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Realization Right to Health in the Context of Pharmaceutical under International Law

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**GOLDEN GATE UNIVERSITY
SCHOOL OF LAW**

**Realization Right to Health in the Context of Pharmaceutical
under International Law**

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Huei-Ying, Lucille, Hsu

**SUBMITTED TO THE GOLDEN GATE UNIVERSITY SCHOOL OF LAW,
DEPARTMENT OF INTERNATIONAL LEGAL STUDIES, IN FULFILMENT OF THE
REQUIREMENT FOR THE CONFERMENT OF THE DEGREE OF *SCIENTIAE
JURIDICAE DOCTOR* (SJD).**

Professor Chris N. Okeke, Professor Sompong Sucharitkul, and Professor Sophie Clavier

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Introduction

Globalization, Health and Diseases

Just as individuals cannot live in isolation, nation states need to commune, exchange and cooperate with others. Even the most self-reliant nation states must trade in order to survive and maintain sustainable development. However, globalization¹ has complex and far-reaching effects on the world population. For example, diseases also spread across national boundaries via goods and people. Pharmaceuticals used in the treatment and prevention of diseases also flow into the global trading system and are delivered into the hands of patients or consumers all over the world.

Globalization promotes national macroeconomic and social policies; regulates environments and institutions. Economic growth and technological advances offer incentives for the research and development (R&D) of new drugs or vaccines which provide disease-preventing and life-saving benefits. On the other hand, globalization jeopardizes the health of populations and highlights severe gaps in health inequity. In the struggle between the rich and the poor, the North and the South, the health of innocent people is too often the first sacrifice.

A study of projected global deaths for selected cause of death, 2002-2030², predicts world

¹ WHO, Globalization, Trade and Public Health: Tools and Training for National Action: Report of an Intercountry Expert Group Meeting, P.3, 2001, available at

http://whqlibdoc.who.int/searo/2001/SEA_HSD_244.pdf (last accessed on March 16, 2009)

Globalization refers to three distinctive and interrelated phenomena: increasing cross-border flows of goods, services, money, people, Globalization, trade and public technology and ideas; opening of national economies and boundaries to such flows; and development of international institutions and rules governing these cross-border flows. Globalization can scale up the effective public health interventions. It can affect the national health budget, access to health goods and products (drugs, vaccines, medical supplies, etc.), international mobility on health care services and influencing knowledge on policies. Globalization can also increase the environmental and occupational hazards. The movement of people brought about different life styles, and the spread of diseases.

² WHO, *World Health Statistics*, P.12, 2007, available at

deaths will show a substantial shift from a younger age group to an older age group and from infectious diseases to chronic diseases. Deaths due to communicable, maternal, perinatal and nutritional causes are expected to decrease from 30% in 2005 to 22% in 2030, with the exception of HIV/AIDS³. Childhood vaccination in developed countries has resulted in fewer cases of childhood infectious diseases; however, this is not yet the case in developing countries. At the same time, the aging of the global population of developed countries will result in a significant increase in chronic diseases and will likely account for almost 70% of all deaths in 2030.⁴

Indeed, the four leading causes of global death in 2030 are projected to be chronic heart disease, stroke, HIV/AIDS and chronic obstructive pulmonary disease. The total number of deaths attributable to tobacco use is projected to rise from 5.4 million in 2005 to 6.4 million in 2015 and to 8.3 million in 2030. Tobacco is projected to kill 50% more people in 2015 than HIV/AIDS, and to be responsible for 10% of all deaths.⁵ In developed countries, due to diet, tobacco-use and aging⁶ populations, there are many more people with chronic diseases than with infectious diseases; however, developing countries are still haunted by both chronic diseases and infectious diseases.

<http://www.who.int/whosis/whostat2007.pdf> (last accessed on March 16, 2009)

³ WHO, *World Health Statistics*, P.14, 2008, available at

http://www.who.int/whosis/whostat/EN_WHS08_Full.pdf (last accessed on March 20, 2009)

Although the total number of people living with HIV has increased significantly over the years, the proportion of infected has not changed since the end of the 1990s. In fact, the number of people who become infected every day (over 6800) is greater than the numbers who die of the disease (around 6000). Worldwide, 0.8% of the adult population (aged 15-49 years) is estimated to be infected with HIV, with a range of 0.7-0.9%.

⁴ WHO, *World Health Statistics*, P.12, 2007, available at

<http://www.who.int/whosis/whostat2007.pdf> (last accessed on March 20, 2009)

⁵ WHO, *World Health Statistics*, P.12, 2007, available at

<http://www.who.int/whosis/whostat2007.pdf> (last accessed March 20, 2009)

⁶ UN News Centre, 'New UN estimates Predict 2.5 Billion Increase in World Population by 2050', 2007, available at

<http://www.un.org/apps/news/story.asp?NewsID=21847&Cr=populat&Cr1=&Kw1=UN+estimates+predict+2.5+billion+increase+in+world+population+by+2050&Kw2=&Kw3=> (last access on March 16, 2009)

Infectious Diseases

In 2005, 30% of all deaths were caused by infectious disease,⁷ which represented more than 15 million deaths; of those, 6.7 million were children, mostly in developing countries. HIV-AIDS, malaria and tuberculosis are the three main diseases which cause of death and claimed around 5.7 million lives per year worldwide.⁸ The vast majority of those infected are due, unsurprisingly, to the international trade of goods, movement of people and vectors. In addition, an increasing and expanding world population, environmental change and degradation, trans-boundary pollutants and sanitation problems, and increasingly resistant strains of viruses and genetic mutations have made diseases even harder to prevent and treat. Some of the viruses even cross the barrier of species from animals to the human population, becoming a more serious threat to health.⁹

The burden of diseases has influential impacts on poverty and national economies. Pharmaceuticals products and immunization have therefore become the most desirable and cost effective methods of fighting against infectious diseases. As a result of how infectious diseases spread beyond boundaries and sovereignty, nation states cannot deal with infectious diseases by themselves or by border control despite advancements in medical technology. International co-operation and surveillance are essential to early warning and preparation efforts aimed at

⁷ WHO, WHO World Health Statistics, 2006, available at <http://www.who.int/whosis/whostat2006.pdf> (last accessed on March 22, 2009).

⁸ Maureen Birmaingham and Claudia, 'The Burden of Vaccine-Preventable Diseases', Barry R. Bloom, Paul-Henri Lambert edited, The Vaccine Book, P.14, Academic Press, 2002 and WHO, 'HIV-related TB Deaths Higher than Past Estimated', 2009, available at

http://www.who.int/mediacentre/news/releases/2009/tuberculosis_report_20090324/en/print.html (last accessed on March 24, 2009)

There are 1.37 new TB cases in 2007 among HIV-infected people, says new global TB control report.

⁹ Take the example of bird flu, which has been identified as common flu in bird species has now, cross the barrier as the H5N1 and could cause infection on human populations. This dissertation also proposes that in order to have right to health to human bring, attentions should also by paid to pharmaceutical products to possible vectors.

controlling the global threat posed by the emergence and re-emergence of infectious diseases.

Chronic Diseases

The major cause of deaths among children is infectious diseases; by contrast, the current major cause of death among adults is chronic diseases. Globally, of the 58 million deaths in the world in 2005, 35 million were attributed to non-communicable diseases. This number is double the number of deaths from infectious diseases, including HIV/AIDS, tuberculosis and malaria, maternal and perinatal conditions, and nutritional deficiencies.

The number of deaths caused by chronic diseases is fairly equal for men and women. Out of the 35 million of deaths, 45% occurred prematurely, 16 million were under 70 and around 80% of deaths occurred in developing countries.¹⁰ In addition to the high death toll, the burden of chronic diseases is also heavy skewed. When measuring the burden of disease by disability adjusted life year (DALY)¹¹, approximately half of the disease burden is due to chronic disease. Among the chronic diseases, the leading causes are cardiovascular diseases, cancer, and chronic respiratory disease.¹² Unlike the death rate for chronic diseases that predominate in developing countries, chronic diseases contribute considerably to the disease burden of all income groups.¹³

¹⁰ WHO, *World Health Statistics*, P.14, 2006, available at <http://www.who.int/whosis/whostat2006.pdf> (last accessed on March 22, 2009)

The rate is higher and the age of death is younger in the developing countries, where most of the world population lives.

