinquirer.net/inquirer/news/2203330/japan-ratifies-acta-agreement

New, William (2009), 'WCO Kills SECURE Group, But Creates Health Enforcement Mandate', *IP Watch*, 9 July, [Online: Web], Accessed 5 July 2017, URL: https://www.ip-watch.org/2009/07/09/wco-kills-%e2%80%9csecure%e2%80%9d-group-but-creates-health-enforcement-mandate/

New, William (2014), 'UN Office Of Drugs And Crime Enters Debate Over Fake Medicines And IP', *Intellectual Property Watch* 09/12/2014, [online: web] accessed 5 July 2017, URL: https://www.ip-watch.org/2014/12/09/un-office-of-drugs-and-crime-enters-debate-over-fake-medicines-and-ip/

New, William (2016), 'US, India Trade Ministers Agree List Of IP Enforcement Actions For India, USTR Says', *Intellectual Property Watch* 20/10/2016, [online: web] accessed 5 July 2017, URL: https://www.ip-watch.org/2016/10/20/us-india-trade-ministers-agree-list-enforcement-actions-india/

New, William (2017), 'WHO Board Agrees To Drop The Word 'Counterfeit' After 30 Years', *Intellectual Property Watch* 30/01/2017, [online: web] accessed 5 July

2017, URL: https://www.ip-watch.org/2017/01/30/board-agrees-drop-word-counterfeit-30-years/

News Corp Australia Network (2015), "Woman dies after dropping iPhone handset in the bath while it was charging", February 13, accessed 5 July 2017, URL: http://www.news.com.au/technology/gadgets/woman-dies-after-dropping-iphone-handset-in-the-bath-while-it-was-charging/news-story/1cd4ab415b3af70e2d360795a681b66d

OECD (2008), "*The Economic Impact of Counterfeiting and Piracy*," OECD Publications: Paris, France

OECD (2009), "*Magnitude of Counterfeiting and Piracy of Tangible products: An Update*," November 2009, OECD Publications: Paris, France

Okediji, Ruth (2003), 'New Treaty Development and Harmonization of Intellectual Property Law' in Christophe Bellmann, Graham Dutfield and Ricardo Meléndez-Ortiz (eds.) *Trading in Knowledge Development Perspectives on TRIPS, Trade and Sustainability*, Geneva: ICTSD & London • Sterling, VA: Earthscan

Okediji, Ruth (2004), 'Fostering Access to Education, Research and Dissemination of Knowledge through Copyright' (Draft), University of Minnesota & UNCTAD-ICTSD Dialogue on *Moving the pro-development IP agenda forward: Preserving Public Goods in health, education and learning*, Bellagio, 29 November – 3 December 2004, [online web] accessed 5 July 2017, URL: http://www.iprsonline.org/unctadictsd/bellagio/docs/Okideiji_Bellagio4.pdf

Otten, Adrian and Hannu Wager (1996), "Compliance with TRIPS: The Emerging World View", *Vanderbilt Journal of Transnational Law*, 29: 391-414.

Outterson, K., (2009), '*Import Safety Rules Should Not Hinder Legitimate Generic Drug Markets',* Boston University School of Law Working Paper No. 09-25, [Online: Web] Accessed 5 July 2017, URL: https://papers.ssrn.com/sol3/papers.cfm?abstract_id=1407250

Outterson, Kevin and Ryan Smith (2006), "Counterfeit Drugs: The Good, The Bad and The Ugly", *Albany Law Journal of Science & Technology,* 16 (3): 525-544.

Overview: Survey on enforcement of intellectual property rights in third countries, visited 7 July 2017, URL: http://trade.ec.europa.eu/doclib/docs/2004/august/tradoc_113229.pdf

Martin, Elizabeth A. (2003) (ed.), *A Dictionary of Law*, fifth edition (reprint), Oxford, Great Britain: Oxford University Press

Pang, Laikwan (2006), *Cultural Control and Globalization in Asia: Copyright, piracy, and cinema*, London and New York: Routledge.

Paster, B. G. (1969), "Trademarks - their early history", *The Trademark Reporter*, 59: 551-72.

