



FACULTY OF LAW
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[Patent Right and Access to Medicine]

Master thesis
30 credits

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Master's Programme in International Human Rights Law and
Intellectual Property Law

[Fall 2010]

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Summary

The reasons for the lack of access to essential medicines are manifold, but in many cases the high price of drugs is a barrier to needed medicines. The unaffordable prices of drugs are often the result of strong intellectual property protection.

This thesis lay out the conflicts between patent right protection and access to medicine as human right, especially the impact of TRIPS Agreement on the availability and prices of drugs in developing countries. Previously many developing countries allowed only for limited patent protection in pharmaceutical products, but the TRIPS Agreement brought a big change and makes the granting of patents for pharmaceuticals obligatory in the member states. The issue in terms of patents and access to drugs has drawn large attention of a wider public and intrigued a global thinking.

The patent provisions in TRIPS have been subjected to much criticism for failing to reach an appropriate balance with respect to patent protection and access to life-saving medicines in developing and least-developed countries. It was also criticized that the provisions in TRIPS Agreement are more in favor of owners of intellectual property to facilitate global trade. Although TRIPS does offer safeguards to remedy negative effects of patent protection or patent abuse, in practice it is unclear whether and how countries can make use of these safeguards when patents increasingly present barriers to medicine access.

Access to medicine as human right – right to life, right to health and right to enjoy the benefits of scientific progress and its application -- should be protected since these fundamental human rights are embed in various international human rights convention and instruments. The state party hold human rights obligation to promote access to essential medicines, and the private sectors are also accountable to respect human rights and make contribution to promote access to essential medicines.

The human rights based approach to intellectual property rights, as a solution to alleviate people's suffering from lack of access to medicines, requires a balance between public interest and legitimate interests of the patent owner. However, human rights primacy doesn't mean patent holder's interests were push into the background. It converts the patent right from a property rule (right to exclude) to a liability rule (right to be paid) in the specific situation where human rights protection is needed to increase access to medicines.

Preface

My supervisor Anna Maria Nawrot gave me very helpful suggestions on constructing logic framework for my thesis writing. She encouraged me to discuss this problem from not only legal perspective but also social movement perspective, and encouraged me to give my own definition of “Access to medicine” although there is a lack of standard and authoritative definition. I would like to thank her always support.

Abbreviations

“Doha Declaration”	The 2001 Doha Declaration on the TRIPS Agreement and Public Health
ECHR	European Convention on Human Rights
ECtHR	European Court of Human Rights
EFTA	European Free Trade Association
EPC	Convention on the Grant of European Patents
EPO	European Patent Office
FTA Watch	Free Trade Agreement Watch
GATT	General Agreement on Tariffs and Trade
ICCPR	International Covenant on Civil and Political Rights
ICESCR	International Covenant on Economic, Social and Cultural Rights
MPEP	Manual of Patent Examining Procedure
MSF	Médecins sans Frontières
OECD	Organization of Economic Cooperation and Development
Paris Convention	Paris Convention for the Protection of Industrial Property (1883)
PCT	Patent Cooperation Treaty
TRIPS Agreement	Agreement on Trade-Related Aspects of Intellectual Property Rights
UNCSECR	U.N. Committee on Social, Economic and Cultural Rights
UNDP	United Nations Development Programme
USTR	U.S. Trade Representative
VDPA	Vienna Declaration and Programme of Action
WHO	World Health Organisation
WIPO	World Intellectual Property Organisation

1 Introduction

1.1 Background

Over the last decades, public health and development issues have become topics of great international concern. Public health in many parts of the world has reached crisis level: over hundreds of millions people are killed by infectious disease, HIV/AIDS, malaria, and other lesser known disease each year, and most of which are predominantly affect developing countries. However, most illness, especially infectious disease are preventable or treatable with existing medicines, but large numbers of people, particularly in developing countries, became victim due to lack of access to medicines. The World Health Organization estimates that over 1.7 billion people – nearly one third of the world’s population – have inadequate or even no access to essential medicines and the lack of access is particularly concentrated in Africa and India.¹ It is an urgent time for the world to comes together to resolve the public health crisis, especially the vicious cycle between poverty and illness.

The public debate on the issue is most concentrated on the health-related issues of developing countries, more particularly, the conflicts between patent regulations under Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and the lack of accessibility and affordability to much needed drugs. Until 1994 the problem was not acute, because up to that time states decided what could be patented or not in tier country. Many countries chose not to grant patent for pharmaceutical products, which enable their infant industries to freely copy the products and produce them. However in 1994 this situation changed since the adoption of TRIPS Agreement requires member states of World Trade Organization (WTO) to grant patent “for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve and incentive step and are capable for industrial application”.² In other words, they cannot exclude certain fields of technology from patentability, including pharmaceutical products.

Another question is the patent rights owners sell patented products at price that many people could not afford it and therefore determines who has access to essential life-saving medicines and who has not. Many people think it is unfair. In their view, patent rights are instruments used by western

¹ WORLD HEALTH ORGANIZATION (WHO), THE WORLD MEDICINES SITUATION 61 (2004), p.61-63; Available at: http://www.searo.who.int/LinkFiles/Reports_World_Medicines_Situation.pdf (search date: 02/03/2010)

² Agreement on Trade-Related Aspects of Intellectual Property Rights (“The TRIPS Agreement”), article 27, para.1. The TRIPS Agreement is Annex 1C of the Marrakesh Agreement Establishing the World Trade Organization, signed in Marrakesh, Morocco on 15 April 1994.

pharmaceutical companies to charge unaffordable prices for commercial interests.

1.2 Research Questions

There are many factors determine the public health crisis and the complex question regarding lack of access to medicine. This thesis aims to give an overview of the intension between patent protection and access to medicine, especially the implication of TRIPS Agreement on the pharmaceutical sector in developing countries. A lot of fundamental questions need to be answered: Is there any conflict between patent rights protection and access to medicine? How does the conflict arise? What is the substance of the conflict? Does responsibility for a substandard public health system lie on the government? But who is responsible for the violation on such human right of access to medicine, and what is the remedy? What are the options for resolving the conflict and how to find a balance between pressing public health needs and legitimate private intellectual property interests? How to build up human rights-based approach into intellectual property law to mitigate the suffering?

1.3 Objective and Methodology

The thesis is examined in the introductory and comparative method. In order to answer the above-mentioned questions, an examination of the legislation, case law and legal literature on a national, regional and international level (within the framework of the various patent treaties and international human rights conventions) have been undertaken.

It will investigate the problem of access to pharmaceuticals in the context of intellectual property rules and human rights. The attention is paid to specific aspects of human rights attributes of intellectual property rights, and then it will make a comparison between the human rights attributes of patent law and international human rights law, since the common social goals of protect public interests set forth in both patent law and international human rights law. Based on the discovered human rights attributes, the thesis tries to find a balance between the interests of public health and the interests of the patentee and to resolve the conflicts between them.

This thesis does not venture an exhaustive exploration of the empirical evidence and materials relating to access to medicine. Instead, it examines the legal mechanism as groundwork for possible ways to resolve the tension, and build up human rights based approach to intellectual property right as remedy mechanism for promoting access to essential medicines.

1.4 Delimitation

Except constructing appropriate patent regulation, many other factors, which have created and continue to perpetuate the ongoing health crisis in developing countries, need to be taken into consideration to alleviate the suffering from devastating health crisis, such as logistical supply and storage problems, substandard drug quality, inappropriate selection of drugs, wasteful prescription and inappropriate use, inadequate production, and prohibitive prices and the pressure posted by developed countries and multinational pharmaceutical companies to prevent developing countries to bring down the price of medicines.

The multi-sided solutions to this problem come across broad spectrum: on one hand, internally in the developing countries, how to get financial resources to build and maintain access to medicines and proper healthcare system, improve living conditions, satisfy the needs for food and clean water to remove some of the conditions leading to illness and disease, minimize the effects of poor economic planning and policies, transfer technology in developing countries and build up a competent local pharmaceutical industry, run-down the information gap, introduce genetic competition to reduce the price of drugs, reduce society problems and disruption such as corruption, work out proper means for distributing and administering medicine, reduce disproportionate tariffs and taxes on the importation of essential medicines, and how to remove the physical and infrastructure barriers due to resources limits.

On the other hand, externally, how to achieve international cooperation on a massive scale to not only ensure that the developing world has access to essential medicines but to also create incentives to stimulate or directly fund research and development into new medicines and vaccines to treat the neglected disease primarily affecting the developing world, as well as the government in developing countries would like to make political commitment to control and alleviate the problem and prioritize healthcare.

How to promote access to medicine and find solution to alleviate the suffering from lack of essential medicine is a very complex issue involving in the analysis from various perspectives: political, economic, scientific, legal, cultural etc. It is time-consuming and difficult to discuss it in a comprehensive way from different angles. Thus this thesis just focuses on studying the barrier to access to medicine causing by patent protection, especially the problems arising from patent regulation in TRIPS Agreement.

1.5 Structure

The thesis is divided into 4 parts. In the first part (Chapter 2), before examining the legal questions raised in detail with respect to the paradox between human rights and intellectual property rights, it is worthwhile to presenting some significant events, in particular the HIV/AIDS pandemic

issues, which brought the issue to stand at the forefront of the international debate.

In the second part (Chapter 3), the thesis analyzes the patent law framework with respect to access to medicine, and explores the human rights attributes – morality and social interests – of patent rights under national patent law, and international patent law with a focus on patent regulations in TRIPS Agreement, since intellectual property contract is social contract and intellectual property product is social product.

In the third part (Chapter 4), the thesis defines “access to medicine” and study legal sources international human rights law. It considers access to medicine as human rights: right to life, right to health, and right to enjoyment of the benefits of scientific progress and its application. In this part the thesis also set forth the state party’s human rights obligation to promote access to medicine. It studies the justiciability of Civil and Political Rights as well as Economic, Social and Cultural Rights, and argues that the violation on right to access to medicine as human right shall be protected and repaired.

The last part strikes the balance between patent protection for pharmaceutical products and access to medicine as human rights. It accordingly argues human rights based approach to intellectual property rights should be established as one kind remedy mechanism, such as incorporating TRIPS flexibility into national intellectual property law to promote access to medicine, and suggests human rights based approach to medicine as one solution for alleviating public health crisis.

2. Big Events of the Debate

Before examining the legal questions raised in detail, it is worthwhile to present some of the events that have caused the issue to stand at the forefront of the international debate, and help us to understand the legal argument. Most of the events presented focus on the HIV/AIDS pandemic. The HIV/AIDS is currently the most important example of the conflict between patents and access to medicine, but it is not the only one. Other examples, such as Myriad Genetic's patent on breast cancer related gene brought a discussion on patent health in Canada.³

Since 1981 year in New York several young gay men were identified with an unusually aggressive case of a rare skin disease, AIDS has become a serious worldwide pandemic in a short time. According to estimates from the UNAIDS 2009 AIDS Epidemic Update, around 31.3 million adults and 2.1 million children were living with HIV at the end of 2008. During 2008, some 2.7 million people became infected with the human immunodeficiency virus (HIV), which causes AIDS. The year also saw 2 million deaths from AIDS - a high global total, despite antiretroviral (ARV) therapy, which reduced AIDS-related deaths among those who received it.⁴

Around half of the people who acquire HIV become infected before they turn 25, and AIDS is the second most common cause of death among 20-24 year olds. By the end of 2007, the epidemic had left behind 15 million AIDS orphans, defined as those aged under 18 who have lost one or both parents to AIDS. These orphans are vulnerable to poverty, exploitation and themselves becoming infected with HIV. They are often forced to leave the education system and find work, and sometimes to care for younger siblings or head a family.⁵

In many countries, life expectancy has dropped due to AIDS, e.g. in Cambodia it is estimated to be four years lower than it would have been without the disease.⁶ The devastating effects are felt in every sector of society: staggering numbers of AIDS orphans have to be supported, teachers ratio are reduced due to high infection rates among teaching staff, household income declines significantly where AIDS affects a working family

³ E.Richard Gold and DK Lam, "Balancing Trade in Patents – Public Non-Commercial Use and Compulsory Licensing", *Journal of World Intellectual Property*, January 2003, Vol.6, Issue 1, pp.5-31.

⁴ Please see "Worldwide HIV&AIDS Statistics Commentary", Website of AIDS Charity AVERT in action; Available at <http://www.avert.org/worlstatinfo.htm> (Search date: 09/03/2010)

⁵ George.C.Patton et al (2009), "Global patterns of mortality in young people: a systematic analysis of population health data", *Journal of The Lancet*, 12th September 2009, Vol.374, Issue 9693, pp.881-892.

⁶ UNAIDS, 2006 Report on the Global AIDS Epidemic, UNAIDS/06.20E, English original, May 2006, p.83.

member, economic growth suffers, health system are over stretched, and so on.

Typically, many of the countries affected already belonged to the poorest countries in the world before the advent of the pandemic. The overwhelming majority of people with HIV live in the developing world. Sub-Saharan Africa accounts for two-thirds of all infected people. South and South-East Asia has the second highest number of infected people⁷. However, even though Africa is hardest hit, other regions should not be lost from sight: the pandemic is spreading in America and Eastern Europe, too.

Undoubtedly, the public health has been endangered by the HIV/AIDS. However, the private company obtained a patent on the use of the drug against AIDS in several countries and priced the drug in such a way that many people could not afford it, causing an outcry by AIDS activists. The conflict is particularly remarkable in developing countries and South African pharmaceutical trial brought the issue of patents and access to drugs to the attention of a wider public.

In sub-Saharan Africa, more than three in four (76 per cent) AIDS-related deaths occur in the Saharan region. Today, these statistics have become gloomier with the rate of infection increasing on a daily basis. Worse still, the Saharan region accounts for 67 per cent of the world's least developed countries and millions of its inhabitants infected with HIV do not have access to medicines. In the Saharan region, prices charged for essential lifesaving drugs make the difference between life and death. Per capita annual incomes in these countries are as low as \$300/year, but a year's "treatment" of HIV/AIDS with patented, brand name antiretroviral can cost up to \$10,000 per person.⁸ The reasons for the lack of access to essential medicines are manifold, but in many cases, patent regulation has therefore put the price of life-saving drugs beyond the means of the masses. This gives credence to scholars who have argued against some of the assumptions used to justify the prevailing patent system.

On the other hand, government in developing countries that attempt to bring the price of medicines down have come under pressure from industrialized countries and multinational pharmaceutical industry. Local companies are also unwilling and unable to manufacture generic types of such antiretroviral vaccines, which may sell for less than \$200 a year per person, for fear of litigation from giant pharmaceutical patent holders.⁹

⁷ Please see "Worldwide HIV&AIDS Statistics Commentary", Website of AIDS Charity AVERT in action; Available at <http://www.avert.org/worlstatinfo.htm> (Search date: 10/03/2010).

⁸ See Joseph E. Stiglitz "Economic foundations of intellectual property rights", Duke Law Journal, Vol.57, page 1701 of 1693-1724.

⁹ See Poku Adusei "Regulatory Diversity as Key to the 'Myth' of Drug Patenting in Sub-Saharan Africa", JOURNAL OF AFRICAN LAW, VOL.54, No.1, (2010), P.34.

The topic burst into the global public spotlight in 2000 when 39 pharmaceutical companies took the South African government to court over its introduction of allegedly unlawful legislation, South African Medicines and Related Substances Control Amendment Act 1997, which gave the minister of health the right to import generic versions of patented drugs and allowed generics to be manufactured locally through compulsory licenses.¹⁰ In order to make medication affordable facing the fact that drug prices in South Africa were at times higher than in some developed countries,¹¹ provision of parallel imports of a drug was issued in the act 1997 to import patented drug without authorization by the patentee from a country where patentee placed the drug on the market at a lower price. Compulsory licenses authorized the third party to manufacture and sell the patented drug without the consent of the patentee, or to import the drug from a country where it has been put on the market by a third party manufacturer, in return for adequate remuneration for the patentee. This also caused the US trade representative to blacklist South Africa under the US Special 301 watch list, which lists the countries denying adequate and effective intellectual property protection.¹²

After this trial, the terms parallel importation, compulsory licensing, intellectual property, generic drugs and TRIPS (the World Trade Organization's agreement on trade-related aspects of intellectual property rights) became part of the vocabulary of many nongovernmental organizations and policy-makers seeking to improve access to medicines in the world's poorest countries.

¹⁰ HIGH Court of South Africa, *Pharmaceutical Manufacturers' Association of South Africa et al v President of the Republic of South Africa*, Case No 4183/98, Notice of Motion (1998).

¹¹ Statement by South Africa in Council for Trade-Related Aspects of Intellectual Property Rights, *Special discussion on Intellectual Property and Access to Medicines*, IP/C/M/31 (10 July 2001).

¹² See Patrick, Bond "Globalisation, pharmaceutical pricing, and South African health policy: Managing confrontation with US firms and politicians", *International Journal of Health Services*, Vol.29, Issue 4, (1999), p.765.

3. Access to Medicine in Patent Law framework

3.1 Development of National Patent Law

Patents for a long time were granted by national authority as an instrument to advance national development, not as a right of the inventor. Legislators have always endeavoured to achieve a balance in patent law to preserve its positive effects as an incentive for innovation while minimizing its negative effects, such as higher prices.

Although documents that can be referred to in modern terms as patent may go back as far as the ancient Greeks, the legal protection as we know it received its origin in the year 1474, when the Public of Venice issued the first patent statute to protect the inventor's ownership of all new and inventive devices putting into public use or practice, and forbade others to make the same or similar devices without the consent of the patentee for ten years. The legislator tried to achieve balance by allowing the government to take and use the device on the condition that no one but the patentee should operate it.¹³ The protection was justified in the preamble of the statute by arguing that it would induce more people to invent devices for the common good.

In England, the crown of England issued letters patent providing any person with a monopoly to produce particular goods or provide particular service. However, this power used to raise money for the crown was widely abused, because the Crown granted patents in respect of all sorts of common goods (e.g. salt). Consequently, the Parliament issued the statute of monopolies, in which restricted the Crown's power explicitly so that the King could only issue letters patent to the inventors or introducers of original inventions for a fixed number of years. The law was amended further in the reign of Queen Ann, around 1710, when it was required that a written description of the invention or process had to be submitted in order for a patent to be granted.¹⁴

Later centuries some other countries announced the establishment of patent system, such as the French Patent Act passed in 1791, the First patent Act of the US in 1790, establishment of a patent system in Australia in 1794, Russia followed in 1812, Sweden in 1834 etc.¹⁵

¹³ Holger Hestermeyer (2007), Human Rights and the WTO: The case of Patent and Access to Medicine, Oxford University Press, P.20, para.2.

¹⁴ See "The history of Patent Law", Wikipedia Website, available at http://en.wikipedia.org/wiki/History_of_patent_law (Search date: 06/03/2010).

¹⁵ See "The history of Patent Law", Wikipedia Website, available at http://en.wikipedia.org/wiki/History_of_patent_law (Search date: 06/03/2010)

However, in the second half of the 19th century the further spread of patent laws succumbed to a growing anti-patent mood connected to the free-trade movement of the 19th century. Patent, with their ability to exclude others from a country's market, were regarded as an impediment to free trade and therefore as harmful.¹⁶ Britain re-evaluated its patent system. The North German Federation decided not to adopt such a system and in Switzerland proposals for a patent system failed. In the Netherlands, opposition to patent laws was so fierce that the Dutch Patent Act was repealed in 1869.¹⁷ Switzerland and Netherlands both industrialized without a patent system.

With the end of the free-trade movement in the 1870s, the spread of patent law could continue, but some countries regulated large exceptions of patentability, on the purpose of developing economics.

From the history of patent law, we can find that the patent system was originally devised on a balance between the fairness of rewarding innovators and society interest. Patents were granted as means to promote the industrial advancement of the nation. The legislators have always tried to tailor patent laws to the goal of inducing the introduction of new knowledge within their territory with minimal disadvantages to society.

3.2 The Patentability of Pharmaceutical Product

The phrase "patent medicine" comes from the late 17th century marketing of medical elixirs, when those who found favor with royalty were issued letters patent authorizing the use of royal endorsement in advertising.¹⁸ "Patent medicine", originally referring to medications whose ingredients had been granted government protection for exclusivity, has become particularly associated with drug compounds in the 18th and 19th centuries.

Actually the recipes of most 19th century patent medicines were not officially patented, since attempting to monopolize a drug, medical device or medical procedures was considered unethical by standards upheld even during the era of patent medicine.¹⁹ Furthermore, most promoters sought to avoid of patenting these remedies which requires publicly disclosing its ingredients. Many industrialized countries used to be against granting product patent protection for pharmaceutical products until recently.

In the U.S., the larger proprietary medicine companies formed a national association to protect their interests against impending patent legislation

¹⁶ H.I. Dutton, "The patent system and inventive activity during the Industrial Revolution, 1750-1852", Manchester University Press, May 1984, p.24.

¹⁷ Eric, Schiff, "Industrialization without National Patents", Princeton University Press, 1971, P. 21.

¹⁸ See Wikipedia, "Patent History"; Available at: http://en.wikipedia.org/wiki/Patent_medicine (Search date: 08/03/2010).

¹⁹ See Wikipedia, "Patent History"; Available at: http://en.wikipedia.org/wiki/Patent_medicine (Search date: 08/03/2010).

concerning their products in the latter decades of the 19th century. The drugs have been patentable as chemical products since 1925 when the chemical patents came into use.²⁰ The US recognize two different forms of patent: the producing process of drugs may be patented independently of the chemical formula for the drug. Until 1984 the U.S. patent law treated medical discoveries in the same way as other innovations, and no special treatment was reserved for drugs.²¹

In most of the continent Europe, until recent years only the process of producing a drug could be patented. Before it was legal to produce the same drug in a different way of doing so, due to the negative social value which considered patenting a specific product, such as patenting a new pharmaceutical product, would exclude other from producing it, even through different processes. In Italy, pharmaceutical products and processes were not covered by patents until 1978; the same was in the Switzerland for processes until 1954 and for products until 1977.²²

In France, the patent law of 1844 excluded drugs from patentability until 1960, to ensure the patents of health products would not used for purely commercial purposes. This exclusion of “pharmaceutical compositions or remedies of all kinds” in the 1844 law did not extend to processes of preparation of remedies, which were patentable.²³ During the period of World War I, there was a debate on the patentability of pharmaceutical inventions and industrial property rights on chemical and pharmaceuticals, on the purpose of providing better incentive for the invention of new manufacturing techniques. Thus, the explicit recognition of pharmaceutical process patents was enshrined in 1944 French patent law.²⁴ Later, the executive Order of February 4, 1959, and then, the law of January 2, 1966 finally introduced limited patents for pharmaceutical products in France. The ban on patenting drugs was completely lifted only in 1978.²⁵

The first patent law which passed in Germany in 1877 introduced patents for both chemical and pharmaceutical processes, but excluded the patentability of pharmaceutical products. The Law of April 4, 1891 extended patent protection to products obtained via a patented process. Finally, the general patentability of chemical and pharmaceutical products was introduced by the law in 1967 in Germany.²⁶

²⁰ See Wikipedia, “Patent History”; Available at:

http://en.wikipedia.org/wiki/Patent_medicine (Search date: 08/03/2010).

²¹ Michele Boldrin and David K. Levine, “Against Intellectual Monopoly”, Cambridge University Press, 2008, Chapter 9. P.2.

²² Michele Boldrin and David K. Levine, “Against Intellectual Monopoly”, Cambridge University Press, 2008, Chapter 4, P.3

²³ Maurice Cassier, “Patents and public health in France: Pharmaceutical patent law in the making at the patent office between the two world wars”, History and Technology, Vol. 24, No. 2, June 2008, p.135.

²⁴ Ibid.

²⁵ Michele Boldrin and David K. Levine, “Against Intellectual Monopoly”, Cambridge University Press, 2008, Chapter 9. p.3.

²⁶ Ibid.

From the history of patent medicine, we can find that pharmaceutical products considered to be goods unlike any others were crucial. Thus the government took into account the social value of patentability of medicine and grant patent cautiously to balance the society's requirement. The rules and laws of patent law have traditionally been designed to achieve optimal balance between two ends: the reward of innovation and the social benefit related to patent monopolies. Even if today, except to consider promoting technology innovation, the general benefits of the public to enjoy right to health should not be ignored.

