FACULTY OF LAW
Lund University

Li Muzi

Balance of the Access to Health and Intellectual Property protection in the Globalization

Master thesis
30 credits

Supervisor **Dr. Anna Maria Andersen Nawrot**

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

Spring 2012

Contents

Summary

Preface

Abbreviations

1. Introduction

1.1 Outline 8

1.2 Background 8

1.2.1 Global Health and Intellectual Property 9

1.2.2 Global Society and Access to health 9

1.2.3 Health, Economy and Development 10

1.3 Methodology 10

2. Theories

2.1 Globalization 12

2.1.1 Definition 12

2.1.2 Effects of globalization 12

2.1.3 Globalization and access to health 13

2.2 Access to health as the Element of Human Rights 14

2.3 Democracy 15

2.4 Balance and Equity 16

2.5 A2K：Health Is Knowledge. 18

3. Legislations

3.1 Intellectual Property Rights under the Human Rights Framework 20

3.1.1 UDHR 20

3.1.2 ICESCR 21

3.1.3 General Comment No.14 23

3.2 Human Rights in the Intellectual Property Regime 23
3.2.1 TRIPS 23
3.2.2 The Declaration on the TRIPS Agreement and Public Health 25
3.1.3 The Decision of 30 August 2003 29
3.1.4 Amendment of the TRIPS Agreement 29

4. Problem Solving
4.1 Global Access Requirement: Global Drug Gap 31
4.1.1 Access to health and global drug gap 31
4.1.2 Health democracy 34
4.1.3 Government obligation 35
4.2 Global Access Obstacle: High Medicine Price and Related Issues 35
4.2.1 Market reality 36
4.2.2 The jurisprudential economic of price 38
4.2.3 Price and intellectual property 39
4.3 Global Access Guarantee: Compulsory license 40
4.3.1 History 40
4.3.2 Effect 42
4.3.3 Lessons learned 43

5. Discussion
5.1 The Barriers between Access to health and Intellectual Property 45
5.2 Innovation and Intellectual Property 48
5.3 Human Rights Make Access to health Global and Universal 49

6. Conclusion **52**

Bibliography **54**

Acknowledge **57**

to health , to human

Summary

Though the paradox between Human Rights and Intellectual Property Rights has been discussed, their relationship remains unclear. In this paper, to clarify the relationship between human rights and intellectual property rights in the process of globalization, I will examine the legislation and analyze the function of the legal regime we have today and present my arguments.

The first Chapter is the introduction. I have set globalization as my background and discuss my topic in the limitation of economic changes brought by the process of globalization. On this ground, will give a milieu of global statute and society reality related to access to health in the globalization.

The second chapter is the theories part, the essential theories and relevant terms have be cleared and recalled. I have give a comprehensive explain of the theories I will used in my topic, such as globalization, access to health, health democracy, equity and A2K movement.

The third chapter is the normative part. I have examined the international human rights system and pointed out the relevant legal support for the equity access to health. These human rights like right to health and right to development should be treat as the fundamental rights for humans. It should be fulfilled universally. Besides, I have analyzed the intellectual property regime and figure out what we should revise under the direction of human rights.

Turn to chapter four, it is a function examination of all the theories and doctrines mentioned above. The interesting problems spurt from the unbalanced global economy statute will be discussed. To some extent, Global medicine gap caused by the price block should be seen as the bomb point for the unequal access to health. Although under the requirement of universal human rights, like health democracy, the intellectual property regime has raised so-called compulsory license to balance the global problem, there still leave a huge margin for us.

Finally, in the fifth part, the subject about innovation and health democracy will be considered broadly related to both human rights law and intellectual property law.

To conclude, the process of globalization raised the new problem for intellectual property and caused the inequity access to health worldwide. On the one hand, because the human rights standard regulated in the international law is universal and broadly, it supplied a mechanism for the international trade market to balance the terrible situation. On the other hand, the intellectual property regime should also take the human rights provision into account and to be changed to suit for the global society.

Key Word: Access to Health; Health Democracy; Human Rights; Intellectual Property; Globalization

Preface

The exploration of the relationship between intellectual property and access to health has been steadily increasing in the related field as the process of globalization. Because access to health can be seen as the essential element of human rights, I hold the opinion that the human rights should be put in the center stage of this topic and we need new democracy named health democracy today. Only the intellectual property rights being contest within the human rights, can it be efficient and benefit for all in the global society.

Abbreviations

WHO	World Health Organization
WIPO	World Intellectual Property Organization
WTO	World Trade Organization
UDHR	Universal Declaration of Human Rights
ICESCR	International Covenant of Economic Social and Civil Rights
ICCPR	International Covenant of Economic, Social and Cultural Rights
GC	General Comment
LDCs	Least Developing Countries
TRIPS	Trade-Related Aspects of Intellectual Property Agreement
UN	United Nations
IP	Intellectual Property
HR	Human Rights

1. Introduction

How to connect Human Rights issues with Intellectual Property standpoint has sparked spirit debates in recent years. Though the paradox between Human Rights and Intellectual Property Rights has been discussed, their relationship remains unclear. These discussions have stirred up serious antagonism, above all developed and developing countries, and have been the cause of intensive debate in international conferences at international level. As health is a factor that is crucial to the survival and welfare of mankind in the globalization, so how to play its role as a promoter of development, how to treat Access to health in the Human Rights regime and how to balance the proportion of Access to health and Intellectual Property Rights among different economic unit has become an urgent problem.

As a response to these topics, this paper therefore aims to take a broad look and give an analysis to both Human Rights regime and Intellectual Property Rights system with the subjects of the various balance issues. It will deal with the argument of the relationship of Access to health and Intellectual Property in the context of globalization.

As far as I can see, currently, as the economic development and knowledge access movement, the world health situation is pessimistic and unbalance. Intellectual property seems to set a barriers for the all the access to health in some sense. And globalization enlarged this gap. On the other hand, access to health as the element of human rights should be fulfilled without any condition. Thus, it would be not hard to conclude that there should be a balance involvement between Access to health and Intellectual Property Rights in the era of globalization.

1.1 Outline

In the first two chapters I will give a milieu of global statute and society reality related to access to health in the globalization. The essential theories and relevant terms need to be cleared and recalled. Furthermore, in the third chapter, the provision of International Human Rights Law and Intellectual Property Law will be analyzed and explained. Turn to Chapter 4, the interesting problems spurt from the unbalance economy statute, such as global medicine gap and price related issues will be discussed. Finally, I will examine the relationship between accesses to health under the intellectual property law framework. The subject about innovation and health democracy will be considered in a broadened context of globalization.

1.2 Background

Before I go through the further discussion, I need to set a global background related to my analysis below, for example, the global health situation, intellectual property statue and the association of these concepts with development. When I discussed the issues exist in the globalization, I choose to narrow my topic on the economic perspective and used the international human rights and intellectual property as the supports for my arguments

1.2.1 Global health and intellectual property

Nowadays, the global health crisis reflects widening inequalities within and beyond countries. The reason of increasing unequal access to health lies in the fact that the Intellectual Property Rights which are the protection of the private rights for the inventors or advance technology right holders in health care system has set the huge barrier for the poor to enjoy the benefit for free or in low price. In other word, the advantage science and technology can only secure a better health for a small fraction of the world's upside population. Noticeably, the access to health is unbalanced and varying from country to country.

According to the statistics given by WIPO[1], in 2011, USA, Germany and China [2]occupied the first three places of the resident medicine patent application. Simultaneously, the health related situation update reflects that these countries indeed guarantee more comprehensive health access, such as health insurance (not the concern of this paper), comprehensive health instruction and access to advanced health resources like medicine and medical technology. That is to say, the intellectual property rights have a close relationship with access to health. The patent grants not only improve the innovation, but also provide an advanced health care.

On the contrary, coincidently, the countries who own less medicine or health related patent maintains a seriously urgent health situation. Taking a glimpse of the global situation, approximately two billion people — one-third of the world's population — have no access to the essential health they need nowadays because of the high price of the medicine and health care and patent protection of relevant technology. In some of the LDCs in Africa and Asia, it is even worse that the figure rises to more than half of the population. These statistics undeniably reveal the significant difficulty for the poor to access the technological advances created by humankind in the field of medical and health care.

On this ground, the intellectual property rightholder or advanced scientific technology definitely guarantees a higher protection and accessibility of health. Like the two sides of one coin, despite of the health guarantee and technology protection, the accessibility remains a major and priority challenge for the international community and intellectual property framework.

1.2.2 Global society and access to health

It is obviously that the paradox of intellectual property and access to health is raised through the process of globalization. In the other word, because we live in the global society, we need to balance the access to health and intellectual property rights under the direct of human rights principle.

To illustrate, human beings have lived with a continual change since the migration of *Homo erectus* out of Africa a million years ago. And it is no doubt that, as the migration, we are already living in a global society now.[3]Thus, all the activities

---

[1] WIPO. *World Intellectual Property indicator*. Geneva, 2011.

[2] Ibid. According to the data showed in the table of Contribution of field of technology to the change in volum of fillings (1995-2008), the pharmaceutical contribution of China, Germany, and United States occupied 6.5%, 6.3% and 8.8%, respectively.

[3] Kelley Lee. "Globalisation: what is it and how does it affect health?" *The medical journal of Australia* Med J Aust 2004, 180 (4): 156-158. Available at: https://www.mja.com.au/journal/2004/180/4/globalisation-what-it-and-how-does-it-affect-health (access MAY 2012).

we have today will have an effect globally. This evolution of human societies is so called globalization. But the phrase, globalization of access to health, used in my paper is distinctive in its unprecedented intensity and extent of change. It focuses on the global influence raised by economic and knowledge movement.

In addition, dramatic differences in the health and life chances of peoples around the world reflect imbalance in the power and prosperity of nations. And the individual's health pertains not only to the individual, but also to the greater social organism. Hence, as the global changes, the undoubted social globalization initials profound unequal distributed of health related issues.

Furthermore, in addition to globalization, access to health as an element of fundamental human rights also has the global characteristic, which guarantees the universal human dignity for all. The human rights require equity global accessibility without any excuse. Therefore, it formed the foundation for global health access in the globalization as well.

So, it is no doubt that the access to health is not only an element of universal human rights, but also the requirement of global society. They are interacted.

1.2.3 Health, economy and development

Health has become not a condition of biology but one of social statues nowadays. It is important to the society development.

Health is not only an important indicator of the economic development of a society but also a determinant factor of the development: 'more and more economic have come to recognize that the relationship between health and economic growth is not only demand driven, but that health itself is an important determinant if economic growth'.[4] To be more specific, health related production is increasing characterized by the need to perform as an economic good[5] with the scientific research tied to the market, both the development of the products and the decisions as to what products to investigate are influenced by profitability. The health demand will influence the research and innovation direction (discuss below). In recent days, as more and more attention has been put into health improvement according to the GDP growth, the economic value of the health products market has increased dramatically.

Hence, health, economic and development has already formulated a triple-acting form with the globalization through the international trade market. this interrelationship between health and development is significant in the context of human rights, such as the right to development and right to food. These rights also incorporate health as an essential component, and ensure this relationship.

1.3 Methodology

In order to support my conduct the research, I have used following methods to get the information and database I need.

---

[4] Zon, A. van, muysken, J.*Health as a principle determinant of economic growth in Lopez-Casasnovas*. 2005. G. et al. (ed). *Health and economic growth: finding and policy implications*. Cambridge MA: MIT Press, page 41.

[5] Lupton, D. *Medicine as culture.* 2003,2nd ed. London: SAGE, page 8-11.

(1) Information filter

I should achieve as much as possible the current information. More specifically, literatures of fundamental theories, international instruments, reports and working papers, EU legislations and case law are mainly available from libraries and the internet. Chinese laws, policies, cases and industry reports are mostly within good reach in terms of the researcher's Chinese background, although sometimes necessary translation work needs to be done.

(2) Case study and legal interpretation

I will give an examination of cases and legislations. It can be analyzed by means of conducting empirical research on current international and national resources concerning the subject.

(3) Factual inquires

The circumstances interviews and investigations will be taken for collection of advanced information and data. I will analyze these statistics and discuss the related issues with lead researchers from different fields. I try to make my research to be practical and efficient.

(4) Comparative study

I will compare different legal systems and interpret it in a practical way. I will attempt to consider the culture behind the law when I interpret the law and the case.

(5) Synthesis and meta-analysis

On the ground of the information I have got, I will give an analyze or a solution.

Overall, as the society globalization, the health situation all over the world have appears new symbols and these society and economic changes have increased the unbalance of access to health under the protection of intellectual property. It turned to be an urgent task for the society to find an efficient international mechanism which can be universal and global accessed to relieve the pressure global situation. It cannot be denying that we can form an international intellectual property regime based on international human rights which is practical and useful in the globalization.

2. Theories

There are many complicated theories is mixed up in the trend of globalization. And it is difficult to distinguish them separately. In this part I will clear several main stream concepts, like globalization, access to health, democracy, equity and A2K movement, and linked these expressions with international human rights law and intellectual law. These theories work to each other and have an inter-effect as well.

2.1 Globalization

2.1.1 Definition

The term globalization usually is seen as a process driven by revolutions in communication and transportation.[6]The revolution makes it possible for people to move from here to there around the world, which will increase the economic and culture exchange.

When discussing the globalization-health nexus, the term ‘globalization’ should be treated as a catch-all expression.[7]First, it is certain that the rise of multinational enterprises who want to take advantage of certain health production and distribution efficiencies is one of the key reasons for the health globalization. Besides, to the health issues associated to intellectual property market, globalization can be seen as a function of the simultaneous rise of significant amount of trade and investment. However, to focus on my topic, the globalization in my paper should been described as “a process of gradual integration within the world economy and culture through cross-border movements of goods, services and technology, which lead increasingly to economic decisions being influenced by global conditions.”[8] The globalization through impacts on local cultures, attitudes, social behavior and contributes to the formation of global values, as well as to political participation, human rights fulfillment and the spread of democracy to get the world development integration.

2.1.2 Effects of globalization

The impact of globalization on access to health is mediated through different sets of factors.