¹¹ WHO, *Prevention Chronic Diseases: A Vital Investment*, P.39, 2005, available at www.who.int/chp/chronic_disease_report/full_report.pdf (last accessed on March 16, 2009)

The method of the disability adjusted life year (DALY) is using the combination of number of year of healthy life lost to premature death with the time spent in less than full health. One DALY can be thought of as one lost healthy year of life.

¹² WHO, *World Health Statistics*, P.14, 2006, available at <http://www.who.int/whosis/whostat2006.pdf> (last accessed on March 22, 2009)

¹³ WHO, *Prevention Chronic Diseases: A Vital Investment*, P.61, 2005, available at www.who.int/chp/chronic_disease_report/full_report.pdf (last accessed on March 16, 2009)

The burden of infectious and chronic diseases is both loaded in middle and low countries. The figure might imply

An estimated 17.5 million people died from cardiovascular disease in 2005, representing 30 % of all global deaths.¹⁴ Cancer, as the second leading cause of death, claimed 7.6 million lives in 2005¹⁵, which is about 13% of the world's deaths, and 70% of the deaths were in developing countries. The high prevalence of cancer is ominously shifting from developed nations to the poorer, less medically equipped countries. It is estimated that by the end of 2015, the number of deaths caused by cancer will rise to 9 million, and could reach 11.5 million by the end of 2030.¹⁶ Respiratory tract diseases are diseases of the airways and other structures of the lung that affect the air passages, including the nasal passages, the bronchi and the lungs.¹⁷ The top five chronic respiratory diseases account for 17.4% of all deaths and 13.3% of all Disability-Adjusted Life Years (DALYs).¹⁸ An estimated 2.2 million people died from diabetes in 2005.¹⁹ 80% of the deaths occurred in developing countries. Almost 50% of the deaths occurred in people under 70, and 55% of the deaths were women.²⁰

Diseases affect the public health as well as individual health. The global trade in goods

that the socioeconomic status do have some relationship between the condition of health.

¹⁴ WHO, Cardiovascular Diseases, available at

www.who.int/topics/cardiovascular_diseases/en/ (last accessed on March 16, 2009)

¹⁵ WHO, *The World Health Organization's Fight Against Cancer: Strategies that Prevent, Cure and Care*, P.4, 2007, available at

www.who.int/cancer/publicat/WHOCancerBrochure2007.FINALweb.pdf (last accessed on March 16, 2009)

At least 7 million of people die from cancer. The number of death is even more than the total deaths of the combination of HIV/AIDS, malaria and tuberculosis. Thus, chronic disease has been a real problem to the population.

¹⁶ WHO, *The World Health Organization's Fight Against Cancer: Strategies that Prevent, Cure and Care*, P.3, 2007, available at

www.who.int/cancer/publicat/WHOCancerBrochure2007.FINALweb.pdf (last accessed on March 16, 2009)

¹⁷ WHO, Chronic Respiratory Diseases, available at

www.who.int/respiratory/en/ (last accessed on March 16, 2009)

¹⁸ WHO, WHO Strategy for the Prevention and Control of Chronic Respiratory Diseases, 2002, available at

www.who.int/entity/respiratory/publications/WHO_MNC_CRA_02.1.pdf (last accessed on March 16, 2009)

¹⁹ WHO, 'Diabetes: Fact Sheet', 2008, available at

www.who.int/mediacentre/factsheets/fs312/en/print.html (last accessed on March 16, 2009)

WHO projects that death caused by diabetes will increase by more than 50% in the next 10 years without urgent action. Most notably, diabetes deaths are projected to increase by over 80% in upper-middle income countries between 2006 and 2015.

²⁰ WHO, 'Diabetes: Fact Sheet', 2008, available at

www.who.int/mediacentre/factsheets/fs312/en/print.html (last accessed on March 18, 2009)

and people spreads infectious diseases and worsens the burden of chronic diseases worldwide. The burdens of diseases seriously affect countries' economies and societies in both developed and developing countries.

The Problem

The effects of the globalization, urbanization, and population-aging drive social, economic and cultural change, especially with regards to the underlying determinants. The rapid changes of underlying determinants affect individual health and public health in diseases and pharmaceuticals. Health inequalities have expanded from the risk of infectious diseases to risk factors for chronic diseases. The burden²¹ of diseases causes poverty and hinders the economic development of many countries. Diseases can turn poverty into a downward spiral of worsening disease and poverty while the socioeconomic inequalities jeopardize a population's health.²²

Health and health-related issues, particularly regarding how to balance the interests of transnational pharmaceutical corporations by offering incentives for R&D while providing accessible and affordable pharmaceutical products for patients/consumers to realize the international human right to health, get enmeshed in the field of foreign policies and political

²¹ WHO, *World Health Statistics*, 2006, P.14, available at <http://www.who.int/whosis/whostat2006.pdf> (last accessed on March 22, 2009)

Applying the widely used "DALYS" summary measure of the burden of disease (disability-adjusted life-years), which combines years of healthy life lost to premature death with time spent in less than full health. When compared with 13% by injuries and 39% by communicable diseases, maternal and perinatal conditions and nutritional deficiencies combined, non-communicable diseases cause almost half of the global burden of disease.

²² WHO, *Prevention Chronic Diseases: A Vital Investment*, P.66, 2005, available at www.who.int/chp/chronic_disease_report/full_report.pdf (last accessed on March 18, 2009)

Disease and poverty will fall into a cycle. The burdens of disease have direct and indirect economic impact of individuals and families, which makes the health services and pharmaceutical even more inaccessible and unaffordable.

economy.

Ideally, globalization would cause actors in the international community to form a global village and conduct trade in a cooperative and supportive manner, but in practice, the globalization of pharmaceuticals gets stuck in a bottleneck when it comes to distributing interests, thus jeopardizing the equality necessary for maintaining the health of the world population.

Health and diseases are national and political issues falling within the obligations for which each state is responsible and accountable. The emerging global economy promotes and changes the rapid attention to the involvement of non-state actors on the global health and the commercialization of pharmaceutical-related science and technology. The tangle of globalization, international relations, and politics makes health issues even more pressing and certainly more complicated.²³ Issues of availability and affordability of pharmaceuticals, especially in developing countries, have become an urgent problem in need of practical solutions,²⁴ and require a deeper understanding of the impact of globalization on human right and health concerns.

Carrying a special mission, pharmaceutical products have been both the front line and last resort contributing to the human rights to health, and often determining life or death; however,

²³ WHO, *Globalization, Trade and Public Health: Tools and Training for National Action*, P.1, 2001, available at http://whqlibdoc.who.int/searo/2001/SEA_HSD_244.pdf (last accessed on March 18, 2009)

“While globalization and trade liberalization have implications for health, a consensus on the mechanisms by which they affect the health of populations and pathways for the protection of health has remained elusive.”

²⁴ Bhushan Patwardhan, *Traditional Medicine: Modern Approach for or Affordable Global Health: Could more effective use be made of them in providing affordable treatments*, P.17, 2005, available at www.who.int/intellectualproperty/studies/B.Patwardhan2.pdf (last accessed on March 18, 2009)

Globalization has the most impact in developing countries. The disproportionate growth and the diseases, the burden of diseases has gone beyond for the reach of the population. The poverty, the burden of diseases falls into a vicious circle.

pharmaceutical products are also one of the goods which are the subject of global trade. All actors involved in the international community have to recognize the right to health in the context pharmaceuticals as a basic human right in order to realize the right and co-operate under international law.