3.3 Development of International Patent Law

3.3.1 Paris Convention for the Protection of Industrial Property (1883)

Patent law on an international scale was boosted by the Paris Convention for the Protection of Industrial property in 1883 (Paris Convention), which aimed at harmonizing as far as possible intellectual property legislation in different countries. It stipulated that an inventor can file an initial patent application (a "priority application") at one patent office, usually at the patentee's home country, and then file the patent during a period of up to one year in any member state of the Convention. In addition, the Paris Convention of 1883 provides that each contracting State may take legislative measures for the grant of compulsory licenses, which is provided for the public interests in a very liberal way. Article 5A (2) of the Paris Convention reads:

"Each country of the Union shall have the right to take legislative measures providing for the grant of compulsory licenses to prevent the abuses which might result from the exercise of the exclusive rights conferred by the patent, for example, failure to work".²⁷

Actually the first appearance of historical appearance of the compulsory license regulation was at the Vienna Convention in 1873 for "cases where the public interests made it necessary",²⁸ and later it reappeared in Paris Convention. However, Paris Convention provides protection for public interests by compulsory license in an inadequate way. The Stockholm Revision (1967) of the Paris Convention brought a modification in terms of "compulsory licensing" that made it more difficult to apply, since it

²⁷ Article 5A (2), Paris Convention for the Protection of Industrial Property, Entry into force: April 26 or May 19, 1970. See also Article 20. Source: International Bureau of WIPO.

²⁸ See Cícero Gontijo, "Changing the patent system from the Paris Convention to the TRIPS Agreement", Global Issue Papers, No.26, December 2005, English version, p.9, para.2.

established that the license had to be refused if the holder could justify his inaction with legitimate reasons.²⁹

On the other hand, under this convention, member states were free to determine the standards of protection, the period of protection and the subject matter protection. The differences can be observed in the case of patenting pharmaceutical product. For instance, the countries can reject patent neither the process of manufacturing a drug nor the final drug. In 1988 pharmaceutical products were not patentable in 49 member states, methods for the treatment of the human or animal body were not patentable in 44 member states, chemical products were not patentable in 22 member states, and pharmaceutical processes were not patentable in 10 member states.³⁰ The Paris Convention got considerable criticism that it provided little real substantive protection for inventors.

3.3.2 Patent Cooperation Treaty (“PCT”) (1970)

In the mid-1960s, the developed countries’ economies began to enter an era of “knowledge-based economy”, in which patents were fast becoming one of the most essential assets of the industry. However, the whole patent system were in crisis, since the number of patent applications increased so rapidly that the examination backlogs in the national patent offices were huge, and the patent examination pendency lasting long kept the public and potential competitors in the dark because the application were kept secret during such pendency, or even if published, they were published without data which may have helped competitors in formulating opinions on the claimed invention’s chances of obtaining patent protection. Another complaint in the 1960s was that the applicant had to file several applications if they want to seek patent protection in several countries, which means duplicative patent application and examination worldwide and no patent office had access to the work of other patent offices.³¹

In order to solve these problems, The PCT concluded in 1970, which opens to States Party to the Paris Convention (1883) and administrated by the World Intellectual Property Organization (WIPO), provides unified procedure for filing patent applications to protect inventions in each of its contracting states. The main advantages of PCT international protection of invention via single patent application which save not only cost but also time. However the PCT does not provide for the grant of an “international patent”, as such multinational patent does not exist and the grant of patent is

²⁹ Ibid.

³⁰ Joseph Straus, “Implications of the TPIPS agreement in the field of patent law” in F.K.Beier and G Schricker (Eds), “From GATT to TRIPs—The agreement on trade-related aspects of intellectual property rights”, 1996, p.160, p.174.

³¹ World Intellectual Property Organization, “The First Twenty-Five Years of the Patent Cooperation Treaty (PCT, 1970-1975)”, WIPO Publication No.884 (E), 1995, p.10.

a prerogative of each national and regional authority.³²

3.3.3 The modern approach: Trade-Related Aspects of Intellectual Property Rights

Although the effort had been made to initiate and then build up international patent system, they still perceived that the protection was inadequate in the following respects:

1. The membership of Paris Convention far from universal. Many developing countries particularly were reluctant to sign the agreement;³³
2. Lack of effective implementation mechanism: the international obligations incurred by states with respect to patent laws were not enforced well. For example, pursuant to Article 28 of Paris Convention provides that disputes about the interpretation and application of the convention could be brought to the International Court of Justice, but not all the parties adhered to the convention.
3. The limited effects stressed the necessity of a more complete and integrated patent system. For example, Although Patent Cooperation Treaty simplified the patent application process; it does not centralize the patent granting phase, which remains the responsibility of the national patent authorities in the designated States.³⁴
4. Lack harmonization of all aspects of national patent laws leading to lack of protection: no minimum patent terms was set, the regulations of compulsory license was too liberal; countries were free to exclude areas from patentability.³⁵

The developed countries criticized that Paris Convention and PCT failed to provide pharmaceutical companies adequate patent protection in developing countries. The developed countries argued that the innovation and R&D costs a lot, whereas countries without strong patent protection free-ride on the innovation, profiting from the knowledge without contributing to the costs of its development.³⁶ In addition, copying a product in the countries with weak patent protection is legal, which leads to serious piracy in developing countries and the industries' significant economic losses.

³² See Case *Oxonica Energy Ltd v Neuftec Ltd*, Case No: HC 07 C 00437, In the High Court of Justice, Chancery Division, Patents Court, London, September 05, 2008, (2008) EWHC 2127 (Pat), item 45.

³³ D.Matthews, "Globalising Intellectual Property Rights: The TRIPS Agreement", publisher of Routledge, July 2002, pp.325-326.

³⁴ Marta Pertegas Sender, "Cross-boarder enforcement of patent rights: An analysis of the interface between intellectual property and private international law", Oxford private international law series, Oxford University Press, 2002, chapter 1, p.6, para.3.

³⁵ See Abbott F.M., "Protecting first world assets in the Third World: intellectual property negotiations in the GATT multilateral framework", *Vanderbilt Journal of Transnational Law*, Vol.22, Number 4, 1989, pp.703-704.

³⁶ J.H.Reichman, "Intellectual Property in International trade: opportunities and risks of a GATT Connection", *Vanderbilt Journal of Transnational Law*, Vol.22, 1989, p.22.

The developed countries called for strong patent protection with firmer mandatory minima and guarantees of effective enforcement, and post pressure on developing countries, especially the US. The notorious case was the United State's use of section 301 of the US Trade Act of 1974, which designed to force open other country's markets by the threat of depriving trading partners' access to the U.S. market. It was described as "the principal statutory authority under which the United States may impose trade sanctions against foreign countries that maintain acts, policies and practices that violate, or deny U.S. rights or benefits under, trade agreements, or are unjustifiable, unreasonable or discriminatory and burden or restrict U.S. commerce".³⁷ "Special" 301 is a part of the section 301 remedy that focus on intellectual property rights, requiring that the U.S. Trade Representative (USTR) to go through identifying countries that "deny adequate protection for intellectual property rights".³⁸

Pharmaceutical patent protection has played an important role in the "Special 301" proceedings, which was witnessed by the noteworthy case – the 1987 PMA (the U.S.-based Pharmaceuticals Manufacturing Association) case against Brazil for its lack of patent for pharmaceutical products. After Brazil refused to alter its policy, the United States placed a 100 percent retaliatory tariff (totaling \$39 million) on imports of Brazilian pharmaceuticals, paper products, and consumer electronics.³⁹

It became apparent that the existing patent system was no longer so well adapted to the realities of trade, and couldn't protect adequately, in particular the developed countries, industries' competitiveness depending on technology and creativity. Argument for strong protection of intellectual property rights including patent rights worldwide was made a prerequisite for the granting of the benefits anticipated in the WTO agreement. Thus intellectual property was added to the agenda of the Uruguay Round Trade negotiations.

In 1995 year the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), became effective as part of the Uruguay Round of the General Agreement on Tariffs and Trade (GATT), and obliged all the WTO's member states to alter their domestic legislations and recognize a minimum standard of protection for intellectual property in all fields of technology, including pharmaceuticals.⁴⁰ Correspondingly, many countries made significant changes in the national intellectual property laws which have a direct bearing on the pharmaceutical industry.

³⁷ See "Special 301 Report", Wikipedia website, available at: http://en.wikipedia.org/wiki/Section_301 (Search date: 15/04/2010)

³⁸ "Special 301" was introduced by the Omnibus Trade and Competitiveness Act of 1988, 102 Stat 1107, 23 August 1988.

³⁹ "Differences over Code on Patents", *Latin American Regional Reports – Brazil*, RB-91-04, London: Latin American Newsletters, 2 May 1991, p.4.

⁴⁰ Office of the United States Trade Representative, Statement of Administrative Action, Agreement on Trade-Related Aspects of Intellectual Property Rights (September 27, 1994), p.11, para.1-2, available at 1994 WL 761796.

The inadequacies of protection and rules related to patent rights enforcement, together with the absence of an international dispute settlement system is thought to be improved in the TRIPS agreement.

Firstly, the TRIPS widen the scope of patentable subject matter including pharmaceuticals. The minimum standards mentioned in the TRIPS agreement ensured the protection that the patent shall be granted for any inventions, whether product or processes, in all fields of technology under the conditions that they are new, involve an inventive step and are capable of industrial application without any discrimination to the place of invention or to the fact that products are locally produced or imported.

Secondly, the TRIPS agreement has established detailed provisions on enforcement to make sure effective action against any act of infringement, as well as a mandatory dispute settlement process, which had a major impact on the harmonization process. In Part III of the Agreement, the provisions of section 1 (Article 41), lays down general obligations and basic principles that all enforcement procedures must meet. The following sections, which deals with civil and administrative procedures and remedies (Article 42 to Article 49), provisions measures (Article 50), special requirements related to boarder measures and criminal procedures (Article 51 to Article 61), does offer safeguards to remedy negative effects of patent protection or patent abuse, but in practice it is unclear whether and how countries can make use of these safeguards when patents increasingly present barriers to medicine access.⁴¹

Thirdly, the TRIPS agreement made contribution to the promotion of technological innovation and to the transfer and dissemination of technology in a manner conducive to social and economic social welfare (Article 7) and to permit members to adopt measures necessary to protect public health and to promote the public interest in sectors of vital importance to their economic and technological development (Article 8). The TRIPS Agreement then permits member countries to include in their legislations some flexibilities and public health safeguards. The main flexibilities built into the TRIPS Agreement are: compulsory licensing (Article 31), parallel imports (Article 6), experimental use (Article 30), Bolar exceptions (Article 30) and health sector participation in analyzing pharmaceutical patent claims (implicit in Article 8).⁴²

The pre-TRIPs era saw the world have restrictive patent laws providing for process patents and non-grant of product patents in drugs & pharmaceuticals and later allow patent in both products and processes. While not all the nations have the same tone and pace in patent drugs. TRIPs attempted to

⁴¹ See World Trade Organization, "Overview: the TRIPS Agreement", para.1. Available at: http://www.wto.org/english/tratop_E/TRIPS_e/intel2b_e.htm (Search date: 16/04/2010).

⁴² See Gabriela Costa Chaves, Marcela Fogaça Vieira, Renata Reis, "Access to medicines and intellectual property in Brazil: reflections and strategies of civil society", Sur. Revista Internacional de Direitos Humanos, Vol.5, No.8, pp.21-22.

harmonize the Intellectual property laws by bringing the disparities into focus and providing guidance for them by setting the minimum standards for the protection of intellectual property, including patents for pharmaceuticals. TRIPS agreement made a substantive change and impact on the pharmaceutical patents. Before the enactment of the TRIPS Agreement, patent protection for pharmaceutical products was virtually nonexistent in many poor, developing nations, but now the WTO members have to adopt the patent law protecting pharmaceutical products.

3.4 Patent right versus Access to Medicine: from a technical issue to a social issue

At the time the TRIPS agreement came into force in 1995, there was little awareness of the relation between intellectual property rights and public health, and how would the issue of patent protection impact on access to medicine. The World Trade Organization (WTO) TRIPS Agreement was meant to help achieve a balance between two related public health goals: to enhance incentives for R&D into new drugs and to ensure affordable access to existing drugs.⁴³

However, later the debate and blame arise from the pharmaceutical industry and TRIPS for the lack of accessibility and affordability of much needed drugs in developing countries. Many developing countries hold that the standardization of the different national legislations that results from the ratification of the TRIPS agreement does not take into account the relevant differences between developing and developed countries, and the TRIPS agreement is unbalanced in that it favors developed countries and transnational corporations, but it is unhelpful or even harmful to their own interests, since their domestic firms lack of the capacity to innovate this field.

Developing countries are not alone in their criticism of TRIPS. By the mid 1990s public health activists and NGOs expressed their worries that patent protection and the new TRIPS rules would lead to barriers to access to medicine for developing countries. The NGOs also have criticized TRIPS on the grounds that it imposes various costs on developing countries — such as more expensive drugs, agricultural inputs and foreign-owned technologies — without producing sufficient longer-term gains in areas like trade and investment. Médecins sans Frontières (MSF), together with other NGOs, formulated their drugs concern that increased patent protection leads to such higher price that people in developing countries are out of reach essential drugs and the gap between developed countries and developing

⁴³ See “WTO Agreements and Public Health - A Joint study by the WHO and WTO Secretariat”, Geneva, Switzerland: World Health Organisation and World Trade Organisation, 2002, p. 2, para.8.

countries will be widen.⁴⁴

Non-governmental organizations (NGO) have played a key role in drawing attention to provisions of TRIPS that can be used to increase access to medicines, especially by exercising compulsory licensing. The Amsterdam Conference on Increasing Access to Essential Drugs in a Global Economy was organized by Médecins sans Frontières (MSF) in 2000 year, which brought together 350 participants from 50 countries on the eve of the Seattle of WTO ministerial conference to discuss the issues of the impact of trade policies on people in developing and least-developing countries, and providing a public health framework for the interpretation of key features of WTO agreements.⁴⁵ The Statement drawn up at this conference (“Amsterdam Statement”), which came up with the idea to establish a working group in the WTO on TRIPS and access to medicines, has served as a guide for the work of NGOs and other advocates on TRIPS and public health.⁴⁶ The working group takes charge of addressing questions related to the use of compulsory licensing to increase access to medicines, mechanisms to allow production of medicines for export markets to a country with no or insufficient production capacity, patent barriers to research, and urging national government to develop new and innovative mechanisms to ensure funding for R&D for neglected disease. The NGOs’ active involvement and partnership with the UN, government and the pharmaceutical industry have paved the way for drawing the world’s concern on this issue, and improving a better access to medicine for developing countries.

In addition, the civil society movement including NGOs, professionals and grass root movements both in industrialized and developing countries, has set up alliances and networks to defend the principle of human dignity and health should come before private interests and profits.

For example, In Thailand, the civil society groups have been key to establishing the human rights to health by challenging the practices of the multinational pharmaceutical industry and government of industrialized countries. In 1999 the Didanosine Working group was formed as a result of concern about Thailand’s patent laws, which they believe constituted a major barrier to access to HIV/AIDS drugs. With the assistance from WHO, the mission recommended that the Public Health Ministry review its patent provisions on compulsory licensing and institute a means of monitoring drugs prices.⁴⁷

⁴⁴ Scherer M.F., Watal J., Post Trips Options for Access to Patented Medicines in Developing Countries, WHO, 2001. Available at www.cmhealth.org/docs/wg4_paper1.pdf (Search date: 10/04/2010).

⁴⁵ See Ellen’t Hoen, “TRIPS, Pharmaceutical Patents, and Access to Essential Medicines: A Long Way from Seattle to Doha”, Chicago Journal of International Law, Vol.3, No.1, 2002, p.33-34.

⁴⁶ Ibid.

⁴⁷ Boulet P., “Assessment of the situation of HIV/AIDS related drugs in Thailand: report of UNAIDS/WHO fact finding mission in Thailand”, Geneva: World Health Organization, 1999.

A lawsuit, which was filed in May 2001 at the Thai Central Intellectual Property and International Trade Court by the AIDS Access Foundation (a Thai foundation that provides social support to people with HIV/AIDS) and two patients with HIV against Bristol-Myers Squibb (A global biopharmaceutical company), was believed to be the first time a court decision has used the Doha Declaration to protect public health and the rights of patents. It concluded that “injured parties . . . are not limited to manufacturers or sellers of medicines protected by patent. Those in need of the medicine are also interested parties to the granting of the patent.”⁴⁸

In March 2005 a coalition of Thai groups called FTAWatch submitted a request to the 84th Session of the UN Human Rights Committee to raise the committee’s concern about the effect of TRIPS-plus rules in FTAs on the right to life when they review the State report of Thailand.⁴⁹ Furthermore, in June 2005 a coalition of seventeen NGOs from EFTA countries and sixteen NGOs from Thailand submitted two letters of request to the UN Special Rapporteur on the Right to Health, urging him to intervene in Thailand’s FTA negotiations with the US and EFTA.⁵⁰ These efforts urged parties to respect their international human rights obligations in all aspects of the trade negotiations and to undertake human rights impact assessments of proposed trade rules.

In Thailand, successful opposition on increased patent protection has come from people with HIV/AIDS, who have fought for their rights by forming effective coalitions, bringing together a range of experience and expertise.⁵¹

⁴⁸ Nathan Ford, David Wilson, Onanong Bunjumong, Tido von Schoen Angerer, “The role of civil society in protecting public health over commercial interests: Lessons from Thailand”, Article of Medicines Sans Frontiers, available at http://www.msf.org/msfinternational/invoke.cfm?objectid=59C1DA17-F039-4EF8-B00FA85B625CF09A&component=toolkit.article&method=full_html (Search date: 22/03/2010).

⁴⁹ FTA Watch, “Thailand’s Free Trade Agreements and Human Rights Obligations, Submission to the 84th Session of the UN Human Rights Committee”, March 2005, Available at: http://www.ftawatch.org/autopage1/show_page.php?t=22&s_id=3&d_id=3 (Search date: 18/02/2010).

⁵⁰ See also FTA Watch, Request for an urgent appeal on the impact of strict intellectual property rules in free trade agreements (FTAs) on access to affordable medicines in Thailand, June 2005. Available at: http://www.ftawatch.org/autopage1/show_page.php?t=22&s_id=3&d-id=3 (Search date: 18/02/2010).

⁵¹ Reichman, Jerome H., “Intellectual Property in International Trade: Opportunities and Risks of a GATT Connection”, Duke Law Faculty Scholarship, Paper 453, 1989; Available at: http://scholarship.law.duke.edu/faculty_scholarship/453 (Search date: 12/03/2010).

3.5 Access to Medicine in TRIPS Agreement Framework

3.5.1 General overview of the TRIPS Agreement

The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement), as a very important multinational agreement, is administered by the World Trade Organization (WTO) and aimed at strengthening and harmonizing certain aspects of the protection of intellectual property rights at the global level. The preamble, in conjunction with the provision of Articles 7-8, establishes the object and the goals of TRIPS Agreement: In order to “reduce distortions and impediments to international trade”, and to the Members shall take into account both the need for intellectual property protection and the need to prevent that protection from itself becoming an barriers to legitimate trade. The preamble recognizes “the underlying public policy objectives of national systems for the protection of intellectual property, including developmental and technological objectives”.

There are three main features of the agreement. Firstly, it incorporates the provisions of the Paris Convention and built on them. It requires member states to ensure minimum standards of protection for the various intellectual property rights, leaving them the choice of how they achieve this. The main elements of protection is defined, namely the subject-matter to be protected, the rights to be conferred and permissible exceptions to those rights. In doing so, it strikes a balance between the long term benefits in promoting creativity and innovation, social and economic welfare and short term cost to society through various exceptions, for example to tackle public health, as is stated in Article 8 of the TRIPS Agreement.⁵²

“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.”

Secondly, TRIPS agreement provides rules for the enforcement of intellectual property rights in member states. With respect to protection of IPR, each member nation is obligated to provide domestic procedures and remedies which are “fair and equitable”, and “not unnecessarily complicated or costly, or entail unreasonable time limits or unwarranted delays”. The agreement laid down certain general principles applicable to all IPR enforcement procedures, as well as certain other provisions on civil and administrative procedures and remedies. The general obligation of member states to provide enforcement mechanism requires that enforcement procedures should be available under their national law to make sure the

⁵² See TRIPS Agreement, Article 7, objectives.

right holders can protect their interests effectively. In addition, the Agreement permits member states to exclude the grant of injunctions in circumstances involving compulsory licenses and other uses.

Thirdly, it provides the resolution of disputes in relation to the TRIPS Agreement in accordance with the WTO's dispute resolution procedures. The TRIPS Agreement establishes the transparency requirements which obligate the member states to publish or make available legal texts such as laws and judicial decisions, and notify those laws and regulations to TRIPS council or to WIPO.

In addition, the TRIPS Agreement also provides for certain basic principles, such as "National Treatment" (Article 3) -- Equal treatment for foreigner and domestic individuals and companies, and "Most Favored Nation" (Article 4) -- Equal treatment for nationals of all trading partners in the WTO. The obligations under the agreement will apply equally to all Member States, but developing countries will have a longer period to phase them in. Special transition provisions are applied in the situation where a developing country does not presently provide product patent protection in the area of pharmaceutical.⁵³

The TRIPS Agreement is not a uniform law; instead it is a minimum standards agreement which allows Members to provide more extensive protection of intellectual property and also leaves freedom to the Members to determine the appropriate method of implementing the provisions of the Agreement within their own legal system and practice.

3.5.2 Overview of TRIPS provisions on patent

In the patent regime, the TRIPS Agreement prescribes the subject matter, for which patent protection must be provided, the rights that must be afforded to patentees, and the minimum term of protection. The TRIPS Agreement (Part II, section 5) contains standards generally applicable to patent covering both substantive standards as well as specific issues of enforcement. The TRIPS Agreement covers various patent issues, including patent subject matter and patentability requirements; non-discrimination; *Ordre Public* and morality; rights and exceptions; disclosure of information; non-voluntary uses; and process patents: burden of proof, compulsory licenses and so on.

With respect to patentability, the TRIPS Agreement imposes an obligation on member countries to scrutinize by two steps: (1) is the technological advance claimed in the patent application an "invention"? (2) Is that invention "novel", "inventive" and "industrial applicable"? For those patented invention, The TRIPS Agreement requires WTO members to

⁵³ "TRIPS: A MORE DETAILED OVERVIEW OF THE TRIPS AGREEMENT", para.5, TRIPS materials on the WTO website, available at http://www.wto.org/english/tratop_e/trips_e/intel2_e.htm (Search date: 1st May, 2010).

provide protection for a minimum term of 20 years from the filing date of a patent application for any invention including for a pharmaceutical product or process. The minimum patent rights must be conferred by preventing unauthorized persons from using the patented process and making, using, offering for sale, or importing the patented product, but countries are required to make the grant of a patent dependent on adequate *disclosure* of the invention and they may require the information on the best mode for carrying it out.

On the other hand, patent rights are not absolute but can be subject to the following limitations or exceptions:⁵⁴

- Article 30 of the TRIPS Agreement defines the exceptions in broad terms, which allow the countries to make limited *exceptions* as long as 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 legitimate interests of the third parties. Under this provision there is considerable freedom for national legislation to define the kind and extent of exceptions to be granted. For example, a research and experimentation exceptions permits use of the invention without compensation to the owner for the purpose of teaching, or the purpose of foster technological process on “inventing around”, or for other legitimate purposes, such as to test whether the patent is valid.⁵⁵ However, if the inventions do not enhance the public welfare as ultimate goal of the patent system, they may be excluded from patentable subject matter even if they represent a significant scientific and technological advancement and make contribution for technical progress.

- Countries may authorize the use by third parties (*compulsory licenses*) or for public non-commercial purposes (*government use*) without the authorization of the patent owner under number of conditions and balance between the public interests and legitimate interests of the patent owner, (see Article 31). A patentee cannot stop the third parties from using his patented invention, but he is entitled to remuneration against such use.