First, the policy and legislation of access to health has been changed with the globalization and occurred new symbols. To be specifically, the international and national policy factors which are consciously aimed at facilitating global economic integration are affecting health include the independent choices of economic agents in

[6] Alejandro Portes. *Globalization from Below: The Rise of Transnational Communities*. WPTC-98-01. Princeton University, September 1997.

[7] Giovanni Andrea Cornia , Stefano Rosignoli , Luca Tiberti . Globalization Knowledge Network. *Globalisation and Health: Pathways of Transmission and Evidence of Impact.* WHO Commission on Social Determinants of Health. 27 November 2006.

[8] Globalization Knowledge Network. *Towards Health-Equitable Globalization: Rights, Regulation and Redistribution*.2007.

the fields of consumption, health innovation, health and reproductive behavior, migration[9], and so on. As the globalization, the policy and legislation should be set on the international level and the national legislation need to be amended by the way.

Second, because globalization affects how we perceive and experience physical or territorial space, which will increase the unbalance of achievement of health care due to the financial reasons and raise the pressure of local health resources consumption, so new legal regime for the market and re-balance lever should be built based on international human rights law.

Third, globalization affects how we perceive and experience, which accelerate the information and knowledge achievement among the world. On the one hand, social interaction is speeding up through modern communication and transportation technologies. We need to share and open access our exclusive rights, such as some intellectual property rights. On the other hand, the globalization also offered a multinational payback for this open access.

To conclude, as analyzed above, the globalization expressed in this paper is caused by the culture and economic change. It result many unbalanced distribution and unequal access. So the human rights doctrine should be taken into consideration without payback and laid the foundation of the legislation and policy needed in the globalization, because human right, particularly access to health, is the universal rights which can parallel[10] with globalization.

2.1.3 Globalization and access to health

It would be inaccurate to describe globalization as either “good” or “bad” for health.

For example, globalization affects the spread of disease. For high-income countries, the debate surrounding globalization and health tends to focus on the perceived threat from low- and middle-income countries, of acquiring certain acute and epidemic infections, such as HIV/AIDS, tuberculosis, plague and, more recently, severe acute respiratory syndrome (SARS).[11] Besides, the speed of modern transportation systems means that infections can potentially move around the world within a few hours (as illustrated by the SARS outbreak in 2002–03).[12] However, the medical technical also spread with the occurring of the disease. And the modern technology potentially enables the health community to respond more quickly to such emergencies. For instance, an international network of institutions coordinated by the World Health Organization (WHO) via global telecommunications can readily detect

[9] Giovanni Andrea Cornia , Stefano Rosignoli , Luca Tiberti . Globalization Knowledge Network. *Globalisation and Health: Pathways of Transmission and Evidence of Impact.* WHO Commission on Social Determinants of Health. 27 November 2006.

[10] The relationship among human rights, intellectual property and the trend and effect of globalization is cohesion and interaction, which can be seen as a parallel relationship. In other words, it is balanced.

[11] Institutes of Medicine. *America’s vital interest in global health.* Washington DC: National Academy Press, 1997.

[12] Syed Q, Sopwith W, Regan M, Bellis MA. “Behind the mask: Journey through an epidemic: some observations of contrasting public health responses to SARS.” *J Epidemiology Community Health* ,57(2003): 855-856.

and rapidly respond to changes in the influenza virus.[13] To response to these changes, it requires further international cooperation among countries and it need to create new or amend the current polity and legal system globally. We hope to build an efficient, equity and harmony regime under the human rights framework.

Similarly, due to globalization, the migration appears throughout the world, which asked for equity access globally. Developed countries fear the potential financial burden of unhealthy populations migrating from the developing and least develop countries. There is also a tendency to overlook the benefits to high-income countries from population mobility — the migration of health professionals from poorer countries offers benefits to understaffed health systems in high-income countries (but at the expense of capacity in the developing world).[14] In other words, the increased movement of people and other items creates a complex equation of pluses and minuses for each society. People all over the world need an equity access to health despite nationality, in-come and other personal condition.

Finally, the cognition of health, ethic and human rights has been changed by globalization. The global advertising and marketing has result some new diseases, such as so-called "lifestyle" diseases, in certain populations within low- and middle-income countries. For illustrate, the shift in the tobacco pandemic to the developing world has been clearly driven by the tobacco industry.[15] It is estimated that, by 2030, 70% of all tobacco-related deaths (7 million annually) will occur in developing countries.[16] Nevertheless, global consciousness is also leading to the increased sharing of principles, legal values and standards that underpin decision making about health. In 1964, Helsinki declaration on ethical principles for medical research involving human subjects, the International code on the marketing of breast-milk substitutes adopted by the WHO and the United Nations Children's Fund (UNICEF) in 1981, and the Framework convention on tobacco control adopted by the WHO in 2003. The concept of human rights has been spread with the health globalization.

Therefore, as the international trade and economic harmony, we have to rethink the concept access to health in the context of globalization. This trend caused unbalanced access in the global range. We should value the ethic proportion in our activities related to health issues. And it is no doubt that the intellectual property law can play an essential role in this drift although some new changes need to be done complied with international human rights law.

---

[13] WHO. WHO global influenza surveillance network. *"Communicable Disease Surveillance and Response"*. Geneva 2003. Available at: www.who.int/csr/disease/influenza/surveillance/en (accessed Jan 2012).

[14] Collin J, Lee K. *Globalisation and transborder health risk in the UK: case studies in tobacco control and population mobility.* London: The Nuffield Trust, 2003.

[15] Collin J. *Think global, smoke local: transnational tobacco companies and cognitive globalization.* In: Lee K, (ed). *Health impacts of globalization: towards global governance.* Palgrave Macmillan, 2002, page 61-85.

[16] WHO. "*Confronting the epidemic: a global agenda for tobacco control research. Tobacco Free Initiative*". Geneva, 1999. Available at: whqlibdoc.who.int/hq/1999/WHO_NCD_TFI_99.12.pdf (accessed May 2012).

2.2 Access to health as the Element of Human Rights

"Access to health", as a complex problem with many different aspects involved, cannot be reduced as a unilateral Intellectual Property Rights or Human Rights problem. This concept as a link of human rights and intellectual property should be seen as the most important element of the realization of some fundamental human rights.

According to the General Comment 14, the right to health contains four elements. Obviously, the accessibility is the fundamental one there. Accessibility as the fundamental element has four overlapping dimensions: non-discrimination; physical accessibility; economical accessibility (affordability); information accessibility. It requests health facilities, goods and services accessible to everyone within the jurisdiction of the State party.

Firstly, access to health does not mean the right to be healthy. Access to health means that governments must generate conditions under which everyone can be as healthy as possible. Such conditions range from ensuring availability of health services, healthy and safe working environments and adequate housing. Since health is a product of the combined action of a series of variables, some of them beyond human control, so access to health demands the right-holders to guarantee that the decision making have combined the situation, like good, medicine assistance, hygiene, health service and so on. According to General Comment 14, moreover, the access to health contains both freedoms and entitlements, which includes the right to be free from non-consensual medical treatment; the right to a system of health protection, the right to prevention, treatment and control of diseases; the right to healthy natural and workplace environments; and the right to health facilities, goods and services.

Secondly, the expression of access means not only physical access but also active participation and manipulation. Participation in health-related decision-making at the national and international levels is another important entitlement. Equity of access should be measured in terms of the availability, utilization or outcomes of services. Both horizontal and vertical dimensions of equity need to be taken into consideration. In another word, not only what but also how to access should be considered by the actors. Non-discrimination and equality are critical components of the access to health. States have an obligation to prohibit discrimination and ensure equality to all in relation to access to health care and the underlying determinants of health. States must recognize and provide for the differences and specific needs of population groups, such as women, children, or persons with disabilities, which generally face particular health challenges, such as higher mortality rates or vulnerability to specific diseases.

Overall, access to health has a "core content" referring to the minimum essential level of the human right. On this ground, we should turn the Intellectual Property into a supportive factor for the fulfilling of access.

2.3 Democracy

Democracy, like respect for human rights, is not an end in itself, but a means to individual and social development.[17] Nowadays, the more people realize their right to

[17] Dinah Shelton. "Symposium on the future of international human rights: challenges to the future of civil and political rights". 55 *Wash &Lee Law Review* 669, 1998.

health, they ask for the more democracy of health through the court and government.

The term “democratization”, according to O′Donnell and Schmitter, implies the application of the norms and procedures of citizenship to those institutions that have been governed by other principles, such as coercive control, social tradition, and judgment of specialists or bureaucratic processes.[18]Democratization also implies applying these norms and procedures to individuals who did not always enjoy the benefits and duties of citizenship, such as women, young people and children, ethnic minorities or workers in the informal sector of the economy. Aristotle, in his work “Politics”, states that what defines a citizen is the possibility of holding office.[19] In other sources, the term citizen is associated with a range of rights and duties, of a diverse nature, not only political, as defined within a constitution.[20] In his “Class, Citizenship and Social Development”, Marshall recognizes three types of rights involved in the idea of citizenship: Civil, political, and social.[21] Civil rights are those that define individual liberty: Freedom of thought and expression, the right to own property, and the right to an impartial trial. The institutions more directly related to civil rights are the courts. Political rights include the right to participate in the government of one’s own country. The procedures through which these rights are exercised include voting, free political competition, and access to public information. Finally, social rights include those rights that guarantee the participation in the social heritage, including the right to adequate housing, health, education, and culture. Marshall states that citizenship culminates with the implementation of social rights, which are delivered through institutions such as the educational and health systems.[22]

So, just like the UNDP report has highlighted the efforts needed to incorporate these rights into legislation and ensure their implementation in ways which offer tangible benefits to all citizens.[23]It is no doubt that the reforms of extending the access to health to all the population have strengthened the procedures and institutions of democracy. Certainly, the democratization of health can contribute to the health of democracy.

2.4 Balance and Equity

It is certain that although Access to health and intellectual property seems to be contrary from certain perspective, we should build a human rights framework to make them balance and construct a win-win situation.

This balance should be equity. To some extent, the balance does not necessarily mean equal distribution. For instance, when dealing with the same issue, such as

[18] G. O’Donnell and P. Schmitter. *”Transiciones desde un gobierno autoritario*”. Paidos, 1991, page 22–23.

[19] Aristotle. *The politics.* The University of Chicago Press, 1984, page 87.

[20] R. Scruton*, A dictionary of political thought*. London: Macmillan, 1996, page 71–72.

[21] T. H. Marshall. *Class, citizenship and social development*. Doubleday Anchor Books. 1965.

[22] Julio Frenk, Octavio Gómez-Dantés, Felicia Marie Knaulc. *“The Democratization of Health in Mexico: Extending the Right to Health Care”*. Swiss Human Rights Book. 25 May 2009.

[23] Julio Frenk and Octavio Gómez-Dantés. “*The Democratization of Health in Mexico: Extending the Right to Health Care”*. Swiss Human Rights Book. 25 May 2009.

Intellectual Property protection, in both developing country and developed country, different standards which accord to their local economy might be applied, owing to diverse problems stemmed from different economic and culture levels. Otherwise, equal application will only lead to inequality.

So-called equity is frequently defined as an expression of social justice. It has to do fundamentally with a fair distribution of benefits from health and social development. It goes beyond equality of access to health care. It calls for responses that are in accord with the needs of the individual in relation to the needs for all.

Furthermore, from the point of view of health, equity can be defined in various ways: a.) equal resources supply and expended for each individual; b.) equal resources expended for each case of a particular condition; c.) equal access to health services; d.) equal quality of health care; e.) equal status of health for all; f.) equal healthy life gained per dollar expended; g.) care according to needs and demand. Apparently, it involves both process and outcome. [24]An operational approach would be to assess the impact of specific health decisions on equity and to ensure that decisions taken do enhance equity. Equity might not have a direct relation to aggregate health indicators.

There are two perspectives on achieving equity. One is the "solidarity approach", which focuses on the society as a whole but may ignore or subjugate the needs of some members or groups. [25]The opposite extreme to this approach is "the individual right approach" according to which each individual should have equal access to health care and equal outcome. It is obvious that this can only be achieved in a wealthy, politically stable community. Most third-world countries, which suffer the greatest burdens of disease, cannot fulfill these criteria. Sometimes the right of the individual to attain the highest state of health in a poor country would lead to inequities through exhausting the limited resources available for health in highly expensive health interventions. [26]A balance has to be established where priority is given to support the basic health needs for the community. If the language of human rights were to be strictly adhered to in developing countries, it would set the good of the individual against the good of the whole community. The tension even exists in one of the richest countries, USA, where Lawrence Gostin notes that: "although public health authorities assuredly are empowered to constrain the freedoms and rights of individuals if necessary to achieve a collective good, they must do so consistent with constitutional constraints on government action. Achieving a just balance between the powers and duties of the state to defend and advance the public health and legally protected rights of human beings represents an enduring interest of those immersed in the discipline of public health law"

As processes of globalization bring us closer together as peoples and nations, we begin to see the interdependence of our aspirations – aspirations for human security, including protection against poverty and exclusion, and aspirations for human freedom[27], not just to grow and flourish as individuals but to grow and flourish together. So we recognize the value and necessity of collective action– nationally and

---

[24] Mamdouh Gabr. *"Health Ethics, equity and human dignity".* Available at : http://www.humiliationstudies.org/documents/GabrHealthEthics.pdf. (Accessed MAY 2012).

[25] Ibid.

[26] Ibid.

[27] Sen, 1999. See Carlos M. Correa. *"Phamaceutical innovation, increamental, patenting and compulsory licensing".* Availiable at : http://www.ungs.edu.ar/globelics/wp-content/uploads/2011/12/ID-246-Correa-Privatization-of-knowledge-Intellectual-Property-Right.pdf. (access MAY 2012).

globally – to correct the corrosive effects of inequality of life chances. This argument has been supported by the A2K movement as well. We need to share our knowledge product and use human rights spirits as a bridge for associating. It is not the requirement of the human dignity, but also the outcome of globalization.

2.5 A2K: Health Is Knowledge

Historically, knowledge is the essential element for all human activities and values, including freedom, economic, social and personal development. Knowledge goods, such as health related goods, are also fundamentally different from physical goods and services. For example, they are invisible but they can be copied. They should be shared and update daily. They are common and not scarce, everything is consisted by knowledge. All these characteristic lead to an equity access regardless the rich and the poor.