Examining the problems of realizing the right to health in accessible and affordable pharmaceutical product, this dissertation begins in Chapter 1 with the legal personality of the actors involved in the realization of the right to health. Chapter 2 further explores the uniqueness of pharmaceutical products and development of the pharmaceutical industry. Chapters 3 describes the development of intellectual property protection on pharmaceutical products. Chapter 4 then focuses on the international human rights development of the right to health and discusses on the relationship of the right to health to accessible and affordable pharmaceutical products. Chapter 5 describes in greater detail the responsibility and accountability of the right and how international law should adapt to the global world. Lastly, Chapter 6 returns to the problem of the international human right to health and proposes a resolution to balance the interests.

Section I. Subject of International Law

Chapter One: Legal Personality of Actors Involved in the Human Right to Health

1.1 Legal Personality

International laws form into legal frameworks, in which state actors and non-state actors, such as individuals, private corporate entities, and international organizations, interplay and interact in the international community. Traditionally, the so called public “inter-national” law regulates the relationship between its primary subjects, nation states. However globalization has given non-state actors a growing importance into the international community under international law.

With the vigorously growing global economy, private corporate entities which operate and trade globally gradually becoming transnational corporations, sell their products or service everywhere in the world and are able to negotiate with national governments. Their powers have been so influential that when their businesses constitute the major industries of a nation state, often they influence the negotiation of treaties and engage involvement of foreign policies between nation states. While non-state actors are exercising their powers and influences on the forming or negotiation international law, non-state actors essentially participate in rule-making activities.

As subjects of the various legal systems, persons or entities can hold rights and bear duties,²⁵ and whether non-state actors have the legal personality to bear obligations and are accountable and responsible under international law is the subject of ongoing debate.²⁶ The traditional concept of state-centered public international law has dominated the law for years.

²⁵ Chris N. Okeke, *New Subject of Contemporary International Law*, P.9, P.19, 1973

²⁶ Andrew Clapham, *Human Rights Obligations of Non-State Actors*, P.62, Oxford University Press, 2006

Due to the effects of globalization, some approaches propose to expand international law's reach to cover non-state actors as well as state actors, while other approaches object to claim the legal responsibility and accountability beyond the traditional concept of state-centered international law.²⁷

One approach insists that states are the main actors and the only obligor of human rights under international law. The state actors will be accountable for failing to establish legal systems to enforce their own laws against the non-state actors. State actors are responsible for regulating the non-state actors, and ensuring that they comply with and do not violate international law. This approach suggests that having new subjects in international law might diffuse accountability.²⁸

A second approach addresses the increasing irrelevance and powerlessness of state actors in the globalized world. This theory claims that there should be legal systems and transnational justice to respond to globalization. This approach recognizes the importance of non-state actors, but it does not seek to impose duties on non-state actors as subjects of international law directly; state actors would still remain as the main actors in international law. According to this theory, the interactions between state actors and non-state actors do not create customary international law; only interaction between state actors can create such law. Thus, there are cases in which non-state actors might be bound by international agreements, but these non-state actors do not enter the international law making processes.²⁹

²⁷ Chris N. Okeke, *New Subjects of Contemporary International Law Through Their Treaty-making Capacity*, P.9, P.19, 1973

²⁸ Andrew Clapham, *Human Rights Obligations of Non-State Actors*, P. 25-29, Oxford University Press, 2006

²⁹ Andrew Clapham, *Human Rights Obligations of Non-State Actors*, P. 25-29, Oxford University Press, 2006

This dissertation suggests the third approach postulating rights and duties through capacity rather than traditional concept of subjectivity. In his epic work Professor Christian Okeke outlines three essential elements of a qualified subject of a legal system. Firstly, that entity is capable of claiming benefits of the rights conferred by the law; secondly, such an entity must bear duties for violation of those duties; thirdly, with the capacity that entity can pose contractual capacity or other legal relationship with other subjects of the system, but the extent may vary with the nature of the person or entity.³⁰ Daniel O'Connell also states that capacity implies personality, as in the capacity to do those particular acts.³¹ Here, capacity refers not only the capacity to enjoy rights and obligations, but also the capacity to be held accountable for failure to fulfill those obligations.

This approach claims to retain the importance of state actors within public international law, but proposes to expand and goes beyond the traditionally state-focused aspects of international law and subjects of international law to some non-state actors; however, this approach does not suggest that all non-state actors could serve as law makers.³² International law does not prescribe which if any entities are entitled to an international personality, or which are recognized as being subject to international law. When the non-state actors serve important functions and hold the same power as state actors, such as the Vatican's Holy See, insurgent or belligerent parties, non-governmental organizations, or transnational corporations, these entities

³⁰ Chris N. Okeke, *New Subjects of Contemporary International Law Through Their Treaty-making Capacity*, P.9, P.19, 1973 and see also Emeka Duruigbo, 'Corporate Accountability and Liability for International Human Rights Abuses: Recent Changes and Recurring Challenges', 2008, <http://www.law.northwestern.edu/journals/JIHR/v6/n2/2/> (last accessed on March 22, 2009)

³¹ Andrew Clapham, *Human Rights Obligation of Non-State Actors*, P.71, Oxford University Press, 2006

As Klabbers concludes, personality is just like subjectivity in international law.

³² Andrew Clapham, *Human Rights Obligations of Non-State Actors*, P. 25-29, Oxford University Press, 2006 and Chris N. Okeke, *New Subject of Contemporary International Law*, P.205-206, 1973

are said to assume into international legal responsibility and accountability.³³

International law has already addressed the concerns regarding the duties and obligations of individuals both in their public and private capacities. Today, international law has also extended this concern to inter-governmental organizations.³⁴ The role of non-state actors in today's world cannot be ignored, yet there is no international standard or framework to explain the rights and duties of transnational corporations (TNCs) under international law.

1.2 Transnational Corporations and International Human Rights Law

The issue of whether the TNCs can be held accountable or responsible for international human rights depends on the status and characteristics of non-state actors under international law in the global world. Responding to the increasing importance and influential status of TNCs, there are various approaches addressing the application of these obligations to TNCs.

Traditionally TNCs are not parties to international human rights treaties even though TNCs play essential roles in global trade and participate in shaping international law indirectly.³⁵ State actors are bound by international law to ensure TNCs' conformity to international human rights protection; whether nation states have power to enforce and ensure international human rights protection on TNCs is another question.³⁶ The state-centered approach suggests that the

³³ Chris N. Okeke, *New Subject of Contemporary International Law*, P.220, 1973

³⁴ Remigius Chibueze, 'The Legal Personality of Non-State Entities in International Law: A Settled Issues?', Chima Centus Nweze edited, *Contemporary Issues on Public International Law: Essays in Honor of Professor Dr. Christian Nwachukwu Okeke*, P.171-188, Vandepas Publishing, 2009

³⁵ Emeka Duruigbo, 'Corporate Accountability and Liability for International Human Rights Abuses: Recent Changes and Recurring Challenges', 2008, available at www.law.northwestern.edu/journals/JIHR/v6/n2/2/ (last accessed on March 18, 2009)

³⁶ Many corporations, especially multinational corporations, have more power, resources or influence than many small nation states in the world now.

extension of international human rights protection to TNCs will thereafter chip away at the foundation of the human rights movement, thereby accelerating the chances of its eventual disintegration and ruin.³⁷

International human rights protection is the very fundamental protection of the dignity of human beings. Today, international human rights protections have new needs and demands because of the participation of influential and important non-state actors in the international community. International law and international human rights machinery and norms should respond to these needs and demands in order to continue offering effective and sustainable international human rights protections.³⁸

A corporation has legal personality under the national domestic law of the state of its incorporation or establishment. The issue of the legal subjectivity of TNCs to international law is even more complex. There has been strong resistance to including TNCs within legal definitions as having international legal personality, thereby acquiring responsibility and accountability on international human rights protection.³⁹ There are fears that treating non-state actors with the same status as nation states would implicitly suggest that non-state actors are being endowed with the rights and obligations of nation states, and would be called upon to perform important and influential functions. However, the reality is that some of the TNCs are more influential than some nation state actors. Disregarding the status of these TNCs under

³⁷ Andrew Clapham, *Human Rights Obligation of Non-State Actors*, P.32, Oxford University Press, 2006

³⁸ Andrew Clapham, *Human Rights Obligation of Non-State Actors*, P.32, Oxford University Press, 2006

As Christine Chinkin states, “[t]here is apprehension that to transform the vision of human rights to include acts by private individuals would disturb and undermine the entire edifice of human rights. ... If human rights law is so fragile that it cannot withstand such re-conceptualization, then it is barely worth preserving.”