- Countries have the right to take measures, consistent with TRIPS provisions, against anti-competitive practices. When a practice has been determined to be anti-competitive after exhausting due process of law, the conditions for issuing compulsory licenses are more flexible. Members may adopt appropriate measures to prevent the abuse of IPRs by right holders or

⁵⁴ See Karin Timmermans and Togi Hutadjulu, “THE TRIPS AGREEMENT AND PHARAMACEUTICALS”, Report of an ASEAN Workshop on the TRIPS Agreement and its Impaction Pharmaceuticals, Jakarta, 2-4 May 2000. The workshop was hold by the Organization “Directorate General of Drug and Food Control” and World Health Organization, p.28, para.4

⁵⁵ See Rebecca S.Eisenberg, “Patents and the Progress of Science: Exclusive Rights and Experimental Use”, University of Chicago Law Review, 1989, No. 56, No.3, pp.1017-1086.

to prevent the resort to practices that unreasonably restrain trade or adversely affect the international transfer of technology.⁵⁶

3.5.3 Patent Standards in TRIPS Agreement

3.5.3.1 Eligibility for Patentability

The key obligation of the TRIPS Agreement with respect to patents is contained in Article 27, which requires patent protection to be available for any invention when the conditions of patentability under the TRIPS Agreement are fulfilled, including a pharmaceutical product or process.

Article 27 defines the subject matter that is eligible for patent protection, and the requirements for patentability of such eligible subject matter. As a central provision on patent protection, Article 27 of TRIPS Agreement prescribes that:

1. *Subject to the provisions of paragraphs 2 and 3, patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application. Subject to paragraph 4 of Article 65, paragraph 8 of Article 70 and paragraph 3 of this Article, patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.*
2. *Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect ordre public or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law.*
3. *Members may also exclude from patentability:*
 - (a) *diagnostic, therapeutic and surgical methods for the treatment of humans or animals;*
 - (b) *Plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective sui generis system or by any combination thereof. The provisions of this subparagraph shall be reviewed four years after the date of entry into force of the WTO Agreement.*

Article 27 not only set up a patentable subject matter threshold by the word “inventions”, but also distinguishes between inventions that are not

⁵⁶ See TRIPS Agreement, article 8 (2), “Principles”. See also article 40 in section 8, “Control of anti-competitive practices in contractual licences”.

patentable and inventions are not by requiring that patentable inventions be “new, inventive and industrial applicable”. That means an alleged invention is only patentable if it satisfied a two-step test:

(a) Is the alleged invention “an invention”? That is, is it patentable subject matter?

If the answer is “no”, the subject matter is not patentable;

If the answer is “yes”, then:

(i) Is it new?

(ii) Does it involve an inventive step? And

(iii) Is it capable of industrial application?

If answers to all the questions are in the affirmative, then the alleged invention is patentable.

3.5.3.1.1 Patent Subject Matter

What can be patented? Article 27.1 of TRIPS mandates that patent protection be afforded for “*any inventions whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application*”.

In consistent with the broad scope of eligibility defined by Article 27.1, certain pharmaceutical substances can’t be excluded from the scope of subject matter eligible for patent protection. Although the TRIPS Agreement fails to define the term of “technology”, it is undisputed that the pharmaceutical field is included according to this article and patents have to be made available in that field.

On the other hand, Article 27.1 also establishes the non-discrimination based on the field of technology, “*patent shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology...*”, which means Members can’t deny a patent for inventions if the technology sector meet the requirements of the national law for novelty, inventive step and industrial application.

However, the TRIPS Agreement neither defines “inventions”, nor does it contain the delimitation between “inventions” and mere “discoveries”, which traditionally in patent law not eligible for patenting, such as abstract ideas, the law of nature, and materials discovered in nature.⁵⁷ Under this

⁵⁷ See Article 52(2) of the Convention on the Grant of European Patents (“EPC”) of 5 October 1973. Text as amended by the act revising Article 63EPC of 17 December 1991 and by decisions of the Administrative Council of the European Patent Organization of 21 December 1978, 13 December 1994, 20 October 1995, 5 December 1996, 10 December 1998 and 27 October 2005 and comprising the provisionally applicable provisions of the act revising the EPC of 29 November 2000. Available at: <http://www.epo.org/patents/law/legal-texts/html/epc/1973/e/ma1.html> (Search date: 05/05/2010); See also CM Correa, “Intellectual Property Rights, the WTO and Developing Countries”, The TRIPS Agreement and Policy Options (2000), pp.23–24.

distinction the substances with medical properties found in nature should be excluded from patentability. In practice, the countries establish their own criteria for these terms. Some countries precisely identify categories of subject matter that are not inventions, and which types of inventions the government will not patent,⁵⁸ and other countries define eligibility in a broad terms.⁵⁹

Article 27.1 also requires Members to make patents available for both products and processes. If a patent is issued for a production process, then the rights have to extend to the product directly obtained from the process. Under certain conditions alleged infringers may be required by a court to prove that they have not used the patented process.⁶⁰ The distinction between a Process Patent and Product Patent is that Process patent gives the owner exclusive right over the manufacturing process but the Product Patent provide exclusive right on the product even if they are produced through different processes. In other words, under a process patent, the patented medicine or drugs can still be manufactured by others using a different process from the process that is patented, but under the Product Patent, it is prohibited to manufacture, sell, distribute and import those medicine and drugs product without the authorization of the patent holder. So the Product Patent regulated by the TRIPS is more stringent since it assigns the exclusive right of producing patented drug to the patentee. Some people concern that the accessibility and affordability of drugs will be reduced as a result of Product Patent, since the patent owner's monopoly on the market for 20 years without competition leads to high price of drugs.

Article 27.1 of the TRIPS Agreement addressed one of the main omissions of the Paris Convention, namely a definition of what inventions must be eligible for patents,⁶¹ and established for the first time what has been called

⁵⁸ See, e.g., EPC, supra note 57, Article 52(2) (identifies discrete categories of subject matter that are not inventions); and EPC, Article 52(4) (categorizes the inventions that are deemed to not possess an industrial application and thus are ineligible to be patented); and EPC, Article 53 (lists the inventions that are not to be patented regardless of whether they meet the standards of industrial applicability, novelty and inventive step)

⁵⁹ See 35 U.S.C. § 101, Manual of Patent Examining Procedure (MPEP), The Eighth Edition, August 2001, Latest Revision July 2010, United States Patent and Trademark Office; (The U.S. patent system defines “any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof” to be eligible to be patented). Available at:

http://www.uspto.gov/web/offices/pac/mpep/documents/appxl_35_U_S_C_101.htm

(Search date: 18/03/2010).

⁶⁰ See WTO Website, “Understanding the WTO: The Agreements: Intellectual property: protection and enforcement”, WTO, para.26. Available at:

http://www.wto.org/english/thewto_e/whatis_e/tif_e/agrm7_e.htm (Search date: 12/03/2010).

⁶¹ See Paris Convention, supra note 27. Under the Paris Convention, countries were free to exclude areas from patentability, as well as to provide special rules for certain types of inventions. In addition, they had freedom to define the requirements for patentability. The TRIPS Agreement has changed this situation. Article 27(1) includes a general obligation of patentability addressing in this manner one of the major concerns raised by the pharmaceutical industry with respect to prevailing regimes prior to TRIPS Agreement. See the TRIPS Agreement, supra note 2, Article 27(1).

a “general principle of eligibility to be patented” for both products and processes in all fields of technology. Under the Paris Convention, States were free to exclude areas from patentability, to provide special rules for certain types of invention, as well as to define the requirements for patentability. 49 states parties to the Paris Convention had exempted pharmaceutical products from patentability and ten states parties to the Paris Convention excluded pharmaceutical processes.⁶² The TRIPS Agreement has changed this situation by mandating the obligation of patentability, prohibiting the discrimination between sectors and on the basis of place of invention, and limiting the power of States to differentiate the treatment conferred to products locally produced and imported.

3.5.3.1.2 Exceptions of patentability

Literally interpreted, Article 27.1 does not permit the exclusion from patentability of medicines in general, but Article 27.2 and Article 27.3 provide discretion to Members to exclude certain categories of subject matter from patentability. Pharmaceutical products do not figure on this list of the TRIPS Agreement designated subject matter exclusions.

Article 27.2 indicates that non-patentability on grounds of “*ordre public*” is permissible if necessary to prevent commercial exploitation. It authorizes certain exclusion from patentability, depending on public ethics, especially in the areas of inventions whose commercial exploitation is to be prevented to protect public order or morality, human, animal, plant life or health or to avoid serious prejudice to the environment. For instance, in some countries, the law explicitly provides that the human body at the stage of development and modifying germ line genetic identify of humans are not patentable. There is no universally accepted notion of “*ordre public*”⁶³, leaving member countries some flexibility to define which situations are covered, depending on their social and cultural values. Many countries exclude those inventions from patentability if their exploitation is against the general public interest and morality, and the term “*ordre public* and morality” is interpreted on a case-by-case basis, reflecting the fundamental values of society in a given context.

Article 27.3 provides that Members may exclude certain methods, plant and animal inventions other than microorganism from patent eligibility, since patent such subject matters raise serious ethical, religious and culture

⁶² Negotiating Group on Trade-Related Aspects of Intellectual Property Rights, including Trade in Counterfeit Goods, “Existence, Scope and Form of Generally Internationally Accepted and Applied Standards/Norms for the Protection of Intellectual Property”; Note Prepared by the International Bureau of WIPO, MTN.GNG/NG11/W/24/Rev.1 at Annex II (15 September 1988).

⁶³ For instance, under the Guidelines for Examination of the European Patent Office (published by the European Patent Office), “*ordre public*” is linked to security reasons, such as riot or public disorder, and inventions that may lead to criminal or other generally offensive behavior (Part C, chapter IV, 3.1); Available at: <http://www.epo.org/patents/law/legal-texts/html/guix/e/index.htm> (Search date: 25/03/2010).

questions and therefore reject their patentability, and furthermore the commodification and marketing of life structures violates the society's culture practice.

Article 27.3(a) excludes inventions concerning diagnostic, surgical or therapeutic methods for the treatment of humans or animals from patentability based on the humanitarian and public health concerns, but in some other countries those inventions are not patentable because they are regarded as inventions lack of industrial applicability. On the other hand, some laws expressly clarify that this exclusion does not apply to any apparatus or products, such as medical device, medical products and medical substances, which may be used for the purpose of diagnosis, surgery or therapy.⁶⁴

Article 27.3(b) provides exclusions from patentable subject matter concerning inventions relating to plants and animals, but not the plants and animals *per se*. Since the TRIPS Agreement provides certain flexibility, the exclusions vary significantly among the different laws. In some countries, no provision is regulated to exclude this category of inventions from patentability. There is a need to distinguish unpatentable "plant and animal varieties" and patentable "plant and animals". For instance, in Europe the distinction was determined in such a way that if the technical feasibility of the plant invention is not confined to a particular plant variety, then it is regarded as patentable subject matter.⁶⁵ A patent grouping which is characterized by a particular gene and not its whole genome doesn't fall into plant varieties protection, and thus is eligible for a patent if it comprises new varieties of plants.⁶⁶

3.5.3.2 Patentability Requirements

Patent system imposes a number of conditions on those wishing to obtain a patent for an invention to justify the government's awarding patent and ensure the inventor enjoy the rights corresponding to the contribution made. As most patent system, the TRIPS Agreement uses three standards,⁶⁷ namely 1) novelty of the invention, 2) inventive steps and, 3) industrial application, to determine whether patent an invention or not.

⁶⁴ See "Exclusion from patentable subject matter and exceptions and limitations to the rights", Document prepared by the Secretariat, STANDING COMMITTEE ON THE LAW OF PATENTS, Thirteenth Session, WIPO, Geneva, March 23 to 27, 2009, SCP 13/3, para.53.

⁶⁵ Directive 98/44/EC of the European Parliament and of the Council on the legal protection of biotechnological inventions, Article 4(2); Implementing Regulations to the Convention on the Granting of European Patents, Rule 27.

⁶⁶ Directive 98/44/EC of the European Parliament and of the Council on the legal protection of biotechnological inventions, Recital 31.

⁶⁷ See TRIPS Agreement, *supra* note 2, Article 27.

3.5.3.2.1 Three Standards: Novelty, Incentive Step and Industrial application

TRIPS Article 27.1 grants WTO Members the authority to require a showing of novelty as a condition of granting a patent. Under the novelty standards, the invention must not be identically disclosed in the “prior art” including “everything made available to the public by means of a written or oral description, by use, or in any other way” to the original application date.⁶⁸ The novelty requirement in modern patent laws is generally based on an assessment of the prior art on a universal basis, namely anywhere in the world. Generally, novelty is destroyed by previous written publication, prior use or other form of public communication of the invention.⁶⁹

“Inventive step”, interpreted as synonymous with “non-obvious”,⁷⁰ means a feature of an invention that involves technical advance as compared to the existing knowledge which makes the invention not obvious to the person skilled in the art. In other words, a “person having ordinary skill in the art” would not know how to solve the problem at which the invention is directed by using exactly the same mechanism.⁷¹ A patentable invention must represent a development in prior art, otherwise the Members will deny the patent for a “novel” invention due to the lack of an inventive step.

In the chemical and pharmaceutical field, for the cases that a close structure relationship between a compound claimed as new and inventive, and the known compounds, such as salts of acids, bases, isomers and homologues, it may be often deemed *obvious to try* the new compounds, thus leading to its non-patentability.⁷² The European Patent Office (“EPO”), for instance, take into account that the fact that certain advantages were predictable made it obvious to prepare a new compound.⁷³ In the United States, by contrast, the presence of a predictable advantage is not considered sufficient to exclude patentability.⁷⁴

The last, the invention must be capable of being used in any kind of industry. The condition requires that the inventions must, in some way, be

⁶⁸ See, e.g., Convention on the Grant of European Patents, Article 54 (2), October 5, 1973, *supra* note 57.

⁶⁹ Carlos Correa, , “*Integrating public health concerns into patent legislation in developing countries*”, University of Buenos Aires, Argentina, 2000, p.40, para.4.

⁷⁰ See the TRIPS Agreement, Article 27(1), footnote 5 (specifically permits a Member to consider “inventive step” synonymous with “non-obvious”).

⁷¹ See Wikipedia, “Inventive step and non-obviousness”, available at http://en.wikipedia.org/wiki/Inventive_step_and_non-obviousness (Search date: 20/04/2010)

⁷² Carlos Correa (University of Buenos Aires, Argentina), “*Integrating public health concerns into patent legislation in developing countries*”, World Health Organization, 2000, p.46, para.2. Available at: <http://apps.who.int/medicinedocs/en/d/Jh2963e/> (Search date: 22/04/2010).

⁷³ See Jay Dratler, “Intellectual property law: commercial, creative, and industrial property”, Intellectual Property Series, Law Journal Seminars-Press, New York, 1991.

⁷⁴ Grubb, Philip, “Patents for Chemicals, Pharmaceuticals and Biotechnology: Fundamentals of Global Law, Practice and Strategy”, Oxford University Press, 1999, pp.195-196.

beneficial to the public. The TRIPS Agreement requires a showing of industrial application or usefulness as a condition of granting patent. The concept of industrial applicability varies different from different countries, especially in biotechnological inventions. Another question is what level of proof is required to be included in the patent application in order to demonstrate an adequate “industrial application”? Despite jurisdiction differences, many countries require inventors to states specific use; hypothetical uses often do not meet the requirements.⁷⁵ However for some inventions, such as genetic product, which has vast and several unknown possibilities, specific use requirements may limit the capacity of applicants to obtain patents.

3.5.3.2 Adequate Disclosure:

Article 29.1 of the TRIPS Agreement imposes requirements on Members, which demands an applicant to provide technical information about the invention so that others are able to reproduce what the inventor claims in his or her patent application.

Article 29.1 of the TRIPS Agreement provides that:

Members shall require that an applicant for a patent shall disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art and may require the applicant to indicate the best mode for carrying out the invention known to the inventor at the filing date (...).

Although the granting of exclusive rights is considered as an incentive for investment in innovative activities, the disclosure requirement is necessary to balance the interests of parties and minimize the potential inefficiency of the market power created by the abuse of exclusive right. The Disclosure requirement, as one of the jurisdiction of patents and a key part of the social contract of granting a patent, can fulfill the social purpose of sharing benefit, since it makes publicly available important and useful technical even during the patent term, and ensures that the invention truly falls into the public domain after the expiry of the patent term.

3.5.3.3 Transition Period

The TRIPS Agreement pays considerable attention to the need to find an appropriate balance between the interests of rights holders and users, which is not only reflected in the basic underlying balance related to disclosure and providing an incentive for R&D, but also in the limitations and exceptions to rights that are permitted and in the transition provisions.

⁷⁵ Kirsten E.Zewers, “*Debated Heroes from the Deep Sea – Marine Genetic Resources*”, WIPO Magazine, 2/2008, para.11. Available at http://www.wipo.int/wipo_magazine/en/2008/02/article_0008.html (Search date: 06/05/2010).

Taking into consideration of Member States' different levels of economic development, the TRIPS Agreement provides transition periods for developing and least-developed countries to give them enough time to implement the various TRIPS standards on intellectual property rights at national level.⁷⁶ Under the TRIPS Agreement, all countries have to provide for protection of product patents from January 1, 1995, but for the developing countries which do not presently provide product patent protection, the transition period was provided by the TRIPS agreement, permitting developing countries additional time to bring legislation and practice into conformity with TRIPS provisions until 2005 year. The transition period may still be extended by the TRIPS Council on request of least-developed countries until 2016 with respect to patents on pharmaceutical products and exclusive marketing rights by the Doha Declaration on the TRIPS Agreement and Public Health. The transition periods have meant that pharmaceuticals or medicines patented before developing countries implemented their TRIPS obligations will not receive patent protection.

3.5.3.4 Compulsory License

Article 5A of the Paris Convention, as part and parcel of the TRIPS Agreement,⁷⁷ provides that each WTO Member has the right “to take legislative measures providing for the grant of compulsory license to prevent the abuses which might result from the exercise of the exclusive rights”. This is echoed by Article 30, 31 of the TRIPS Agreement which specifies certain circumstances under which a country has the right to issue Compulsory License to act on a patent monopoly provided for the public interest.

Article 30 of TRIPS allows unauthorized use and the accompanying circumvention of patent rights under the conditional circumstances:

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

Article 31 of TRIPS, detailing a list of procedural requirements for a limitation to exclusivity, provides another ground for a Member State to issue compulsory license if all the procedural requirements are met, such as the unauthorized use must be considered on case-by-case basis,⁷⁸ be limited in “scope and duration” and subject to review,⁷⁹ and the unauthorized user

⁷⁶ See TRIPS Agreement, Article 66(1)

⁷⁷ See Article 2.1 of TRIPS: “In respect of Parts II, III and IV of this Agreement, Members shall comply with Articles 1 through 12, and Article 19, of the Paris Convention (1967)”.

⁷⁸ The TRIPS Agreement, Article 31(a).

⁷⁹ The TRIPS Agreement, Article 31(c), (d), and (i). These provisions are further qualified when particular circumstances are present.

must have made prior efforts to license the patented technology before getting allowed unauthorized use.⁸⁰

“Where the law of a Member allows for other use of the subject matter of a patent without the authorization of the right holder, including use by the government or third parties authorized by the government, the following provisions shall be respected: ...”

A compulsory license is a government license that allows itself or a third party to practice the patent without the patentee’s consent. It is an essential and important government instrument to intervene in the market and limit patent rights if a patent owner abuses the rights by, for example, refuse to make the invention available on the market (failure to “work” the patent), or offer it at a abnormally high price which potential buyers cannot afford. For instance, Article 69 of Brazil’s 1996 Industrial Property Law allows the government to issue a compulsory license if the patentee does not manufacture the patented technology locally within three years of the patent’s issuance.⁸¹

Each country will have its own priorities for compulsory licensing. In the United States and Europe, there is much interest in compulsory licensing for broad biotechnology patents, research tools, dependent patents, and as a remedy for unreasonable prices. For instance, In the United States, the National Institutes of Health examined compulsory licenses in order to facilitate broader dissemination of biotechnology “research tools”.⁸² In developing countries compulsory licenses are used to obtain lower prices pharmaceuticals for AIDS, tropical illnesses, various vaccines and other essential medicines. For example, the Thai government announced in 2006 that it intended to issue a compulsory license for a patent covering AIDS treatment drug.⁸³ The Brazil government has successfully used the threat of issuing compulsory licenses to persuade drug companies to negotiate price discount on new HIV drugs.⁸⁴

On the other hand, Article 31 also relaxes limiting the use of compulsory license when there are certain substantive reasons for allowing the unauthorized use. The grounds for issuing compulsory license without making prior efforts to license fall into two categories --where there is an

⁸⁰ The TRIPS Agreement, Article 31(f).

⁸¹ See Paul Champ & Amir Attaran, “Patent Rights and Local Working under the WTO TRIPS Agreement: An Analysis of the U.S.-Brazil Patent Dispute”, 27YALE Journal of International Law, (2002), pp.365, 380–383.

⁸² See CPTech Website, “Health Care and Intellectual Property: Frequently asked questions about compulsory licenses”, January 20, 1999. Available at <http://www.cptech.org/ip/health/cl/faq.html> (Search date: 25/04/2010).

⁸³ Announcement of the Department of Disease Control, Ministry of Public Health, Thailand on the Public Use of Patent for Pharmaceutical Products (Nov. 29, 2006), available at www.wcl.american.edu/pjip/documents/ThailandCLAnnouncement.doc.

⁸⁴ See Naomi A. Bass, “Implications of the TRIPS Agreement for Developing Countries Pharmaceutical Patent Laws in Brazil and South Africa in the 21st Century”, 34 George Washington International Law Review, (2002), pp.191, 209.

overriding public interest to the level of “a national emergency or other circumstance of extreme urgency”,⁸⁵ or where the compulsory license is used to remedy anti-competitive practices such as high prices result from domination of the market and failure to supply necessary products including drugs at affordable prices.⁸⁶

Normally, in the case of anti-competitive practice, prior consultation is not required, but the original manufacture should get the agreed royalties, namely money paid to the patent holder to make up for the loss of profit exclusivity. However, the 2001 Doha agreement provides that a country can issue a compulsory license for a drug that threatens a disease causing a severe health emergency in that country without royalties being paid.

Compulsory licensing under TRIPS is a complex matter due to the legal uncertainty and risk:

- Firstly, Article 31 does not specify whether “third party” authorized by the government should be local or foreigner manufactures, or whether a WTO Member is obligated to recognize the effect of foreign compulsory licensing. The right to issue compulsory licenses would be meaningless, especially for developing countries, if they couldn’t grant a license to a foreign manufacturer.
- Secondly, under Article 5B of the Paris Convention, lack of local working which means local industrial use (manufacturing), and commercial use (selling and importing patent protected product), is expressly allowed as ground for issuing compulsory licenses. However, Article 31 of TRIPS doesn’t mention nor excludes it. In this case, one could argue that TRIPS allows granting of compulsory licenses for lack of local working. From the history of TRIPS Agreement negotiation, it is known that local working was one of the most controversial issues during the Uruguay Round negotiations. Developing countries insisted on that local working was one of the obligations of the patentee and pushed for an express recognition of compulsory licensing for lack of local working, while mainly the US was rather arguing for a narrowing of the scope of Article 5A.⁸⁷
- Article 31(f) specifies that the compulsory licenses are issued “*predominantly to supply their domestic market*”, but it doesn’t prohibit the exportation of those products manufactured under compulsory license. Consequently there is an inherent risk that those products manufactured locally under compulsory license will find their way to third country markets where they might come into

⁸⁵ The TRIPS Agreement, Article 31(b).

⁸⁶ The TRIPS Agreement, Article 31(k).