Furthermore, when talking about knowledge in the legal system, intellectual property must be mentioned. Intellectual property as an organic system which is not only relevant to maximizing economic efficient but also resonates with immediate significance knowledge, which is the most useful legal tool made by the market associate with knowledge products. Access to these knowledge products, like medicines, as they are regulated through the intellectual property system raised numerous problems in the globalization. Therefore, the international organizations and other social organs launched the A2K movement to revise the relationship within the human rights framework.

Admittedly, A2K is a coalition of civil society organizations, academics and other individuals that is concerned with facilitating access to knowledge as a fundamental principle of justice, freedom and economic development. In particular, A2K is especially addressing the relationship between private intellectual property rights and the possible obstacles to the rights to knowledge, education and public health. This has implications that knowledge being context of access to actual medicine product but also in term of access to scientific information, publications and medical research. While the A2K movement is concerned about fairness and access to knowledge, it also is supportive of creative and inventive communities. For example, the health related knowledge, like medicines, can be accessible through A2K and benefit the whole global society.

But I have to point out that the "material interests" mentioned in A2K are not simply equivalent to current intellectual property provisions, not least because these rights are saleable and transferable, and therefore not "inalienable". The right to access is ultimately the more important part of the right. Current levels of IP protection seem out of balance with Article 27[28], according to A2K theorists:

"... in a very real sense, rights delayed are rights denied. Had access to oral rehydration therapy and second-generation vaccine technologies been delayed for twenty years ... three million children would have died. Even for less life- and-death technologies, a twenty-year delay works an immense limitation on enjoyment of the right. For cultural works, the situation is even worse; protection lasts longer than a human lifetime."

---

[28] *Universal Declaration of Human Rights*. Adopted and proclaimed by General Assembly Resolusion,G.Res.217A(III).

As to the question of access to health, the adoption of the Doha Declaration was another contributing step towards the emergence of a coordinated movement against the IP maximalist agenda of developed countries, as pushed by powerful IP exporting industries. It was also the beginning of a close link between the intellectual property and the access to health knowledge movement.

Hence, as I claimed in this chapter, access to health as an essential element of human rights is a link between the global society, intellectual property rights and the human rights regime. In the process of globalization raised by migration and international economic movement, free and equitable to access the necessary health safeguard and enjoy the health democracy turned to a foundation of international cooperation on this point. But we still have a long way to go to balance this paradox between human rights and intellectual property rights.

3. Legislation

Historically, the debate on the relationship of Intellectual Property and Human Rights has laid distinctions between exclusive rights and universal rights. However, I argued that those discourses are balanced in the era of globalization. Access to health as an essential element of universal human right should not be violated by Intellectual Property. And the international legislation has given a clear answer to it.

3.1 Intellectual Property Rights under the Human Rights Regime

The term "access to health" is currently used in the context of Human Rights as an initial element, referring to different provisions stipulated in international treaties and fundamental Human Rights principles. "Access to health" as the realization of universal relative human rights, is supported by the International Human Rights Law I analyzed below.

3.1.1 UDHR

Health was identified as part of the inclusive right to an adequate standard of living in the Universal Declaration of Human Rights (UDHR).[29] Obviously, as the global health economic movement, these definition of access to health and related human rights deviates from the conception of rights held in the18th and 19th centuries, which only restrained the state from actively denying citizens their basic civil and economic rights.[30]

In article 25, it provides that everyone has "the right to a standard of living adequate for the health and well-being of himself and his family, including…medical care".[31]

At the same time, article 27 recognizes that "Everyone has the right to freely participate in the culture life of the community, to enjoy the arts and share in scientific advancement and its benefits."[32]

---

[29] *Universal Declaration of Human Rights*. Adopted and proclaimed by General Assembly Resolusion,G.Res.217A(III).

[30] Eide A, Alfredsson G, Melander, A, Rehof, LA, Rosas, A. (Ed). with collaboration of Swinehart, T. *The Universal Declaration of Human Rights: A commentary.* Scandinavian University Press , 1992, Page 385-404.

[31] Ibid. *Universal Declaration of Human Rights* .article 25(1)

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

[32] Ibid. *Universal Declaration of Human Rights* .article 27

(1) Everyone has the right freely to participate in the cultural life of the community, to enjoy the arts and to share in scientific advancement and its benefits.

(2) Everyone has the right to the protection of the moral and material interests resulting from any scientific,

UDHR contends that states must also take action to ensure that all citizens have the right to enjoy an adequate standard of living. It recognizes food, clothing, housing, health care and social services as essential components of a standard of living adequate for health and well-being as well. That is to say, the Access to health, recognized as an element of Human Right, provides not only a direct right to appropriate and timely health care, but also a right to access the underlying determinants of health, such as scientific benefits, care condition, and medicines. We shall to focus on the achievement of relevant scientific knowledge and how to raise the awareness of the approach for access to health.

It is obvious that the access to adequate health operates directly or indirectly as a prerequisite to all other human rights recognized in treaties; to deny the access to health of someone can be seen as to deny or damage the other universal individual rights. Without health, individuals are denied their right to be contributing members of the community and to provide for their families. Individuals who lack adequate health care and have no health democracy guaranteed by ICCPR can thus lose some or all ability to exercise fully the civil, political, economic, social, and cultural rights they possess.

3.1.2 ICESCR

The International Covenant on Economic, Social and Cultural Rights (ICESCR), adopted 16 Dec 1966, established the right to public health as a fundamental Human Right.

Regard to access to health, it contains a similar provision to UDHR, which states that the State parties should recognize the right of everyone to take part in culture life and to benefit from the protection of the moral and material interests resulting from any scientific production[33].

To be more specific, article 2(1)[34] has pointed out the obligation of States, which includes the adoption of legislative measures where necessary to give the full realization of the rights recognized in the Covenant. It is worthy to say that although legislative measures are an important and necessary measure by which to guarantee the full effectiveness of the ICESCR, but other mechanisms also deserve to give a close attention. Significantly, the full realization of access to health should be

---

literary or artistic production of which he is the author.

[33] *International Covenant on Economic, Social and Culture Rights*, article15(1)

The States Parties to the present Covenant recognize the right of everyone:

(a) To take part in cultural life;

(b) To enjoy the benefits of scientific progress and its applications;

(c) To benefit from the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author.

[34] *International Covenant on Economic, Social and Culture Rights*, article 2

1. Each State Party 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.

undertaken "by all appropriate means"[35] with the normative effect of the ICESCR together with the implementation of the provisions at the legislative level.[36]

In particular, article 12(2)(c)[37] refers to the entitlement to prevention, treatment and control of disease, and is defined as requiring the establishment of prevention and education program as well as a system of urgent medical care in the case of epidemics. Moreover, the right to health includes a right to facilities, goods and service, as provided article 12(2)(d)[38].

Besides, article 15[39] ICESCR identifies a need to balance the protection of both public health and private interests and set forth that due the nature of access to health, it requires to be treated globally and universal. On one hand, article 15 recognizes the right of everyone to take part in culture life and to enjoy the benefits of scientific progress and its applications. On the other hand, it states 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. Therefore, the ICESCR have struck a balance between promoting general public interest and private interest, which meet the paradox of human rights and intellectual property rights. However, linked with the intellectual property regime, the international human rights law assurances the global and universal access which should be the standpoint of all the other legislation. The intellectual property provision should apply

---

[35] CESCR, General Comment No 3,1990.

[36] Johanna Gilbson. *Intellectual Property, Medicine and health*. Ashgate public,2008, page 46.

[37] *International Covenant on Economic, Social and Culture Rights*,article 12(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:

(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.

[38] *International Covenant on Economic, Social and Culture Rights*. article 12.

[39] *International Covenant on Economic, Social and Culture Rights.* article 15

1. The States Parties to the present Covenant recognize the right of everyone:

(a) To take part in cultural life;

(b) To enjoy the benefits of scientific progress and its applications;

(c) To benefit from the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author.

2. The steps to be taken by the States Parties to the present Covenant to achieve the full realization of this right shall include those necessary for the conservation, the development and the diffusion of science and culture.

3. The States Parties to the present Covenant undertake to respect the freedom indispensable for scientific research and creative activity.

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

an efficient way for all the people to enjoy the scientific benefit and access to equity health care, which should be treated as the universal and fundamental notification in that framework.

But we cannot deny that the inequities still exist in our society. More than 30 countries have not yet ratified the International Convention on Economic, Social and Cultural Rights and 60 countries do not recognize the access to health in their national constitution.

3.1.3 General Comment No.14

In 2000, the CESCR adopted General Comment No.14 on the implementation of ICESCR article 12, which sets that "Health is a fundamental Human Right indispensable for the exercise of other Human Rights. Every human being is entitled to the enjoyment of the highest attainable standard of health conductive to living a life in dignity"[40]. It defines the obligation of states so as to realize the universal human rights at the national level and the normative content named "the four essential elements"- availability, accessibility, acceptability and quality. It is the first time that the international authority has cleared and guaranteed accessibility as an essential element of all human rights, especially for health.

Access to health which is the way for achieving opportunities and resources for health has been confirmed as an element of Human Right. According to the General Comment No.14, the right to health is not to be understood as a right to be healthy. The right to health contains both freedoms and entitlements.[41] In this regard, General Comment No.14 has made special reference to the access to affordable health care, in particular essential drugs; HIV/AIDS; and national measures to promotion of the right to health. In the General Comment, it recalled international cooperation for finding the solution to solve the relevant health economic issues according to the international human rights law and cleared the relationship between international human rights law and intellectual property law, such as TRIPS. It also pointed out the human rights provision and standard as fundamental theories should be balanced and impressed in the intellectual property law and the global health economic market.

Overall, as I pointed out above, because the human rights have a characteristic named universal access, so we should admitted that the international human rights law has already laid down a legislation foundation for the process of globalization. It turns to be the instruction of the global economic activities. We should give a universal respect to it.

3.2 Human Rights in the Intellectual Property Rights Regime

Turn to the intellectual property system, recently, because of the globalization has brought a lot of new problems into legal field, the legislator try to introduce the human rights law into the intellectual property regime. And the balanced relationship between Intellectual Property Rights and Human Rights has been indeed recognized by the international authority. Other than the solo performance of international and national patent law, an increasing number of treaties and international documents

[40] CESCR, General Comment No 14,2000, Paragraph 8.

[41] Johanna Gilbson. *Intellectual Property, Medicine and health.* Ashgate public, 2008, page 50.

allow for space of "Access to health" and established many practical standards.

3.2.1 TRIPS

The WTO's Agreement on Trade-Related Aspects on Intellectual Property Rights TRIPS established minimum standards of IP protection which all WTO Members have to comply with.

TRIPS lays down standards for providing protection to patent holders, but these rights are not absolute. Although this agreement is not a particular intellectual property law related to access to health, it already draw the attention all over the world and provide many important and milestone solution to the fulfillment of universal human rights and balancing the unequal global intellectual property market. Moreover, like Dr. Gro Harlem Brundtland, director general of WHO, addressed:"The present regime of international trade agreements has been designed to strike a balance between the rights of patent holders and the rights of patients, and the TRIPS agreement contains important public health safeguards".[42]

TRIPS introduced numerous rules to ensure the people worldwide can access to the important patent in connection with health.

Firstly, the term compulsory licensing actually used in the agreement is "other use without authorization of the right holder." It allows governments to permit a person other than the patent holder to produce the product without the owner's consent. If a compulsory license is issued, a market-rate fee must be paid to the patent holder, the license can be used only in the domestic market and must be rescinded once conditions change. Furthermore, in the event of a national emergency, a compulsory license can be issued without first trying to seek permission from the owner of the patent.[43]

Secondly, governments can permit parallel importing, in which a product manufactured under a patent held in one country but sold at lower prices in another country can be imported from that second country without permission from the patent holder. TRIPS states that governments permitting parallel imports cannot be challenged under the WTO dispute settlement system, provided they do not discriminate on the grounds of the nationality of the patent holder.[44]

Third, the "Bolar" provisions, namely permit on generic manufacturers to prepare production and regulatory procedures before patents expire so that products can be ready for sale as soon as the patent ends, rather than having to go through the lengthy preparatory process only after the patent period is over.[45]It is the essential way for the state to deal the emergency health crisis. And this provision has given a

[42] Gumisai Mutume. *Health and 'Intellectual Property' Poor nations and drug firms tussle over WTO patent provisions. Africa Recover*, June 2001. See WIPO. *FACT SHEET: TRIPS and pharmaceutical patent*s. Geneva, September 2006.

[43] Gumisai Mutume. *Health and 'intellectual property' Poor nations and drug firms tussle over WTO patent provisions. Africa recovery*, June 2001. See WIPO. *FACT SHEET: TRIPS and pharmaceutical patent*s. Geneva, September 2006.

[44] Ibid.

[45] Ibid.

legal solution to the unbalanced global market.[46]

Although some argue that the standards provide by TRIPS still create the barrier to access to health, for example, the flexibilities norms held that that members could implement at the national level, we have to say that the access crisis has existed since long before TRIPS came into force. Admittedly, TRIPS attempts to beat the unbalance between the long term social objective of providing incentives for the future inventions and creation and the short term objective of allowing people to use existing inventions and creations in the globalization. Obviously, it is almost successful. Access to health, on the perspective of globally, has already stroke the absolute control of the patent limitation and willing to build a balance platform due to TRIPS. The human rights have been put into consider and involved in the international decision-making. Conclusion can be made from the result of imply this agreement that the human rights theories indeed can adjust the intellectual property system and the global economic marketing.

In spite of the entry into force of the TRIPS Agreement, the state of protection of pharmaceutical products is still not uniform throughout the world. Some countries had already amended their legislation, even before signing the Agreement. Some were compelled to do so by the risk of economic reprisals from their main trading partners, while still others acted in expectation of possible access to better and wider markets. The majority of the small, less developed countries, however, are making not amended their legislation.

In the end, one important point should be mentioned as well is that some developed countries, especially the United States of America, insist that the provision of TRIPS still cannot provide sufficient protection for equity access to the global health market, so they advocated a bilateral arrangement that introduce a retroactive system where there has hitherto been no protection for pharmaceutical products and the law changes. And a period of grace is allowed during which it is possible to patent products that have already been patented in order countries, but have not yet been actually market in those countries. [47]This system is known as the pipeline system, and has been introduced in the legislation of countries including Mexico and Brazil.