³⁹ Remigius Chibueze, ‘The Legal Personality of Non-State Entities in International Law: A Settled Issues?’, Chima Centus Nweze edited, *Contemporary Issues on Public International Law: Essays in Honor of Professor Dr. Christian Nwachukwu Okeke*, P.189-196, Vandeplas Publishing, 2009

international law would be very dangerous and harmful, especially with regard to the international human rights protection. Professor Andrew Clapham observes that “[i]f international law is to be effective in protecting human rights, everyone should be prohibited from assisting governments in violating those principals, or indeed prohibited from violating such principle themselves.”⁴⁰

International human rights protection has traditionally been regulated by the relationship between the national governments, individuals and groups. With the impacts and increased roles of non-state actors at both the national and international level, attention must be paid to the responsibilities and accountabilities of non-state actors. However, to date, the practical meaning of the link between non-state actors, business, and human rights remains uncertain, and there is much debate over how and which human rights can and should apply to non-state actors.⁴¹

1.3 Transnational Pharmaceutical Corporations and TRIPS

With the recent trend towards economic globalization, pharmaceutical corporations have also acquired or merged beyond their national boundaries. Many of the pharmaceutical corporations are now composed as TNCs.⁴² The transnational pharmaceutical corporations are among the most important non-state actors in the international community, because their products and influences have a global impact on both public and individual health.

⁴⁰ Andrew Clapham, *Human Rights Obligation of Non-State Actors*, P.80, Oxford University Press, 2006

⁴¹ Office of the United Nations High Commissioner for Human Rights, *Globalization—Business and Human Rights*, available at

<http://www2.ohchr.org/english/issues/globalization/business/index.htm> (last accessed on March 18, 2009)

⁴² Global 500 Industry, 2008, available at

<http://money.cnn.com/magazines/fortune/global500/2008/industries/21/index.htm> (last accessed on March 18, 2009)

Transnational pharmaceutical corporations have influential powers on the national government and also the international organizations, which they exert by lobbying both their individual and collective interests. Transnational pharmaceutical corporations and the interested state actors influence negotiations and jointly promote their interests on a global scale during the negotiation and formation the Agreement on Trade-Related Aspect of Intellectual Property Rights (TRIPS), 1994,⁴³ and through the patent protection on pharmaceutical products, all WTO members are bound to minimum protection pharmaceutical products.

1.4 Concluding Summary

Transnational pharmaceutical corporations are important non-state actors on the global stage, exerting influence on international policy as well as impacting the life or death and well being of entire populations through their policies and business practices. These transnational pharmaceutical corporations demonstrated their power during the TRIPS negotiation and shape the public international law to provide legal grounds to protect their interest and inject their value in global economic and political policies and foreign relations. Therefore, by playing important roles and functions in this international community, transnational pharmaceutical corporations should not only be subject to international law but also bear responsibility and accountability international human rights.

⁴³ Susan Sell, *Private Power, Public Law: The Globalization of Intellectual Property Rights*, P.1-2, Cambridge University Press, 2003

The US-based Intellectual Property Committee (IPC) played a pivotal role in TRIPS. IPC consists of executive officer from main industry of the US, representing pharmaceuticals, entertainment and software industries. Mohamed Mmar Gad, *Representational Fairness in WTO Rule-Making: Negotiating, Implementing and Disputing the TRIPS Pharmaceutical-Related Provisions*, P.87-92, British Institute for International & Compara, 2006

Section II. Pharmaceuticals in International Law

Chapter Two: Pharmaceutical Status and Pharmaceutical Industry

2.1 Introduction.

Pharmaceutical products not only provide enormous benefits to the length of human life, but also improve the quality of life by relieving pain, preventing diseases and reducing the rate of death or disability that results from disease. From the perspective of health economics, pharmaceuticals reduce the cost of treating diseases.

Pharmaceutical products are unique consumer products with special characteristics. Most pharmaceuticals are not substitutable because they treat different illnesses due to their special methods depend on patients' personal conditions. Therefore pharmaceutical products should not be treated as common goods and allowed to flow into the relevant markets without special treatment and regulations.

Consuming Process and Decision Making in the Use of Pharmaceutical Products

The process of consuming pharmaceutical products is very different from other consumer products, except the over-the-counter drugs (OTC)⁴⁴. The consuming process of pharmaceuticals is: the pharmaceutical companies manufacture the pharmaceuticals, the sales representatives promote the drugs to physicians, the physicians⁴⁵ prescribe the medicines to end users, and the patients pay for the prescriptions. The end user and the consumer are different most of the time and the physicians are agents of patients, acting as experts to choose suitable

⁴⁴ The purchase decision of the OTC drugs is made by consumers/patients for self-medication by following the direction on the label. The decision making of the use of prescription-only drugs is made by physicians only.

⁴⁵ Therefore, the demand of pharmaceutical products is not ultimately depend on patients, but physicians and the retail and hospital pharmacists who dispense the prescriptions.

pharmaceuticals.

Normally, patients are not responsible for the decision-making process to determine the use of specific pharmaceuticals; physicians are responsible for prescribing medicines.⁴⁶ Patients make the decision to buy pharmaceutical products. Most of the time, physicians' and patients' decisions are influenced by the trademark, marketing promotions from the pharmaceutical sales persons, and advertisements. A third-party, such as hospital utilization or insurance companies' review, may have influence on the demand for pharmaceutical products. Monitoring third-party payers can help to ensure physicians appropriately prescribe their medicines.⁴⁷

Easy Reproduction

Some of the pharmaceuticals can be reproduced easily because the ingredients and the formulas are disclosed under the requirements of laws and regulations. Because of this special characteristic, pharmaceutical companies try hard to lobby for stricter laws and regulations to protect their investments from infringement. Patent protection is applied as an exchange in which the inventors disclose the best mode of the invention; in return, the patent laws protect the economic profits of the patent right holders over a period of time, which is usually an exclusive right for twenty years.⁴⁸ Pharmaceutical patent holders can then prevent potential competition.

⁴⁶ Yet, the physicians usually select of high-priced, brand-name drugs when there are comparable generics.

⁴⁷ Rexford E. Santerre and Stephen N. Neun, *Health Economics: Theories, Insights, and Industry Studies*, 3rd Ed., P.439-440, South-Western College Pub, 2003

⁴⁸ Rexford E. Santerre and Stephen N. Neun, *Health Economics: Theories, Insights, and Industry Studies*, 3rd Ed., P.444-445, South-Western College Pub, 2003

The effective duration of patent protection is usually shorter due to the drug administration takes a few years to approve a pharmaceutical product for commercial introduction. In US, the passage of Drug Price Competition and Patent Term Restoration Act of 1984 (Hatch-Waxman Act), the effective life of a new drug patent is extended by a maximum of 5 years, but not beyond 14 years of effective life.

While pharmaceutical products are still under the protection of their patents, due to the inaccessibility or unaffordability of the pharmaceutical products, counterfeit or unauthorized reproductions of the medicines often appear in the black market. Because these medicines are unregulated, they are almost invariably substandard and pose serious health risks.

2.2 Chemical Compound Medicines

2.2.1 Present State of Chemical Compound Medicines

Chemical compound pharmaceutical products are the major product of the pharmaceutical industry today. The majority of the users of chemical compound pharmaceuticals are in developed countries, for the possible reason that the chemical compound pharmaceuticals are more available and affordable for them.