⁸⁷ See Group of Negotiation on Goods, “Multilateral Trade Negotiations -- The Uruguay Round”, Negotiating Group on Trade-Related Aspects of Intellectual Property Rights, including Trade in Counterfeit Goods, Meeting of Negotiating Group of 12-14 July 1989, Document No. MTN/GNG/NG11/14, pp. 38-39.

competition with identical products protected in the third country market. In this case, those imports would be considered illegal.⁸⁸

- For those smaller developing countries where no local manufactures would have the capacity to produce the medicine under compulsory license in sufficient quantities and quality, the right provided to that country under Article 31 would have no effect in practice, unless it was possible to entrust production to a foreign manufacturer.

It is noteworthy that compulsory licensing may be executed by means of parallel importation from compulsory licensees of patent products where the size of the market does not justify the local manufacturing.

3.5.3.5 Parallel Import

Parallel importation is the cross border import and resale, without authorization of the patent holder when there is a significant price difference for the same good in different market. The rationale for parallel importation is to enable the import of patented product from countries where they are sold at lower price into those countries selling the same patented product with a higher price. According to the principle of exhaustion, the patent holder and other authorized parties cannot prohibit the subsequent resale of that product since the moment it is placed in the market.⁸⁹ In other words, the patent holder's rights over a patented product are "exhausted" by the act of selling it. Parallel importing is an important tool enabling the access to affordable medicines because the price of pharmaceutical is very different in different countries and the parallel import can change the price discrimination in the market, so that more patients may have access to cheaper medicine.

Parallel import is allowed in the TRIPS Agreement, while the TRIPS Agreement doesn't address this issue explicitly. Although Article 28 of the TRIPS Agreement grants the exclusive right of import to the patent holder, Article 6 of the TRIPS Agreement enable Members to limit the patent holder's right under the principle of the exhaustion doctrine, and provides that the issue of exhaustion of rights shall not be a matter of dispute settlement; thereby it leaves the countries free to determine their own policy to legalize parallel imports in this respect. They can adopt either national or international exhaustion and the WTO dispute settlement system will not address exhaustion doctrine disputes.

"For the purposes of dispute settlement under this Agreement, subject to the provisions of Articles 3 and 4 nothing in this Agreement shall be used to

⁸⁸ The ECJ held that the holder of a patent can oppose importation of a product produced in another Member State under compulsory license (*Case 19/84, Pharmon BV v. Hoechst AG*, European Court of Justice, E.C.R.2281, [1985] 3 C.M.L.R. 775, 1985).

⁸⁹ See G. Velasquez, P. Boulet, *Globalization and Access to Drugs. Perspectives on the WTO/TRIPS Agreement*, 1999, WHO Health Economics and Drugs, DAP Series, No.7, p.22.

address the issue of the exhaustion of intellectual property rights.”(Article 6)

Based on Article 6, if Members adopt the principle of international exhaustion of patent rights in national law, which means it allows any party to import into the national territory a patented product from any other country in which the product was placed on the market by the patent holder or any authorized party without the consent of the patent holder.⁹⁰ However, the flexibility allowed in TRIPS with respect this means it is not obligation for Members to translate this principle into national regimes. Some scholars argued that it is necessary and recommended that specific legal provision be enacted in national laws.⁹¹

The WHO supports its members in the use of WTO/TRIPS-related safeguard such as compulsory licenses and parallel import to enhance affordability and availability of existing medicines.⁹² Both of them are important tools to promote supply of low-priced drugs or ingredients needed for local production. In some circumstances, Parallel import may be a better alternative means for improving access to essential medicine, comparing with compulsory license, for those developing countries which do not have sufficient technology to produce or to innovate the drugs even if issued by the compulsory licensing.

3.5.3.6 TRIPS Agreement in public health context

The intellectual property standards in TRIPS, historically derived from the developed countries, cannot provide strong support for countries struggling to meet health and development needs, although TRIPS tries to take protection of public health into account. Developing countries can therefore use the flexibility of TRIPS provisions and its safeguard to protect public health.

A noteworthy article with respect to exceptions of patentability is Article 8.1 of the TRIPS Agreement, which authorizes exclusion of pharmaceuticals from patentability, and recognizes the rights of Members to adopt policies in accordance with public health concern. Under Article 8.1, Members may within the scope of the TRIPS Agreement, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition:

⁹⁰ See G. Velasquez, P. Boulet, “Globalization and Access to Drugs. Perspectives on the WTO/TRIPS Agreement”, 1999, WHO Health Economics and Drugs, DAP Series, No.7, p.23.

⁹¹ See Carlos M. Correa, “Implications of the Doha Declaration on the TRIPS Agreement and Public Health”, 2002, WHO Health Economics and Drugs, EDM Series, No.12. CID Working Paper, No.92, p.18.

⁹² See Robert Weissman, “Aids and Developing Countries: Democratizing Access to Essential Medicines”, Foreign Policy in Focus, Vol.4, No.23, August 1999 at 1; Available at <http://www.foreignpolicyinfocus.org/briefs/vol14/v4n23aids.html> (Search date: 28/03/2010).

“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.”(Article 8.1)

Under Article 8.1 developing countries and least developed countries have the discretion to adopt internal measures which are necessary to protect public health and consistent with the TRIPS Agreement, but they might be challenged in respect of measures such as pharmaceutical price controls as well. Some developing countries suggest to amend the article and to eliminate the requirement of “consistent with the TRIPS Agreement”.

In addition, a country could try to invoke the national security exception pursuant to Article 73 of the TRIPS Agreement, which stipulates that:

- *Nothing in this Agreement shall be construed:*
(...)
(b) *To prevent a Member from taking any action which it considers necessary for the protection of its essential security interests;*

Although there is a broad view on the definition of security, the term “security” can be interpreted in the domain of public health, such as diseases which threatens the country’s essential security interests. The Secretary-General’s High-level Panel on Threats, Challenges and Change listed AIDS as a threat to international peace and security.

In the public health context, how to improve the affordability of essential drugs is a public health priority. However, the TRIPS Agreement just establishes general rules, such as the criteria for patentability, with respect to provide patent protection for pharmaceutical products. Some scholars have tried to argue that pharmaceuticals or at least essential pharmaceuticals can be excluded from patentability under one of the exceptions that the TRIPS Agreement contains, allowing Members to exclude certain areas from patentability.⁹³ Some others argued that poorer populations in developing countries should not be expected to pay the same price as do the wealthy developed countries for the drugs, and TRIPS-compliant mechanisms can be used to lower the drug prices. Certain international organizations, such as the WHO, WTO, and United Nations High Commission on Human Rights, also made every endeavor to search feasible schemes which enable many developing countries to improve the affordability to essential medicines. Initiated by the Africa Group, WTO Members are engaged in a series of special discussion on TRIPS and public health, and clarifying the role of intellectual property rights and their impact on access to medicines. At the TRIPS Council meeting in June, 2001 the issue of the TRIPS Agreement and public health for the first time was put on the agenda. Zimbabwe, representing the African Group, made a

⁹³ Holger Hestermeyer, *Human Rights and the WTO: The case of Patent and Access to Medicine*, Oxford University Press, 2007 Year.

statement proposing that Members issue a special declaration on the TRIPS Agreement and Access to Medicines at the Ministerial Conference in Qatar.⁹⁴

Thereafter the most significant achievement of those international actions came, followed by the 2001 Doha Declaration on the TRIPS Agreement and Public Health. The Doha Declaration recognizes the gravity of public health problems affecting many developing countries and least-developed countries. It marks a turning point and a significant milestone on the agenda of providing access to medicine.⁹⁵

3.5.3.7 The 2001 Doha Declaration on the TRIPS Agreement and Public Health (“The Doha Declaration”)

In 2001, WTO Members adopted a special Ministerial Declaration – “The Doha Declaration on the TRIPS Agreement and Public Health”, at the WTO Ministerial Conference in Doha to clarify ambiguities between the need for government to apply the principles of public health and the terms of the Agreement on TRIPS Agreement, with particular concerns on the patent rules which might restrict the access to affordable medicines for developing countries.⁹⁶

As paragraph 3-4 of Doha Declaration states:

*“We recognize that intellectual property protection is important for the development of new medicines. We also recognize the concerns about its effects on prices”.*⁹⁷

*“We agree that the TRIPS Agreement does not and should not prevent members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, 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”.*⁹⁸

The Doha Declaration acknowledge that medicines and IPR rights play important role in the discussion of public issues, but IP protection also produces negative effects, particularly on prices.

⁹⁴ WTO Council for TRIPS, “Special Discussion on Intellectual Property and Access to Medicines”, WTO Document No.IP/C/M/31 (Restricted), 10 July 2001, p. 4.

⁹⁵ See Frederick M. Abbott, “The Doha Declaration on The TRIPS Agreement and Public Health: Lightening a Dark Corner in WTO”, *Journal of International Economic Law*, Vol.5, issue 2, 2002, pp. 480-489.

⁹⁶ See “The Doha Declaration on The TRIPS Agreement and Public Health”, WTO Website; Available at http://www.who.int/medicines/areas/policy/doha_declaration/en/index.html (Search date: 04 April 2010).

⁹⁷ The Doha Declaration, supra note 96, Para. 3.

⁹⁸ The Doha Declaration, supra note 96, Para. 4.

On one hand, The Members reiterate their commitment to implement the TRIPS Agreement to support public health, and on the other hand, The Doha Declaration affirmed the right of Members to use the flexibilities in the TRIPS agreement to achieve the goal of promoting access to medicine, as well as highlights the importance of the substantive clarifications in the following aspects:

1. The right of individual countries to issue compulsory licenses of public emergencies was clarified and emphasized in the 2001 Doha Declaration on the TRIPS Agreement. The Doha Declaration states that each Member has the freedom to determine the grounds upon which compulsory licenses are granted, and determine what constitutes a national emergency or other circumstances of extreme urgency.⁹⁹ It addresses the problems faced by the countries wanting to declare HIV/AIDS as a national emergency.

2. The Declaration resolves that “the effects of the provision in the TRIPS Agreement that are relevant to the use of exhaustion of intellectual property rights are to leave each member free to establish its own regime for such exhaustion without challenge”.¹⁰⁰

3. With respect to the transition period for undeveloped countries, the Doha Declaration have granted an extension to them such that they will not be obligated, with respect to pharmaceutical products, to implement or apply the patent or disclosed information sections of the TRIPS Agreement until 1 January 2016”.¹⁰¹

4. The Declaration 2001 doesn't propose explicitly which kind of medicine products should be promoted, i.e. patented medicine, or active ingredients or intermediate products and patented production processes. In general developing countries wanted wide public health-related product coverage, but most industrialized countries wanted to limit the product scope of pharmaceutical products and patented process. Therefore a compromised solution was suggested in the 1 September 2003 decision of “implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and public health”. It defines the “pharmaceutical product” as the following:¹⁰²

- “pharmaceutical product” means any patented product, or product manufactured through a patented process, of the pharmaceutical sector needed to address the public health problems as recognized in paragraph 1 of the Declaration. It is understood that active ingredients necessary for its manufacture and diagnostic kits needed for its use would be included.

⁹⁹ The Doha Declaration, supra note 96, Para. 5.

¹⁰⁰ The Doha Declaration, supra note 96, Para. 5 (d).

¹⁰¹ The Doha Declaration, supra note 96, Para.7.

¹⁰² See “Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and public health”, WIPO, General Council, WT/L/540 and Corr.1, 1 September 2003, Para. 1(a). Available at: http://www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm#asterisk (Search date: 23/05/2010).

5. In TRIPS Agreement, Article 31(f) stipulates that the use of compulsory licenses “shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use. The Doha Declaration recognized this problem in paragraph 6 that for those countries without technological capacity to reverse engineer and manufacture drugs locally, it is difficult to make effective use of compulsory license, which constitutes an obstacle to promote access to medicine:¹⁰³

- We recognize that WTO members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement. We instruct the Council for TRIPS to find an expeditious solution to this problem and to report to the General Council before the end of 2002.

In 2003 year, the Council for TRIPS responded through a decision permitting member states with insufficient pharmaceutical manufacturing capacities temporary waiver to article 31(f) under TRIPS Agreement.¹⁰⁴ The countries with manufacturing capacity can export essential medicines to countries with no or insufficient manufacturing capacity.

However this decision created additional hurdles to the paragraph 6 problem. A developing country wishing to import the medicine and the exporting members must notify the Council for TRIPS of the grant of the license.¹⁰⁵ This notification will cause some delay in case of urgent need of drugs. A restriction is also placed on the quantity of medicines that can be produced for export under a compulsory license.¹⁰⁶ Another important issue is that for those least developed country without sufficient capacity, their health service will rely upon the medical and pharmaceutical industry of developed and developing countries who already do have patent regime over those sector in these days. In such a condition the exemption given by Doha Declaration is unable to help Least Developed Countries to give good access to medicine to their poor people. Thus the more important task is to think about the effective implementation of Doha Declaration on Least Developed Countries.

The scholar Sirinivas summarizes the changes created by this decision as the following:

“Under this deal however serious the health situation be a developing nation which lacks the capacity to manufacture the needed drugs will have

¹⁰³ See The Doha Declaration, supra note 96, Para.6.

¹⁰⁴ See “Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and public health”, WIPO, General Council, WT/L/540 and Corr.1, 1 September 2003.

¹⁰⁵ See “Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and public health”, WIPO, General Council, WT/L/540 and Corr.1, 1 September 2003, Para. 2(c).

¹⁰⁶ See “Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and public health”, WIPO, General Council, WT/L/540 and Corr.1, 1 September 2003, Para.2 (b) (1).

to request another government to invoke compulsory licensing or suspend the rights of the patent holder and provide license to local firm or firms to produce and export the needed drugs. The deal adds many layers of procedures to the whole process. They have to notify the TRIPS Council, about the intention to use this system and the country that has issued the compulsory license has to meet many conditions and all these measures not only will delay the manufacture and supply but also increase the cost of the drugs.”¹⁰⁷

In conclusion, The Doha Declaration stressed the need for the TRIPS Agreement to be a part of the solution in addressing public health challenges, and further reassures that the safeguards contained in the TRIPS should be used to overcome the barrier intellectual property may pose to access to medicine. The Doha Declaration refers to several aspects, including the right to grant compulsory licenses and the freedom to determine the grounds upon which licenses are granted, the right to determine what constitutes a national emergency and circumstances of extreme urgency, and the freedom to establish their own scheme of exhaustion of intellectual property rights without challenge under any of the WTO Agreements.

Although The Doha Declaration proposed a more effective mechanism for balancing IPR protection and public health comparing with the TRIPS Agreement, developing countries still faced difficulties in implementing the flexibilities in the TRIPS Agreement, specially how to solve the technical problem in paragraph 6. The implementation decision of paragraph 6 posts the additional administrative burden and cost, which blocks, rather than promotes the access to medicines for people in developing countries.

¹⁰⁷ See K.R. Sirinivas, “Interpreting Paragraph 6: Deal on Patents and Access to Drugs”, Economic and Political Weekly, Vol.38, Issue 38, 20 September 2003.

4. Access to medicine as Human Rights

The thesis will firstly set up the principle norms under international human rights law relating to access to medicine, since how norms relating to access to medicine have been interpreted at the national and international levels can lead us to understand the normative evolution of rights concepts, especially in recent years the international jurisprudence has developed so rapidly. The thesis examines the obligation under human rights instruments, which could provide the practical basis for policy-making and legislation, and then it will discuss especially the government's duties established under international law: to respect, protect, and to fulfill.

The legal right to access to medicine is not mentioned explicitly in any agreement, but commonly based on the Right to Health, Right to Life and Right to Enjoy the Benefits of Scientific Progress and its applications. These basic human rights are protected by international human rights law, especially treaty law. When the main human rights instruments were drafted, access to medicine was considered as one of a number of reasonable measures constituting healthcare, but the lack of access to medicine was progressively realized that it was contrary to human rights. More and more people argue the right to access to medicine is indispensable for leading a life in human dignity and it is a prerequisite for the realization of other human rights.

Treaty sources of international human rights law include both international and regional treaties. Among those international instruments, the two most widely recognized international human rights treaties are the International Covenant on Civil and Political Rights (ICCPR),¹⁰⁸ which requires States to respect and ensure a range of civil and political rights including the right to life, and the International Covenant on Economic and Social Rights (ICESCR)¹⁰⁹, which requires States to realize a range of substantive economic, social and cultural rights to establish the basic conditions for a dignified life, including right to life, right to enjoy the benefits of scientific progress and its application. All these two treaties are built upon and codify with the basic norms set up in Universal Declaration of Human Rights (UDHR).¹¹⁰ Other significant legal sources are widely accepted conventions,

¹⁰⁸ International Covenant on Civil and Political Rights, G.A.Res.2200(XXI), 21 U.N.GAOR Supp.(No.16), U.N.Doc.A/6316 (1966), 993 U.N.T.S. 171, adopted 16.12.1966, entry into force on 23.3.1976. Ratified by 154 countries as of June 2005.

¹⁰⁹ International Covenant on Economic, Social and Cultural Rights, G.A. Res.2200A (XXI), 21 U.N.GAOR Supp.(No. 16), at 49, U.N. Doc.A/6316 (1966), 993 U.N.T.S. 3, adopted 16.12.1966, entry into force 3.1.1976. It was ratified by 151 countries in June 2005.

¹¹⁰ "Universal Declaration of Human Rights "(UDHR), adopted 10 December 1948, G.A. Res. 217A (III), U.N. GAOR, 3rd Session (Resolutions, pt.1) at 71, U.N. Doc, A/810 (1948).

other UN documents, regional conventions and treaties, as well as state regulation or legislation.

Lack of access to medicine similarly implicate on the right to life, since the enjoyment of the right to health is dependent on other rights, such as human dignity, right to life, etc. The Vienna Declaration and Programme of Action, also known as VDPA, emphasizes that all human rights are of equal importance, and there is no neat distinction between civil and political rights and economic, social and culture rights. The interrelatedness, interdependence and indivisibility of all human rights were pronounced in Part 1, para.5 of VDPA:¹¹¹

“All human rights are universal, indivisible and interdependent and interrelated. The international community must treat human rights globally in a fair and equal manner, on the same footing, and with the same emphasis”.

Inability of Africans to have access to life-saving medications in the context of life threatening diseases, such as HIV/AIDS, malaria and so on, erode their rights to life and rights to health. National courts in Costa Rica, India, Colombia, Argentina, and South Africa, among others, have determined that the state has an obligation to provide drugs for citizens suffering from HIV/AIDS and other infectious diseases.¹¹²

On the other hand, although an argument for the right to medicine could be based on the Right to Life and Right to Health and Right to Enjoy the Benefits of Scientific Progress and its applications, the enforcement mechanism provided by the treaties does not offer much practical assistance to individuals demanding fulfillment of the right. Doha Declaration on TRIPS and Public Health does affirm “that the Agreement can and should be interpreted and implemented in a manner supportive of WTO Member’s right to protect public health and, in particular, to promote access to medicines for all”.¹¹³ The affirmation speaks to only the state’s right to promote access to medicines for all, not an individual right to demand access to medicine.

Many rights, whether classified as civil and political, or else as economic, social, and cultural rights, “can only be defined with specificity when located in a given context.”¹¹⁴ The term “access to medicine” suggests many questions: What does access to medicine mean in the context of human rights? Can it be translated into a legal right? Can it be made operational at the level of international human rights law? If it recognized as means of

¹¹¹ VIENNA DECLARATION AND PROGRAMME OF ACTION, UN Doc.A/CONF.157/23, 12 July 1993, Part I, Para.5

¹¹² Alicia Ely Yamin, “Not Just a Tragedy: Access to Medications as a Right under International Law”, Boston University International Law Journal, Vol.21, Issue 178, p.339 (2003).

¹¹³ The Doha Declaration on TRIPS and Public Health, supra note 96, para.4

¹¹⁴ J.P.Alston, “Making Space for New Human Rights: The Case of the Right to Development”, Harvard Human Rights Yearbook, Vol.1, (1988), p.35.

enjoyment of right to life, right to health, and other human rights, how can those rights be enforced or implemented since no person and no government can guarantee good health to an individual?

4.1 Definition of Access to Medicine

When we talk about access to medicine, it has the following dimensions:

Firstly, the medicine means all the essential and available medicine. It includes not only end products or medicines but also all public health-related products, including active pharmaceutical substances and diagnostic kits, as well as related technical process.

Accessibility requires that the essential medicines must be:¹¹⁵ (a) economically accessible and affordable to all, not only for rich people, but also for those living in poverty; not only in developed countries, but also in developing countries; (b) the availability in sufficient quantities of pharmaceuticals and medical technology; (c) medicines must be accessible without any discrimination on any of the prohibited grounds, such as sex, race, ethnicity and social-economic status; (d) the assurance that pharmaceuticals or medical technologies are scientifically and medically appropriate and of good quality.

According to the General Comment No.14 “*The right to the highest attainable standard of health*”, medicines must be available in sufficient quantity, without discrimination, overcoming physical and economical constrictions, respecting medical ethics, being scientifically and medically appropriate, which are in line with the WHO Statement that essential medicines should be available within the context of health systems in adequate amounts all the times, in the appropriate dosage forms, with assured quality and information, and at a price that the individual and community can afford.¹¹⁶

The World Health Organization defined the concept of essential medicines as “that the priority health care needs of the population”, and “access to medicines depends on four factors: rational selection, affordable prices, sustainable financing and reliable health systems”.¹¹⁷ As to how to select essential medicines, the WHO Expert Committee recommended several criteria for selection and use of essential medicines, such as only medicines for which sound and adequate evidence of efficacy and safety in a variety of

¹¹⁵ Alicia Ely Yamin, “Not just a tragedy: Access to medications as a right under international law”, p.132, para.3.

¹¹⁶ Xavier Seuba, “Round Table: A human rights approach to the WHO Model List of Essential Medicines”, Bulletin of the World Health Organization, Bull World Health Organ, Vol.84, No.5, Geneva, May 2006, p.405, para.2.

¹¹⁷ “WHO Policy Perspectives on Medicines: The Selection of Essential Medicines”, Issue No.004, World Health Organization, Geneva, June 2002, para.1. Available at: <http://apps.who.int/medicinedocs/en/d/Js2296/> (Search date: 28/05/2010).

settings is available should be selected; relative cost-effectiveness is a major consideration for choosing medicines; each medicine selected must be available in a form in which adequate quality can be ensured; its stability under the anticipated conditions of storage and use must be determined.¹¹⁸

4.2 Right to Life

The Right to Life, which has attained *jus cogens* status under international law, is a fundamental human right. It is nowadays universally acknowledged as a basic human right and the enjoyment of right to life is a necessary condition of the enjoyment of all other human rights.

4.2.1 Legal sources of “Right to life”

The Universal Declaration of Human Rights and general treaties on human rights, such as the International Covenant on Civil and Political Rights, the European, African and Inter-American human rights conventions, all include the right to life as one of the fundamental human rights of human person. The “right to life” provisions may currently be considered binding on all States by virtue of customary international law.

The Right to life, as a fundamental right, was written in Article 3 in the UDHR: “Everyone has the right to life, liberty and security of person”. Article 6(1) of the International Covenant on Civil and Political Rights (ICCPR) clearly set forth a right to life: “Every human being has the inherent right to life. This right shall be protected by law. No one shall be arbitrarily deprived of his life”. Pursuant to Article 4 of the ICCPR, no derogation is permitted even if times of a public emergency threatening the life of the nation.

Other provisions relating to the life in the Universal Declaration and the International Covenant on Civil and Political Rights are the prohibition of torture or cruel, inhuman or degrading treatment, which are recognized and provided for in the UN Covenant on Civil and Political Rights, Article 7; the European Convention on Human Rights, Article 3; the American Convention on Human Rights, Articles 4 and 5.

¹¹⁸ See Xavier Seuba, “Round Table: A human rights approach to the WHO Model List of Essential Medicines”, *Bulletin of the World Health Organization* 2006, 84: p.405, para.2.

¹¹⁷ “WHO Policy Perspectives on Medicines: The Selection of Essential Medicines”, Issue No.004, World Health Organization, Geneva, June 2002, para.3. Available at: <http://apps.who.int/medicinedocs/en/d/Js2296e/> (Search date: 28/05/2010).