3.2.2 The Declaration on the TRIPS Agreement and Public Health

The Declaration on the TRIPS Agreement and Public Health (the Doha Declaration) adopted on 14 November 2001 during the WTO's Doha Ministerial Conference attempted to give a political answer to the issue as to the relationship between IP and public health by recalling to members the existence of some so-called flexibilities that are contained in the TRIPS Agreement that members could implement at the national level. Furthermore, this Declaration clarified and interpreted some of the concepts provided under the TRIPS Agreement that were at the centre of disputes, such as, *inter alia*, compulsory license, situation of the national emergency, use of an exhaustion of rights regime.

The Doha Declaration represents a major political victory for the developing

[46] Ibid.
[47] Silvia Salazar. *Intellectual property and right to health*.

countries. Although it is only a political statement and does not modify the TRIPS Agreement in any way, it has important legal implications. It provides an understanding of the purpose of the TRIPS Agreement in relation to public-health issues that should guide any future rulings by WTO dispute-resolution panels dealing with such issues.[48] The declaration gives developing-country governments a degree of security in adopting national-level measures necessary to meet public-health objectives, and several developing countries, such as Malaysia, Thailand, Indonesia, Brazil, Zimbabwe, and Ghana, have since taken advantage of compulsory licensing to gain access to affordable generic medicines.[49] Many countries have also amended their laws to include the various TRIPS flexibilities. In other words, the Declaration acknowledged the importance of the public interests for Access to health by giving leeway to member countries to implement or interpret the TRIPS Agreement in a more flexible manner and they have the freedom to determine what a national emergency was.

Today, the declaration has also become a common rallying platform for developing-country governments to take action to access affordable medicines and developed-country governments accountable for what they agreed to in Doha, particularly that "the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health" and that "the Agreement can and should be interpreted to protect public health and in particular, to promote access to medicines for all." [50]

According to the Doha Declaration, every state, no matter developing country or developed country, should keep an eye on balance the Access to health and Intellectual Property Rights, such as apply for the compulsory license regime. It addresses the restriction on the flexibility of the compulsory license in the context of Human Right to health[51].

Ellen't Hoen has remarked that the Doha Declaration has had a galvanizing impact upon nation states:' between 2001 and end 2007, 52 developing and LDCS have issued post-Doha compulsory licenses for production or import of generic versions of patented medicines, given effect to government use provisions, and/or implemented the non- enforcement of patents.'[52] The Doha Declaration and the waiver have somewhat alleviated the deleterious impact of TRIPS on access to medicines. However, they have not completely solved the problem.[53] For example, it is uncertain about the extent of the application of the Declaration and the waiver to

[48] Correa, *"Implications of the Doha Declaration on the TRIPS Agreement and Public Health."*

[49] Martin Khor, *"Patents, Compulsory License and Access to Medicines: Some Recent Experiences"*. February 2007. available at http://www.policyinnovations.org/ideas/policy_library/data/patents_compulsory_license (accessed March 2012).

[50] *Doha Declaration on TRIPS and Public Health.* Adopted on 14 November 2001, paragraph 6.

[51] Ibid, paragraph 4.

[52] Ellen't Hoen, *the global politics of pharmaceutical monopoly power: drug patents, access, innovation and the application of the WTO Doha Declaration on TRIPS and public health*. 2009, xvi.

[53] See generally, Oxfam. "Patients versus Patents: Five years after the Doha Declaration." Oxfam Briefing Paper 95 (2006). Available at http://www. oxfam.org/en/policy/briefingpapers/bp95_patent_svspatients_061114.(Accessed April 2012).

health crises beyond epidemics; the TRIPS initiatives may do little to enhance access to drugs for sufferers of cancer or heart disease, or other lethal non-communicable diseases.

The Doha Declaration was a political turning point in the way public health is governed globally, WTO Director-General Pascal Lamy said at the event's outset, since the declaration's adoption, the perception that intellectual property rights and public health has changed.

The Doha Declaration and the waiver have somewhat alleviated the deleterious impact of TRIPS on access to medicines. However, they have not completely solved the problem.[54] For example, it is uncertain about the extent of the application of the Declaration and the waiver to health crises beyond epidemics; the TRIPS initiatives may do little to enhance access to drugs for sufferers of cancer or heart disease, or other lethal non-communicable diseases. Indeed, the US threatened trade sanctions against Thailand in 2007 for its proposal to issue compulsory licenses with regard to medication for heart disease and cancer.[55] Furthermore, by December 2008, only Rwanda had notified the WTO of an intention to make use of the waiver as an importing state.[56] It may be that even generic drugs are too expensive for some states; that there is insufficient commercial incentive for generic manufacturers to produce drugs for such impoverished consumers; that pressure is being applied behind the scenes to discourage use of the scheme; or that there are delays in amending local legislation. Alternatively, the availability of the new scheme may be prompting pharmaceutical corporations, who feel threatened by compulsory licensing schemes, to make their products available to the least developed states on a cheaper, or even cost free, basis.[57] Indeed, numerous corporations have adopted such a strategy.[58]

First of all, The Doha Declaration has numerous advantages.

The Doha Declaration addresses real and urgent problems faced by many developing countries in the area of public health. It is not intended to amend the TRIPS Agreement in any substantial manner. Rather, it aims to clarify the relationship between the TRIPS Agreement and Public Health policies of Member countries, and confirm the rights that Members have retained under the Agreement, particularly by defining the flexibility allowed in certain key areas.

The Doha Declaration is a strong political statement that can make it easier for developing countries to adopt measures necessary to ensure access to health care without the fear of being dragged into a legal battle. The Declaration is also a Ministerial decision with legal effects on the Member States and on the WTO bodies.

[54] See generally, Oxfam. "Patients versus Patents: Five years after the Doha Declaration." Oxfam Briefing Paper 95 (2006). Available at http://www. oxfam.org/en/policy/briefingpapers/bp95_patent_svspatients_061114. (Accessed April 2012).

[55] Kevin Outterson. "Should access to medicines and TRIPS flexibilities be limited to specific diseases?" *34 American Journal of Law and Medicine* (2008): 279- 282.

[56] Canada notified the WTO that it would manufacture and export generic anti-HIV drugs to Rwanda.

[57] Adam McBeth. "When Nobody Comes to the Party: Why Have No States Used the WTO Scheme for Compulsory Licensing of Essential Medicines?"*3 New Zealand Journal of International Law*1 (2006): 23–30.

[58] See for example, http://www.diflucanpartnership.org/en/welcome/Default.aspx regarding Pfizer's initiatives.

It states the purpose of the TRIPS Agreement in the area of public health, interprets the TRIPS Agreement with regard to some important aspects, instructs the Council for TRIPS to take action, and decides on the implementation of the transitional provisions for LDCs.

Second, the problem existed in the Doha Declaration system.

First one, the purpose of the Declaration has not been fulfilled.

In the declaration, ministers stress that it is important to implement and interpret the TRIPS Agreement in a way that supports public health — by promoting both access to existing medicines and the creation of new medicines. But the Declaration itself does not make out the direct outline and resolve developing country concerns regarding access to medicines and TRIPS in practice.

In addition, according to the third paragraph of the Declaration, which said "We recognize that intellectual property protection is important for the development of new medicines. We also recognize the concerns about its effects on prices", it raised a controversial juxtaposition: patents are 'important', high prices raise 'concerns'. Obviously, it is a relatively weak way of acknowledging that patents have negative consequences in the form of higher prices, thereby reducing access to medicines, particularly among the poor. Whether patent protection does indeed encourage research and development on drugs for diseases especially relevant to them has not been touched.

Second one, the function of the Declaration, such as parallel importation, compulsory license, exhaustion and LDC.

Since many patented products are sold at different prices in different markets, the rationale for parallel importation is to enable the import of lower priced patented products. Parallel importing can be an important tool enabling access to affordable medicines because there are substantial price differences between the same pharmaceutical products sold in different markets. The Doha Declaration has reaffirmed that Members do have this right, stating that each Member is free to establish its own regime for such exhaustion without challenge.

This appears to leave each Member with the discretion to determine whether it will recognize compulsory-licensed marketing or sale of a product in a country of export as exhausting the patent holders' rights in the country of import to consent to importation and resale. Although the Doha Declaration appears to resolve the issue of exhaustion based on marketing under compulsory license, it may be useful to consider the legal issues in more detail and give more limitation to it, such as give a limit on international exhaustion to marketing with the consent of the patent holder. However, since in adopting the Declaration, Members have exercised their exclusive competence to interpret a WTO agreement, and it would be extremely difficult to challenge the adopted interpretation.

It should be stressed that the Doha Declaration is not self-executing and both developed and developing countries should adopt the legal amendments necessary to implement it. Developing countries, in particular, should ensure that they are using to the full extent possible the flexibilities allowed by the TRIPS Agreement to protect public health and facilitate access to health care by all.

Then, turn to LDCs, the situation of LDCs received special attention at the Doha

Conference, but the paragraph 7 action item did not represent any significant improvement for the great majority of them. Hence, the problems faced by LDCs to gain access to needed pharmaceuticals are likely to require further consideration by the WTO Members, in order to accomplish the objectives sought by the Doha Declaration.

Therefore, some arguments have been raised to propose to make the Declaration into a treaty.

To be concluded, as explained above, although the Doha Declaration has connected intellectual property to Public Health and try to balance these two subjects, it still has a long way to go.

3.2.3The Decision of 30 August 2003

Art 31.f of TRIPS generally requires that a compulsory license must be limited to mainly supply the local market. This means that those countries do not have the capacity to manufacture pharmaceuticals products could not make use of the compulsory license flexibility. The TRIPS Council was therefore asked to find a solution to the problems faced by those countries with insufficient or no manufacturing capacities in the pharmaceutical sector that could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement. On 30 August 2003 the members of the WTO agreed unanimously on a solution to enable compulsory licensing of medicines for export.

3.2.4 Amendment of the TRIPS Agreement

The Amendment of the TRIPS Agreement[59]was agreed in December 2005. The agreement reached the agreement for a workable solution for compulsory licensing for export but maintains respect for Intellectual Property. It works out a balance in ensuring that the right holder can invest in Research & Development (R&D) for badly needed new vaccines and medicines for patients in the developing world, whilst allowing for compulsory licensing of patents where it is necessary for protect public health.

According to the movement of revise, it reflects that “Access to health” under the structure of Intellectual Property regime plays a more and more important role in the global era. Duty holders are trying to find the more efficient and practical way to keep the balance and solve the flexible in both developed and developing country. The universal human rights theories can be find in all the intellectual property laws and still have a profound influence on them. It is not only the requirement of the global market which share the same nature with human rights, but also the need of the intellectual property. The fundamental human rights play an essential role in balance the economic proportion in the globalization and it is the bottom line of all kinds of social activities.

Thus, we can conclude a trend from the revise timeline that the intellectual property rights have been discussed on the international level nowadays and more and more issues about success to health and implement of intellectual property limitation have been recognized. Consistent with the international human rights law I explained in 3.1, we find the cohesion of these two systems. And it has meet to the requirement

[59] WTO General Council. *Amendment of the TRIPS Agreement*. Decision of 6 December 2005.

of globalization.

To be conclude, because the trend of the globalization occurred in recent days, more and more policy and legislation should be enforced on the international level. Due to the universal and fundamental nature of human rights, the international human rights law should be treated as the basic standard of all other legal documents. And in contrast, the other international treaties or agreement must reflect and respect human rights principle. As we can see from these international legal documents I listed above, the provision given under the intellectual property have already taken the human rights such as access to health into account and intended to balance the unequal access among countries while we still need to amend them time after time. It is the demand of the globalization as well.

4. Problem Solving

Nowadays, as the problems of balance access to health and intellectual property rights popped out spirit, it draws the attention from all social circles. Many strategies have been launched to reduce the downside influence bring by various economic situation and globalization, such as global drug strategy and implement of compulsory license. My analysis will use human rights, intellectual property and economy approach to explain how did the intellectual property and market trade affect the price of health related products and examine the function of the international law to explore the distinctive problem raised by the globalization.

4.1 Global Access Requirement: Global Drug Gap

4.1.1 Access to health and global drug gap

The debate over access to health and lack of basic medicines takes place against the background of staggering health discrepancies: both between affluent and deprived countries and also, within the latter, between rich and poor.

Among the world's poor, some eighteen million die annually from a group of causes – communicable diseases, material and prenatal conditions and nutritional deficits which bring only minimal harm to the rich. Eighteen million is equivalent to just over 30 per cent of all human death. Life expectancy is 79.4 in the high- income countries and 49.2 in the Africa region.[60] Similarly, dramatic health inequalities exist within the less developed countries. In Peru, under-five mortality is 11 per 1,000 among the richest 20 per cent of the population versus 63 among the poorest 20 per cent, for example, and in Nigeria the corresponding figures are 79 versus 257.[61]

The huge health discrepancies stem in part from the fact that poor people are at greater risk of diseases, due to lack of food, shelter, uncontaminated water, poor clothing and physical security. Another crucial factor is that the world's poor have little access to health system and, in particular, to the medicines and health care that could help them cope with their debilitation and constant life-threatening conditions.

To be explicit, this lack of access to essential medicines has three aspects. First, medicines for diseases aiming at the poor are neglected by pharmaceutical research. This phenomenon has come to known as the "10/90 gap", alluding to the claim that 'only 10 per cent of global health research is devoted to conditions that account for 90 per cent of the global disease burden'.[62] In reality, most diseases and the need for

[60] WHO, *The global burden of disease: 2004 update*,2004. 10,5.

[61] United Nations Development Programme. Human Developmemt Report 2007/2008(2007). Table 8: 255-6.