Phelps, Shirelle (2003), *Gale Encyclopedia of Everyday Law*, Volume One, Detroit: Thomson Gale

Peng, Mike W. et al. (2017), "History and the Debate Over Intellectual Property", *13(1) Management and Organization Review: 15-38*

Pepitone, Julianne (2012), *SOPA explained: What it is and why it matters,* visited 5 July 2017, URL: http://money.cnn.com/2012/01/17/technology/sopa_explained/index.htm

Petersen-Padberg, Anja (2008) "COUNCIL REGULATION (EC) No. 1383/2003, Introductory Remarks" in Thomas Cottier and Peter Veron (eds.), *Concise International and European IP Law- TRIPS, Paris Convention, European Enforcement and Transfer of Technology*, The Netherlands, Kluwer Law International

Pratap, Ketan (2016), "iPhone 7 Allegedly Burns Woman While Sleeping", NDTV Gadgets, November 15, accessed 5 July 2017, URL: http://gadgets.ndtv.com/mobiles/news/iphone-7-allegedly-burns-woman-while-sleeping-1625767

*Proposal for a Directive of the European Parliament and of the Council on Measures and Procedures to Ensure the Enforcement of Intellectual Property Rights, COM (2003) 46 final (Jan 30, 2003)

PSI, Pharmaceutical Security Institute, [Online: Web] Accessed 5 July 2017, URL: http://www.psi-inc.org/about.cfm

Raseroka, Kay (2006), 'Access to Information and Knowledge', in Rikke Frank Jørgensen (ed.), *Human Rights in the Global Information Society*, Cambridge, Massachusetts; London, England: The MIT Press

Ravi Kanth, D (2010), "India, Brazil drag EU to WTO", *Business Standard*, Geneva, May 13 2010.

Register of the Data Protection Officer, "DPO-3670.2 Processing in the COPIS database of data contained in application for action for the enforcement of intellectual property rights by customs authorities in the Member States", Directorate-General: DG Taxation and Customs Union , Controller: LARRIEU Pierre-Jacques, Publication: 07-07-2015, [online: web], accessed 5 July 2017, URL: http://ec.europa.eu/dpo-register/details.htm?id=39708

Reichman, J H (1995), 'Universal Minimum Standards of Intellectual Property Protection under the TRIPS Component of the WTO Agreement', *The International Lawyer*, 29 (2): 345

Reichman, J.H. (1997), "Enforcing the Enforcement Procedures of the TRIPS Agreement", *Vanderbilt Journal of Transnational Law*, 37: 335

Rens, Andrew, Achal Prabhala and Dick Kawooya (2006), 'Intellectual Property, Education and Access to Knowledge in Southern Africa', Research Paper co-supported by ICTSD, UNCTAD and TRALAC.

Report on the protection and enforcement of intellectual property rights in third countries, Commission Staff Working Document, Brussels, 1.7.2015, SWD (2015) 132 final, European Commission: Brussels

Reynell, Stella (2016), "Not only Samsung, iPhone explodes too", *The Technews*, December 7, accessed 5 July 2017, URL: http://thetechnews.com/2016/12/07/not-only-samsung-iphone-explodes-too/

Ricketson, S. (2003), 'WIPO Study on Limitations and Exceptions of Copyright and Related Rights in the Digital Environment' WIPO Standing Committee on Copyright and Related Rights, Ninth Session – June 23 to 27, 2003, (SCCR/9/7) Geneva: WIPO

*Role of the Patent System in the Transfer of Technology to Developing Countries', U.N. Doc. No. TD/B/AC.11/19 (1974)

Ruse – Khan, Henning Grosse (2009) "Access to knowledge under the international copyright regime, the WIPO development agenda and the European Communities' new external trade and IP policy", *Research Handbook on the Future of EU Copyright*, Estelle Derclaye (ed.), Cheltenham, UK & Northampton, MA, USA: Edward Elgar

Ryan, Michael P. (1999), "Competitive Strategies for Protection of Intellectual Property", in '*Markets, Institutions, Intellectual Property Rights, and Development in a Knowledge-Based World Economy*', Owen Lippert (ed.), Vancouver, Canada: The Fraser Institute. [Online: web] Accessed 5 July 2017, URL: https://www.fraserinstitute.org/sites/default/files/CompetitiveStrategiesProtectionIntellectualProperty.pdf

Saez, Catherine (2013), 'Interpol, Pharma Join Hands Against The Crime Of Fake Pharmaceuticals', *Intellectual Property Watch* 14/03/2013 [online: web] accessed 5 July 2017, URL: https://www.ip-watch.org/2013/03/14/interpol-pharma-join-hands-against-the-crime-of-fake-pharmaceuticals/