At the regional level, The European Convention for the Protection of Human Rights and Fundamental Freedoms states in article 2(1): “Everyone’s right to life should be protected by law.”¹¹⁹

In the Inter-American system, article 4 of the American Convention on Human Rights states that: “Every person has the right to have his life respected. This right shall be protected by law and, in general, from the moment of conception. No one shall be arbitrarily deprived of his life”.

4.2.2 Interpretation of the concept of “Right to Life”

Along with the development of international human rights law, the traditional and narrow approach to right to life as strictly a civil right has moved into a modern and wider approach to it, which encompasses the minimum conditions for an adequate and dignified standard of living.

The fundamental right to life comprises not only the right of every human being not to be deprived of his life, which falls into the area of civil and political rights, but also the right to have the appropriate means of subsistence and a decent standard of life, which belongs to the category of economic, social and culture life.¹²⁰ Without an adequate standard of living, such as “the prevention, treatment and control of epidemic, endemic, occupational and other diseases” regulated in Article 12(c) in the ICESCR, the right to life can’t be realized in a full sense.¹²¹ Thus the UN General Assembly affirms that all people and all individuals have an inherent right to life, and that the safeguarding of this foremost right is an essential condition for the enjoyment of the entire range of economic, social and cultural, as well as civil and political rights.¹²²

From this perspective, right to health lies at the basis of full realization of right to life, and access to essential medicines can be considered as extension or corollary of the right to life. In other words, right to life in a wide dimension entailed the needed recognition of access to medicine as human rights, since it protect the life of human person as a means of survival. The Inter-American Commission on Human Rights also holds the opinion that “the rights connected to life and integrity should be accompanied by parallel improvements in the standards of living of the

¹¹⁹ European Convention for the Protection of Human Rights and Fundamental Freedoms; it was opened for signature November 4, 1950, 213 U.N.T.S. 221, 224 (entered into force Sept. 3, 1953).

¹²⁰ F. Przetacznik, “The Right to Life as a Basic Human Right”, Human Rights Journal, Vol.IX, Issue 4, 1976, p.603.

¹²¹ Th. C.Van Boven, “People Matter: Views on International Human Rights Policy, published by Meulenhoff Amsterdam, 1st edition, 1982 year, p.77.

¹²² The UN General Assembly Resolution 37/189 A, “Human rights and scientific and technological developments”, 18 December 1982, para.13.

population, in relation to economic, social and cultural rights, the implementation of which should be a priority for the state”.¹²³

International institutions and national constitutional courts are increasingly interpreting the right to life as encompasses a right to conditions that sustain life, including a right to minimum standards of health.¹²⁴ For instance, in the case of *F. Hoffman-La Roche Ltd. & Anr. Vs. Cipla Limited*, the Delhi High Court in India refused to injunct the defendant to manufacture Roche’s patented lung cancer drug “Tarceva” on the ground of public interest and right to life. The court has stated that right to life of the end-users of the life-saving drugs will outweigh the right to exploit a patented drug vested by the patentee.¹²⁵ Also, the Supreme Court in Costa Rica has held the opinion that a denial of access to life-saving medicine for people infected with HIV is infringement on their right to life.¹²⁶

In General Comment 6 (16) on article 6, the Committee has interpreted the right to life in Article 6 of the ICCPR more broadly:

*“Moreover, the Committee has noted that the right to life has been too often narrowly interpreted. The expression ‘inherent right to life’ cannot properly be understood in a restrictive manner, and the protection of this right requires that States adopt positive measures. In this connexion, the Committee considers that it would be desirable for States to take all possible measures to reduce infant mortality, to increase life expectancy and to take measures to eliminate malnutrition and epidemics”.*¹²⁷

4.2.3 Access to medicine as Right to Life

Does right to life include access to medicine? Traditionally, the right to life is viewed as a negative right to prevent intentional loss of lives. The right is limited to prohibit the state from killing persons, but it does not guarantee an appropriate standard for living, food, housing and medical care.¹²⁸

¹²³ See Annual Report of the Inter-American Commission on Human Rights 1991, Inter-American Commission on Human Rights, at chapter 4, OEA/Ser.L/V/II.81 (1992). Available at www.cidh.org/annualrep/91span/cap.IVc.guatemala.htm (Search date: 01/05/2010).

¹²⁴ Melissa McClellan, “Tools for Success: The TRIPS Agreement and the Human Right to Essential Medicines”, Washington and Lee Journal of Civil Rights and Social Justice, Vol.12, 2005, p.15, para.2.

¹²⁵ See the case *F. Hoffman-La Roche Ltd. & Anr. Vs. Cipla Limited*, in the High Court of Delhi At New Delhi, FAO (OS) 188/2008, Date of decision: April 24th 2009; Available at: <http://www.indiankanoon.org/doc/401740/> (Search date: 06/06/2010)

¹²⁶ A.E. Yamin, “Not Just a Tragedy: Access to Medication as a Right under International Law”, 21 Boston Univ. ILJ (2003) p.326.

¹²⁷ See Report of the Human Rights Committee, Official Records of the General Assembly, Thirty-seventh Session, Supplement No. 40, (A/37/40) (1982), annex V, para.5.

¹²⁸ Y Dinstein, “The Right to Life, Physical Integrity and Liberty” in L Henkin (Ed), *The International Bill of Rights. The Covenant on Civil and Political Rights*, Cambridge University Press, November 1981, p.115.

However, recent developments now consider the right to life as a positive right placing an obligation on states to protect universal loss of lives,¹²⁹ which distinct the “protection of life” to “protection of right to life”. The right to life has been extended to the basic conditions of life, the component necessary for survival, even if that part of right is to some extent coextensive with economic, social and culture rights, which includes access to life saving medicines.¹³⁰ Given the dispensability of these medicines to life, the lack of accessibility and affordability to such medicine will ultimately deprive people of their right to life. In addition, inequitable distribution of medicine, if they result in an arbitrary deprivation of life, would constitute the violation of the right to life provisions provided by the international human rights instruments.

The access to essential drugs, as means of survival, falls into the realm of right to life. In fact, the inter-American Commission on Human Rights has been attentive to address the requirement of survival as a component of the right to life: it interpreted that the right to life comprises or requires not only protection in the form of preventive measures against all forms of ill-treatment and threats to life and health, but also the realization of “the economic and social aspirations” of all peoples by pursuing policies that assign priority to “the basic needs of health, nutrition, and education”; in the words of the Commission, “the priority of the ‘right of survival’ and ‘basic needs’ is a natural consequence of the right to personal security”.¹³¹ Similarly, when spoke to the right of life, the Commission on the Rights of the Child emphasized that States Parties shall ensure to the maximum extent possible the survival and development of the child.¹³² So the duty to provide access to essential medicines is clearly originated from the expanded notions of obligations deriving from the right to life.

4.3 Right to health

Access to medicine constitutes an integral part of right to health, which is set out in fully many treaties and instruments. Right to health has undergone remarkable normative development and clarification in recent years.

¹²⁹ Ebenezer Durojaye, “Compulsory Licensing and Access to Medicine in Post Doha Era: What hope for Africa?”, *Netherlands International Law Review*, Vol.55, Issue 1, 2008, page 37 of 33-71, para.4; also see Rebecca J. Cook, et al., “Reproductive Health and Human Rights Integrating Medicine, Ethics and Law”, Oxford University Press, USA, 1st edition, June 2003, p. 161, para.3.

¹³⁰ Holger Hestermeyer, “Human Rights and the WTO: The case of Patent and Access to Medicine”, Oxford University Press, 2007 Year, p.116, para.2.

¹³¹ See Brown Weiss, “*Environmental change and international law: New challenges and dimensions*”, chapter 3: The fundamental right to life at the basis of the ratio legis of international human rights law and environmental law, The United Nations University Press, 1992.

¹³² Convention on the Rights of the Child, G.A. res. 44/25, annex, 44 U.N. GAOR Supp. (No. 49) at 167, U.N. Doc. A/44/49 (1989), entered into force September 2 1990, Article 6(2).

4.3.1 Legal sources of “Right to health”

The Right to health, as a fundamental right, is entrenched in the international human rights instruments. The ICESCR and ICCPR elaborate upon the foundation laid by the Universal Declaration of Human Rights. Both of them have been ratified by large numbers of States and are extremely important in providing the specific legal obligations of State actors with regard to all aspects of human rights protection.

Article 25.1 of the Universal Declaration of Human Rights affirms: “Everyone has the right to a standard of living adequate for the health of himself and of his family, including food, clothing, housing and medical care and necessary social services”.

Article 12 of ICESCR contains similar language which guarantees the right to highest attainable standard of health to everyone.

“(1) The States Parties to the present Covenant recognize the right of everyone to the enjoyment of the highest attainable standard of physical and mental health”.

The right to health is also set out in other international treaties. For instance, Article 24 of the Children’s Convention provides a similar regulation as that of the ICESCR in terms of the right of children. Article 24(1) of the Children’s Convention states:¹³³

“States Parties recognize the right of the child to the enjoyment of the highest attainable standard of health and to facilities for the treatment of illness and rehabilitation of health. States Parties shall strive to ensure that no child is deprived of his or her right of access to such health care services”.

Article 5(e) of The International Convention on the Elimination of All Forms of Racial Discrimination of 1965 stipulates that States Parties undertake to prohibit and eliminate racial discrimination in all forms and to guarantee right of everyone in the enjoyment of the right to public health, medical care, social security and social services.¹³⁴ Similarly, Article 12 of the Convention on Elimination of All Forms of Discrimination against Women of 1979 obligates State Parties to eliminate gender-based discrimination in health care.¹³⁵

¹³³ Convention on the Rights of the Child, Adopted and opened for signature, ratification and accession by General Assembly resolution 44/25 of 20 November 1, Entry into force 2 September 1990.

¹³⁴ International Convention on the Elimination of All Forms of Racial Discrimination, Adopted and opened for signature and ratification by General Assembly resolution 2106 (XX) of 21 December, entry into force 4 January 1969.

¹³⁵ Convention on the Elimination of All Forms of Discrimination against Women, G.A. res. 34/180, 34 U.N. GAOR Supp. (No. 46) at 193, U.N. Doc. A/34/46, entered into force Sept. 3, 1981.

Several regional human rights instruments also recognize the right to health, such as the European Social Charter of 1961 as revised (Article 11), the African Charter on Human and Peoples' Rights of 1981 (Article 16) and the Additional Protocol to the American Convention on Human Rights in the Area of Economic, Social and Cultural Rights of 1988 (Article 10), American Declaration on the Rights and Duties of Man (Article 33).

Similarly, the right to health has been proclaimed by the Commission on Human Rights In its resolution 1989/11, as well as in the Vienna Declaration and Programme of Action of 1993 and other international instruments.

On the domestic level, the right to health or a more limited right to health care, either as a directive principle or as a fundamental right, is enshrined in over sixty national constitutions.¹³⁶ The domestic courts are increasingly finding specific state obligations to provide medication as part of the right to health. For instance, among many countries, the national courts in Costa Rica, India, Venezuela, Colombia, Argentina, and South Africa held that the state has obligations to provide medications in HIV/AIDS cases and for other diseases.¹³⁷

4.3.2 Interpretation of the concept of “Right to Health”

Traditionally health, understood as the “absence of disease”, was seen as falling within the private, rather than public realm. In the 1843 Mexican institution included references to the state’s responsibility for preserving public health, but it didn’t mention right to health specifically.¹³⁸

The first time the right to health was recognized internationally by the WHO Constitution, which affirms that “The enjoyment of the highest stainable standards of health is one of the fundamental rights of every human being without distinction of race, religion, and political belief, economic or social conditions.”¹³⁹

¹³⁶ See “The Right of Everyone to the Highest Attainable Standard of Physical and Mental Health”, Report of the Special Rapporteur, Paul Hunt, submitted in accordance with Commission Resolution 2002/31”, U.N. ESCOR, 59th Session, Agenda Item 23, U.N.Doc.E/CN.4/2003/58 (2003).

¹³⁷ See Alica Ely Yamin, “Not just a tragedy: Access to medications as a right under international law”, Boston University of International Law Journal, 2002, 21: 352-370.

¹³⁸ See “The right to health, Economic, Social & Cultural Rights Activism: A Training resources”, University of Minnesota. Available at http://www1.umn.edu/humanrts/edumat/IHRIP/circle/modules/module14.htm#_edn2 (Search date: 08/05/2010)

¹³⁹ The World Health Organization Constitution, p.1, para.3; Available at: <http://www.who.int/governance/eb/constitution/en/index.html> (Search date: 15/05/2010).

In intentional human rights literature and in recent human rights instruments, the terms “right to health” are used as a convenient abbreviation for the more accurate expression “right of everyone to the enjoyment of highest attainable standard of physical and mental health”.

In 1988 the Organization of American States adopted an Additional Protocol to the American Convention on Human Rights in the area of Economics, Social and Culture Rights, of which Article 10 states directly that “everyone shall have the right to health, understood to mean the enjoyment of the highest level of physical, mental and social well-being”.¹⁴⁰ It provides that in order to ensure the exercise of the right to health, the States Parties agree to recognize health as a public good, and take measures to make sure that essential health care is available to all individuals and families, and extension of benefits of health services to all individuals subject to the State’s jurisdiction.¹⁴¹ It also provides a significant measure not expressed in other international human rights treaties, namely “satisfaction of the health needs of the highest risk groups and of those whose poverty makes them the most vulnerable”.¹⁴²

However, right to health should not be given the interpretation of guarantee health to each individual. It is a misconception that the State has to ensure everyone be healthy, since good health is influenced by several factors that are outside the direct control of States. Rather, the right to health refers to the right to the enjoyment of a variety of goods, facilities, services and conditions necessary for its realization, which includes the access to essential medicine.

4.3.3 Access to medicine as Right to Health

To what extent access to medicine interferes with the right to health? In recent years, right to health has gone through a remarkable development. It is increasingly recognized that health is a fundamental human right indispensable for the exercises of other human rights, and access to medicine is the core content of right to health.

Pursuant to Article 12.2(c) (d) of ICESCR, the right to health care includes the right to emergency care and health facilities, goods and services. Access to medicine, is the core content of the right to health, both as treatment for

¹⁴⁰ Additional Protocol to the American Convention on Human Rights in the Area of Economic, Social and Cultural Rights “Protocol of San Salvador”, adopted in San Salvador on November 17, 1988 (not yet in force).

¹⁴¹ Additional Protocol to the American Convention on Human Rights in the Area of Economic, Social and Cultural Rights “Protocol of San Salvador”, adopted in San Salvador on November 17, 1988 (not yet in force), Article 10(a) and Article 10(b).

¹⁴² Additional Protocol to the American Convention on Human Rights in the Area of Economic, Social and Cultural Rights “Protocol of San Salvador”, adopted in San Salvador on November 17, 1988 (not yet in force), Article 10(f).

epidemic and endemic diseases and as part of medical attention in the event of any kind of sickness.

The United Nations Committee on Economics, Social and Culture Rights states that the right to health contains a series of interrelated and minimum four elements in General Comment No.14: availability, accessibility (affordability), acceptability (medical ethics) and quality.¹⁴³

(a) *Availability*. Functioning public health and health-care facilities, goods and services, as well as programmes, have to be available in sufficient quantity within the State party.

(b) *Accessibility*. Health facilities, goods and services have to be accessible to everyone without discrimination, within the jurisdiction of the State party. Accessibility has four overlapping dimensions:

- Non-discrimination: health facilities, goods and services must be accessible to all, especially the most vulnerable or marginalized sections of the population;
- Physical accessibility: health facilities, goods and services must be within safe physical reach for all sections of the population, especially vulnerable or marginalized groups, such as ethnic minorities and indigenous populations, women, children, adolescents, older persons, persons with disabilities and persons with HIV/AIDS;
- Economic accessibility (affordability): health facilities, goods and services must be affordable for all based on the principle of equity. Equity demands that poorer households should not be disproportionately burdened with health expenses as compared to richer households;
- Information accessibility: accessibility includes the right to seek, receive and impart information and ideas concerning health issues.

(c) *Acceptability*. All health facilities, goods and services must be respectful of medical ethics and culturally appropriate, i.e. respectful of the culture of individuals, minorities, peoples and communities, sensitive to gender and life-cycle requirements.

(d) *Quality*. Health facilities, goods and services must also be scientifically and medically appropriate and of good quality.

General comment 14 not only embodied the right to essential medicines, but also established that the provision of essential medicines is one of the state's

¹⁴³ "General Comment No.14, "The right to the highest attainable standard of health: 08/11/2000", New York: United Nations Committee on Economic, Social and Culture Rights, 22nd Session, Agenda item 3, Doc. E/C.12/2000/4, 2000, para.12.

minimum core duties under the ICESCR.¹⁴⁴ The state members to the covenant are legally obligated that they do not violate the right to essential medicine.

In addition, in 2000, the Committee in its General Comment No.14 had interpreted the obligation under Article 12(2)(d) of ICESCR – “the creation of conditions which would assure to all medical service and medical attention in the event of sickness” – to include the provision of essential drugs.¹⁴⁵

The Commission on Human Rights adopted a resolution in 2001, in which it recognized “that access to medication in the context of pandemics such as HIV/AIDS is one fundamental element for achieving progressively the full realization of the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.”¹⁴⁶ It reaffirmed that in this context access is a fundamental element of the progressive realization of the right to health.

4.4 Right to Enjoyment of the Benefits of Scientific Progress and Its application

Comparing to Right to Life and Right to health, the international human rights community doesn't pay much attention to the right to enjoyment of the benefits of scientific progress and its application although it is very important human right written down in many international instruments. Although in the past decade the UN human rights apparatus has expressed increasing concerns about the implications of intellectual property norms for the realization of human rights, it does not specifically address the subject of the impact on science and technology.

The ongoing process of science poses challenges for the general theory of human rights in the world today. Scientific advances in medicine plays an important role in curing more disease and enhance the quality of life. However, these advances are driven primarily by market consideration and the pursuit of commercial benefits that often do not correspond to the health needs of the world's populations, especially the health needs in developing countries, thus affecting the right to health and right to life.

¹⁴⁴ See General Comment No.14, “The Right to the Highest Attainable Standard of Health”, New York: U.N. CESCR, 22nd Session, Agenda item 3, Doc.E/C.12/2000/4, 2000, para.43(d); available at [http://www.unhchr.ch/tbs/doc.nsf/\(symbol\)/E.C.12.2000.4.En](http://www.unhchr.ch/tbs/doc.nsf/(symbol)/E.C.12.2000.4.En) (Search date: 20/05/2010).

¹⁴⁵ General Comment No.14, “The right to the highest attainable standard of health: 08/11/2000”, New York: United Nations Committee on Economic, Social and Culture Rights; Doc. E/C.12/2000/4, para.17.

¹⁴⁶ Commission on Human Rights Resolution 2001/33, Access to medication in the context of pandemics such as HIV/AIDS, UN Doc.E/CN.4/RES/2001/33, 20 April 2001, Para. 1.

4.4.1 Legal sources of Right to enjoy the benefits of scientific progress and its application

The enjoyment of benefits of science and is considered to be a fundamental human rights that belongs to everyone. The right to enjoy the benefits of scientific progress and its applications is enshrined in various international and regional instruments.

It was proclaimed for the first time in Article XIII of the American Declaration of the Rights and Duties of Man (1948) which states that:¹⁴⁷

“Every person has the right to take part in the cultural life of the community, to enjoy the arts, and to participate in the benefits that result from intellectual progress, especially scientific discoveries”.

The right to enjoy the benefits of scientific progress and its application was further affirmed in Article 27 of the Universal Declaration of Human Rights (1948) which provides that “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”.

Building on the UDHR, the right became a binding norm when it was written down in the ICESCR. Article 15(b) stipulates that “the State Parties to the present Covenant recognize the right of everyone to enjoy the benefits of scientific progress and its applications”.

4.4.2 Interpretation of the concept of Right to Enjoy the benefits of scientific progress and Its application

There was neglect with conceptualizing the right to benefits of scientific progress and its applications under a human rights framework, including the access to medicine. Traditionally science has been viewed as an area of study or research to seek knowledge and truth about the world, which was rarely addressed through a human rights lens. However, more recently the development of science, especially applied science and technology, has been recognized to be conflict to human rights to some extent.

In the mid-1970s, United Nations Educational, Scientific and Cultural Organization (UNESCO) presented science as a resource to promote the realization of human rights and fundamental freedoms. The Declaration on the Use of Scientific and Technological Progress in the Interest of Peace and for the Benefit of Mankind, noted that “scientific and technological progress

¹⁴⁷ American Declaration of the Rights and Duties of Man, O.A.S. Res. XXX, adopted by the Ninth International Conference of American States (1948), reprinted in Basic Documents Pertaining to Human Rights in the Inter-American System, OEA/Ser.L.V/II.82 doc.6 rev.1 at 17 (1992).

has become one of the most important factors in the development of human society, and provide ever increasing opportunities to better the conditions of life of peoples and nations, in a number of instances they can give rise to social problems, as well as threaten the human rights and fundamental freedoms of the individual”.¹⁴⁸

The right to enjoy the benefits of scientific progress and its application was referred by Vienna Declaration and Programme of Action. It states that “Everyone has the right to enjoy the benefits of scientific progress and its applications”, and that “certain advances, notably in the biomedical and life sciences as well as in information technology, may have potentially adverse consequences for the integrity, dignity and human rights of the individual, and calls for international cooperation to ensure that human rights and dignity are fully respected in this area of universal concern”.¹⁴⁹

The significant point to conceptualizing a human right to enjoy the benefits of science and its application is to consider what scientific progress and its application, and access to benefits mean. An analysis of the *travaux préparatoires* interprets that the term “benefits” must be understood as material benefits, that everyone should be able to enjoy it in everyday life. State parties were therefore obligated to distribute the application of scientific progress to everyone because there was a universal right to share in the benefits of scientific advancement.¹⁵⁰ “Scientific progress and its application” imply that not only the information about new science, but also the practical use of the scientific advancement be available to everyone.

In the context of Article 15(1)(b) ICRSCR, enjoyment of scientific progress as “participation” is distinct as actual “sharing” in the benefits of scientific progress and its application. The distinguishment between the terms “participate” and “share” was brought up and discussed by the General Assembly. It was generally agreed that participation was more active, and such participation could not expected from everyone, but everyone have the right to share in the benefits of scientific advancement. It is also agreed that even if all persons could not play an equal part in scientific progress, they should indisputably be able to participate in the benefits derived from it.¹⁵¹

The scientific progress and its application is to be benefit to everyone without discrimination is another important dimension of the concept. The

¹⁴⁸ Declaration on the Use of Scientific and Technological Progress in the Interests of Peace and for the Benefit of Mankind, Proclaimed by General Assembly resolution 3384 (XXX) of 10 November 1975, para.1-2

¹⁴⁹ See Vienna Declaration and Programme of Action, Adopted by the World Conference on Human Rights in Vienna on 25 June 1993.

¹⁵⁰ Audrey R. Chapman, “Towards an understanding of the right to enjoy the benefits of scientific progress and its applications”, *Journal of Human Rights*, Vol.8, Issue 1, 2009, p.9, para.2.

¹⁵¹ General Assembly Official Records 1948: Draft international declaration of human rights, Third Session of the Commission on Human Rights (24 May to 18 June 1948), report (forwarded through the Economic and Social Council): U.N. Doc. E/800 (28 June 1948), item 79, p.627.

scientific advancement needs to be broadly disseminated within a nation "without discrimination of any kind as to race, color, sex, language, religion, political or other opinion, national or social origin, property, birth or other status".¹⁵² However the unfair development of and diffusion of technologies within and across societies, as well as the current bias against investment in scientific research targeting to meet the needs of the poor are still big issue. Scientific innovation and product development are concentrated in high-income OECD (Organization of Economic Cooperation and Development) countries and to a less extent a handful of middle-income countries in Asia Latin America.¹⁵³ Although the UN Committee attached considerable importance on the realization of the right of the poor, minorities and other disadvantaged groups to enjoy the benefits of science with non-discrimination in their reporting guidelines, the more important is the state parties' effort on the poor and the disadvantaged groups.