The largest groups of products in the world-wide market used to be antibiotics, but are now cardiovascular pharmaceuticals.⁴⁹ All the therapeutic segments showed significant growth in 2003 (over 20%).⁵⁰ The IMS estimates that due to the influence of the transitional period of the patent expiry blockbusters and the new pharmaceuticals, the industry has seen declining costs of drug treatment in major therapy areas, increased uncertainty over safety, pricing and market access and other intellectual property issues. IMS also forecasts that the global pharmaceutical market will shift from the top seven markets to emerging markets⁵¹ and from primarily

⁴⁹ Ronald P. Evens edited, *Drug and Biological Development: From Molecule to Product and Beyond*, P.12, Springer, 2007

In the 200 products in therapeutic market, the top was cardiovascular products, followed by central nervous systems, oncology, infectious diseases, gastrointestinal diseases and respiratory areas.

⁵⁰ John P. Griffin and John O'Grady edited, *The Textbook of Pharmaceutical Medicine*, 5th Ed., P.342, BMJ Books, 2006

⁵¹ Because of the profit margins are not as good as before, pharmaceutical companies start to engage in R&D in the pharmaceutical products which reflect the markets in the developing potential countries, such as China, India and Brazil and IMS, 'IMS 2008 Global pharmaceutical Market Forecast, 2008', available at

care-driven practice to specialty care-driven drugs.⁵²

The Blockbuster

Blockbuster pharmaceuticals are defined by sales levels of at least \$1 billion per year, and these drug patents are usually held by the top 10 companies. The ten best selling drugs account for 12% of all medicine production.⁵³ The blockbuster pharmaceutical market included 94 products accounting for \$186 billion US worldwide, which represent 33.8% of the total pharmaceutical sales in 2004. The patent expiry blockbusters have made pharmaceutical companies very nervous because of the difficulties in R&D of new pharmaceuticals, and the new pharmaceuticals cannot make up to the loss suffered by the off-patent pharmaceuticals.⁵⁴

www.imshealth.com/web/content/0,3148,64576068_63872702_70260998_82829532,00.html (last accessed on March 18, 2009)

Global pharmaceutical sales will still grow 5~6%, which is over US\$735 billion in 2008, but is lower than 6~7% compared with sales in 2007. In the U.S and Europe's top five markets, growth of 4~5 % is expected - an all time low for the U.S. - while Japan will see an even smaller increase of 1~2%. The seven "pharmerging" markets of China, Brazil, Mexico, South Korea, India, Turkey and Russia will experience growth of 12-13 percent to reach \$85-90 billion, driven by greater access to generic and innovative new medicines as primary care improves and becomes more available in rural areas, and as more people take out private health insurance. The seven largest markets will contribute just half of overall pharmaceutical growth, while seven emerging markets will contribute nearly 25 percent of growth worldwide.

⁵² IMS, 'IMS 2008 Global pharmaceutical Market Forecast', 2008, available at www.imshealth.com/web/content/0,3148,64576068_63872702_70260998_82829532,00.html (last accessed on March 18, 2009)

⁵³ WHO, *The World Medicines Situation*, P.3, 2004, available at

www.searo.who.int/LinkFiles/Reports_World_Medicines_Situation.pdf (last accessed on March 18, 2009)

⁵⁴ Ronald P. Evens edited, *Drug and Biological Development: From Molecule to Product and Beyond*, P.12, Springer, 2007

* Blockbuster Pharmaceuticals in 2004⁵⁵

Lipitor	11.59	Pfizer/Astel	Risperdal	3.05	J&J
Piavix/Iscover	5.39	BMS/S-A	Remicade	2.90	J&J/Sch-PI
Zocor	5.20	Merck	Cozaar/Hyzaar	2.82	Merck
Advair/Seretide	4.50	GSK	Neurontin	2.72	Pfizer
Norvasc	4.46	Pfizer	Pravachol	2.64	BMS
Zyprexa	4.42	Lilly	Singulair	2.62	Merck
Nexium	3.88	AstraZen	Rituxan/MabThera	2.62	Riche/Gen
Procrit/Eporex	3.59	J&J	Epogen	2.60	Amgen
Novo-insulin	3.43	NovoNord	Prevacid	2.59	Tap
Zoloft	3.36	Pfizer	Enbret	2.58	Amgen/Wy
Effexor	3.35	Wyeth	Aranesp	2.47	Amgen
Celebrex	3.30	Pfizer	Lovenox/Clexane	2.37	San/Aven
Fosfamax	3.16	Merck	Duragesic	2.08	J&J
Diovan/Co-Diovan	3.09	Novartis			

Generic Pharmaceuticals

Pharmaceutical products enjoy patent protection for a limited time, usually twenty years. Once the patent expires, generic competition rapidly enters the market. With the pharmaceutical prices and patent expiry blockbuster pharmaceuticals, generic pharmaceuticals continue to grow at an expected rate of 14-15%. When the patent expired, the generic products will be substituted for 55% of the patented prescriptions. The greater use of generics is driven by incentives from new government policies that encourage the use of these less expensive generic pharmaceuticals⁵⁶

Essential Medicines

The essential medicine framework is encouraged by the WHO to offer lists of the essential medicines which are intended to be available within the context of functioning health care

⁵⁵ Ronald P. Evens edited, *Drug and Biological Development: From Molecule to Product and Beyond*, P.12, Springer, 2007

⁵⁶ IMS, 'IMS 2008 Global Pharmaceutical Market Forecast', 2008, available at http://www.imshealth.com/web/content/0,3148,64576068_63872702_70260998_82829532,00.html (last accessed on March 18, 2009)

systems at all times and in adequate amount, in the appropriate dosage forms, with assured quality, and at affordable price for individuals and the community.⁵⁷ The essential medicines are in an inventory of medicines with ensured safety, efficacy, and cost-effectiveness so that they can treat pressing global health concerns.⁵⁸

2.2.2 Industry

The development of the pharmaceutical industry started in the late 1800s with the synthetic versions of natural compounds in Europe. The research-based pharmaceutical industry began with the development of sulfanilamide in the mid-1930s and penicillin in 1938. During the Second World War, because of increased demand for pharmaceuticals, the production of pharmaceuticals changed from handcraft methods of drug preparation for individual prescriptions to mass production techniques.⁵⁹

Following the high potential profits of the pharmaceuticals, the pharmaceutical industry drew upon further innovation, expanding exponentially by the postwar period. Since the late 1980s, pharmaceutical companies have been undergoing significant reconstruction towards the formation of larger and fewer companies through mergers, acquisitions, joint ventures and

⁵⁷ WHO, 'Essential Medicines', available at www.who.int/medicines/services/essmedicines_def/en/print.html (last access on March 18, 2009)

⁵⁸ WHO, 'Essential Medicines', available at www.who.int/medicines/services/essmedicines_def/en/print.html (last access on March 18, 2009)

The model list of essential medicines was created by the WHO expert panel in 1997, and gives member states a guide to adapt to the needs of various nations. The list is revised every two years to reflect current health challenges. Currently, 156 out of the 193 member states have official essential medicine lists. In 1977, the first list identified 208 essential medicines to battle the global disease burden at that time. Today, the list comprises up to 340 medicines to treat diseases by prioritizing various conditions such as malaria, HIV/AIDs, tuberculosis, reproductive health, and chronic diseases such as cancer and diabetes.