Saez, Catherine (2014), 'ITU Looks Into Issues Of Counterfeit, Substandard ICT Products', *Intellectual Property Watch 18/11/2014*, [online: web], accessed 5 July 2017, URL: https://www.ip-watch.org/2014/11/18/itu-looks-into-issues-of-counterfeit-substandard-ict-products/

Saez, Catherine (2015), 'Medicrime Convention Against Counterfeit Drugs To Enter Into Force In 2016', *Intellectual Property Watch*, 01/10/2015, [online: web] accessed 5 July 2017, URL: https://www.ip-watch.org/2015/10/01/medicrime-convention-against-counterfeit-drugs-to-enter-into-force-in-2016/

Saez, Catherine (2016), 'WHO Group Suggests New Name for Falsified Medicines, Dropping 'Counterfeit', *Intellectual Property Watch*, 28/11/2016 [online: web], accessed 5 July 2017, URL: https://www.ip-watch.org/2016/11/28/group-suggests-new-name-falsified-medicines-dropping-counterfeit/

Samuelson, Pamela (1996), *The U.S. Digital Agenda at WIPO*, 37 *Va. J. Int'l L.* 369, [online: web] visited 5 July 2017, URL: http://scholarship.law.berkeley.edu/facpubs/882

Samassékou, Adama (2006), 'Foreword' , in *Human Rights in the Global Information Society*, Rikke Frank Jørgensen (ed.), Cambridge, Massachusetts; London, England: The MIT Press

Sanders, Anselm Kamperman (2007), "The Development Agenda for Intellectual Property Rational Humane Policy or 'Modern-day Communism'?" in Christopher Heath and Anselm Kamperman Sanders (eds.), *'Intellectual Property and Free Trade Agreements',* Oxford and Portland, Oregon: Hart Publishing.

Schonwetter, Tobias et al. (2010), "Copyright and Education: Lessons on African Copyright and Access to Knowledge", *The African Journal of Information and Communication* 10: 37-52

Scotchmer, Suzanne (2004), *Innovation and Incentives*, Cambridge, Massachusetts& London, England: The MIT Press.

Sell, Susan (2003), '*Private Power Public Law- The Globalization of Intellectual Property Rights*', Cambridge and New York: Cambridge University Press

Sell, Susan K. (2008), "The Global IP Upward Ratchet, Anti-Counterfeiting and Piracy Enforcement Efforts" 9 June 2008, (unpublished paper), [Online: web] accessed 5 July 2017, URL: http://ip-watch.org/files/SusanSellfinalversion.pdf

Shankar, Ramesh (2008), "WHO's new definition of counterfeit drugs intended to hurt Indian co. s: IPA", *Pharmabiz*, 19 November, [online: web] accessed 5 July, 2017, URL: http://www.pharmabiz.com/article/detnews.asp?articleid=47036&sectionid=&z=y

Shashikant, Sangeeta and Riyaz Tayob (2008), "Development: UN postal agency being roped in to enforce IPR agenda", TWN Info Service on Intellectual Property Issues (Aug08/01) 8 August, *Third World Network*. Published in *SUNS* #6534, 8 August, [online: web] accessed 5 July 2017, URL: https://www.twn.my/title2/intellectual_property/info.service/2008/twn.ipr.info.080801.htm

Spinello, Richard A. (2009) and Maria Bottis, '*A Defence of Intellectual Property Rights*', Cheltenham, UK • Northampton, MA, USA: Edward Elgar

Staake, Thorsten and Elgar Fleisch (2008), *Countering Counterfeit Trade: Illicit Markets Insights, Best Practice Strategies, and Management Toolbox*, Germany: Springer- Verlag.

Stewart, W J and Robert Burgess (eds.) (2002), *Dictionary of the Law*, Second Edition, New York: HarperCollins

Stiglitz, Joseph (2008), 'Economic Foundations of Intellectual Property Rights', *52 Duke Law Journal 1693*

**Stop Online Piracy Act*, H.R. 3261, 112th Cong. (2011)

Strategy for the Enforcement of Intellectual Property Rights in Third Countries, (2005/C 129/ 03) OJ C129

Su, Evelyn (2000), 'The Winners and the Losers: The Agreement on Trade Related Aspects of Intellectual Property Rights and Its Effects on Developing Countries,' *23:1 Houston Journal of International Law*

Suber, Peter (2007), 'Creating an Intellectual Commons through Open Access' in *Understanding Knowledge as a Commons: From Theory to Practice*, Charlotte Hess and Elinor Ostrom (eds.), Cambridge, Massachusetts London, England: The MIT Press