The 1991 Guidelines prepared by the Committee on Economic, Social and Cultural Rights indicate several dimensions of Article 15 of ICESCR that it considers to be pertinent.¹⁵⁴

"Please describe the legislative and other measures taken to realize the right of everyone to enjoy the benefits of scientific progress and its applications, including those aimed at the conservation, development and diffusion of science. In particular, provide Information on the following:

(a) Measures taken to ensure the application of scientific progress for the benefit of everyone, including measures aimed at the preservation of mankind's natural heritage and at promoting a healthy and pure environment and information on the institutional Infrastructures established for that purpose.

(b) Measures taken to promote the diffusion of information on scientific progress.

(c) Measures taken to prevent the use of scientific and technical progress for purposes which are contrary to the enjoyment of all human rights, including the rights to life, health, personal freedom, privacy and the like.

(d) Any restrictions which are placed upon the exercise of this right, with details of the legal provisions prescribing such restrictions.

¹⁵² International Covenant on Economic, Social and Cultural rights 1966, article 2(2).

¹⁵³ UNDP (United Nations Development Programme), "Human Development Report 2001: Making new technologies work for human development", Oxford University Press, 2001, p.39.

¹⁵⁴ See Committee on Economic, Social and Cultural Rights, "Revised general guidelines regarding the form and contents of reports to be submitted by states parties under articles 16 and 17 of the International Covenant on Economic, Social and Cultural Rights", E/C.12/1991/1.

Another issue is the collective dimension of the right to enjoy of benefits of scientific progress and its application. When we refer to this right a collective approach is often called. Scientific progress and its application, as public goods and collective interests, can benefit the population in a whole and the individual can only enjoy the right in community. That is, there is an individual right holder but the right is implemented by a collective effort.

4.4.3 Access to medicine as Right to enjoy the benefits of scientific progress and Its application

Human rights are interdependent and interrelated.¹⁵⁵ The right to enjoy the benefits of scientific progress, as a significant human right, is close related to other human rights, including right to life, right to health, and right to an adequate standard of living. The realization and enjoyment of those basic human rights depend upon the sharing of the benefits of scientific progress and its application.

Scientific advances and development in the field of medical research and medicine, as scientific progress and application, should be accessible for all. In 2003 the International Declaration on Human Genetic Data, adopted by the UNESCO General Conference, addresses the issue directly with respect to access to medicine and the right to enjoy the benefits of science. Article 19 of the Declaration provides sharing of benefits as the following:

(a) In accordance with domestic law or policy and international agreements, benefits resulting from the use of human genetic data, human proteomic data or biological samples collected for medical and scientific research should be shared with the society as a whole and the international community. In giving effect to this principle, benefits may take any of the following forms:

(i) Special assistance to the persons and groups that have taken part in the research;

(ii) Access to medical care;

(iii) Provision of new diagnostics, facilities for new treatments or drugs stemming from the research;

(iv) Support for health services;

(v) capacity-building facilities for research purposes;

(vi) development and strengthening of the capacity of developing countries to collect and process human genetic data, taking into consideration their specific problems;

¹⁵⁵ See Vienna Declaration and Programme of Action, Adopted by the World Conference on Human Rights in Vienna on 25 June 1993.

(vii) any other form consistent with the principles set out in this Declaration.

All human rights derive from the inherent dignity of the human person. Scientific and technologic development can contribute to human development and human's dignity by enhance human capabilities, benefit human lives and improve living standard and conditions. Without any doubt that the new medicine, as technological innovation, can enhance human's health. Thus access to medicine is crucial for the people to fully enjoy the right to life and right to health.

4.5 Obligations of State Party

The general rule that in any legal system the recognition of a right in favor of a person automatically creates duties towards other persons, applies in the field of human rights law. Discussion about fulfilling basic rights would be meaningless without identifying who and how to guarantee the rights. So, who is bound by international human rights law to implement the human rights? The ordinary meaning of international human rights norms, such as the words "every human being has the inherent right to life", indicates that all the social actors, including government, private parties, and non-government organizations, and individuals are all players for bearing the burden of fulfilling fundamental human rights. However the government should play the role of pacemaker to implement human rights, since the international conventions impose duties directly on the States, rather than private groups, international organizations or individuals, to promote the recognized human rights.

Poverty prevents the enjoyment of human rights to some extent. However respect for civil and political rights doesn't depend on significant resources, they should be guaranteed by the government to all citizens. With respect to economic, social and culture rights, States doesn't need deliver all the rights immediately; rather they need to work towards their progressive realization given resources constraints.

4.5.1 Generic obligations

The nature of legal obligations of State parties is set out in international conventions. In ICCPR and ICESCR, the states are bound by the obligations to implement human rights. Article 2(1) of ICCPR defined the state's obligations that: "Each State Party to the present Covenant undertakes to respect and to ensure to all individuals within its territory and subject to its jurisdiction the rights recognized in the present Covenant, without distinction of any kind, such as race, color, sex, language, religion, political or other opinion, national or social origin, property, birth or other status".

The duties that the internationally conventions impose on States Parties are put down in Article 2(1) of the ICESCR as well:

“Each State to the present Covenant undertakes to take steps, individually and through international assistance and co-operation, especially economic and technical, to the maximum of its available resources, with a view to achieving progressively the full realization of the rights recognized in the present Covenant by all appropriate means, including particularly the adoption of legislative measures”.

States must make every possible effort, within available resources, to realize fully the fundamental rights, and all States must meet their obligations to respect, protect and fulfill. With respect to particular countries with difficult financial situation, the availability of resources and the development context should be taken into consideration. However, the States must guarantee the basic rights to the maximum of their available resources, and no State can justify a failure to respect its obligations due to a lack of resources. States should also ensure a minimum level of access to the essential material components in the case of enjoyment of human rights, such as the provisions of essential drugs and medication services.

State obligations to realize all human rights are of three types or levels: to respect, protect and fulfill every rights. In turn, the obligation to fulfill incorporates both an obligation to facilitate and an obligation to provide.¹⁵⁶ Failure to perform any one of these three obligations constitutes a violation of such rights.¹⁵⁷ It is worth mentioning that according to Maastricht Guidelines, failure of States to provide essential primary health care to those in needs may amount to a violation of the rights to health and medical care.¹⁵⁸

(1) To respect means not to interfere with the exercise of a right. The obligation to respect human rights requires states to refrain from interfering in the liberty of the individual to satisfy and enjoy the rights, which includes respecting efforts made by the people themselves to realize their rights.

(2) To protect means to prevent violations of such rights by the third party, primarily through effective regulation and remedies. The obligation to protect requires the States to provide appropriate protection of an

¹⁵⁶ See “Substantive issues arising in the implementation of the international covenant on economic, social and cultural rights: General Comment 12, the right to adequate food (article 11)”, E/C.12/1999/5, Committee on economic, social and cultural rights, 12 May 1999, para.15. Also see Mary Dowell-Jones, “Contextualizing the International Covenant on Economic, Social and Cultural Rights: Assessing the Economic Deficit”, Leiden: Martinus Nijhoff Publishers, 2004, p.29.

¹⁵⁷ “Masstricht Guidelines on Violations of Economic, Social and Cultural Rights”, Commission of Jurists the Faculty of Law of the University of Limburg and the Urban Morgan Institute for Human Rights University of Cincinnati, Published by United Nations, January 22-26, 1997, para.6.

¹⁵⁸ Masstricht Guidelines on Violations of Economic, Social and Cultural Rights, supra note.157, January 22-26, 1997, para.6.

individual's rights against infringement by state authorities or by non-state actors, and resolve any conflicts which may arise in the exercise of rights. This protection is to be granted equally to all.

(3) To fulfill means to take appropriate measures, such as appropriate legislative, administrative, budgetary, judicial and other actions towards the full realization of such rights, including promoting rights, facilitating access to rights, and providing for those unable to provide for themselves.

4.5.2 Specific Obligation

The right to life, right to health and right to enjoy the benefits of scientific progress and its application are formulated in the various international instruments which have been drafted jointly by the world community and associated with the State's obligations. A consensus has emerged that certain parts of international human rights law have gained the status of customary international law, and these obligations are binding upon all states, regardless of whether individual states have ratified the instrument containing the specific obligation.¹⁵⁹

4.5.2.1 States' obligation on full realization of right to life

The tradition view consider that civil and political rights entail only negative obligations, while economic, social and cultural rights give rise to the more complex issue of positive State obligations which require resources to be expended. The United Nations Committee has interpreted right to life guaranteed by the ICCPR as entailing positive obligations. Thus, under international human rights instruments, the assertion of the inherent right to life is accompanied by the negative obligation not to deprive arbitrarily of one's life, and positive obligation to take all appropriate measures to protect and preserve human life.

4.5.2.2 States' obligation on full realization of right to health

Like the right to life, the right to health entails negative as well as positive obligations. As a fundamental right, on one hand, the right to health is an individual right in that it requires the protection of the physical and mental integrity of the individual and his dignity; on the other hand, it is also a social right in that it imposes on the state and society the collective responsibility for the protection of the health of the citizenry and the prevention and treatment of diseases. To fulfill right to life requires a duty

¹⁵⁹ See Özgür Can and Sara L.Seck, "The legal obligations with respect to human rights and export credit agencies", final legal discussion paper for ECA-Watch, Halifax Initiative Coalition and ESCR-Net, July 2006, p.10, para.2-3.

to avoid depriving people of the substance of their rights, to protect people against deprivation of life, and to aid them when they are deprived of their rights to life.

Article 12(2) of ICESCR refers to the steps to be taken to implement the right to health:

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:

(a) The provision for the reduction of the stillbirth-rate and of infant mortality and for the healthy development of the child;

(b) The improvement of all aspects of environmental and industrial hygiene;

(c) The prevention, treatment and control of epidemic, endemic, occupational and other diseases;

(d) The creation of conditions which would assure to all medical service and medical attention in the event of sickness.

The State parties' obligations to take steps to implement the right to health are also list in other conventions. For instance, Article 24 of the Convention on the rights of the Child provides that State Parties shall take appropriate measures to diminish infant and child mortality, ensure the provision of necessary medical assistance and health care to all children with emphasis on the development of primary health care, combat disease and malnutrition, including within the framework of primary health care, ensure appropriate pre-natal and post-natal health care for mothers, develop preventive health care, guidance for parents and family planning education and services, and take all effective and appropriate measures with a view of abolishing traditional practices prejudicial to the health of children.

The Committee on Economic, Social and Culture Rights in General Comment No.14 also defined the State's obligations to take steps that must be deliberate, concrete and targeted towards the full realization of the right to health in national level. The right to health, like all human rights, imposes three types or levels of obligations on States parties: the obligations to respect protect and fulfil.¹⁶⁰

The obligation to respect the right to health requires States to refrain from denying or limiting equal access for all persons to preventive, curative and palliative health services; abstain from enforcing discriminatory practices as a State policy; and abstain from imposing discriminatory practices relating to women's health status and needs, as well as the further obligations to

¹⁶⁰ See General Comment No.14 (2000), The right to the highest attainable standard of health, 08/11/2000 (article 12 of the International Covenant on Economic, Social and Cultural Rights), E/C.12/2000/4, Committee on Economic, Social and Cultural Rights, para.30, 33.

refrain from prohibiting or impeding traditional preventive care, healing practices and medicines, from marketing unsafe drugs and from applying coercive medical treatments, limiting access to health services as a punitive measures.¹⁶¹

The obligations to protect obligates the States to adopt legislation or to take other measures ensuring equal access to health care and health-related services provided by third parties; to ensure that privatization of the health sector does not constitute a threat to the availability, accessibility, acceptability and quality of health facilities, goods and services; to control the marketing of medical equipment and medicines by third parties; and to ensure that medical practitioners and other health professionals meet appropriate standards of education, skill and ethical codes of conduct, to measures to protect all vulnerable or marginalized groups of society, and ensure that third parties do not limit people's access to health-related information and services.¹⁶²

The obligation to fulfill requires States parties to give sufficient recognition to the right to health in the national political and legal systems, preferably by way of legislative implementation, and to adopt a national health policy with a detailed plan for realizing the right to health. States must ensure provision of health care, including immunization programmes against the major infectious diseases, and ensure equal access for all to the underlying determinants of health, provide a public, private or mixed health insurance system which is affordable for all, the promotion of medical research and health education, as well as information campaigns, in particular with respect to HIV/AIDS.¹⁶³

In addition, the obligation to fulfill also contains obligations to facilitate, provide and promote the right to health, and to take positive measures that enable and assist individuals and communities to enjoy such right. States parties are obliged to fulfill (provide) a specific right contained in the Covenant when individuals or a group are unable, for reasons beyond their control, to realize that right themselves by the means at their disposal. The obligation to fulfill (promote) the right to health requires States to undertake actions that create, maintain and restore the health of the population.¹⁶⁴

The Committee also emphasized the core obligations with respect to health, which includes providing essential drugs, as defined under the WHO Action Programme on Essential Drugs, providing measures to prevent, treat and control epidemic and endemic diseases, ensuring right of access to health facilities without discrimination, especially for the poor, and otherwise vulnerable and disadvantaged groups; ensuring equitable distribution of all health facilities, goods and services, adopting and implementing a national public health strategy and plan of action, on the

¹⁶¹ Ibid., para.34.

¹⁶² Ibid., para.35.

¹⁶³ Ibid., para.36.

¹⁶⁴ Ibid., para.37.

basis of epidemiological evidence, addressing the health concerns of the whole population.¹⁶⁵ For these core obligations, all States, regardless of their level of development, are required to take immediate actions to implement them. Even if for the developing countries with inadequate resources and infrastructures, they should invest their resources in an equitable manner, assign priority to public health measures. Other actors, except governments, are expected to assist, to provide international assistance and cooperation, particularly economic and technical, which enable developing countries to fulfill their core obligations.¹⁶⁶

4.5.2.3 States' obligation on full realization of right to enjoy the benefits of scientific progress and its application

Both the obligation to make full use of technical and scientific knowledge and the right to share the benefits of scientific progress can lead to full fulfillment of human rights. The provisions of article 15(2) and (4) impose two sets of specific obligations on state parties to implement right to enjoy the benefits of scientific progress and its application:

“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”.

“4. The States Parties to the present Covenant recognize the benefits to be derived from the encouragement and development of international contacts and cooperation in the scientific and cultural fields”.

To fulfill the mandate for the conservation, development, and the diffusion of science is significant obligation for the State to respect the right to enjoy the benefits of scientific progress and its application. This obligation requires States not to interfere with the freedom of scientists to undertake research and creative activities. The nature of intellectual property laws, a policy area that is of increasing significance to scientific progress, has been identified as a potential obstacle.¹⁶⁷ There is widespread concern that in the scientific community the commercialization and intellectual property restrictions will respect scientists' access to data needed for their research.¹⁶⁸ Thus, how to make strategic policy, legislation and measures to balance the intellectual property rights and the right to enjoy the benefits of scientific progress and its application is a big task. One central criterion is

¹⁶⁵ Ibid., para.43.

¹⁶⁶ Ibid., para.45.

¹⁶⁷ Audrey R.Chapman, “Towards an understanding of the right to enjoy the benefits of scientific progress and its applications”, *Journal of Human rights*, 8:1-36, 2009, p.19, para.3

¹⁶⁸ “Bits of Power: Issues in Global Access to Scientific Data -- Committee on issue in the transborder flow of scientific data”, U.S. National Committee for CODATA, Commission on Physical Sciences, Mathematics, and Applications, National research council, Washington, DC: National academy press, p.111.

that intellectual property standards must be consistent with the realization of rights under the ICESCR.¹⁶⁹ Moreover, the State should prevent the use of scientific and technical progress for purposes contrary to human rights and dignity by excluding inventions from patentability whenever the commercialization would jeopardize the full realization of human rights.¹⁷⁰

The obligation to protect the right to enjoy the benefits of scientific progress and its applications requires the State to protect against violation of Human rights, since the right to enjoy the benefits of science is interrelated with other human rights, such as the right to life, the right to health, the right to development and so on. The United Nations Declaration on the Use of Scientific and Technological progress in the interests of peace and for the benefits of Mankind has a number of relevant provisions regarding the need of the States to protect the citizens against potential violations of human rights resulting from science and technology:

“All States shall take appropriate measures to prevent the use of scientific and technological developments, particularly by the State organs, to limit or interfere with the enjoyment of the human rights and fundamental freedoms of the individual as enshrined in the Universal Declaration of Human Rights, the International Covenants on Human Rights and other relevant international instruments”. (Article 2)

“All States shall take effective measures, including legislative measures, to prevent and preclude the utilization of scientific and technological achievements to the detriment of human rights and fundamental freedoms and the dignity of the human person”. (Article 8)

To what extent the obligations to fulfill the right to enjoy the benefits of scientific progress and its application are not addressed explicitly by international human rights instruments. However, according to the above legal analysis in this thesis, it can be suggested that the States should take steps, including setting policies, developing legislation, establishing institutions to promote the development and diffusion of science and technology, create and broaden distribution systems which can bring scientific and technological benefits to individuals, groups and communities widely, especially to the poor and disadvantaged groups. All those measures need to be implemented in a manner consistent with fundamental human rights principles.

The obligation to fulfill also implies the State to identify whether there are any factors preventing the exercise of this right and then seek to remove these obstacles. For instance, the availability of products resulting from scientific progress must be considered crucial in relation to the right to

¹⁶⁹ Committee on Economic, Social and Cultural rights, General comment 17, The right of everyone to benefit from the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is author, E.C.12/GC/17, 2005, para.11.

¹⁷⁰ Ibid, para.35.

health, and the States has an obligation to facilitate the availability of essential medicine.

In addition, Obligations under article 15(4) doubly reinforce the state's mandate to respect for the diffusion of science, which regulated in article 15 (2). States should not only actively support co-operation between members of the scientific community, and ensure the results of scientific and technological achievements are used co-operatively for the purpose of strengthening economic and social development, but also "take steps through international assistance and cooperation, especially economic and technical, to the maximum of its available resources, with a view to achieving progressively the full realization of the rights recognized",¹⁷¹ particularly the social and economic rights of the developing countries.

4.6 Justiciability of the recognized Rights and Case Study

4.6.1 Justiciability of Human Rights

Justiciability refers to the capability of rights to be enforced by a judicial or quasi-judicial organ and the existence of procedures to contest and redress violations, that is the judicial and quasi-judicial accountability established through legislation and its implementation, and that is the possibility of alleged victims of violation of rights to file a complaint before an impartial body and request adequate remedies. The extent to which rights are justiciable at any level depends on the content or definition of rights and the existence of procedures for their judicial enforcement.¹⁷² Human rights obligations would be pointless if the duty bearers could not be held accountable to rights holders and to society at large.

The justiciable base of civil and political rights is set up in ICCPR and its optional Protocol. Article 1 of the Optional Protocol allows the individuals claiming a violation of their rights under the ICCPR: "A State Party to the Covenant that becomes a Party to the present Protocol recognizes the competence of the Committee to receive and consider communications from

¹⁷¹ Article 5, Declaration on the Use of Scientific and Technological Progress in the interests of peace and for the benefits of Mankind, G.A.Res.3384 (XXX),30 U.N.GAOR Supp. (No.34) at 86, U.N.Doc.A/10034 (1975).

¹⁷² Sisay Alemahu Yeshanew, "The justiciability of human rights in the Federal Democratic Republic of Ethiopia", Social science research network, available at http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1530825 (Search date: 08/06/2010).

individuals subject to its jurisdiction who claim to be victims of a violation by that State Party of any of the rights set forth in the Covenant”.¹⁷³

The controversial issue is whether economic, social and culture rights can be appropriately expressed and the court’s role is limited. According to some critics, Economic, Social and Culture Rights (ESC rights) are by their nature different with civil and political rights, and are not suitable for judicial adjudication.¹⁷⁴ Unlike the ICCPR requiring the states to develop the possibility of judicial remedy through its optional Protocol, there is no equivalent provision in the ICESCR. Considering ESC rights as unsuitable subjects for judicial enforcement is a misguided idea, although some aspects of ESC rights may make judicial adjudication more complicated.

Firstly, in 1993 the Vienna World Conference on Human Rights reiterated that “... *all human rights are universal, indivisible, interdependent and interrelated*”,¹⁷⁵ which means that civil and political rights as well as ESC rights have to be treated in an equal manner. Different components of the right connect closely to be an adequate standard of living. Article 8 of the UDHR states that “*everyone has the right to an effective remedy by the competent national tribunals for acts violating the fundamental rights granted him by the constitution or by law*”. The Declaration recognizes ESC Rights and there is nothing to indicate that this provision just apply to civil and political rights. The UN independent expert concluded that the rights guaranteed under ICESCR are “essentially justiciable” in its report:¹⁷⁶

“The question of the justiciability of economic, social and cultural rights, In the light of the experience gained in recent years from the application of international, regional and national human rights instruments and mechanisms, the independent expert notes that there is no longer any doubt about the essentially justiciable nature of all the rights guaranteed by the Covenant.”

Secondly, international law, especially in the monistic legal systems, is part of domestic law and can be invoke before courts, and there are an amount of comparative case law in which judges adjudicate situations of alleged violations of ESC rights. For example, the constitution of South Africa Constitutional Court specifically refers to social and economics rights, and

¹⁷³ Optional Protocol to the International Covenant on Civil and Political Rights, G.A. res. 2200A (XXI), 21 U.N. GAOR Supp. (No. 16) at 59, U.N. Doc. A/6316 (1966), 999 U.N.T.S. 302, entered into force March 23, 1976, article 1.

¹⁷⁴ See, For example, Aryeh Neier, “Social and Economic Rights: A Critique”, Human Rights Brief, Center for Human Rights and Humanitarian Law, The American University, Washington College of Law, cite as 13, No.2, 2006, pp.1-3.

¹⁷⁵ World Conference on Human Rights: Vienna Declaration and Programme of Action, Part I, para. 5. UN Doc. A/CONF.157/23.

¹⁷⁶ See Commission on Human Rights, fifty-ninth session, Item 10 of the provisional agenda, “Economic, social and cultural rights, Status of the international covenants on human rights”, Report by Mr. Hatem Kotrane, independent expert on the question of a draft optional protocol to the International Covenant on Economic, Social and Cultural Rights, para.2.

the Constitutional Court considers that the doctrine of the separation of powers does not impede its ability to make decisions that require the Government to adopt policies that are consistent with its obligations under the Constitution.¹⁷⁷

Although in many places these rights are not enshrined in the constitution or domestic laws, but the court still plays significant role of acknowledging and interpreting the fundamental rights. There are more and more cases that ESC rights won the recognition by the court accumulatively. In other cases, ESC rights themselves have been directly from civil and political rights (e.g. the right to life implies the right to health). The best example of this type of protection is found in Indian Constitutional jurisprudence. For instance, in the *Francis Coralie Mullin* case, the Indian Supreme Court declared that:¹⁷⁸

“The right to life includes the right to live with human dignity and with all that goes with, namely, the bare necessities of life such as adequate nutrition, clothing...in any view of the matter, include the bare necessities of life and also the right to carry on such functions and activities as constitute the bare minimum expression of the human self.”

Thirdly, the Economic, Social and Cultural Rights Committee in its comment 9 states that: “The central obligation in relation to the Covenant is for States parties to give effect to the rights recognized therein. By requiring Governments to do so “by all appropriate means”, the Covenant adopts a broad and flexible approach which enables the particularities of the legal and administrative systems of each State, as well as other relevant considerations, to be taken into account.”¹⁷⁹ The Committee analyses that the ICESCR contains no direct counterpart to article 2, paragraph 3 (b), of ICCPR which obligates States parties to, *inter alia*, develop the possibilities of judicial remedy. It further argues that a State party seeking to justify its failure to provide any domestic legal remedies for violations of economic, social and cultural rights would need to show either that such remedies are not “appropriate means” within the terms of article 2, paragraph 1, of the ICCPR, or that, in view of the other means used, they are unnecessary.¹⁸⁰

¹⁷⁷ See the website of Human Rights Commission in New Zealand, Report “Human Rights in New Zealand today: Chapter 2, the international human rights framework”, available at <http://www.hrc.co.nz/report/chapters/chapter02/framework01.html> (Search date: 26/06/2010).