[62] Drugs for Neglected Diseases Working Group, "fatal imbalance：the crisis in research and development for drugs for neglected disease." 2001. Available at www.msf.org/sourse/access/2001/fatal/fatal.pdf,10.(Accessed

medicines necessity occurred in the poor countries. The second side of the access problem of the poor is that the existing medicines are, during their initial years on the market, typically priced vastly higher than their costs of production.[63] Such high prices are partly due to patents, which grant the patentee the exclusive right to produce and distribute the medicine. Interestingly, this holds even within many poor countries, where the profit- maximizing price often excludes a majority of the national population.[64] The third aspect of poor people's lack of access to essential medicines is the dearth of basic minimally adequate local health infrastructure. In most LDCs, there is great scarcity of clinics and hospitals, of diagnostic equipments, as well as of doctors and nurses who are often actively recruited to move to more affluent countries. The effect of poor health infrastructure is that poor patients get no competent diagnosis and end up with no medicine at all, or with the wrong medicine, or with fake or diluted medicine, or without instructions about how to take the medicine to get optimal effect.

Therefore, during the 1990s, to response to developing countries' need to increase the availability and improve the use of medicines and fulfill "access to health", WHO initiated a medicine policy called the "Revised Drug Strategy". This Strategy was built mainly on the concept of "essential drugs". The purpose of this strategy is to strengthen activities of the WHO in support of the action required to make drug use more reasonable throughout the world.[65] The key elements that such a policy related to access to medicines should contain includes measures to improve the way medicines are regulated, measures to improve the way they move in international commerce, and measures to improve the way they are advertised and used.[66] According to the WHO, essential drugs are "those that satisfy the primary health care needs of the population. They should be available at a price that the individual and the community can afford."[67] However, the meaning of "essential" and "afford" is difficult to interpret.

Therefore, the WHO further recommends that "essential medicines are selected with due regard to disease prevalence, evidence on efficacy and safety, and comparative cost-effectiveness. Essential medicines are intended to be available within the context of functioning health systems at all times in adequate amounts, in the appropriate dosage forms, with assured quality, and at a price the individual and the community can afford." Inventions related to pharmaceutical products included in the WHO Model List of Essential Drugs—the Essential Medicines List—should not

---

May 2012)

[63] Drugs for Neglected Diseases Working Group, fatal imbalance: the crisis in research and development for drugs for neglected disease,2001.Available at www.msf.org/sourse/access/2001/fatal/fatal.pdf,,122. (Accessed April 2012)

[64] Sean Flynn, Aidan Hollis and Mike Palmedo. " *An Economic justification for open access to essential medicine patents in developing countries*."2009. 37 *journal of law, Medicine &Ethics* 184.

[65] Director General Dr. Mahler

[66] WHO, the Rational Use of Drugs: Report of the Conference of Experts, Nairobi, November 26–29, 1985. Geneva: World Health Organization, 1987.

[67] WHO, *The Selection of Essential Medicines*. Geneva: World Health Organization, June 2002.

be patentable.[68] This measure was taken to prevent abusive pricing of essential medicines that could result from the new patent rules.

The essential medicines concept can be applied in all countries and at various levels (national, provincial, district, hospital). It is especially valuable in poor-resource settings, as it allows one to get the best medicines for the resources available. The concentration on a few essential drugs has also lowered prices, due to economies of scale.

To be more specified, about 95 % of the 300-odd medicines on the WHO's list of essential medicines[69]are off-patent. Medicines on the list (divided into a core list and a complementary list) are "the most efficacious, safe and cost-effective medicines for priority conditions". The list is supposed to be a practical tool for developing countries in deciding what medicines to procure. Thus, it does take the prices of medicines into account. However, some patented medicines may be excluded for this reason.[70]

Obviously, "Access to essential medicines" is an indicator for the fulfillment of the access to health. In recent years two important mechanisms have been created to assess, as objectively as possible, the commitment and performance of governments towards the fulfillment of the right to health and both use access to essential medicines as an indicator. [71] Firstly, the UN High Commissioner for Human Rights has created sets of indicators for 12 aspects of human rights, including the right to housing and shelter, the right to education, the right to freedom of expression and the right to health[72]. Secondly, in 2008 The Lancet published a first independent assessment of the fulfillment of the right to health in all countries of the world[73]. Of 72 indicators used, 8 measured access to essential medicines, largely taken from those used by WHO and by the UN High Commissioner for Human Rights.

Apparently, the fundamental human rights constitutes important principles in our time and translate the values of equity, freedom, fairness, social justice and non-discrimination into practical entitlements for individuals, which increasingly guide public policies and national judicial systems. Human Right framework provides a different account of government duties on medicines that significantly re-prioritizes public needs for medicines. The provision of essential medicine is seen to place a core

---

[68] See Article 7(e) of Decision 344, *Common Regime on Industrial Property*, available on-line at http://www.sice.oas.org/trade/JUNAC/decisiones/DEC344e.asp. (accessed March 17, 2009).

[69] WHO model list of essential medicines. Available at http://www.who.int/medicines/publications/essentialmedicines/en/.

[70] Tuberculosis kills about 2 million people each year, of which 98 % in developing countries. Patents do not restrict access to TBC medicines – rather, it is lack of R&D. The treatment involves a cocktail of off-patent medicines that were developed 40-60 years ago. CLs are therefore no solution to improved access in this case.

[71] *The world medicine situation 2011*.WHO,2011.

[72] Office of the High Commissioner for Human Rights, Report on indicators for promoting and monitoring the implementation of human rights, 6 June 2008. Document HRI/MC/2008/3. Available at:http://www2.ohchr.org/english/bodies/icm-mc/docs/HRI.MC.2008.3EN.pdf. (Accessed April 2012).

[73] Backman G et al. *Health systems and the right to health: an assessment of 194 countries.* Lancet, 2008; 372:2047–2085.

duty on governments that cannot be traded with private property interests or domestic economic growth. The concept of essential medicines with its focus on equity, solidarity and social justice is already in line with the principles of human rights. Yet the daily practice of national essential medicine policies and programs can learn from the growing human rights movement and its emphasis on transparency, accountability and freedom from discrimination. But, the question who should pay for the invention and research is still a subject to debate.

Indeed, the provisions of essential drugs under the WHO Action Program on Essential Drugs are identified as one of the core obligations to be met in order to give full realization to the access to health.[74] However, access to health as recognized in the ICESCR is more than access to medicine. It also involves access to health care, access to food, access to health facilities and so on. For example, at least one third of the world's population has no regular access to medicines. Inequity in access to essential medicines is only a part of the inequity in health care. Key evidence to document such inequities is rarely collected. More than 30 countries have not yet ratified the International Convention on Economic, Social and Cultural Rights and 60 countries do not recognize the right to health in their national constitution. Therefore, beyond the promotion of strategy like "essential drug list" we should pay attention to improve other perspectives as well.

At the same time, we can use the characteristic, like territory, limited scope, disclosure and exclusivity, of intellectual property to insure the other countries where the health products have not been grant the patent to get the use of the products. And of course, the LDCs need to increase the ability of innovation as well. They can use the open resources to improve their scientific technology according to the A2K movement I claimed in Chapter 2.

4.1.2 Health democracy

Health democracy can be seen as the enforceability of the right to access to health through the courts.[75] The health democracy is the human rights basement for eliminate the global medicine gap.

Most countries in the world have acceded to or ratified at least one global or regional covenant or treaty confirming the right to health. Ratifying such treaties creates binding State obligations and individual entitlements. However, what does this mean in practice? Can these individual entitlements be enforced through the courts? In 2006, the WHO presented the results of a systematic search to identify completed court cases in low- and middle-income countries in which individuals or groups had claimed access to essential medicines with reference to the right to health in general, or to specific human rights treaties ratified by their government.[76] A total of 71 court cases from 12 countries were identified, mostly from Central and Latin America. In 59 of these cases access to essential medicines as part of the fulfillment of the right to

---

[74] ECSCR, General Comment No.14(2000), paragraph 12.

[75] The world medicine situation 2011,WHO.

[76] Hogerzeil HV et al. *Access to essential medicines as part of the fulfillment of the right to health – is it enforceable through the courts*? Lancet, 2006; 368:305–311.

health could indeed be enforced through the courts. The study concluded that the right to health cannot be restricted by limitations in social security coverage, that government policies have successfully been challenged in court, and that skillful litigation can help to promote that governments fulfill their constitutional and international treaty obligations, especially when governments are developing systems of social security. However, it should be noted that human rights accountability is more than the purely judicial accountability studied here. Sometimes referred to as "constructive accountability" this oversight may also include parliamentary committees, ombudsmen and national human rights institutions.

4.1.3 Authority obligation

Nowadays, inequity and discrimination in access to health remain the key public health challenge of our times. The national and international Authorities should fulfill their core human rights based responsibility through the law and policy. [77]

Specify the obligations of the authority and other stakeholders with regard to social welfare, the provision of health-care services and access to essential medicines. This will establish a further expression of authority commitment, and will also serve as a basis for planning, monitoring, transparency and accountability.[78]

To illustrate, in my opinion, the government can collect and publish disaggregated statistics and targeted surveys to monitor access to essential medicines. Besides, they had better to create more necessary legal instruments for enforcement and redress to support different forms of accountability.

Additionally, the UN, including the WHO, should also do some recommendations for countries on this issue. For instance, constant reporting on access to essential medicines in its annual reporting on progress in reaching Millennium Development Goal 8.2 which will continue to attract governments' attention to essential medicines as part of the right to health and as part of achieving the Millennium Development Goals. What is more, prepare model texts for national constitutions on government commitment to the fulfillment of the right to health, including access to essential medicines. Political opportunities to update the constitution occur from time to time, presenting a chance to align national values and aspirations with international human rights standards.

So, the national and international authorities need to work together in the trend of globalization and ensure the constitution and other legal provisions on the fundamental right to the enjoyment of the highest attainable standard of health, on the right to life and on the right to non-discrimination are in place, which will express and enshrine government values and commitments and will create a supportive environment for promoting and enforcing universal access. [79]At the same time, the

[77] The world medicine situation 2011. WHO, Geneva, 2011.

[78] Ibid.

[79] Ibid.

authorities should enlarge the concept of democracy and involved the health democracy into context. This is the spirit of the ICESCR and ensured by the ICCPR. It will be the theories foundation of the global drug strategies and promote these activities.

4.2 Global Access Obstacles: High Medicine Price and Related Issues

Why do millions of people across the globe go without the treatments they need? The reasons are now becoming clear that the price and availability of medicines to those who need them are the crucial factors. Prices for poor people are simply too high and products are often not available. This may not be news to the sick and poor, but it has been news for those whose responsibility is to secure the health of citizens.[80]

4.2.1 Market reality

One third of the global population lacks reliable access to needed medicines[81]. The situation is even worse in the poorest countries of Africa and Asia, where as much as 50% of the population lacks such access. While some 10 million lives a year could be saved by improving access to essential medicines and vaccines – 4 million in Africa and South-East Asia alone[82] – a major obstacle to achieving this goal is price.[83]

Average per capita spending on pharmaceuticals in high-income countries is 100 times higher than in low-income countries – about US$ 400 compared with US$ 4. The WHO estimates that 15% of the world's population consumes over 90% of the global production of pharmaceuticals (by value)[84].

Not only are medicines unaffordable for large sectors of the global population, they are a major burden on government policy budgets. In developing countries today medicines account for 25–70% of overall healthcare expenditure, compared to less than 10% in most high-income countries[85]. Moreover, up to 90% of the population in low and middle-income countries must pay for medicines out of pocket due to lack of

---

[80] WHO.*Measuring medicine prices, availability, affordability and price components,*2nd Edition, WHO, 2008.3.

[81].WHO. *WHO medicines strategy 2004–2007.* Geneva, 2004 (WHO/EDM/2004.5) .Available at: http://whqlibdoc.who.int/hq/2004/WHO_EDM_2004.5.pdf, accessed May 2012.

[82] *Increasing access to essential medicines in the developing world: UK Government policy and plans.* London, Department for International Development, 2004 . Available at http://www.dfi d.gov.uk/Pubs/fi les/ accessmedicines.pdf, (accessed December 2010).

[83] WHO. *WHO medicines strategy 2004–2007.* Geneva, 2004 (WHO/EDM/2004.5) .Available at: http://whqlibdoc.who.int/hq/2004/WHO_EDM_2004.5.pdf, accessed May 2012.

[84] WHO. *WHO medicines strategy 2004–2007*. Geneva, 2004 (WHO/EDM/2004.5) .Available at: http://whqlibdoc.who.int/hq/2004/WHO_EDM_2004.5.pdf, accessed May 2012.

[85] WHO. *WHO medicines strategy 2004–2007*. Geneva, 2004 (WHO/EDM/2004.5) .Available at: http://whqlibdoc.who.int/hq/2004/WHO_EDM_2004.5.pdf, accessed May 2012.

social insurance and inadequate publicly subsidized services.[86] Although medical policies are greatly needed to improve health infrastructure and financing as well as to ensure the rational use of medicines, high medicine prices are one of the biggest obstacles to access.[87]

In many low- and middle-income countries, national medicine pricing policies have been shifting from price controls to deregulation under the influence of structural adjustment and reform programmed. Duties, taxes, mark-ups, distribution costs and dispensing fees are often high, regularly constituting between 30 to 45% of retail prices, but occasionally up to 80% or more of the total[88]. The higher the manufacturer's contribution to the besides adding, the more these elements increase the market price.

Additionally, prices of the same medicines frequently vary between countries[89]; some commonly used medicines have been found to be more expensive in developing countries than in industrialized ones[90]; and many studies have shown that affordability is unrelated to purchasing power. In other words, prices are influenced by factors such as whether the country observes patents and the level of flexibility allowed under international treaties. The monitoring of prices and cross-country comparisons are therefore important in the era of globalization.

The difficulty in finding reliable information on medicine prices and availability – and therefore in analyzing their components – hinders governments in constructing sound medicine pricing policies or evaluating their impacts. It also makes it difficult for them to evaluate whether their expenditure on medicines is comparable to that of other countries at a similar stage of development.[91] Moreover, those responsible for

---

[86] McIntyre D et al. "What are the economic consequences for households of illness and of paying

for health care in low- and middle-income country contexts?" Social Science and Medicine, 2006, 62:858–65.

[87] *Public health, innovation and intellectual property rights*. Report of the Commission on Intellectual Property Rights, Innovation, and Public Health. Geneva, World Health Organization, April 2006, page 125.

[88] Bale H. "*Consumption and trade in off-patented medicines.*" *Commission on Macro economics and Health, Working Paper Series, Paper* No. WG4:3, 2001 http://www.icrier.org/pdf/bale65.PDF. (Accessed December 2011).