Sunder, Madhavi (2006), 'IP^3', *Stanford Law Review*, 59 (2): 257-332

Suthersanen, Uma (2005), 'Education, IPRs and Fundamental Freedoms: The Right to Knowledge', research paper at UNCTAD / ICTSD / BA Regional Arab Dialogue "*Intellectual Property Rights (IPRs), Innovation and Sustainable Development*" 26 – 28 June, Alexandria, Egypt. [Online: web] accessed 5 July 2017, URL: http://www.iprsonline.org/unctadictsd/docs/Suthersanen_A2K.pdf

Symposium: Trade-Related Aspects of Intellectual Property (1989)**,** *Vanderbilt Journal of Transnational Law*, 22: 370

**The Berne Convention on the Protection of Literary and Artistic Works*, 1886, as last revised at Paris on July 24, 1971 [amended in 1979], 1161 U.N.T.S. 30

**The Copyright (Amendment) Act 2012 [No 27 of 2012]*, passed 22 May 2012; brought into force 7 June 2012

**The Customs Act 1962 [No. 52 of 1962],* December 13, 1962, entry into force February 1, 1963

**The Paris Convention on the Protection of Industrial Property*, 1883, as last revised at the Stockholm Conference, July 14, 1967, 21 U.S.T 1583; 828 U.N.T.S. 303

**The Partnership Agreement between the members of the African, Caribbean and Pacific Group of States of the one part, and the European Community and its Member States of the other part"* or the *Cotonou Agreement*, O.J. L 287, 04 November 2010

**The Polo Lauren Company LP v. PT. Dwidua Langeng Pratana International Freight Forwarders*, ECJ 6.4.2000, Case C-383/98, ECR [2000]; I-2519, GRUR Int. 2000, 748; IIC 2001, 209.

Third World Network (2014), "Fraudulent medicines model law promotes pharma interest", TWN Info Service on Intellectual Property Issues (Dec14/01) 8 December 2014, [online: web] accessed 5 July 2017, URL: http://twn.my/title2/intellectual_property/info.service/2014/ip141201.htm

*Thirty-Eighth Session at Ministerial Level Ministerial Declaration, GATT BISD, 30th Supp. At 9 (1983)

Thomas Cottier and Peter Veron (eds.) (2008), *Concise International and European IP Law- TRIPS, Paris Convention, European Enforcement and Transfer of Technology,* The Netherlands: Kluwer Law International.

**Trade in Counterfeit Goods- Fortieth Session of the CONTRACTING PARTIES- Action Taken on 30 November, 1984* (GATT Doc. No. L/5758 (20 December, 1982).

*TRADE MARKS ACT, 1999 [Act No. 47 of Year 1999 dated 30th. December, 1999]

Trimble, Marketa (2012), *Global Patents: Limits of Transnational Enforcement*, New York: Oxford University Press.

Uhlir, Paul (2003), 'Discussion Framework' of 'Session 1: The Role, Value, and Limits of Scientific and Technical (S&T) Data and Information in the Public Domain' in *The Role of Scientific and Technical Data and Information in the Public Domain Proceedings of a Symposium*, Julie M Esanu and Paul F. Uhlir (eds.) Washington D.C.: The National Academic Press.

UNCTAD (2005), United Nation Conference on Trade and Development, *Resource Book on TRIPS and Development -UNCTAD-ICTSD*, Cambridge & New York: Cambridge University Press.

UNCTAD (2010), *Development Dimensions of Intellectual Property in Uganda: Transfer of Technology, Access to Medicines and Textbooks- A Report by the UNCTAD-ICTSD Project on Intellectual Property Rights and Sustainable Development,* Geneva: UNCTAD.

UNCTAD-ICTSD (2005), *Resource Book on TRIPS and Development*, New York: Cambridge University Press

UNESCO (2006), 'Anti-Piracy Training for Trainers (APTT) in Namibia' First workshop held in September 2006, [Online: Web] accessed 5 July 2017, URL: http://portal.unesco.org/en/ev.php-URL_ID=34227&URL_DO=DO_TOPIC&URL_SECTION=201.html

UNICRI (2012), *Counterfeit Medicines and Organised Crime* , United Nations Interregional Crime and Justice Research Institute- Agenzia Italiana del Farmaco (Italian Pharmaceutical Agency), emerging crimes emerging policies series, Advanced Unedited Edition, Turin, Italy [Online: Web] accessed 5 July 2017 URL: http://www.unicri.it/topics/counterfeiting/medicines/report/Ctf_medicines_and_oc_advance_unedited2013.pdf