⁵⁹ Rexford E. Santrees and Stephen P. Neun, *Health Economics: Theories, Insights, and Industry Studies*, 3rd Ed., P.434, South-Western College Pub, 2003

Chemical firms, such as Lederle and Merck, found ways to produce drugs in bulk form, which were then transformed into dosage form (e.g., powders and tablets) by drug companies, such as Upjohn. Pfizer developed a fermentation process to allow penicillin to be produced in large quantities.

strategic alliances. The reconstruction of the companies offers the benefits of increasing scale of operations, diversities, range of the products, and concentration of the investments.⁶⁰

Currently, the global pharmaceutical market is worth US\$300 billion a year and it is expected to increase to US\$400 billion within 3 year.⁶¹ The world's top ten pharmaceutical companies represent at least one-third of that market. Some of the sales are more than US\$10 billion a year, with profit margins of about 30%.⁶² The top ten pharmaceutical companies are mostly located in the US and Europe. A few transnational pharmaceutical companies dominate the global production, trade and sale of medicine. Ten of the mega transnational pharmaceutical companies now account for almost half of all sales.⁶³

The medicine production is concentrated in developed countries, with over 90% of the world production located in the USA, Japan, Germany, France, and the UK, which account for

⁶⁰ Kelley Lee edited, *Globalization and Health: An Introduction*, P.71, 2003

The concentration deals of the pharmaceutical industry were estimated to be \$80 billion US between 1994 and 1997. During 1996 to 2001, the figure raised up to \$500 billion, with another half of 2000 including the merger of Glaxo Wellcome and Smith Kline Beecham (US\$160 billion) and Pfizer and Warner-Lambert (US\$85 billion) and IMS, 'New Patterns Emerge in Pharma M&A', available at www.imshealth.com/web/content/0,3148,64576068_63872702_70261002_77707758,00.html (last accessed on March 18, 2009)

Since the tortuous demise of healthcare giant Johnson & Johnson's proposed \$24 billion acquisition of medical device manufacturer Guidant in January 2006, the era of the mega-merger within the pharmaceutical and biotechnology industries appeared to be at an end. The last such deal took place in August 2004, when the acrimonious marriage between Sanofi-Synthelabo and Aventis was consummated. While mega-mergers no doubt lead to increased critical mass, as demonstrated by the global rankings of Pfizer (including, for example, Pharmacia, Warner-Lambert), GlaxoSmithKline (Glaxo Wellcome, SmithKline Beecham) and sanofi-aventis, many industry executives now acknowledge that they do not always bring a solution for every problem - particularly poor R&D productivity. Indeed, mergers can actually disrupt the work of researchers as pipelines are reviewed and projects reprioritised. GSK, for one, has since split up its R&D teams into smaller groups based on therapy areas, to encourage the levels of innovation seen in smaller biotechnology rivals.

⁶¹ CNN, 'Global 500 Industry', 2008, available at <http://money.cnn.com/magazines/fortune/global500/2008/industries/21/index.htm> (last accessed on March 18, 2009)

⁶² WHO, Pharmaceutical Industry, available at www.who.int/trade/glossary/story073/en/print.html (last accessed on March 18, 2009)

⁶³ WHO, *The World Medicines Situation*, 2004, P.3, available at www.searo.who.int/LinkFiles/Reports_World_Medicines_Situation.pdf (last accessed on March 18, 2009)

two-thirds of the value of all medicine produced.⁶⁴

* The World's Top Ten Pharmaceutical Companies⁶⁵

Company (Headquarters)	Rank	Sales (US \$billion)	Market Share (%)
Pfizer (US)	1	23.1	7.3
GlaxoSmithKline (UK)	2	22.0	6.9
Merck (US)	3	16.5	5.2
Astra Zeneca (UK/Sweden)	4	14.3	4.5
Bristol-Myers Squibb (US)	5	13.3	4.2
Novartis (Switzerland)	6	12.4	3.9
Johnson & Johnson (US)	7	12.3	3.9
Aventis (Germany/France)	8	11.3	3.6
Pharmacia (Sweden/US)	9	10.2	3.2
American Home Products (US)	10	9.6	3.0

Other lower-priced medicines exist in highly competitive countries, such as the domestic markets of China and India.⁶⁶ Countries with innovative capability in pharmaceutical products grow rapidly in their bio-pharmaceutical industries.⁶⁷ The US pharmaceutical market performance is leading among the group. According to the annual US Pharmaceutical Market Performance Review, the overall sales growth in the US prescription market was 3.8% in 2007, and total sales reached \$286.5 billion, the slower sales growth resulting from loss of patent expiry pharmaceuticals, fewer new product approvals, and the impact of safety issues.⁶⁸

The market is highly competitive, with a large number of equally-sized pharmaceutical

⁶⁴ WHO, *The World Medicines Situation*, 2004, P.6, available at www.searo.who.int/LinkFiles/Reports_World_Medicines_Situation.pdf (last accessed on March 18, 2009) India, for example, has rapidly growing pharmaceuticals biotechnology market currently estimated to be worth over US\$ 1 billion, and in 1999–2000 spent some US\$ 66 million on medicines R&D, up from US\$ 2.2 million in 1976-1977.

⁶⁵ Kelley Lee edited, *Globalization and Health: An Introduction*, P.72, Palgrave Macmillan, 2003

⁶⁶ WHO, *The World Medicines Situation*, 2004, P.3, available at www.searo.who.int/LinkFiles/Reports_World_Medicines_Situation.pdf (last accessed on March 18, 2009)

⁶⁷ WHO, *The World Medicines Situation*, 2004, P.6, available at www.searo.who.int/LinkFiles/Reports_World_Medicines_Situation.pdf (last accessed on March 18, 2009)

⁶⁸ IMS, 'IMS Health Reports U.S. Prescription Sales Grew 3.8 Percent in 2007, to \$286.5 Billion', 2008, available at www.imshealth.com/ims/portal/front/articleC/0,2777,6319_3665_83470499,00.html (last accessed on March 18, 2009)

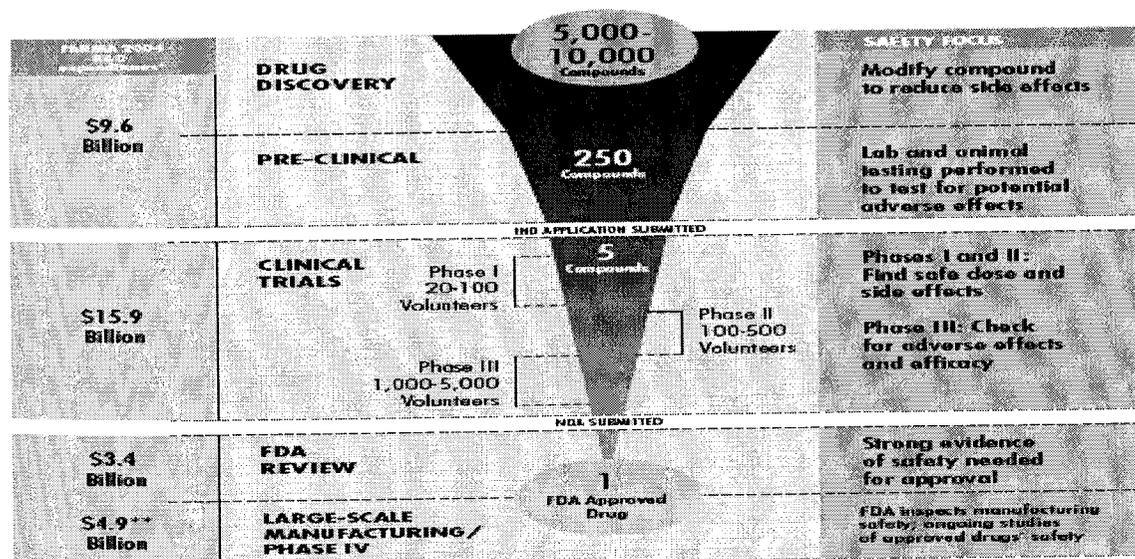
There are many factors contribute to the slower sale, from possibly loss of patent expiry blockbusters, fewer product approvals, stricter safety issues and the leveling year-over-year growth from the US Medicare Part C Program, etc.

companies. Only a few major pharmaceutical companies normally interact within most therapeutic markets, which treat common diseases or illnesses. Thus, the concentration ratios of the therapeutic markets are more monopolistic than the structure of the pharmaceutical industry.⁶⁹

2.2.3 Challenges

Pre-Clinical, Clinical and Post-Clinical Trials

Pharmaceuticals are required to prove safety, efficacy, and quality under the laws of each country by undergoing a series of tests and trials. The pharmaceutical candidates are subject to pre-clinical and clinical trials to pass examination by the regulatory authority in order to put the pharmaceutical products into the market. About 20% of the candidates will fail during these processes.⁷⁰



⁶⁹ Adapted from Appendix Table 4, uncategorized: \$3.2 billion.
⁷⁰ This figure includes Phase IV testing only.