Working document on developing countries' duties and taxes on essential medicines used in the treatment of the major communicable diseases. European Commission, Directorate-General fo Trade, 2003. Available at: http://trade.ec.europa.eu/doclib/docs/2003/june/tradoc_113184.pdf. (Accessed December 2011)

Levison L, Laing R. *The hidden costs of essential medicines.* Essential Drugs Monitor, 2003, 33:20–21. Available at: http://mednet2.who.int/edmonitor/33/EDM33_20-21_Hidden_e.pdf (Accessed December 2011).

[89] Wagner JL, McCarthy E. *International differences in drug prices*. Annual Review of Public Health, 2004, 25:475–95.

[90] Myhr K. "*Comparing prices of essential drugs between four East African countries and with international prices".* Nairobi, Médecins Sans Frontières, 2000 . Availiable at : http://www.accessmed-msf.org prod/publications.asp?scntid=3920012349208&contenttype=PARA& (Accessed December 2012)

Bala K, Lanza O, Kaur SL. "Retail drug prices: the law of the jungle." *Health Action International News*, 1998, 100:2–4:13–16. Bala K, Sagoo K. "Patents and prices." Health Action International News, 2000, 111 (April/May) Available at: http://haiweb.org/pubs/hainews/April2000.html (Accessed 3 December 2011)

[91] WHO.*Measuring medicine prices, availability, affordability and price components*.2ND EDITION. World Health Organization and Health Action International, 2008.

purchasing medicines cannot negotiate cheaper deals because they have no sound basis from which to start their negotiation. Even in countries where consumers and patients have greater purchasing power, governments, insurance funds and hospitals often find it difficult to decide on the selection of medicines because they lack information, such as health knowledge, and health democracy. [92]Therefore, I have to highlight that human rights theories can give a strong support in this problem. Access to health care which has been enshrined in international treaties and recognized by governments throughout the world is a fundamental human right. It recalled that all the people have the right to access to the health knowledge and related products. They also have the self-determination of it.

4.2.2 The jurisprudential economic of price

Pharmaceutical manufacturing is characterized by very high initial costs for research and development of new medicines and very low marginal costs for producing the medicines. The companies must recoup the initial costs by selling the units above marginal cost – at least in some markets. According to the "Ramsey pricing theory", companies would however maximize sales in all types of markets if they adopted a differential pricing strategy. The initial costs would be mainly supported by the richer markets whereas markets with less capacity to pay would absorb marginal costs only. The poor markets would contribute to companies' economies of scale, even if they cannot cover research costs.[93] If Ramsey pricing was routinely practiced, as many as one out of three persons on Earth would probably not lack access to medicines. While most companies maintain differential pricing schemes, the effects are not systematic. Scherer and Watal found for example at best a very weak empirical relationship between medicine prices and country per capita income. In some developing countries, there were actually higher prices than in the US.[94] The reason is that optimal pricing will only take place under the right conditions. Danzon and Towse argue that companies do not use Ramsey pricing because of the risk of parallel importation. Companies need to recoup costs in high-income markets, and this is not possible if low-priced products can be diverted from developing country recipients and "leak" back into high income markets. There is also the risk of "external reference pricing", which occurs when high income countries use prices in developing countries as benchmarks for regulating their own domestic price levels. The rational response of the company when faced with the threats of parallel imports or external reference pricing is to set one international price that will apply to all markets. It will impede the possibility of selling to low income

---

[92] Ibid.

[93] See discussion in Danzon and Towse 2005. Differential pricing is not regulated in TRIPS. See Carlos M. Correa.*Phamaceutical innovation, increamental, patenting and compulsory licensing.* Availiable at : http://www.ungs.edu.ar/globelics/wp-content/uploads/2011/12/ID-246-Correa-Privatization-of-knowledge-Intellectual-Property-Right.pdf. (Access MAY 2012).

[94] Scherer and Watal 2001, page 37-44. See Carlos M. Correa. "*Phamaceutical innovation, increamental, patenting and compulsory licensing."* Availiable at : http://www.ungs.edu.ar/globelics/wp-content/uploads/2011/12/ID-246-Correa-Privatization-of-knowledge-Intellectual-Property-Right.pdf. (Access MAY 2012).

markets, but guard the profit derived from the most important markets.[95] The result is efficiency losses both for the company and consumers. Companies may view external reference pricing as an increasing threat due to developments in high income markets where aging populations and increased use of patented medicines are straining health budgets. There has been growing pressure for lower prices in the rich countries as well, for example in relation to disadvantaged people in the US.[96] In many cases, it is also difficult to say what the Ramsey optimal price would be. Even in very poor countries, there may be a relatively large and growing middle class with higher purchasing power, which companies of course will want to exploit. The government response should be to separate the markets within the country, e.g. by letting only the poor access subsidized medicines through the national healthcare system. The problem in many developing countries is that the healthcare system is too weak to perform this role adequately, which again means that low-priced products may leak back to consumers that could pay more.

4.2.3 Price and intellectual property

Intellectual property rights reward monopoly rights to the creators of new products. Such regimes are said to encourage research, development and innovation, as they ensure that inventors can enjoy commercial benefits from their endeavors before being exposed to competition.[97] Intellectual property protection actually restricts competition, so intellectual property clauses are somewhat anomalous in trade agreements, which are normally designed to decrease trade barriers. Intellectual property rights nevertheless arguably facilitate trade. As traders are less concerned about pirating, global intellectual property rights promote foreign investment and technology transfer. However, as intellectual property laws confer monopoly rights, they generally inflate prices. This circumstance is problematic as goods that are essential for the enjoyment of human rights, such as new medicines, can be priced out of the reach of poor people. And it becomes more significant in the process of globalization.

Thus, prices are likely to be artificially inflated for that 20 year period, as patent holders seek to maximize returns on their investment. For example, the costs of drugs which combat the HIV virus are enormous. A month's worth of Atripla, a relatively new anti-HIV drug, costs USD 1300 a month.[98]2 Such prices are only affordable in

[95] Danzon and Towse 2005, page 438-444. They argue that the most efficient way to increase access to medicineswhile retaining the incentives to invest in R&D is to promote market separation in such a way that allows pricediscrimination based on each market's purchasing power (p 444-456) .See Carlos M. Correa. *Phamaceutical innovation, increamental, patenting and compulsory licensing.* Availiable at : http://www.ungs.edu.ar/globelics/wp-content/uploads/2011/12/ID-246-Correa-Privatization-of-knowledge-Intellectual-Property-Right.pdf. (access MAY 2012)

[96] Abbott 2006, page 29. See Carlos M. Correa.*Phamaceutical innovation, increamental, patenting and compulsory licensing.* Availiable at : http://www.ungs.edu.ar/globelics/wp-content/uploads/2011/12/ID-246-Correa-Privatization-of-knowledge-Intellectual-Property-Right.pdf. (Access MAY 2012)

[97] Sarah Joseph.*Trade and the Right to Health.*Swiss human rights book, page 399, 2009.

[98] Daniel Costello."HIV treatment becoming profitable", *Los Angeles Times*, 21 February 2008.

industrialized countries due to government subsidies, which are not available in the developing world. Clearly, it is impossible for most people in the developing world, where most HIV cases arise, to pay such prices. The result is a health divide: HIV remains a death sentence for most sufferers in the developing world, whereas it can be managed for many years by sufferers in the developed world who have access to alleviating medication.

Patent holder companies argue that the solution to high costs for the poor during a patent term is voluntary donations and differential prices, and these measures are a reason why the Decision has not so far been used. All the large pharmaceutical companies have programs for differential pricing and many donate large volumes of medicines to developing countries, in particular the LDCs. However, for a disease that persists it is not sustainable, and if the disease is widespread (such as AIDS), the donations can never fully meet the demand.[99] The companies can only donate a certain amount before it starts affecting their overall ability to make a profit and continue in the market.

In addition, there is currently an international system of price discrimination even if it does not generally result in systematic links between price levels and a country's level of development. Sometimes there are large price differentials between equally poor countries as well, depending on geographic location. This price discrimination takes place even though there is a risk of high income markets prices being influenced. Incentives to lower prices may not be strong enough in the current situation where markets are not perfectly separate unless these threats are credible.[100] Thus, while donations and differential pricing are extremely important for improving access they cannot be the full or only solution for each and every poor country, or for every product.

Hence, in my opinion, the voluntary system used today cannot result systematic adjustment of price in different market and make it as a unit international market due to globalization and universal human rights requirement. We do need apply a global and universal legislation mechanism and revise the international intellectual property system to balance the price.

4.3 Global Access Guarantee: Compulsory License

As discussed above, the different and vary of accessibility price has set a block on the way of fulfill access to health and other fundamental human rights globally. To some extent, one person out of three on Earth has no access to essential medicines. And the basic reason is of course poverty – many developing country consumers do

[99] UNDP 2001, p 101

[100] Grace 2003, Hammer 2002. See Carlos M. Correa.*Phamaceutical innovation, increamental, patenting and compulsory licensing.* Availiable at : http://www.ungs.edu.ar/globelics/wp-content/uploads/2011/12/ID-246-Correa-Privatization-of-knowledge-Intellectual-Property-Right.pdf. (Access MAY 2012)

not have enough purchasing power. [101] Despite of the market, we also lack of international problem solving mechanism. The national policy and private interest intellectual property rules vary from country to country, which is not compatible to the economic globalization today. However, attributable to the human rights framework, all human beings should have the right to ensure their human dignity, and in this case, had the right to access to health, nevertheless they have the purchasing power. So, the intellectual property system raised a concept of compulsory license, to change to be a promotion mechanism for this trend but not block it.

4.3.1 Background

In respect to intellectual property law, a patent is an exclusive right to an invention with the purpose of stimulating research and development of new products. For illustrate, medicines are expensive to develop but relatively cheap to produce. The owners are therefore dependent on patent protection, a legal monopoly which the patent holder can exploit, to best advantage to be able to set prices that can recoup the investment made in research and development. [102]The research-based industry can to some extent control prices and availability worldwide because more and more countries have introduced patent protection for medicines in the last decade. It makes sense economically for companies to adjust prices to different markets depending on their purchasing power: higher prices in high income countries and lower prices in developing countries. Such price differentiation allows production of larger volumes which leads to economies of scale. It benefits the companies at the same time as it provides better access to the product for consumers.[103]

However, the theoretical model does not always work in real life. There are sometimes large price differentials between equally poor countries and occasionally prices are even higher than in high income countries. The explanation for this paradox is that the ability of companies to adjust prices according to purchasing power is circumscribed for two reasons. Firstly, because there is a risk that medicines sold at lower prices in developing countries are re-exported to high income markets. Secondly, there may be an indirect influence. Many high income countries, including Sweden, regulate medicine prices on a national level. There is a risk that these countries use prices in developing countries as benchmarks (external reference pricing). In both cases, prices are undermined in the most important markets which make it more difficult for companies to use prices in high income countries to cover research costs for new medicines.[104]

To solve this unbalance and give an initiative to involve human rights standard in to intellectual property, in 2003, the WTO approved a set of new rules intended to

[101] *The WTO Decision on Compulsory Licensing: Does it enable import of medicines for developing countries with grave public health problems?* .Kommerskollegium,2008:2.

[102] *The WTO Decision on Compulsory Licensing: Does it enable import of medicines for developing countries with grave public health problems?*. Kommerskollegium,2008:2.

[103] Ibid.

[104] Ibid.

improve access to medicines in developing countries. One of them, so- called "compulsory license" is mentioned in the TRIPS.(in Chapter 3) It was a response to criticism that the WTO rules were part of the obstacles to increased access to essential medicines.

One general restriction in TRIPS on compulsory licenses is that the license should be issued "predominantly for the supply of the domestic market." This provision was problematic, as numerous developing states have no capacity to manufacture generic pharmaceutical products. Such states could not import compulsorily licensed products because other states were prohibited from producing such goods primarily for export.[105] Furthermore, the WTO waived the territorial restriction on compulsory licenses for pharmaceutical products in certain circumstances. Under the waiver, the territorial restrictions on compulsory licenses may only be lifted to facilitate the export of generic drugs to the least developed countries in respect of pharmaceuticals to combat epidemics. Safeguards must be in place to ensure that the relevant pharmaceuticals are not diverted to another market.[106] Patent holders may allow others to exploit their inventions by granting voluntary licenses. Thus, the purpose of the compulsory license is to provide a safeguard against lack of use of a patent or misuse of the patent holder's monopoly rights.

Moreover, Article 31 in the TRIPS agreement allows the granting of compulsory licenses, as long as certain procedures are followed and certain terms fulfilled. So the compulsory license shall be considered on its individual merits and be possible to appeal. It may constitutes a strategic tool for improving the negotiating position of the general public towards the patent holder in order to improve access to a particular invention. There is, however, a risk that compulsory licenses reduce innovation and investment by diminishing the value of a patent.[107](Analyze in the next Chapter)

4.3.2 Effect

The pharmaceutical industry has become highly concentrated through mergers and acquisitions in the last decades. Companies have sought to insure themselves from high costs and risks by growing. Coupled with the full implementation of TRIPS, which has extended patent protection to almost all countries, it is now possible for the big companies to exercise a high degree of control over prices and availability worldwide.[108] So, how could compulsory licensing affect the access to health on the

---

[105] Sarah Joseph.*Trade and the Right to Health.*Swiss human rights book. page 399, 2009.

[106] Carlos M. Correa.*Phamaceutical innovation, increamental, patenting and compulsory licensing.* Availiable at : http://www.ungs.edu.ar/globelics/wp-content/uploads/2011/12/ID-246-Correa-Privatization-of-knowledge-Intellectual-Property-Right.pdf. (Access MAY 2012).

[107] *The WTO Decision on Compulsory Licensing: Does it enable import of medicines for developing countries with grave public health problems?.* Kommerskollegium,2008:2.

[108] Rosenberg 2006, p. 65-71; Abbott 2006, page 28-29. See Carlos M. Correa.*Phamaceutical innovation, increamental, patenting and compulsory licensing.* Availiable at : http://www.ungs.edu.ar/globelics/wp-content/uploads/2011/12/ID-246-Correa-Privatization-of-knowledge-Intellectual-Property-Right.pdf. (Access MAY 2012).

economic perspective in the globalization?