¹⁷⁸ John Nakuta, “The justiciability of social, economic and cultural rights in Namibia and the role of the non-government organizations”, in Horn, Nico&Anton Bösl (Eds), *Human rights and the rule of law in Namibia*, published by Macmillan Namibia, 2008, p.98, para.3, the author cites case *Francis Coralie Mullin v The Administrator, Union Territory of Delhi*, in the Supreme Court of India, Written Petition No. 3042 of 1980, Decided on 13th January 1981.

¹⁷⁹ COMMITTEE ON ECONOMIC, SOCIAL AND CULTURAL RIGHTS, Nineteenth session, Agenda item 3, “The domestic application of the Covenant”, 1998-12-03, E/C.12/1998/24, CESCR General Comment 9, para.1.

¹⁸⁰ *Ibid.* para.3.

Fourthly, the need for remedies and accountability need not to be automatically equated with judicial remedies, instead judicial protection should be considered as another or additional means of enforcement and implementation of ESC rights.¹⁸¹ There are some other ways in which ESC might be effectively vindicated, which includes administrative remedies, and legislative responsiveness to reports by human rights commissions and the like.¹⁸² Services and policies necessary to make these rights a reality are also the kinds of tasks hold by political branches of governments, and even non-government actors. The diversity of actors involved by human rights opens up the opportunity for justiciability.

4.6.2 Case Study

Several judgments can be found relating to the circumstances violating the right to health of persons, which was embraced in Article 3 in terms of violations of “inhuman or degrading treatment”. In the case *Yakovenko v. Ukraine* in 2007,¹⁸³ the applicant, who was arrested and placed in police custody on suspicion of burglary, got HIV and tuberculosis infections but lack of medical assistance and practitioner. The applicant complained that he was neither provided with antiretroviral or anti-tuberculosis treatment nor monitored for infectious. In April 2006, the applicant’s health situation deteriorated and he was sent to hospital twice. The doctor’s recommendation that he should be taken to a specialized treatment was refused. Thus the applicant’s mother lodged a complaint with the Prosecutor General in which she alleged that the detention center had unlawfully refused to hospitalize her son and that he was in a critical condition. The applicant complaint to ECtHR (European Court of Human Rights) about the ill-treatment while in police custody, inhuman conditions of detention and lack of medical care.

The Court held the opinion that the failure to provide timely and appropriate medical care to the applicant in respect of his HIV and tuberculosis infections had amounted to inhuman and degrading treatment and there had therefore been a further violation of Article 3 of ECHR (European Convention on Human Rights).¹⁸⁴ In reality the Court’s practice confirmed the right to health cases adjudicated and remedied under Article 3 of ECHR. However, from a social rights perspective, the scope of the remedy at stake should not be limited to redress of breaches of the prohibition of inhuman and degrading treatment, but should be extended to direct redress of violations on the right to health. By affording damages for violations of the prohibition of inhuman and degrading treatment, the Court has indirectly

¹⁸¹ See Henry J. Steiner, Philip Alston, Ryan Goodman, “International human rights in context: Law, political, morals”, Oxford University Press, August 2000, p.313, para.2.

¹⁸² Ibid. para.3.

¹⁸³ ECtHR, Judgment of the case of *Yakovenko v. Ukraine*, Application No. 15825/06, 25 October 2007.

¹⁸⁴ ECtHR, Judgment of the case of *Yakovenko v. Ukraine*, Application No. 15825/06, 25 October 2007.

redresses violations on the right to health and enforced the social right expressed in the ECHR.¹⁸⁵ According to the normative content of right to health defined by U.N. Committee on Economic, Social and Cultural Rights in General Comment No.14 -- availability, accessibility (affordability), acceptability (medical ethics) and quality -- the case involved serious breaches of the right to access to adequate medical care.¹⁸⁶ This health dimension is also reflected in the damages awarded by the Court. Although the right to health is not reflected in the European Convention, but in practice the Court considered that this rights was justiciable and enforceable against the government.

Given the absence of cases directly bearing on the right to life and right to health relating to access to medical care in ECtHR, it is worth looking briefly at cases in other jurisdictions, especially in national legal practice.

In Costa Rica none of the newer antiretroviral medications were provided until 1997 year. Anyone had to buy the medicines at the commercial price that was beyond the affordability of most AIDS-affected people. In 1995 year the patient coalition in Costa Rica initiated a complaint to pressure the government to provide medications but no progress was made. In July 1997 several patients from the coalition appealed to the Supreme Court, claiming that the social security fund failed to provide medications recommended by physicians for their serious infections.¹⁸⁷ Taken account of the seriousness of the patient's condition, the court vote for the patient's favor and ruled that the social security fund should provide needed modern antiretroviral drugs to patients. The Court expressed that the financial burden and high cost of supplying such medications imposed on the government could not take precedence over the right to life and right to health. The Court affirmed that the provision of effective medical care for people affected by AIDS is an obligation of the state.¹⁸⁸

In the case "Minister of Health v. Treatment Action Campaign", the pressure group (The Treatment Action Campaign) launched a constitutional challenge, alleging that the government violated the right to access to healthcare services.¹⁸⁹ In 2000 year the anti-retroviral drug Nevirapine was offered to prevent the HIV/AIDS infection of children, but the South African Government announced restriction and delay on the mothers' access

¹⁸⁵ See Ingrid Nifosi-Sutton, "Rights to order specific non-monetary relief: a critical appraisal from a right to health perspective", *Harvard Human Rights Journal*, Vol.23, 2010, p.67.

¹⁸⁶ *General Comment No.14, "The right to the highest attainable standard of health:08/11/2000"*, New York: United Nations Committee on Economic, Social and Culture Rights; Doc. E/C.12/2000/4, para.12.

¹⁸⁷ See UNAIDS Best Practice collection, "NGO Perspective on access to HIV-related drugs in 13 Latin American and Caribbean", UNAIDS/98.25, 1998, p.16.

¹⁸⁸ See UNAIDS Best Practice Collection, "NGO Perspective on access to HIV-related drugs in 13 Latin American and Caribbean", UNAIDS/98.25, 1998, p.16.

¹⁸⁹ See Constitutional Court of South Africa, Judgment of the case "*Minister of Health v. Treatment Action Campaign*", Case CCT8/02, 5 July 2002. Available at: http://www.law-lib.utoronto.ca/Diana/TAC_case_study/MinisterofhealthvTACconst.court.pdf (Search date: 06/25/2010).

to these medicines and treatment, since the government considered that the medicine would introduce Mother-to-Child-Transmission in certain pilot sites. The applicants contended that the restrictions were unreasonable and against the right to health services under Section 27 and the right of children to basic nutrition and health care services under Section 28 of the Constitution.¹⁹⁰ The Constitution Court held that pursuant to Section 27(1) and (2) of the Constitution requires the government to “devise and implement within its available resources a comprehensive and coordinated programme to realize progressively the rights of pregnant women and their newborn children to have access to health services to combat mother-to-child-transmission of HIV. The Court also ordered the government to extend availability of Nevirapine to hospitals and clinics, to provide counselors.¹⁹¹ This case establishes a conceptual and remedial framework for judicial review and enforcement of the obligation to ensure access to healthcare and other Economic, Social and Cultural rights.

From the above mentioned cases, it is not difficult to conclude that the evolving jurisprudence on human rights has made it clear that the traditional distinctions between these two categories of right -- civil and political rights and ESC rights -- is overly simplistic, and experience around the world demonstrates that national courts have either applied those rights or extended civil and political rights to include economic, social, and cultural issues. In other words, courts are not only given mandate to adjudicate these fundamental rights, but also capable of adjudicating and enforcing these rights.

¹⁹⁰ Alleged violation of the following sections of the South African Constitution: Section 27: “Everyone has the right to have access to a) health care services, including reproductive health care; The state must take reasonable legislative and other measures, within its available resources, to achieve the progressive realization of each of these rights”. Section 28(1)(c): “Every child has the right to basic nutrition, shelter, basic health care services and social services”.

¹⁹¹ See Constitutional Court of South Africa, Judgment of the case “*Minister of Health v. Treatment Action Campaign*”, Case CCT8/02, 5 July 2002. Available at: http://www.law-lib.utoronto.ca/Diana/TAC_case_study/MinisterofhealthvTACconst.court.pdf . Search date: 06/25/2010.

5. The balance between pharmaceutical patent protection and Access to Medicine as human rights : Human Rights -- based Approach to Intellectual Property Rights

Human rights and intellectual property exhibit distinctive systemic characteristics and in the past ages they developed independently. The intersection between intellectual property regime and human rights field has expanded increasingly in most recent decade. In the intellectual property context, the patent issues illustrate the substantive reach with human rights. Advances in technology and world trade development in the context of globalization, as well as interrelated developments of a broad range of economic, social and political rights have engendered demands for new standards of legal protection of intellectual property rights. Those debatable issues with human rights implications include public health, education, food and agriculture, privacy and free expression.

The human rights-based claims to restrict or expand intellectual property raise important and difficult questions: does intellectual property deserve to be treated as a fundamental right? How does a human rights-inspired conception of intellectual property differ from existing rules that promote innovation and creativity? Should the human rights approach of intellectual property favor the rights of intellectual property owners or the rights of individual users and public consumers? How to strike a distinctive human rights balance among these actors with competing interests? And to what extent shall it to strike the balance?

5.1 Historical foundation of Human Rights Framework for Intellectual Property

From the historical perspective, the place of private property rights in human rights treaties and bills of right has been controversial for decades. Where Human rights are seen as rights that are inherent to human beings by virtue of their humanity, it is not possible to include the right to property as

a human right¹⁹². Property rights provide protection of the individual's autonomy and very little attention has been paid to the interpretation of intellectual property as a human right.

Although the UDHR in 1948 and ICESCR protects authors' "moral and material interests" in their "scientific, literary or artistic production" as fundamental rights and liberties, the human rights law's nominal interest are not incorporated in intellectual property treaties, such as the Paris and Berne Conventions, or in the more recently adopted TRIPS Agreement.¹⁹³ These treaties refer to the protections granted to authors and inventors as "rights" in light of the principle jurisdiction in economic and instrumental benefits that flow from protecting intellectual property products across national borders, rather than based on the interests of fundamental rights and liberties.¹⁹⁴

It was the human rights community that first took notice of intellectual property law on the agenda of human rights law making.¹⁹⁵ Two significant events, namely the neglected rights of indigenous people and the consequences of linking of intellectual property and trade through TRIPS Agreement, contributed to draw the attention to the serious normative deficiencies of intellectual property law from a human rights perspective.¹⁹⁶

In particular the strengthening of intellectual property rights standards through TRIPS Agreement has great impact to affect the realization of human rights, in particular the right to health. Many countries once denied patenting new drugs on public health grounds; however the TRIPS Agreement obligates the Members to recognize and enforce patents in all the fields of technology, including medicines, which brought the world community's and society's concern about the impact brought by existing intellectual property rights on the realization of human rights. The relation between human Rights and intellectual property is becoming intimate gradually. The international, regional and national legislation seek to balance the society's interest in the development of economic, science and culture, the individual and collective rights to take part in and enjoy the fruits of scientific development, as well as the rights of specific individual or collective contributions to the development of science, arts and culture.

The U.N human rights system first paid attention to TRIPS with respect to the relation between human rights and intellectual property in 2000. The U.N.Sub-Commission on the adopted resolution 2000/7 figures out that "actual or potential conflicts exist between the implementation of the TRIPS

¹⁹² See Orit Fischman Afori, "Human Rights and Copyright: The Introduction of Natural Law Considerations into American Copyright Law", *Fordham Intellectual Property Media & Environment Law Journal*, Vol.14, No.2, 2004.

¹⁹³ See Laurence R.Helfer, "Human Rights and Intellectual Property: Conflict or Coexistence?", *MINNESOTA INTELLECTUAL PROPERTY REVIEW*, Vol.5, Number 1, 2003, P.50, para.2.

¹⁹⁴ *Ibid.*

¹⁹⁵ *Ibid.*, P.51, para.4.

¹⁹⁶ *Ibid.*, P.52, para.1.

Agreement and the realization of economic, social and cultural rights in relation to impediments to the transfer of technology to developing countries... and restrictions on access to patented pharmaceuticals and the implications for the enjoyment of the right to health.”¹⁹⁷ In the report, the Sub-Commission further declares that “since the implementation of the TRIPS Agreement does not adequately reflect the fundamental nature and indivisibility of all human rights, including the right of everyone to enjoy the benefits of scientific progress and its applications, the right to health, the right to food and the right to self-determination, there are apparent conflicts between the intellectual property rights regime embodied in the TRIPS Agreement, on the one hand, and international human rights law, on the other”.¹⁹⁸

After the adoption of the Resolution UN human rights bodies took action actively and produced numerous documents with respect to the relation and conflicts between human rights and intellectual property rights, such as “*Human Rights Commission Calls on States to Use TRIPS Flexibilities*”,¹⁹⁹ which mandates the states to implement the right to the highest attainable standard of health, to adopt legislation or other measures, in accordance with applicable international law to safeguard access to medications, and the analysis of TRIPS by the U.N. High Commissioner for Human Rights, which argues that intellectual property laws must promote access to knowledge and innovations, opposes the adoption of TRIPS plus treaties, and emphasizes states’ obligations to provide access to affordable medicines to treat HIV/AIDS, as well as other documents.²⁰⁰

However, these critiques of TRIPS and the discussion on the empirical effects of intellectual property agreement on human rights failed to provide a detailed textual analysis of a human rights framework for intellectual property and how that framework interfaces with existing intellectual property protection standards in national and international law.²⁰¹ Until 2001 year the publication of a “Statement on Human Rights and Intellectual Property” by the U.N. Committee on Social, Economic and Cultural Rights (UNCSECR), together with the 2005 general Comment No.17--“the right of everyone 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”, the partial blueprint of a human rights framework for intellectual

¹⁹⁷ United Nations High Commissioner for Human Rights, Sub-Commission on Human Rights Resolution 2000/7, “Intellectual property rights and human rights”, U.N. Doc. E/CN.4/Sub.2/RES/2000/7, 17 August 2000, para.12.

¹⁹⁸ United Nations High Commissioner for Human Rights, Sub-Commission on Human Rights Resolution 2000/7, “Intellectual property rights and human rights”, U.N. Doc. E/CN.4/Sub.2/RES/2000/7, 17 August 2000, para.14.

¹⁹⁹ See “Human Rights Commission Calls on States to Use TRIPS Flexibilities”, Bridges Weekly Trade News Digest, Vol.9, No.13, April 20, 2005, p.5.

²⁰⁰ The High Commissioner, Report of the High Commissioner on the Impact of the Agreement on Trade-Related Aspects of Intellectual Property Rights on Human Rights, para.10-15, 27-58, U.N. Doc. E/CN.4/Sub.2/2001/13 (June 27, 2001).

²⁰¹ Laurence R.Helfer, “Towards a Human Rights Framework for Intellectual Property”, U.C.Davis Law Review, Vol. 40, 2007, p.987, para.2.

property was drawn.²⁰²

5.2 Link between Human Rights and IP: The right to the protection of Interests in Intellectual Creations

The debate on the relation between intellectual property rights and human rights centered on whether they are coexist or are in conflict. The conflict approach sees human rights and intellectual property rights are fundamentally conflictual rights, and it argues that human rights win over intellectual property rights; the coexistence approach sees both rights trying to answer the same questions with struggling to achieve appropriate balance to recognize and reward human creativity and innovation and, at the same time, to ensure public access to the fruits of those endeavors.²⁰³ As Helfer summarized the two approaches:

The first approach views human rights and intellectual property as being in fundamental conflict. This framing sees strong intellectual property protection as undermining — and therefore as incompatible with — a broad spectrum of human rights obligations, especially in the area of economic, social, and cultural rights. The prescription that proponents of this approach advocate for resolving this conflict is to recognize the normative primacy of human rights law over intellectual property law in areas where specific treaty obligations conflict.

*The second approach to the intersection of human rights and intellectual property sees both areas of law as concerned with the same fundamental question: defining the appropriate scope of private monopoly power that gives authors and inventors a sufficient incentive to create and innovate, while ensuring that the consuming public has adequate access to the fruits of their efforts. This school views human rights law and intellectual property law as essentially compatible, although often disagreeing over where to strike the balance between incentives on the one hand and access on the other.*²⁰⁴

For example, with respect to social, cultural and economic rights, the U.N.Sub-Commission on the Promotion and Protection of Human Rights took the conflict approach in the preamble of its solution 2000/7, and it states that strong intellectual property law protection undermine and incompatible with a broad spectrum of human rights obligations, especially

²⁰² Laurence R.Helfer, “Towards a Human Rights Framework for Intellectual Property”, U.C.Davis Law Review, Vol. 40, 2007, p.989, para.2.

²⁰³ Laurence R. Helfer, “Human Rights and Intellectual Property: Conflict or Coexistence?”, Minnesota Intellectual Property Review 47, P.48-49 (2003).

²⁰⁴ Ibid.

in the area of economic, social and cultural rights.²⁰⁵ However, the Commission also noticed that the balance between public and private interests found under article 15 of the ICESCR and article 27 of the UDHR, and asserts that the key question “is where to strike the right balance”.²⁰⁶

However, it is simplified to conclude that the human right overwhelms intellectual property rights, or intellectual property rights should be an absolute trump over the other. In recent years, scholars have begun to advocate the development of a comprehensive and coherent “human rights framework” for intellectual property law and policy.²⁰⁷ Laurance R. Helfer argued that the foundation of constructing “human rights framework” for intellectual property has to take consideration of a series of questions and issues, including how to define the different attributes of the “rights” protected by human rights law system and intellectual property law system; whether such standards apply to governments alone and also to private parties; and the issues in terms of adopting rules to resolve inconsistencies among overlapping international and national laws and policies”.²⁰⁸ He also argues that “a human rights framework for intellectual property must also distinguish situations in which the two legal systems have the same or similar objectives, but may employ different rules or mechanisms to achieve the those objectives, from ‘true conflicts’ of goals of values that far more difficult to reconcile”.²⁰⁹

According to Peter.K.Yu, the existing international instruments have recognized only certain attributes of intellectual property rights as human rights, and international human rights treaties do not protect the remaining non-human-rights attributes of intellectual property rights or those forms of intellectual property rights that have no human rights basis.²¹⁰ For example, Article 27.2 of TRIPS Agreement indicates that non-patentability on grounds of “*ordre public*” or morality, such as protects human, animal or plant life or health or to avoid serious prejudice to the environment, is permissible if necessary to prevent commercial exploitation. *Ordre public* or

²⁰⁵ See e.g., Intellectual Property Rights and Human Rights, Res.2000/7, U.N.Sub-Commission on the Promotion and Protection of Human Rights, 52nd Sess., Doc.E/CN.4/Sub.2/RES/ 2000/7, stating that “actual or potential conflicts exist between the implementation of the TYRIPS Agreement and the realization of Economic, social and cultural rights”.

²⁰⁶ “The Impact of the Agreement on Trade-Related Aspects of Intellectual Property Rights on Human Rights”, Report of the High Commissioner, ESCOR Sub. Commission on the Promotion and Protection of Human Rights, 52nd Sess.,Provisional Agenda Item 4 at 5, U.N. Doc. E/CN.4/Sub.2/2001/13 (2001).

²⁰⁷ L.R. Helfer, “Toward a Human Rights Framework for Intellectual Property”(2007), U.C. Davis Law Review, Vol.40, p.977-1020; P.K. Yu, ‘Reconceptualizing Intellectual Property Interests in a Human Rights Framework’ (2007) 40 U.C. Davis Law Review, 1039–1149.

²⁰⁸ L.R. Helfer, “Toward a Human Rights Framework for Intellectual Property”(2007), U.C. Davis Law Review, Vol.40, p.977, para.3.

²⁰⁹ Ibid.

²¹⁰ Peter K. Yu, “Challenges to the development of a human rights framework for intellectual property”, P.3, para.4. This article was abridged and adapted from P.K.Yu, “Reconceptualizing intellectual property interests in a human rights framework”, U.C.Davis Law Review, Vol.40, 2007, pp.1039-1149.

morality exceptions in patent law safeguard people from suffering harmful applications of technology that violates human rights. From the history of patent law discussed in the second chapter, it is known that the monopoly of patent rights is offered by society in return for information disclosure and a limited duration of the rights granted. Thus, it is misleading too inquire whether human rights and intellectual property rights coexist or conflict with each other. Due to the overlapping human rights attributes, these two sets of rights -- human rights and intellectual property rights-- both coexist and conflict with each other. The more important question is how to alleviate the tension and resolve the conflict between human rights and the non-human-rights aspects of intellectual property protection.²¹¹

To answer this question, Peter.K.Yu divided the conflicts between human rights and intellectual property rights into external conflicts and internal conflicts, and provides two kinds of strategy to solve the problem.²¹² With respect to external conflicts, the key resolution technique is to separate the human rights aspects of intellectual property protection from others that have no human rights basis, and the principle of human right primacy can be used to resolve the external conflict once the human rights attributes of intellectual property have been identified. In terms of internal conflicts, the above resolution technique doesn't work, since all the conflicting rights have human rights bases. Instead, "the just remuneration approach, the core minimum approach and the progressive realization approach" should be adopted to alleviate the conflicts.²¹³ In terms of internal conflicts among the rights with human rights bases, the principle of human rights primacy does not apply. Instead, Peter proposed 3 strategies for policymakers, judges and scholars,²¹⁴ which will be considered as measures to solve the paradox between IP rights and Human rights.

Furthermore, due to those human rights attributes, different kinds of links between intellectual and property rights and human rights can be identified. For example, patent laws recognize that there is a socioeconomic dimension to the rights granted and that a balance is needed between rights and obligations of technology holders, and between the interests of producers and users of technological knowledge, with the wider objective of promoting social and economic welfare.²¹⁵ In order to achieve this balance, TRIPS Agreement allows members to take measures to protect issues relevant to ICESCR, in particular health care, nutrition and the

²¹¹ Peter K. Yu, "Reconceptualizing Intellectual Property Interests in a Human Rights Framework", U.C.Davis Law Review, Vol.40, page 1078 of 1039-1149, para.1.

²¹² Ibid, para.2.

²¹³ Ibid.

²¹⁴ Peter.K.Yu, "Reconceptualizing intellectual property interests in a human rights framework" (2007), U.C.Davis Law Review, Vol.40, page 1039 of 1039-1149, para.2.

²¹⁵ See TRIPS Agreement, Article 7 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".

environment.²¹⁶ With respect to patents, members may authorize third parties to work the patent without the authorization of the patent holder for public interests. Compulsory license and parallel import are the usual referred measures.

Thus, in a human rights framework for intellectual property, the human rights attributes of intellectual property rights should get recognition and protection. It is beyond doubt that an emphasis of the human rights attributes in intellectual property rights is likely to further strengthen intellectual property rights. Accordingly, when facing the conflicts between the private interests protected for the incentive for innovation development and public interests protected to enjoy the basic human rights, the right to the protection of intellectual creations should give way to the protection of fundamental human rights, such as the right to the benefits of scientific progress, the right to life, the right to health, as well as other human rights. As the Sub-Commission Stated in its Statement, the government has a duty to take into consideration their human rights obligations, especially the minimum obligations, in the implementation of intellectual property policies and agreements and to subordinate these policies and agreements to human rights protections in the event of a conflict between the two.²¹⁷

Certainly there are challenges on the human rights framework for intellectual property, which argued that the framework would undermine the balance of existing intellectual property system. Especially for those attributes or forms of intellectual property rights without human basis, they are considered as less important through a human rights lens. Thus how to balance the public interest concerning about the human rights and individual IP rights is very significant for the development of this framework.

5.3 Paradox between IP rights and Human Rights

From a legal perspective, the courses of human rights relating to intellectual property rights are customary international law—the UDHR, the ICESCR and various other human rights instruments. Article 27 of the UDHR and Article 15 of ICESCR protect the moral and material interests of the authors and inventors, and on the other hand, they also recognize the public’s right to benefit from scientific progress that intellectual property products can engender. These clauses identified a need to balance the protection of both public and private interests in intellectual property. These articles bind States to design IP systems that strike a balance between promoting general

²¹⁶ See TRIPS Agreement, Article 8, members may “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”.