UNICRI News (2007), 'A global answer to a growing phenomenon' 14 December 2007, [Online: Web] accessed 5 July 2017, URL: http://www.unicri.it/news/article/0712-3_counterfeiting_crt_foundation

*UNESCO (2003), 'Recommendation Concerning the Promotion and Use of Multilingualism and Universal Access to Cyberspace', UNESCO, Paris. [Online: Web] Accessed 5 July 2017, URL: http://www.unesco.org/new/fileadmin/MULTIMEDIA/HQ/CI/CI/pdf/recommendation_promotion_use_multilingualism_and_universal_access_to_cyberspace_en.pdf

*United Nations Department of Economic and Social Affairs, UNCTAD Secretariat (1974), '*The Role of the Patent System in the Transfer of Technology to Developing Countries*', U.N. Doc. No. TD/B/AC.11/19 (1974)

**United States – Australia Free Trade Agreement,* [online: web] accessed 5 July 2017, URL: https://ustr.gov/trade-agreements/free-trade-agreements/australian-fta/final-text

*_United States Goals for New Multilateral Trade Negotiations_, GATT Doc. L/5846, 12 July 1985.

United States Government Accountability Office (2010), '_Observations on Efforts to Quantify the Economic Effects of Counterfeit and Pirated Goods'_, Report by the Government Accountability Office as part of the Prioritizing Resources and Organization for Intellectual Property Act of 2008. April 12, 2010.

*_United States – Chile Free Trade Agreement_, [online: web], accessed 5 July 2017, URL: https://ustr.gov/trade-agreements/free-trade-agreements/chile-fta/final-text

*_United States – Columbia Trade Promotion Agreement_, [online: web], accessed 5 July 2017, URL: https://ustr.gov/trade-agreements/free-trade-agreements/colombia-fta/final-text

*_United States – Morocco Free Trade Agreement, [online: web],_ accessed 5 July 2017, URL: https://ustr.gov/trade-agreements/free-trade-agreements/morocco-fta/final-text

*_United States – Panama Trade Promotion Agreement_, [online: web], accessed 5 July 2017, URL: https://ustr.gov/trade-agreements/free-trade-agreements/panama-tpa/final-text

*_United States – Peru Trade Promotion Agreement_, [online: web], accessed 5 July 2017, URL: https://ustr.gov/trade-agreements/free-trade-agreements/peru-tpa/final-text

*_United States – Singapore Free Trade Agreement_ [online: web] accessed 5 July 2017, URL: https://ustr.gov/trade-agreements/free-trade-agreements/singapore-fta/final-text

*_Universal Copyright Convention_ as revised at Paris on 24 July 1971, with Appendix Declaration relating to Article XVII and Resolution concerning Article XI 1971 [online: web] accessed 5 July 2017, URL: http://portal.unesco.org/en/ev.php-URL_ID=15241&URL_DO=DO_TOPIC&URL_SECTION=201.html

*UNODC (2011) 'Resolution 20/6 Countering fraudulent medicines, in particular their trafficking', [online: web] accessed 5 July 2017, URL: https://www.unodc.org/documents/commissions/CCPCJ/Crime_Resolutions/2010-2019/2011/CCPCJ/Resolution_20-6.pdf

*UNODC (2014), 'UNODC Draft Model Legislative Provisions on Fraudulent Medical Products Working Document,' Draft of 17 November 2014 [online: web] accessed 5 July 2017, URL: http://www.ip-watch.org/weblog/wp-content/uploads/2014/12/UNODC-Model-Law-17-Nov-2014.docx

UNODC (2010), '_The Globalization of Crime: A Transnational Organized Crime Threat Assessment_', United Nations Office on Drugs and Crime, Vienna: Austria.