⁶⁹ Rexford E. Santrees and Stephen P. Neun, *Health Economics: Theories, Insights, and Industry Studies*, 3rd Ed., P.436-437, South-Western College Pub, 2003

⁷⁰ PHRMA, *Pharmaceutical Industry Profile*, 2006, P.12, available at <http://www.phrma.org/files/2006%20Industry%20Profile.pdf> (last accessed on March 18, 2009)

⁷¹ PHRMA, *Pharmaceutical Industry Profile*, 2006, P.12, available at

Adverse Drug Reaction

After the medicine is produced, it can still pose other safety, efficacy and quality concerns. Medicine treats and prevents diseases, but it can also pose great health risks and may cause adverse reactions in some people. Besides irresponsible use of these drugs due to human error (situations that can be prevented), all medicine has side effects, some of which can be quite damaging. The post-marketing (Phase IV) studies focus on adverse drug reactions. The surveillance studies involve more patients and can provide more information about side effects.⁷²

Substandard and Counterfeit Drugs

Substandard and counterfeit pharmaceutical products are those whose composition and ingredients do not meet the correct scientific specifications. Counterfeit medicines are deliberately and fraudulently mislabeled as to the identity or the sources. They may or may not contain the correct ingredients, active ingredients, or have fake or misleading packaging.⁷³ Substandard and counterfeit pharmaceuticals may occur as a result of human error, insufficient human resources, insufficient financial resources, or the deliberate creation of fake pharmaceuticals.

Counterfeit medicines represent 10% of the global pharmaceutical trade.⁷⁴ The most common counterfeited medicines in developed countries recently have been cholesterol-lowering

<http://www.phrma.org/files/2006%20Industry%20Profile.pdf> (last accessed on March 18, 2009)

⁷² PHRMA, *Pharmaceutical Industry Profile*, 2006, P.14, available at

<http://www.phrma.org/files/2006%20Industry%20Profile.pdf> (last accessed on March 18, 2009)

⁷³ WHO, 'How does WHO define a counterfeit drug (medicine)?', available at

www.who.int/medicines/services/counterfeit/faqs/05/en/print.html (last accessed on March 18, 2009) and WHO, Counterfeit Medicines, Fact Sheet, 2006, available at

www.who.int/mediacentre/factsheets/fs275/en/print.html (last accessed on March 22, 2008)

⁷⁴ WHO, 'Counterfeit Medicines: The Silent Epidemic, WHO convenes Stakeholders to find Global Solution to a Growing Health Threat', 2006, available at

www.who.int/mediacentre/news/releases/2006/pr09/en/print.html (last accessed on March 18, 2009)

medicines, drugs used for treatment of growth hormone deficiency, and those used for cancer treatment. In developing countries, the most counterfeited medicines are those used to treat life-threatening conditions such as malaria, tuberculosis and HIV/AIDS. Antibiotics are also often found among counterfeit medicines.⁷⁵ The WHO estimates that 25-50% of medicines consumed in developing countries are believed to be counterfeit.⁷⁶ A report released by the Centre for Medicines in the Public Interest in the United States projects counterfeit drug sales to reach US\$75 billion in 2010, a 92% increase from 2005.⁷⁷

The purchases and uses of substandard and counterfeit pharmaceuticals are mostly due to the unavailability and unaffordability of pharmaceuticals.⁷⁸ When prices of medicines are high and a great price difference exists between genuine pharmaceuticals and counterfeit pharmaceuticals, there are greater possibilities for the patients/consumers to obtain pharmaceuticals outside the normal supply system. This condition is more serious in rural areas where the normal supply chain fails to reach, or in poorer areas, where the pharmaceuticals are

⁷⁵ WHO, 'The Safety of Medicines', 2005, available at www.who.int/mediacentre/factsheets/fs293/en/print.html (last accessed on March 18, 2009)

⁷⁶ WHO, 'Counterfeit Medicines' Fact Sheet, 2005, available at <http://www.who.int/mediacentre/factsheets/fs275/en/print.html> (last accessed on 22 Mar 2008)

The unregulated market is supplied with stolen and diverted drugs, illicitly manufactured pharmaceuticals sold illegally on the Internet and distributed through the mail and courier services. The consumers/patients do not know that the lower-priced medication is not life-saving drugs, but can take lives. In Africa, the use of counterfeit vaccines in 1995 resulted in 2,500 deaths. The frequent use of substandard or counterfeited medicines can lead to therapeutic failure, drug resistance, or death in some cases.

- During a meningitis epidemic in Niger in 1995, more than 50 000 people were inoculated with fake vaccines resulting in 2 500 deaths. The vaccines were received as a gift from a country which thought they were safe.

- 89 children died in Haiti in 1995 and 30 infants died in India in 1998 due to the consumption of paracetamol cough syrup prepared with diethylene glycol (a toxic chemical used in antifreeze).

- In 2001, in South-East Asia, a Wellcome Trust study revealed that 38% of 104 anti-malarial drugs on sale in pharmacies did not contain any active ingredients.

- In Cambodia, in 1999, at least 30 people died after taking counterfeit anti-malaria's prepared with sulphadoxine-pyrimethamine (an older, less effective anti-malarial) which were sold as artesunate.

⁷⁷ WHO, 'Counterfeit Medicines: The silent Epidemic, WHO convenes Stakeholders to find Global Solution to a Growing Health Threat', 2006, available at

www.who.int/mediacentre/news/releases/2006/pr09/en/print.html (last accessed on March 18, 2009)

⁷⁸ INCB, 'INCB Warns of Counterfeit Medicines Flooding Markets', 2007, available at

www.incb.org/pdf/e/press/2007/annual-report-press-kit-2006-en-2.pdf (last accessed on March 18, 2009)

often unaffordable.⁷⁹

The High Cost in Pharmaceutical R&D

Pharmaceutical R&D is the key driver of the industry. The R&D expenditures have escalated in recent years. The expenses of R&D by the top ten companies in 2004 were \$49.1 billion. For the top fifty world-wide companies, R&D spending as a percentage of total expenditures was 19.4%, ranging from 12.2-31.2%, excluding the generic companies who primarily perform pharmacokinetic equivalence studies and few clinical trials. During the stages of R&D, research spending on clinical trials cost the most, at 35.9%, followed by non-clinical drug work at 21.4% and animal testing at 16.2%.⁸⁰

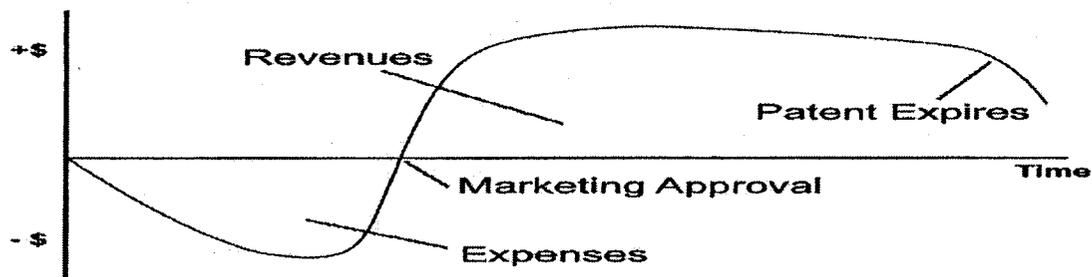


Figure 1.2 Expenses and revenues curve for a new drug

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IMS reported that total U.S. prescription drug spending grew at 8.3 percent in 2004. IMS found that drugs' spending growth was 5.4 percent for 2005 and 5 percent for the 12 months ending July 2006.⁸² Pharmaceutical companies have to ensure a return on the investments

⁷⁹ The major reason for the consumers/patients to buy counterfeit pharmaceuticals is usually the counterfeit pharmaceuticals are cheaper. The sick people believe that they are taking genuine medicine. The major reason for the manufacturer of counterfeit pharmaceuticals is that the pharmaceutical is not hard to reproduce and the marginal profit is so high that individuals could take a risk to manufacture the fake ones.