²¹⁷ United Nations High Commissioner for Human Rights, Sub-Commission on Human Rights Resolution 2000/7, “Intellectual property rights and human rights”, U.N. Doc. E/CN.4/Sub.2/RES/2000/7, 17 August 2000.

public interests in benefiting from new knowledge as well as in protecting the interests of authors and inventors in such knowledge. However the human rights approach to intellectual property protection challenge the monopoly right during the protection period for public interests.

The question is what's the degree of compatibility between Article 15 and traditional IP systems? For example, traditionally, in the patent field a State grant patent to inventors for a limited period in return for the disclosure of the invention. During the period of protection, the patent holder has rights to exclude competitors from making, using and selling patented product, and has market advantage to charge a higher prices over the technology. After this period, the patent holder allows the public to have access to the invention.

A human rights approach requires that the balance between public's and privates' interests under article 15 should be struck with the primary goal of promoting and protecting human rights. In conjunction with article 5 of the ICESCR, which states that "Nothing in the present Covenant may be interpreted as implying for any State, group or person any right to engage in any activity or to perform any act aimed at the destruction of any of the rights or freedoms recognized herein, or at their limitation to a greater extent than is provided for in the present Covenant", the balance in the context of article 15 should not work to the detriment of any of the rights in the Covenant. This position is also consistent with the Vienna Declaration and Programme of Action of the World Conference on Human Rights, which declares that "human rights are the first responsibility of Governments".²¹⁸

Article 15(1) (b) of International Covenant on Economic, Social and Culture Rights (ICESCR) affirms on one hand "the right of everyone to enjoy the benefits of scientific progress and its applications", but on the other hand Article 15(1)(c) provides human rights basis for intellectual property protection by recognizing "the right of everyone 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".

There is an apparent contradiction between these two rights when applied to access to medicine: Article 15(1) (b) emphasizes the right to share in scientific advancement of new drugs and its benefits, but Article 15(1) (c) seems to protect the "right" of pharmaceutical companies to earn a profit from the drugs they develop, by setting prices which may leads to inaccessibility of medicines.

Similarly, in the UDHR, Article 27(1) provides that 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, and on the other

²¹⁸ See Commission on Human Rights, Sub-Commission on the Promotion and Protection of Human Rights, "The impact of the Agreement on Trade-Related Aspects of Intellectual Property Rights on Human rights", Report of High Commissioner, E/CN.4/Sub.2/2001/13, 27 June 2001, para.13.

hand, Article 27(2) requires protection of the moral and material interests of authors in their works.

So, how to get out of this dilemma? The most significant is distinguishing and balancing intellectual property rights from human rights. The intellectual property right, as a lower moral and legal claim comparing with a human right, has a high social value in promoting innovation and creativity, so intellectual property rights can be considered as a temporary monopoly established for the valid social purpose of encouraging scientific invention and artistic creation. However, the intellectual property rights can't be abused for commercial purpose.

Human Rights organs have made effort to address this dilemma. The Committee on Economic, Social and Culture Rights prepared a statement on "Intellectual property rights and Human Rights" in 2001, in which it considered "Human rights are fundamental as they derive from the human person as such" and "human rights are dedicated to assuring satisfactory standards of human welfare and well-being", whereas intellectual property rights derived from intellectual property systems are instrumental, in that they are a means by which States seek to provide incentives for inventiveness and creativity from which society benefits", and "intellectual property rights are generally of a temporary nature".²¹⁹ Thus the Committee suggested that "in adopting intellectual property regimes, States and other actors must give particular attention at the national and international levels to the adequate protection of the human rights of disadvantaged and marginalized individuals and groups".²²⁰ With respect to the contradiction between "the right to enjoy the benefits of scientific progress and its applications" and "the right to benefit from the protection of the moral and material interests", The Committee alludes to "strike a balance between those concurrent Covenant provisions" when adopting and reviewing intellectual property systems. In other words, "in an effort to provide incentive for creation and innovation, private interests should not be unduly advantaged and the public interest in enjoying broad access to new knowledge should be given due consideration".²²¹

In order to help better understand the interplay of intellectual property and human rights, and how such a framework can be developed, the Committee on Economic, Social and Cultural Rights (CESCR) also provided an authoritative interpretation of article 15(1)(c) of the ICESCR in General Comment No. 17.

Firstly, the Committee distinguishes the right to the protection of interests in intellectual creations protected by intellectual property systems and that protected by human rights law system, and pointed out the difference

²¹⁹ Committee on Economic, Social and Cultural Rights, "Human Rights and Intellectual Property: Statement of the Committee on Economic, Social and Cultural Rights", U.N. Doc. E/C.12/2001/15 (2001), 14 December 2001, para.6.

²²⁰ *Ibid.*, para.8.

²²¹ *Ibid.*, para.17.

between the terms “the right to the protection of moral and material interests in intellectual creations” and “intellectual property rights”. As the Committee elaborated:

“Human rights are fundamental as they are inherent to the human person as such, whereas intellectual property rights are first and foremost means by which States seek to provide incentives for inventiveness and creativity, encourage the dissemination of creative and innovative productions, as well as the development of cultural identities, and preserve the integrity of scientific, literary and artistic productions for the benefit of society as a whole.

In contrast to human rights, intellectual property rights are generally of a temporary nature, and can be revoked, licensed or assigned to someone else. While under most intellectual property systems, intellectual property rights, often with the exception of moral rights, may be allocated, limited in time and scope, traded, amended and even forfeited, human rights are timeless expressions of fundamental entitlements of the human person. Whereas the human right to benefit from the protection of the moral and material interests resulting from one’s scientific, literary and artistic productions safeguards the personal link between authors and their creations and between peoples, communities, or other groups and their collective cultural heritage, as well as their basic material interests which are necessary to enable authors to enjoy an adequate standard of living, intellectual property regimes primarily protect business and corporate interests and investments. Moreover, the scope of protection of the moral and material interests of the author provided for by article 15, paragraph 1 (c), does not necessarily coincide with what is referred to as intellectual property rights under national legislation or international agreements.”²²²

Accordingly, it is significant to clarify the nature intellectual property rights and make clear whether it is under the sphere of protection as right to the protection of moral and material interests in intellectual creations.

Afterwards the second questions arises: how to solve the conflicts between two kinds of rights: “the right of everyone to enjoy the benefits of scientific progress and its applications”, and “the right of everyone 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”?

Intellectual property is a social product with a social function, and the nature of IPRs is that of a social contract – The conditions normally attached with the granting of IP rights also stress the obligation to make public his invention. This social contract is a marriage between private good and public interest.

²²² Committee on Economic, Social and Cultural Rights, General Comment No. 17: The Right of Everyone 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 (Art. 15(1)(c)), para. 35, 12 January 2006, U.N. Doc. E/C.12/GC/17.

The international IP regime lays down the concept of public good as basic to protection of intellectual property rights. For instance, The TRIPS Agreement similarly recognizes public policy objectives within its preamble. Moreover, Article 7 appears to allow courts to take into account “social and economic welfare”, whatever this may entail, and urges “a balance of rights and obligations”; whilst Article 8 specifically states that member 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. If we turn to the language of the 1996 WIPO Copyright Treaty, we note that there is another public interest rule lying within the Preamble:

“a need to maintain a balance between rights of authors and the large public interest, particularly education, research and access to information”.

A fair balance has to be drawn between the fundamental right, the interest and welfare of the individual to own and enjoy property and the public interest. As we can find from Article 4 of the ICESCR, which provide guidance on when Covenant rights can be restricted:

“The States Parties to the present Covenant recognize that, in the enjoyment of those rights provided by the State in conformity with the present Covenant, the State may subject such rights only to such limitations as are determined by law only in so far as this may be compatible with the nature of these rights and solely for the purpose of promoting the general welfare in a democratic society.”

The European Convention on Human Rights also contains the similar language: *“Every natural or legal person is entitled to the peaceful enjoyment of his possessions. No one shall be deprived of his possessions except in the public interest...”*²²³

Nevertheless, public interest rule doesn’t mean “one-way ratchet” to protecting public rights. It should also take consideration of individual rights. Otherwise, it may create and escalate the tensions between the intellectual property rights and human rights, in particular the lack of interest and innovation within industries and companies in relation to the needs of people in developing countries. The corporations are not willing to make large investments in research unless they can enjoy benefits from scientific progress.

²²³ “European Convention on Human Rights”, Council of Europe, Rome, 4 November 1950, and its Five Protocols, Protocol 1, PARIS 20 March 1952, Article 1.

Some scholars proposed “just remuneration approach” to relief the tension.²²⁴ Just remuneration, which permits an equitable remuneration to balance and promote the investor’ interests from arguing in the name of the creators. The just remuneration approach is usually undertaken by the courts in constitution law cases in which the constitution mandates free access to work.²²⁵ Under the just remuneration approach individuals are free to use their creative works in the enjoyment of exercise of their human rights, which requires compensatory measures. For instance, granting a compulsory license, as compared to a free license, to the individual to enjoy the human rights from one hand, and on the other hand provide the right holder a right to remuneration, instead of exclusive control. The General Comment links the economic dimension of the right to enjoy moral and material interests to intellectual property creations under article 15(1)(c) to the right to an adequate remuneration as well as the benefits of gaining one’s living by work.²²⁶ The just remuneration approach has also been written down in the TRIPS Agreement as well with respect to the use without authorization of the right holder, stating in Article 31(h): “the right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization.”

The question is how to define an “adequate remuneration”. It is evident that “adequate remuneration” cannot be constructed on a “profit lost” basis. Otherwise the high level of royalty payment would also render human rights protection meaningless. In addition, remuneration should not only include economic compensation, which is focus on the protection of material interests. The Economic, Social and Cultural Committee suggests that the scope of protection of the moral and material interests of the author provided for by article 15, paragraph 1 (c), does not necessarily coincide with what is referred to as intellectual property rights under national legislation or international agreements.²²⁷ The Committee emphasized that the protection of material interests under the Covenant is limited to the basic material interests of authors to allow them to enjoy an adequate standard of living. As to the “moral interests” in article 15, the Committee constructs it as the right of authors to be recognized as the creators of their scientific, literary and artistic productions and to object to any distortion, mutilation or

²²⁴ Peter K. Yu, “Reconceptualizing Intellectual Property Interests in a Human Rights Framework”, U.C. Davis Law Review, Vol.40, page 1059 of 1039-1149, para.2.

²²⁵ See Peter K. Yu, “Reconceptualizing Intellectual Property Interests in a Human Rights Framework”, U.C. Davis Law Review, Vol.40, page 1059 of 1039-1149, para.3, at footnote 211, 212 referring to the statement of German Constitutional Court.

²²⁶ The Right of Everyone to Benefit From the Protection of the Moral and Material Interests Resulting From any Scientific, Literary or Artistic Production of Which He or She is the Author, General Comment No. 17, U.N. ESCOR, Comment on Economic, Social & Cultural Rights, 35th Session, U.N. Doc. E/C.12/GC/17 (2006), para.4.

²²⁷ The Right of Everyone to Benefit From the Protection of the Moral and Material Interests Resulting From any Scientific, Literary or Artistic Production of Which He or She is the Author, General Comment No. 17, U.N. ESCOR, Comment on Economic, Social & Cultural Rights, 35th Session, U.N. Doc. E/C.12/GC/17 (2006), para.2.

other modification of, or other derogatory action in relation to, such productions, which would be prejudicial to their honor and reputation.²²⁸

5.4 Human Rights Approach to Access to Medicine

Without any doubt that the human rights-based approach is used to hold government primarily accountable, and activities supporting accountability could range from public critique to litigation and policy making. How to incorporate a human rights-based approach and integrate human rights standards into national policy making and legislation is very significant for the implementation of right to essential medicines. The main principles of human-rights based approach derive from those rights codified in international convention or other human rights instruments, including empowerment, protection of particularly the most vulnerable groups of society, non-discrimination and equality, the principle of participatory decision-making, the notion of accountability, interdependence of all human rights, and the principle of proportionality. These norms, standards and principles of the international human rights system need be integrated into the plans, policies and processes of development. Thus the specific medicines policies and programmes must be consistent with the human rights-based approach, and it can be assessed in the following aspects in the following aspects:

(1) Ensure the fundamental rights to the enjoyment of the highest attainable standard of health, the right to life and the right to non-discrimination are protected in Constitutional and other legal provisions, and the balance between IP rights and human rights in national legislation should be taken into consideration; (2) Availability of essential drugs defined by the WHO model list of essential medicines must be ensured by the national legislation and medicine policies; (3) The roles and responsibilities of stakeholders, not only the State but also the private groups, need be identified, and the people's awareness of right to essential medicines should be improved progressively; (4) All vulnerable groups have equal access to essential medicines; (5) Remedy mechanism is available for the people to safeguard their rights when it is violated.

Although States bear primary responsibility for the realization of the right to health, its achievement on this target requires a multi-stakeholder approach. The role of the pharmaceutical industry in promoting access to medicines has received particular attention in most recent years. The preambles of the ICCPR and the ICESCR, which serve as context for the purpose of

²²⁸ The Right of Everyone to Benefit From the Protection of the Moral and Material Interests Resulting From any Scientific, Literary or Artistic Production of Which He or She is the Author, General Comment No. 17, U.N. ESCOR, Comment on Economic, Social & Cultural Rights, 35th Session, U.N. Doc. E/C.12/GC/17 (2006), para.13.

interpreting the human rights norms, seem to extend the binding effect of the Covenants to private parties by providing that: “the individual, having duties to other individuals and to the community to which he belongs, is under a responsibility to strive for the promotion and observance of the rights recognized in the present Covenant”. A similar provision is contained in the preamble of the UDHR: “Therefore THE GENERAL ASSEMBLY proclaims THIS UNIVERSAL DECLARATION OF HUMAN RIGHTS as a common standard of achievement for all peoples and all nations, to the end that every individual and every organ of society, keeping this Declaration constantly in mind...”.

In addition Article 29(1) (2) and Article 30 of the UDHR list specific obligations of individuals and groups:

Article 29:

“(1) Everyone has duties to the community in which alone the free and full development of his personality is possible”.

“(2) In the exercise of his rights and freedoms, everyone shall be subject only to such limitations as are determined by law solely for the purpose of securing due recognition and respect for the rights and freedoms of others and of meeting the just requirements of morality, public order and the general welfare in a democratic society”.

Article 30:

“Nothing in this Declaration may be interpreted as implying for any State, group or person any right to engage in any activity or to perform any act aimed at the destruction of any of the rights and freedoms set forth herein”.

The pharmaceutical industry can and should take the responsibility to help states to achieve the full realization of the right to health and should work in partnership with them and other actors through its core capabilities of researching, developing and producing medicines and vaccines to address essential medical needs, and helping to ensure their appropriate distribution. Actually Pharmaceutical companies contribute in various ways to the realization of the right to the highest attainable standard of health, such as providing individuals and communities with important information about public health issues. Important areas where the pharmaceutical industry can play an important role cover the work of promoting right to health in the following ways:

(1) Discover and develop new medicines for neglected diseases prevalent in developing countries; (2) Develop new approaches to access to medicines in emerging and least developed countries by providing affordable prices according to particular countries’ level of economic development. (3) Help states to build health care capacity, strengthen health systems and improve

health education and awareness. (4) In terms of patent issues, the company should respect the right of countries provided in TRIPS Agreement, which allow flexibility for the purpose of promoting access to medicines, including the provisions relating to compulsory licensing and parallel imports, and the Doha Declaration that recognizes a State's right to protect public health and promote access to medicines for all.²²⁹ In low-income and middle-income countries, the company should not apply for patents for insignificant or trivial modifications of existing medicines.²³⁰ (5) With respect to license issuing, "as part of its access to medicines policy, the company should issue non-exclusive voluntary licenses with a view to increase access, in low-income and middle-income countries, to all medicines. The licenses, which may be commercial or non-commercial, should include appropriate safeguards, for example, requiring that the medicines meet the standards on quality, safety and efficacy."²³¹

The participation of organized civil society and the reorganization to question and challenge injustice in all national and global levels, have key role in scrutinizing the practices of multinational pharmaceutical industries and governments. Human rights approach that lacks of social mobilization loses its transformative potential. It is through organized community action and adopting a human rights approach to medicine on the ground of popular engagement that the hard work of realizing rights is best affected. Thus much more needs to be done to set up mechanisms to elevate procedural rights (such as public participation mechanisms, recourse to appeals processes, and administrative justice safeguards in policy development and in ensuring that their implementation is adequately monitored).

In addition, the problem requires a commitment from all members of international community, including not only the government in developed countries, the international organization, but also the research groups and the media, to provide funding and strategic planning to improve the insufficient medical infrastructure in developing world.

Another important way to build up human rights based approach to access to medicine can be using the flexibility of intellectual property rights regulated in TRIPS Agreement to offset the monopoly privileges of patent holders in national intellectual property legislation.

²²⁹ See "Human Rights Guidelines for Pharmaceutical Companies in relation to Access to medicines", preamble, , Published in the report to the General Assembly of the UN Special Rapporteur on the right to the highest attainable standard of health, UN document: A/63/263, dated 11 August 2008, para.26-27.

²³⁰ See "Human Rights Guidelines for Pharmaceutical Companies in relation to Access to medicines", preamble, , Published in the report to the General Assembly of the UN Special Rapporteur on the right to the highest attainable standard of health, UN document: A/63/263, dated 11 August 2008, para.32.

²³¹ See "Human Rights Guidelines for Pharmaceutical Companies in relation to Access to medicines", preamble, , Published in the report to the General Assembly of the UN Special Rapporteur on the right to the highest attainable standard of health, UN document: A/63/263, dated 11 August 2008, para.30.

Firstly, the government can grant compulsory license for reasons of national emergency or extreme urgency, public non-commercial use and other reasons. TRIPS does not limit the grounds or reasons for issuing a compulsory license, but the TRIPS agreement specifies conditions for issuing such compulsory license, which includes: 1) issue compulsory license case by case; 2) try to obtain a voluntary license before issuing compulsory license; 3) provide adequate remuneration to the patent holder; 4) issue such license for the supply of the domestic market; 5) such license shall not be exclusive and assignable. However, such safeguards provided in TRIPS can only be used when incorporated in the national law. Thus, the countries should design and enact legislation to use this measure to protect the public interest.

Secondly, other flexibilities in TRIPS can be used in the national intellectual property law to improve access to medicine. For instance, Article 27(1) regulates that patentable subject matter has to meet the requirements of “being new, involve and incentive step, and capable of industrial application”,²³² but TRIPS doesn’t define those terms and leave the member states to define what constitute a patentable invention. As an example, the States can adopt a strict novelty standard for pharmaceutical inventions to narrow the scope of patentability.

Thirdly, national laws may also permit parallel importation of patented product to purchase or import pharmaceutical products at a lower price if such products are sold at a higher price in their countries.

Fourthly, the national intellectual property legislation can stipulate exceptions to patent rights. For example, scientific research and experimental use exceptions can be helpful to promote dissemination of technology and knowledge and create a safe harbor for scientific activities, particularly for basic research and experimentation.

Fifthly, the national intellectual property law should take consideration of limiting the abuse of the exercise of exclusive intellectual property rights. This flexibility is contained in Article 8.2 of TRIPS Agreement, which authorizes member States 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.²³³ Furthermore, Article 40(2) of TRIPS Agreement regulates the control of anti-competitive practice in contractual licenses and recognizes the right of member states to specify in their legislation licensing practices or conditions that may in particular cases constitute an abuse of intellectual property rights having an adverse effect on competition in the relevant market, and also provides member states to take appropriate measures to prevent and control the

²³² “Agreement on Trade-Related Aspects of Intellectual Property Rights”, signed in Marrakesh, Morocco on 15 April 1994, Article 27(1).

²³³ “Agreement on Trade-Related Aspects of Intellectual Property Rights”, signed in Marrakesh, Morocco on 15 April 1994, Article 8(2).

practices.²³⁴ Thus the countries can enable the national legislation to restrict the abuse of the exercise of intellectual property rights by remedy mechanism, such as fines, price regulation, compulsory licenses and so on.

²³⁴ Agreement on Trade-Related Aspects of Intellectual Property Rights”, signed in Marrakesh, Morocco on 15 April 1994, Article 40(2).

6. Conclusion

A paradoxical relationship exists between patent law and access to medicine. The exclusive patent rights lead to restrictions to the affordability and accessibility of a patented pharmaceutical invention. The international community has realized that there is a point where limits should be imposed on patent protection, especially when health and the human life are involved. The public health crisis in the world and the very fact of access to medicines needed special attention in intellectual property rights legislation and implementation, and the medicines products need to be treated different from other products.

From the history of patent law, we find that patent was granted by national authorities as a means to promote the industrial advancement of the nation, not as a right of the inventor. Granting patents by the legislation is a social contract in which temporary exclusive rights are conferred upon the inventor as a reward for his achievement. In exchange the public can benefit from the patented invention. Legislators have always tried to tailor patent laws to the goal of inducing the introduction of new knowledge with minimal disadvantages to society. When we consider patents on pharmaceutical products, the maintenance of delicate balance becomes even more serious. The social goal and measures to protect public interest should be included in the national legislation encompassing public health issues, especially the access to essential medicines.

Historically international patent norms facilitated the growth of pharmaceutical industries in many countries which lack the capacity to invent and produce drugs, since flexibilities available in the Paris Convention, which means there was no mandate for member states to provide product patent, enable these countries to build their domestic industries and to provide access to medicines at affordable cost.

The international norms set up in the TRIPS Agreement are still not uniformed since the TRIPS Agreement is not uniform law. The minimum standards and conditions for the protection of intellectual property are made operational via the national intellectual property rights legislation. Under the TRIPS agreement, the principle of territoriality remains valid. The TRIPS agreement also allows states to weaken patents in several respects by optional “flexibilities”. For instance, Although TRIPS requires that patents are granted when the typical standards for patentability, that is, novelty, inventive step and industrial applicability, are met. But the Agreement does not specify how these criteria should be defined; WTO member countries may decide how to apply these criteria. Parallel importing is allowed to import patented product with a lower price from the third country without the authorization of the patent holder, and also prevent resale of inexpensive drugs in western markets, since TRIPS explicitly states that it does not

address the issue of parallel import, thereby leaving countries free to determine their own policy in this respect. Another advantage of “flexibilities” safeguard is that the member states can grant compulsory licenses in the case of abuse of intellectual property rights and non-availability of the products. Flexibilities provided by TRIPS can be used as an important leeway to implement public health policies and to create more affordable medicines.

However, TRIPS agreement has not done away with the notion of compulsory licenses but provides a more restricted framework. The multiple controversies concerning patent in health sector leads to Doha Declaration to find better solution. The recognition in the Doha Declaration that TRIPS member-states can use the flexibility provided in the agreement and can, for instance, determine the grounds on which compulsory licences are granted must be understood in the context of generally restrictive international patent regime. These safeguards can be used to mitigate potential negative impacts of increased IPR protection in fundamental human rights including access to medicine.

Viewed in the context of international human rights law and ethics, including the regional and international human rights conventions and instruments, it is obvious that access to medicine as human rights issue, has to be placed in the central when face the conflicts with private interests. International human rights provide a legal structure for advocacy for access to medicine within the legal system. Human rights attributes provide a potential structure -- human rights based approach to intellectual property rights-- to balance the conflicting interests that supported by intellectual property languages and human rights languages. In this human rights framework, the intellectual property legislation should be interpreted to complement and promote fulfillment of substantive human rights norms. Intellectual property protections adopted to protect the fundamental rights of authors and creators are not absolute. Property rights must be limited to the degree necessary to protect the public health and social welfare in democratic societies.

Furthermore, the tension between intellectual property right (patent right) and human rights (access to medicine) are largely resolvable if the national government and international community make a joint commitment to battle. How to promote sustained development in developing countries or least-developed countries, as well as how to secure the international commitment are other big challenges and long-term issue to made widely available and affordable medicines.

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