UNODC (2012), Press release: 'UN drugs and crime office, World Customs Organization make a dent in counterfeit goods and drug shipments', Vienna, 29 June, [online: web] accessed 5 July 2017, URL:

http://www.unodc.org/unodc/en/press/releases/2012/June/un-drugs-and-crime-office-world-customs-organization-make-a-dent-on-counterfeit-goods-and-drug-shipments.html

UNODC (2013), 'Technical Conference on the Trafficking in Fraudulent Medicines Agenda', [online: web] accessed 5 July 2017, URL: https://www.unodc.org/documents/organized-crime/FM/Agenda_EN.pdf

UNOHCHR News (2016), 'Statement by the Independent Expert on the promotion of a democratic and equitable international order, Alfred de Zayas, on the upcoming signing the Trans-Pacific Partnership', [online: web] accessed 5 July 2017, URL: http://www.ohchr.org/EN/NewsEvents/Pages/DisplayNews.aspx?NewsID=17005&LangID=E

UPU (2008), 'UPU and the Challenges of Counterfeit Products', a power-point presentation made by Mr. B.A. Khan, Customs and Airmail expert, Berne, Switzerland, [Online: web] accessed 5 July 2017, URL: http://www.slideserve.com/karlyn/upu-and-the-challenges-of-counterfeit-products

UPU (2015), Universal Postal Union, "General information on UPU standards", 28 January, [online: web] accessed 5 July 2017, URL: https://www.upu.int/uploads/tx_sbdownloader/GeneralInformationOnUpuStandards.pdf

Usher, Ann Danaiya (2013), 'Global Fund pledges fall short of expectations', *The Lancet*, 382: 9910 (50), 21 December 2013 [online: web], accessed 5 July 2017, URL: http://www.thelancet.com/journals/lancet/article/PIIS0140-6736%2813%2962661-6/fulltext

USTR (2007a), 'Trade Facts', "Fact Sheet: Anti-Counterfeiting Trade Agreement", October 2007, [online: web] accessed 5 July 2017, URL: https://www.eff.org/files/filenode/EFF_PK_v_USTR/foia-ustr-acta-response1-doc7.pdf

USTR (2007b), "Ambassador Schwab Announces U.S. Will Seek New Trade Agreement to Fight Fakes", *USTR Press Release*, October, [Online: Web] Accessed 5 July 2017, URL: https://ustr.gov/ambassador-schwab-announces-us-will-seek-new-trade-agreement-fight-fakes

USTR (2009), The Anti-Counterfeiting Trade Agreement - Summary of Key Elements Under Discussion', [online: web] accessed 5 July 2017, URL: https://ustr.gov/sites/default/files/uploads/factsheets/2009/asset_upload_file917_15546.pdf

Vander, Sascha (2009), 'Enforcement of Intellectual Property Rights' in Stoll, Peter-Tobias, Jan Busche and Katrin Arend (eds.), *WTO – Trade-Related Aspects of Intellectual Property Rights*, in Max Planck Commentaries on World Trade Law, Rüdiger Wolfrum and Peter-Tobias Stoll (eds.), Leiden& Boston: Max Planck Institute for Comparative Public Law and International Law& Martinus Nijhoff Publishers.

Viana, Liza Porteus (2007), 'Top Economies To Negotiate Anti-Counterfeiting Trade Pact', *Intellectual Property Watch24/10/2007*, accessed 5 July 2017, URL: https://www.ip-watch.org/2007/10/24/top-economies-to-negotiate-anti-counterfeiting-trade-pact/

Vida, A. (1981), '*Trademaks in Developing Countries*', Philip Thomas Mitches (ed.), Translated by Eva Ruszthy, Budapest, Hungary: Licensing Executive Society International.

Villarreal, M. Angeles and Jennifer E. Lake (2009), '*Security and Prosperity Partnership of North America: An Overview and Selected Issues*', Congressional Research Service Report for Congress [Online: Web] Accessed 19 Nov 2015, URL: http://fas.org/sgp/crs/row/RS22701.pdf

Wadhams, Nicholas (2009), "Kenya Pressured to Implement Anti-Counterfeit Law Despite Access Fears," *Intellectual Property Watch,* 0/07/2009, [online: web] accessed 5 July 2017, URL: https://www.ip-watch.org/2009/07/02/kenya-pressured-to-implement-anti-counterfeit-law-despite-access-fears/

Waelde, Charlotte and Hector MacQueen (2007), *Intellectual Property: The Many Faces of the Public Domain*, Cheltenham, UK & Northampton, MA, USA: Edward Elgar

Walterbach, Maureen (2007), "International Illicit Convergence: the Growing Problem of Transnational Organised Crime Groups Involvement in IP Rights Violations", *Florida State University Law Review*, 34:591.

Watal, Jayashree (2001), *Intellectual Property Rights in the WTO and Developing Countries*, New Delhi: Oxford University Press.