In what way could a compulsory license improve access to medicines? There are two potential scenarios where a compulsory license may result in lower prices.

In the first scenario, compulsory licenses would result in lower prices due to lower development costs for the new producer. Unlike the patent holder, the new producer has no research costs to cover, only costs for starting a production. The new producer only has a license to sell the product in the market where the compulsory license is granted, and thus does not need to be concerned about any influence on prices in high income markets. In the second scenario, the compulsory license is not actually put into use. Its mere existence improves the negotiating position of the importer towards the patent holder, enabling the latter to reduce its own prices.[109]

4.3.3 Lessons learned

It is no doubt that although the compulsory licenses as a intellectual property tools did result in certain downward pressure on prices, it not always in a significant way. The compulsory licensing is only effective if the market is credible and important to the patent holder. To instance, the research on the general use of compulsory licenses in Canada, the US, Thailand, Malaysia, Zimbabwe and Brazil shows that while systematic use of compulsory licenses might harm innovation and investments, sporadic use showed no such effects.[110] So despite the legal regulation like compulsory license, to balance the access problem and the intellectual property protection, another important factor should be considered collectively is how important the market in question is for investment decisions, which are the requirement of universal human rights and the production of globalization. The compulsory license cannot guarantee lower prices, if we apart the patent situation and costs of production from the unequal global market.

Finally, I have to highlight that the rule must be implemented in national legislation before they can be utilized. Implementation is furthermore fully voluntary. On the exporter side, only Canada, Norway, India and the EU have implemented the rules so far. China have also made changes, but not formally notified their new laws to the WTO. There is little information on the legal situation in most potential importing countries. Many of them can probably use the new rules on the basis of existing laws and regulations on compulsory licenses. No attempt to import under the new rules has been completed in the four years that have passed since they were adopted. The organization Médecins Sans Frontières/Doctors without borders applied for a compulsory license in Canada for export of an AIDS medicine on behalf of an unnamed developing country. The organization abandoned the attempt when two Indian companies began marketing copies of the same medicine at a certified quality. These companies did not need to apply for a compulsory license since the medicine

---

[109] *The WTO Decision on Compulsory Licensing: Does it enable import of medicines for developing countries with grave public health problems?*. Kommerskollegium,2008:2.

[110] Ibid.

was not patented in India. All in all, there appears to be a general lack of interest in using the new rules, even though the negotiations appeared to be so important to many parties. It is possible that the rules have had indirect effects even though they have not been used. The new possibility for compulsory licenses can improve importers' negotiating positions, and the mere adoption of the new rules could therefore result in lower prices.[111] However, it is not easy to discover such systematic price effects during the short period that has elapsed. So, because the market and global trade situation is changing from time to time and different countries have different national legislations, we need to improve this intellectual property system with the change of the globalization and under the direction of universal human rights. We should propose a international to national mechanism to ensure the use of this tools.

The conclusion is that the compulsory license is a useful tool in nowadays. It can be an efficient formulation of the people to access to fundamental health resources and indeed balance the intellectual property rights with public health situation. It decreases the gap between the rich and the poor and reduces the certain price of the health related products. What's more, due to the globalization, we also need to associate it with international trade risks and global limitations.

So far, more and more activities and legal mechanism has been raised by different social organs, such as the WHO, the WIPO and the WTO. The globalization also accelerates the speed of international cooperation. Obviously, there still has margin left for the intellectual property law to revise on the perspective of balance access to health. And human rights principle should be the direction and aim for their promotion.

---

[111] *The WTO Decision on Compulsory Licensing: Does it enable import of medicines for developing countries with grave public health problems?*. Kommerskollegium,2008:2.

5. Discussion

After the examination of the legal system and social strategies, I need to reveal the new and existing obstruct for access to health and intellectual property. Set on the human rights framework, I propose the health democracy which will is urgent necessary in the globalization.

5.1 The Barriers between Access to Health and Intellectual Property

It is no doubt that there are multiple barriers to access to health existing in the era of globalization.

The lack of universal trust has seriously hindered establishment of a balanced system between access to health and intellectual property rights. Although the private property holder has certain legal rights to invention defined within the patent, the invention itself is a public good which should be benefit to universal. In other words, there are two simultaneous interests in an invention, one is the legal interest, and the other is the equitable interest in the invention as a public good.

The first pillar is lack of human rights equity.

Regarding to access to health, the people have no right to education. To be specifically, the citizen is lack of health care knowledge and relevant information. People who live in the developing area have no awareness of health protection at all. The cultural, social and geographical obstacles prevent health education, examination and treatment. They even have no idea about the intellectual property protection of their own traditional medicine knowledge and the utility of it. There are little well educated doctors in the poor area where need the more professional doctors and health aids. On the contrary, similar sentiment was seen in understanding the needs of patients. Physicians and the market both believe economic and access to health necessitate no understanding of patient needs, which deny the way for the patient to realize their universal right and ask for it and increase the patient illiteracy.

Besides, the people have no right to health. Honestly, this problem is rooted in poverty, which results in an inability to pay for even the cheapest medicines, including generics. Other factors that impede access are taxes and tariffs that raise prices unnecessarily, and cultural factors such as discrimination. Some inappropriate intellectual property rights also enlarge this unbalance. Moreover, a chronic under-investment in healthcare infrastructure which has led to a lack of clinics and hospitals, poor distribution networks, low numbers of trained healthcare providers, and is a key factor as well.

Additionally, the people have no right to development. According to the World Bank, a per capita spend on healthcare of at least US$14 per year is required to provide a basic healthcare infrastructure.[112] And the expenditure on health of many sub-Saharan African countries is even well below this. This economic and distribute unbalance result the non-restructure health development system. From a long-term perspective, it will form a huge barrier for global sustainable development. Significant additional external funding is essential for medicines and development of the infrastructure needed to deliver them. The International healthcare systems must be strengthened according to the requirement of fundamental human rights. As the current WHO Director General Margaret Chan said in her acceptance speech that: "Health systems are the tap root for better health. All the donated drugs in the world won't do any good without an infrastructure for their delivery."[113]

Hence, it is a common knowledge that markets alone cannot be relied upon to achieve the society trust and interest balance. So we need to promote the human values at stake in intellectual property systems. This is clear, for example, from recent experiences in the areas of public health and education, where intellectual property has complicated progress toward meeting these basic public needs and foundation human rights.[114]

The second pillar is the urgent need of economic equity.

The high price of drugs or huge cost of health service in developing country and the gap between urban and rural area give raise the unequal distribution of health care resources. For instance, there are limited availability and accessibility of medical professionals in some remote rural areas and least developing countries are lack of laboratory equipment, health centers and hospital infrastructure. Poverty which results in an inability to pay for even the cheapest medicines is an obstacle to improving healthcare in the developing world. But at the same time, the high cost of invention, research and patent has increased the price of the Access to health. The right holder in order to finance further research has added the cost into the payment of patients. The balance of Access to health and Intellectual Property seems as the cost vs. the profit. Prices matter, because medicines account for up to 80% of health expenditure in some developing countries and thus strongly influence overall access to health care. In many developing countries there are no general health insurance systems. Most people must finance their medicines privately and at the time of the illness. WHO estimates that 50–90 % of such "out-of-pocket" spending for health care is spent on patent monopolizes medicines. The lack of insurance of course makes high medicine prices extra burdensome for poor people.[115]

---

[112] GlaxoSmithKline. *Intellectual Property & Access to Medicines in Developing Countries*. Available at: http://www.gsk.com/policies/GSK-on-IP-and-access-to-medicines-in-developing-countries.pdf (Accessed MAY 2012).

[113] Dr Margaret Chan, Director-General Elect. **"***Speech to the World Health Assembly***."** World Health Assembly, 9 November 2006. Availiable at : http://www.who.int/dg/speeches/2006/wha/en/index.html (Accessed MAY 2012).

[114] The Washington Declaration on Intellectual Property and the Public Interest. Washington DC, 25-27 August 2011.

[115] WHO figures cited in Ford 2004; WHO 2001. See "Investing for life : Meeting poor people's needs for access to medicines through responsible business practices".*Oxfam Briefing Paper*, November 2007.

However, I think it is the government or any other national and international duty holders who should take the obligation to support, not the people who indeed lack of health but cannot afford it. As stated in the Doha declaration: "We recognize that IP protection is important for the development of new medicines. We also recognize the concerns about its effects on prices". At the same time, we should take the human rights into consideration and change the current intellectual property regime to make the access to health as an element of it as well, which will be a practical way to decline the unbalance of the price related problem.

The third pillar is no legal equity.

Nowadays, over 95% of the 325 drugs on the WHO Essential Medicine List are not patent protected and yet the WHO says that 30% of people in developing countries do not have reliable access to these drugs. This rises to 2/3rds of populations in Africa and parts of Asia.[116] First line treatments for killer diseases like malaria and TB are available as generic products at very low cost, and yet many people are denied access to them because there have little legal certification of these health products. From this perspective, we need to seek a new system to adapt the intellectual property products market and fulfill human rights obligation immediately.

On the one hand, because most intellectual property rights, especially patents, are time-limited rights and the public interest requires that creative and innovative works ultimately become free for all to use as part international intellectual property policy affects a broad range of interests within society, not just those of rights holders. Thus, intellectual property rights should be conducted through mechanisms of transparency and openness that encourage broad public participation. New rules of this human rights based intellectual framework should be made within the existing forums responsible for other related policy, where both developed and developing countries have full representation, and where the texts of and forums for considering proposals are open. All new international intellectual property standards must be subject to democratic balances, including domestic legislative approval and opportunities for judicial review.[117] Although the right to democracy is only guaranteed in ICCPR, some human rights professor raised the opinion of health democracy. The link between ICESCR and ICCPR and the human rights is universal to be protected has been a strong support to it. In my opinion, it is no doubt that the health democracy can be an efficient way for people to fulfill their access to health in many situations despite fighting with intellectual property protection. Moreover, democracy should be an all in one term and adapted to the need of the global society.

On the other hand, to focus on patents as the only barrier to access is misleading and counter-productive. Patent protection stimulates and fundamentally underpins the continued research and development for new and better medicines for diseases

[116] GlaxoSmithKline. "Intellectual Property & Access to Medicines in Developing Countries". *Globle Public Policy Issues*. Available at: http://www.gsk.com/policies/GSK-on-IP-and-access-to-medicines-in-developing-countries.pdf. (Access April 2012).

[117] The Washington Declaration on Intellectual Property and the Public Interest. Washington DC, 25-27 August 2011.

including those which occur in the developing world**.** So, the public domain serves as a foundation of cultural heritage and scientific knowledge from which future creators and inventors necessarily to be underlined. A group of related civil society movements has emerged to promote the benefits of the public domain or openness, including through open licensing, open access, open educational resources, open data, open standards, open government, and related open information policies.[118]It leaves a huge task to finish and balance for the authority and law makers.

Consequently, it cannot be denied that intellectual property particularly patent, to some extent, generally affect the access condition, such as medicine prices, which result many other trust problems like absence of clinics, doctors, information or equity and safe distribution. High medicine prices are certainly not the only thing obstacle to global health, which also emphasized clearly by both WHO and UNAIDS, but still the main cause in this global situation. As the globalization caused by migration and the multinational trade, this intellectual property monopoly and competition influence has been enlarged and become to the barriers of human being to enjoy their human dignity and access to health. However, because human rights are universal to everyone, it should be a surefire way for authority to balance and control the intellectual property and the access blank. In particularly, human rights are fundamental and available globally, so it requires the universal access, which is the same as the aim of international affairs. Hence taking into account of human rights spirit must be the most efficient way for eliminating the barriers I mentioned before.

5.2 Innovation and Intellectual Property

In the context of public health, it is vital to ensure that the individuals should maintain the health, the life and innovation. These three organs should be balanced by intellectual property and none of them could be infringed and its hypertrophy will obstruct the role of others. So we should find the equilibrium of access to health and health related innovation.

Several motivations are impressed by the innovation. First, innovation is important for both, driving economic progress and competitiveness despite of the economic level of the development. It has a global effect. And many governments are putting innovation at the center of their growth strategies. Second, there is increasing awareness that the definition of innovation has broadened, which is no longer restricted to R&D laboratories and published scientific papers. Innovation has formed many models such as social innovation and business model innovation and is more general and horizontal in nature. Finally, recognizing and celebrating innovation in emerging markets is seen as critical for inspiring people, especially the next generation of entrepreneurs and innovators.[119]

What's more, it seems that the intellectual property regime is a unique man-made

[118] The Washington Declaration on Intellectual Property and the Public Interest. Washington DC, 25-27 August 2011.

[119] WIPO. *WIPO magazine*, Geneva. August 2011, page15.

law system to regulate the market. On the one hand, it can reward an exclusive rights for some righholders to protect their rights, on the other hand, it will be a tool or formulate for the market competition, which is established during the economy development. The big company can use it as a protection and instrument for the competition, like Apple. It promotes the innovation and gain on the market profit for rightholders. Only the company who can manage this system and control the society human rights obligation can survive and develop. The patent and other intellectual property rights are the market lever for the rightholder and the whole society. For example, some generic products and research cannot be grant patent in some countries due to the ethic reasons, which is a way the intellectual property tend to protection the human dignity. But this exclusive cannot be treated as the barriers for innovation, on the contrary, it does not prevent the innovative public research. And all the people can have the right to benefit it.

As a possible alternative, I propose a competitive financing scheme that would work through R&D investment intermediates. These R&D funds would be licensed and regulated (like pension funds). Their role would be to manage R&D assets on behalf of consumers. Individuals (or employers) would be required to make minimum contributions into R&D funds, much as there are mandatory contributions to social security or health insurance or to pension funds. [120]Government would set the required contribution, but the individual (or employer) would be free to choose the particular intermediate that received their contributions. Intermediates would compete to attract funds to invest in R&D on the basis of their prowess for drug development and upon their priorities.[121] Different business models for financing R&D could be tested in such a market, with intermediates experimenting with prize systems, direct investments in profit or nonprofit entities, open collaborative public good models, or other approaches.