Watal, Jayashree (2002), 'Implementing The TRIPS Agreement', in Bernard Hoekman, Aaditya Mattoo, and Philip English (eds.) *Development, Trade And The WTO*, Washington DC: The World Bank

Watal, Jayashree (2010), 'US-China Intellectual Property Dispute – A Comment on the Interpretation of the TRIPS Enforcement Provisions' *The Journal of World Intellectual Property 13(5): 605-619*

WCO (2007a), World Customs Organization, June, SECURE, Provisional Standards Employed by Customs for Uniform Rights Enforcement (SECURE) [Provisional Global Customs Standards to Counter Intellectual Property Rights Infringements]

WCO (2007b), World Customs Organization, 'Customs and postal authorities to intensify cooperation', Press release, Brussels 7 September, [Online: Web] Accessed 5 July 2017, URL: http://www.wcoomd.org/en/media/newsroom/2007/october/customs-and-postal-authorities-to-intensify-cooperation.aspx

WHO (1999), 'Guidelines for the Development of Measures to Combat Counterfeit Drugs', [Online: Web], Accessed 5 July 2017, URL: http://www.who.int/medicines/publications/counterfeitguidelines/en/

WHO (2003), World Health Organization, Fact Sheet no. 275, 'Substandard and Counterfeit Medicines November, World Health Organization, [Online: web] Accessed 5 July 2017, URL: http://www.globalforumljd.org/sites/default/files/docs/library/WHO-Substandard%20and%20counterfeit%20medicines.pdf

WHO (2005), "*Constitution of the World Health Organization*" (Amended 15 September 2005), Geneva: World Health Organization

WHO (2006), 'WHO and partners accelerate fight against counterfeit medicines', WHO Media Centre 15 November 2006, Geneva, [online: web] accessed 5 July 2017, URL: http://www.who.int/mediacentre/news/releases/2006/pr69/en/

WHO (2008), *Counterfeit Medical Products*, Report by the Secretariat, 18, EB124/14, [Online: Web], accessed 5 July 2017, URL: http://apps.who.int/iris/bitstream/10665/2121/1/B124_14-en.pdf

WHO (2010), WHA63/2010/REC/1, World Health Organization Sixty-Third World Health Assembly Geneva, 17–21 May 2010, Resolutions And Decisions Annexes, Geneva 2010 [Online: Web], accessed 5 July 2017, URL: http://apps.who.int/gb/ebwha/pdf_files/WHA63-REC1/WHA63_REC1-en.pdf

WHO (2012), WHA65/2012/REC/1, World Health Organization Sixty-Fifth World Health Assembly Geneva, 21–26 May 2012, Resolutions And Decisions Annexes, Geneva 2012 [online: web], accessed 5 July 2017, URL: http://www.who.int/entity/medicines/services/counterfeit/mechanism/WHA65.19_extract.pdf?ua=1

WHO (2016), 'Fifth Meeting Of The Member State Mechanism On Substandard/ Spurious/ Falsely-Labelled/ Falsified/ Counterfeit Medical Products', A/MSM/5/7, 23 November 2016, [online: web] accessed 5 July 2017, URL: http://apps.who.int/gb/ssffc/pdf_files/MSM5/A_MSM5_7-en.pdf

WHO (2017a), Seventieth World Health Assembly, Provisional Agenda Item 13.6, 'Member State mechanism on substandard/ spurious/ falsely-labelled/ falsified/ counterfeit medical products: Report by the Director-General', A70/23, 20 March 2017, [online: web] accessed 5 July 2017, URL: http://apps.who.int/gb/ebwha/pdf_files/WHA70/A70_23-en.pdf

WHO (2017b), World Health Organisation, Media centre 'Seventieth World Health Assembly update, 29 May 2017', News release 29 May 2017, Geneva, [online: web] accessed 5 July 2017, URL: http://www.who.int/mediacentre/news/releases/2017/dementia-immunization-refuguees/en/

Wilson, Jeremy M and Rod Kinghorn (2015), "The Global Risk of Product Counterfeiting: Facilitators of the Criminal Opportunity", *Michigan State University Center for Anti-Counterfeiting and Product Protection (A-CAPP) Backgrounder*, February 2015.