5.3 Human Rights Make Access to Health Global and Universal

We have to admit that although most countries have incorporated access to health as an element to human rights in their Constitution, however in practice, not all individuals had been equally able to exercise it. It still has a long way to go.

Human rights must be fundamental, universal in the sense that it is globally and very widely recognized and guaranteed to everyone. The concern is legitimate and must be taken seriously, at the same time, the list of human rights can never be considered as closed. Although it is impossible to figure out the human dignity in the future, the foundation of all human rights should be guaranteed according to the social reality. The capable of human rights should formulate sufficiently precise as to give rise to legal obligations of state and the international cooperation. Turn to the intellectual property regime, the universal access also meets with the requirement of the global intellectual property market. So, these two systems have a same basement and interaction.

---

[120] James Love and Tim Hubbard. *Code: Collaborative Ownership and the Digital Economy.* Rishab Aiyer Ghosh. (Ed). Cambridg: MIT Press, 2005,page 207-229.

[121] Ibid.

To extent, we need to ensure health democracy based on the access to universal human rights.

First, the legal recognition of right to health as a social right was already there when the debate around the reform started, but its actual implementation was only benefiting certain sectors of the population not all. What is lacking is the definition of the explicit entitlements that ensued from the claim, and the global financial instruments. The effective health services for all according to universal human rights should be translated and present in these instrument, individual and public financial decisions.

Furthermore, according to Brachet, to transform health care into a real social right requires, there are two important things: a defined set of health benefits all citizens, regardless of their labor or socio-economic status. Everyone should receive and can legally demand or established mechanisms through which the costs of these benefits will be distributed to guarantee their financial viability.[122] Thus, because of the universal human rights, in the global marketing shifting, all the Intellectual property holders and rights holders should realize their obligation to respect the universal human rights and balance the individual rights to universal accessible.

For illustration, a new technology is developing in healthcare called "personalized medicine", in which prescription medications are chosen based on each person's genetic profile. Three out of four patients have not heard of personalized medicine. Given the perceptions of biopharma and managed care that personalized medicine will increase the safety and effectiveness of medications, this presents an opportunity to educate patients on the concept. How can patients impact drug development? There is a definite trend towards patients increasingly taking active control of their health, sharing information about treatments with each other and seeing the healthcare system as a partner in making decisions and access their right to health personalize.[123]This new health care form is secured by universal human rights in the globalization. People no matter the territory and other factors can enjoy an equity access the health and make it personally.

Second, the effective exercise of human rights is a key component of citizenship and should be considered an intrinsic objective of all democracies. Universal and global access to health reduces poverty, improves educational outcomes, enhances productivity, and prompts economic growth. Apparently, prosperity and a fair distribution of its benefits contribute to democratic stability.[124] So, owing to the universal human rights theories and its basic equity accessibility, the recognition of health as a universal value favors the establishment of political agreements. These agreements, in turn, help to build social cohesion which nourishes democratic

---

[122] V. Brachet-Márquez. *"Ciudadanía para la salud: Una propuesta" In M. Uribe, López-Cervantes*. Reflexiones acerca de la salud en México. Médica Sur, (ed) Panamericana, 2001, page 43–47.

[123] *New health report*, 2011. Available at: www.quintiles.com/newhealthreport (Accessed MAY 2012).

[124] T, Karl. '*¿Cuánta democracia acepta la desigualdad?*. 69 Este País ,1996. page 46–51.

globalization societies.

Finally, the implementation of human rights in access to health under the intellectual property implies the use of democratic procedures, which also favors the consolidation of not health democracy but also other democracy ensured in the international human rights law. Salient among them are public deliberation, definition of entitlements, transparency, and accountability. Hence, the approval of the legal reforms required broad public discussion involving all the main global health related actors: Health authorities, political parties, academic institutions, and NGOs. Clearly defined benefits have ensured that those who avail themselves of the public insurance scheme know the services and treatments to which they are entitled. At the same time, the implementation of the reform has fostered other important procedures including access to public information, open evaluation and dissemination of report cards, all of which are contributing to the consolidation of a democratic culture.[125]

Therefore, the reforms of extending the access to health to all the population have strengthened the procedures and institutions of democracy. Certainly, the democratization of health can contribute to the health of democracy among the world. Human rights based framework can ensure all the social movement like globalization in the line of universal human rights fulfillment and guarantee the universal democracy in the process of globalization. It is only way to secure and balance human dignity with the global economic benefit especially in the intellectual property era.

To be concluded, in the globalization, equally access, recognition of access to health as a universal value favors the establishment of international legal agreements. These agreements, in turn, help to build social cohesion which nourishes democratic societies.[126] We should use the human rights values to regular other decision making and eliminate the global barriers. Simultaneously, the intellectual property as I analyzed in this part, will not be a block for the innovation and accessibility, contrarily, it will be an insensitive and promotion for development. We need acknowledge and utilize it in the globalization. This is not only a trend but also a demand of the global society and universal human rights requirement.

[125] Julio Frenk and Octavio Gómez-Dantés. “The Democratization of Health in Mexico: Extending” .*Swiss human rights book*, 2009.

[126] Julio Frenk and Octavio Gómez-Dantés.”The Democratization of Health in Mexico: Extending the Right to Health Care”. *Swiss human rights book*, 2009.

6. Conclusion

The call for balance of Access to Health and Intellectual Property during the globalization has raised profound legal question and practice challenges alike for a long time. In the global society nowadays, the calling is gaining growing spirit. Although most people are in favor of balance, there are many blocks on the way to fulfill the accessible set by the characteristic of Intellectual Property and unequal economy world affairs.

This paper has provided a review of Access to Health issues in the era of globalization under the Intellectual Property system and analysis the existing legal framework seeking to find out the significant link between the two regimes in the unique globalization background.

First of all, the issue will only be settled when we addressed three big barriers efficiently, which is namely the lack of trust. Hence, the most important thing for us, human right person, is to raise the personal awareness of health care of local people and make the health knowledge accessible, affordable and borderless. We aim to build the trust between Human Rights and Intellectual Property.

Moreover, because access to health is a complex and multi-faceted problem in the era of globalization, the challenges can only be properly addressed through partnership between developed and developing country governments, international organizations, the industry and charitable organizations. The cooperation among the world is inevitably necessary to achieve the balance. Besides the relevant agenda the international organizations have adopted, like global drug strategy, implement of compulsory license in the world trade market, I propose to find new measures to promote the relationship. We should attempt to create an effective legal cooperation system for the unbalance and universal access problems in the globalization. Only the global and universal methods can balance unequal of the price and accessible to health.

What is more, we need to respect the cohesion of international human rights, intellectual property and the economic development in the globalization. On one hand we have to protect the Intellectual Property Right of the right holder; on the other hand we should respect and fulfill the universal Human Right involved in this field. Obviously, it is an interactive relationship. We should insist on figuring out the original problem like the economic theories of high price and the weakness in the intellectual property nowadays. For example, if we want to cut down the cost of essential medicines, the key point is to reduce the extra service and patent fee paid for the inter-management like WIPO. We should create a win-win situation for both the Human Right and Intellectual Property Right.

Finally, the implementation of the access to health implies the use of democratic procedures, which also favors the consolidation of democracy. The universal exercise of social rights can also contribute to the consolidation of democracy. [127]Universal access to health care reduces poverty, improves educational outcomes, enhances productivity, and prompts economic growth. Prosperity and a fair distribution of its benefits contribute to democratic stability.[128]

Therefore, although the globalization has result a bind of legal, economic and social problems recently, we can apply the human rights which are fundamental and universal existed to balance the varied interests. We should add the health democracy into the human rights regime and use it as a protection for the intellectual property threat. Besides, we need to adjust the intellectual property law and make it as a global standard under the framework of human rights. It should turn to a legal arm for the people and secure their right to access to the health in the global range.

[127] Julio Frenk and Octavio Gómez-Dantés. "The Democratization of Health in Mexico: Extending the Right to Health Care". *Swiss human rights book*, 2009.

[128] T, Karl. *"cuánta democracia acepta la desigualdad?"*69 *Este País*, 1996. Page 46 – 51.

Bibliography

Book

1. Laurence R, Helfer and Graneme W. Austin. *Human Rights and Intellectual Property mapping the global interface*. Cambridge university press, 2011.

2. Thomas Pogge. *Incencives for global public health.* Cambridge university press, 2011.

3. Gaëlle Krikorian and Amy Kapczynski. *Access to knowledge in the age of Intellectual Property*. Zone books, 2010.

4. Willem Grosheid. *Intellectual Property and Human Rights a paradox*. Edward Eglar, 2010.

5. Johanna Gibson. *Intellectual Property, medicine and health*. Ashgate public, 2008.

6. Tshimanga Kongolo. *Unsettled international Intellectual Property issues*. Wolter Kluwer law & business, 2008.

7. Hestmeyer. *Human Rights and the WTO*. Oxford university press, 2007.

Articles

1. Julio Frenk and Octavio Gómez-Dantés. "The Democratization of Health in Mexico: Extending the Right to Health Care". *Swiss human rights book*.

2. GlaxoSmithKline. "Intellectual Property & Access to Medicines in Developing Countries". *Global Public Policy Issues*. Available at: http://www.gsk.com/policies/GSK-on-IP-and-access-to-medicines-in-developing-cou ntries.pdf. (Access April 2012).

3. Sarah Joseph. "Trade and the Right to Health". Swiss *human rights book*. 2009, page 399.

4. "The WTO Decision on Compulsory Licensing: Does it enable import of medicines for developing countries with grave public health problems?", Kommerskollegium,2008.

5. Hogerzeil HV et al. "Access to essential medicines as part of the fulfillment of the right to health – is it enforceable through the courts?" *Lancet*, 2006

6. Adam McBeth. "When Nobody Comes to the Party: Why Have No States Used the WTO Scheme for Compulsory Licensing of Essential Medicines?"3 *New Zealand Journal of International Law*, 2006

7. Kelley Lee. Globalization: what is it and how does it affect health?" Med J

Aust 2004, 180 (4): 156-158. Availiable at: https://www.mja.com.au/journal/2004/180/4/globalisation-what-it-and-how-does-it-affect-health (access MAY 2012).

8. Zon, A. van, muysken, J.Health as a principle determinant of economic growth in Lopez-Casasnovas. 2005. G. et al. (ed). "Health and economic growth: finding and policy implication*s"*. *Cambridge MA*, MIT Press.

9. Dinah Shelton. "Symposium on the future of international human rights: challenges to the future of civil and political rights". 55 *Wash &Lee Law Review* 669, 1998.

10. Mamdouh Gabr. "Health Ethics, equity and human dignity". Available at : http://www.humiliationstudies.org/documents/GabrHealthEthics.pdf. (Access MAY 2012).

11. Kevin Outterson, *'Should access to medicines and TRIPS flexibilities be limited to specific diseases?' 34 American Journal of Law and Medicine* ,2008.

12. Correa. "Phamaceutical innovation, increamental, patenting and compulsory licensing". Available at : http://www.ungs.edu.ar/globelics/wp-content/uploads/2011/12/ID-246-Correa-Privatization-of-knowledge-Intellectual-Property-Right.pdf. (Access MAY 2012).

13. McIntyre D et al. "What are the economic consequences for households of illness and of paying for health care in low- and middle-income country contexts?" *Social Science and Medicine*, 2006, 62:858–65.

Cases

1. *Diamond v. Chakrabarty* 477 U.S. 303 , 1980.

2. Pharmaceutical Manufacturers' Association of South Africa v President of the Republic of South Africa, Case No 4183/98

Document

1. Intellectual Property and Human Rights: panel discussion. WIPO. Geneva, 1998.

2. New health report, 2011. Available at: www.quintiles.com/newhealthreport (Accessed MAY 2012).

3. The Washington Declaration on Intellectual Property and the Public Interest. Washington DC, 25-27 August 2011.

4. Agreement on Trade-Related Aspects of Intellectual Property Rights, 1994.

5.WIPO. World Intellectual Property indicator. Geneva, 2011.

6. Report of the Commission on Intellectual Property Rights, Innovation, and

Public Health. Geneva, World Health Organization, April 2006, page 125

7. ECSCR, General Comment No. 14, 2000.

8. WHO medicines strategy 2004–2007. Geneva, 2004 (WHO/EDM/2004.5) .Available at: http://whqlibdoc.who.int/hq/2004/WHO_EDM_2004.5.pdf (Accessed May 2012).

9. Office of the High Commissioner for Human Rights, Report on indicators for promoting and monitoring the implementation of human rights, 6 June 2008

10. WTO General Council, Amendment of the TRIPS Agreement. Decision of 6 December 2005

11.The world medicine situation 2011. WHO, Geneva, 2011.

12.United Nations Development Programme, Human Development Report 2007/2008,2007.

13.Doha Declaration on TRIPS and Public Health, adopted on 14 November 2001

14.WIPO. *FACT SHEET: TRIPS and pharmaceutical patent*s. Geneva, September 2006.

15.International Covenant on Economic, Social and Culture Rights

Acknowledge

Thanks for my family. I cannot imagine the life I have without your sweet support. There is a place I called home and I know you always be there and waiting for me.

Thanks for my dear supervisor Dr. Anna Maria Nawrot Andersen. She is so kind and careful. She taught me how to think and how to research inside and outside the class. Especially, thanks her efforts for my thesis.

Thanks for Dr Lin Li. He has supplied huge legal information for me when I doing my thesis and taught me many human rights knowledge I can used in my thesis.

Thanks for Prof. Mingde Li. During my internship in the Intellectual Property Center of China Academy of Social Sciences, I have learnt what should be the behavior of a professional researcher from his supervising. He also gave a huge help for my thesis and provide many useful theories for it.

Thanks for Mrs. Hang Gao. She has drawn a future picture for my career by her words. I realized what the ability I need today is.

Thanks for the Copyrights Institution of China. I have got much first-hand information by the study trip to Germany. And I got the valuable chance to exchange my opinions with the directors of the intellectual property field in Germany.

Thanks for Mian, Lu and other friends. They have given a support for my thesis writing by all means.

Thanks for RWI and Lund University. They supplied amount of knowledge resources for my study and provide a wonderful study place for me.

Thanks for Lund. From China to Sweden, from Beijing to Lund. My life is changing. So do I.

Thanks for all. Your concern for this topic will decide our life in the future.