*WIPO (1996), 'WIPO Copyright Treaty (WCT) adopted by the Diplomatic Conference on December 20, 1996' WIPO Doc. CRNR/DC/89 (December 20, 1996), WIPO, Geneva

*WIPO (1996), 'WIPO Performances and Phonograms Treaty, adopted by the Diplomatic Conference on December 20, 1996', WIPO Doc. CRNR/DC/90 (Dec. 20, 1996) WIPO, Geneva

WIPO (2002), '*Report adopted by the Assembly*', WIPO GENERAL ASSEMBLY Twenty -Eighth (13th Extraordinary) Session, Geneva, September 23 to October 1, 2002, WO/GA/28/7, WIPO Geneva

WIPO (2004), World Intellectual Property Organisation, *WIPO Intellectual Property Handbook: Policy, Law and Use*, [Online: Web] accessed 5 July 2017, URL: http://www.wipo.int/edocs/pubdocs/en/intproperty/489/wipo_pub_489.pdf /

WIPO (2007), World Intellectual Property Organization, 'Member States adopt a Development Agenda for WIPO', Geneva, October 1, 2007, PR/2007/521 [Online: Web] Accessed 5 July 2017, URL: http://www.wipo.int/pressroom/en/articles/2007/article_0071.html

WIPR (2014), 'UN launches anti-counterfeiting drive', *World Intellectual Property Review 14 01 2014,* [Online: Web] accessed 5 July 2017, URL: http://www.worldipreview.com/news/un-launches-anti-counterfeiting-drive

World Bank (2005), *Global Economic Prospects Trade: Regionalism, and Development*, World Bank: Washington DC.

World Commerce Review (2009), Preview of the Fifth Global Congress on Combating Counterfeiting and Piracy, Cancun, Mexico, 2-4 June, *World Commerce Review*, 3: 1

*World Trade Organization (2001), *Declaration on the TRIPS Agreement and Public Health*, WT/MIN(01)/DEC/2, 20 November 2001, adopted 14 November 2001.

*World Trade Organization (2001), *Ministerial Declaration of 14 November 2001* (Doha Declaration), WTO Doc No. WT/MIN (01)/DEC/W/2, 41 I.L.M. 746 (2001)

*World Trade Organization, 'Declaration on the TRIPS Agreement and Public Health', WT/MIN(01)/DEC/2 (2002)

*WSIS (2003), World Summit on the Information Society (WSIS), First Phase at Geneva, Geneva Declaration of Principles: Building the Information Society: A Global Challenge in the New Millennium (10–12 December 2003) WSIS-03/ GENEVA/DOC/4-E, WSIS, Geneva

*WSIS (2005), World Summit on the Information Society (WSIS), Second Phase at Tunis, Tunis Agenda for the Information Society (18 November 2005) WSIS-05/TUNIS/DOC/6(Rev. 1)-E, WSIS, Tunis

WTO (2009), "Panel Report, *China—Measures Affecting the Protection and Enforcement of Intellectual Property Rights*, WT/DS362/R (Jan. 26, 2009) (adopted

Mar. 20, 2009)", [online: web] accessed 5 July 2017, URL: https://www.wto.org/english/tratop_e/dispu_e/find_dispu_cases_e.htm#results

Xinhua (2013), "Family claims iphone killed daughter", 2013-07-14, *Xinhua* [online: web] accessed 5 July 2017, URL: http://www.chinadaily.com.cn/china/2013-07/14/content_16774373.htm

Yamey, Gavin (2008), 'Excluding the Poor from Accessing Biomedical Literature: A Rights Violation That Impedes Global Health', *10:1 Health and Human Rights: 21-42*

Yao, Jen-Te (2005), "Counterfeiting and an Optimal Monitoring Policy", *European Journal of Law and Economics*, 19 (1): 95–114.

Yu, Peter K (2004), "Currents and Crosscurrents in the International Intellectual Property Regime", *Michigan University College of Law Legal Studies Research Paper Series*, Research Paper No.02-12

Yu, Peter K. (2016), The RCEP and Intellectual Property Norm-setting in the Asia-Pacific (July 16, 2016). INTELLECTUAL PROPERTY RIGHTS AND MEGA-REGIONAL TRADE AGREEMENTS (Global Perspectives and Challenges for the Intellectual Property System, CEIPI-ICTSD Publication Series No. 4), 2016. Available at SSRN [online: web], accessed 5 July 2017, URL: https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2810579

Zhang, Liguo & Niklas Bruun (2017), 'Legal Transplantation of Intellectual Property Rights in China: Resistance, Adaptation and Reconciliation', *IIC 48: 4–41*

Biber-Klemm, Susette and Danuta Szymura Berglas (2006), 'Problems and Goals', in Susette Biber-Klemm, Thomas Cottier (eds.) *Rights to Plant Genetic Resources and Traditional Knowledge Basic Issues and Perspectives*, Oxfordshire, UK: CABI