⁸⁰ Ronald P. Evens edited, *Drug and Biological Development: From Molecule to Product and Beyond*, P.15, Springer, 2007

⁸¹ Rick Ng, *Drugs: From Discovery to Approval*, P.10, Wiley-Blackwell, 2004

⁸² PHRMA, 'Prescription Medicine Spending Trend', available at

made. It is estimated that large pharmaceutical companies need 4 to 5 new drugs approved every year to maintain their status. However, with the low productivity of R&D, most companies only have 1 to 2 new drugs approved per year.⁸³

Bottleneck of the Substance

Despite the high costs of R&D, R&D productivity is declining. The slow and difficult production of new pharmaceuticals has scared many moguls in the industry. The dearth of new products continues to haunt the pharmaceutical industry. There have only been a few new active substances to reach the market, and even fewer have achieved blockbuster status.⁸⁴ The declining rate in R&D productivity is high in major pharmaceutical companies. In Europe, big pharmaceutical companies are launching a declining proportion of New Molecular Entities (NMEs); by contrast, in the US the proportion of NMEs is declining more gradually.⁸⁵ The annual review from the IMS showed that there are just thirty-six new active substances in 2002, which is a 20-year low. There are not enough new candidates to counter the patent expiration of the blockbusters.⁸⁶

<http://www.phrma.org/files/Prescription%20Medicine%20Spending%20Trends%202006%20FINAL.pdf> (last accessed on March 18, 2009)

⁸³ Rick Ng, *Drugs: From Discovery to Approval*, P.8, Wiley-Blackwell, 2004

⁸⁴ IMS, 'Is the Pharma Industry Weathering the "Perfect Storm?"', available at www.imshealth.com/web/content/0,3148,64576068_63872702_70261000_71488550,00.html (last accessed on March 18, 2009)

⁸⁵ IMS, *Fewer NMEs, Premium lunch Prices, 2005*, available at www.imshealth.com/web/content/0,3148,64576068_63872702_70515404_79037268,00.html (last accessed on March 18, 2009)

There are three main conclusions to be drawn from this. First, leading multinationals appear to be experiencing diseconomies of scale in their R&D investments. Second, the contribution of licensed products to revenues has never been more important. And, third, the industry needs a sustained improvement in R&D productivity to maintain historic growth rates – and to offset the next round of patent expiries on blockbuster products.

⁸⁶ IMS, 'Is the Pharma Industry Weather the "Perfect Storm?"', available at www.imshealth.com/web/content/0,3148,64576068_63872702_70261000_71488550,00.html (last accessed on March 18, 2009)

Once again the US topped the charts for those countries to first launch a product, notching up 58% of world launches. Japan outstripped Europe to become the second most popular country with 22%, and Europe accounted for just 14%. By the end of 2002, only 10 NAS had reached multiple markets. As might be expected, all the drugs

The Patent Expiry Blockbusters and Generic Competition

Patents are the pillars that support the pharmaceutical industry, leading to a positive return of revenue after the drug has been approved by the regulatory authority for marketing. The expiration of patented pharmaceuticals also increases the generic competition in the pharmaceutical markets. Patent expiry blockbusters represent \$17 billion in sales lost in 2007. Thus, pharmaceutical companies try everything they can to maintain or strengthen the legal safeguard for their interests. The generic pharmaceutical companies wait for the moment when a patent will expire (if the patent is not successfully extended) in order to capitalize on these gains.

Profit Margin (cost/profit)

As the development of new chemical entities (NCEs) fall into a bottleneck and expenses for R&D soar, the competition with the generic pharmaceutical companies and the parallel trade policy all pose challenges to profit margin.⁸⁷ Companies are responding to difficulties in the operating environment in their markets. Countries with pricing strategies for cost containment, such as the policy of price control and the use of more generic pharmaceutical products, also increase the competition. The profit margin for pharmaceuticals is not as high as in the past. Thus, it is a trend that more and more companies are investing in the new markets (the so-called developing markets, such as China, India and Brazil) to supply the pharmaceuticals they need.⁸⁸

launched in Japan as their first market.

⁸⁷ IMS, 'Fewer NMEs, Premium lunch Prices', 2005, available at www.imshealth.com/web/content/0,3148,64576068_63872702_70515404_79037268,00.html (last accessed on March 18, 2009)

Pharmaceutical companies are trying to avoid parallel trade by narrowing their price gap. Greater pricing pressure within the EU is making the pharmaceutical companies to set significantly higher prices in Germany and UK.

Greater price preference across countries tends to bring prices closer together.

⁸⁸ IMS, 'Fewer NMEs, Premium lunch Prices', 2005, available at www.imshealth.com/web/content/0,3148,64576068_63872702_70515404_79037268,00.html (last accessed on

2.2.4 Concluding Summary

With the emerging and re-emerging diseases, increasing costs of R&D, the scarcity of new substances, the patent expiration of blockbusters, and genetic competition, the chemical compound pharmaceutical industry is facing the most essential and challenging moment now.

2.3 Vaccine

2.3.1 Present State of Vaccine

A vaccine is a biologically derived substance that elicits a protective immunity. A vaccine protects against and prevents diseases by inducing immunity⁸⁹ to avoid disability, death and infection from the diseases against which a patient is immunized. Immunization saved over 2 million lives in 2003 alone.⁹⁰ Vaccination and immunization have been deemed the most successful and cost effective health intervention ever pursued.⁹¹

Up to now, vaccination has partly controlled ten major diseases.⁹² Immunization is proven to control and eradicate diseases, such as the natural occurrence of smallpox, poliomyelitis,

March 18, 2009)

⁸⁹ WHO, 'Immunization against Diseases of Public Health Importance', 2005, available at www.who.int/mediacentre/factsheets/fs288/en/print.html (last accessed on March 18, 2009)

Vaccines typically provide the immune system with harmless copies of an antigen: a portion of the surface of a bacterium or virus that the immune system recognizes as "foreign." A vaccine may also provide a non-active version of a toxin — a poison produced by a bacterium — so that the body can devise a defense against it. Once an antigen is detected by the immune system, white blood cells called B-lymphocytes create a protein called an antibody that is precisely designed to attach to that antigen. If a true infection of the same disease occurs, still more antibodies are created, and as they attach to their targets they may block the activity of the virus or bacterial strain directly, thus combating infection. In addition, once in place, the antibodies make it much easier for other components of the immune system (particularly phagocytes) to recognize and destroy the invading agent. Immune systems are designed to "remember" — once exposed to a particular bacterium or virus, they retain immunity against it for years, decades, or even a lifetime — and so are prepared to defeat a later infection, and to do so quickly.

⁹⁰ WHO and UNICEF GIVS, Global Immunization Vision and Strategy 2006-2015, 2006, available at www.who.int/vaccines-documents/DOCPDF05/GIVI_final_EN.pdf (last accessed on March 19, 2009)

⁹¹ WHO, 'Immunization against Diseases of Public Health Importance', 2005, available at www.who.int/mediacentre/factsheets/fs288/en/print.html (last accessed on March 19, 2009)

⁹² Stanley A. Plotkin and Walter A. Orenstein edited, *Vaccines*, 4th Ed., P. 1, Saunders, 2004

measles and maternal and neonatal tetanus. For the later development of vaccines, toxoids against diphtheria and tetanus were introduced in the early 1900s; the bacillus Calmette-Guérin vaccine (against tuberculosis) in 1927; the Salk polio vaccine in 1955; and vaccines against measles and mumps in the 1960s.⁹³ Some of these diseases have been eradicated, but more needs to be done to fight against the emergence and re-emergence of these diseases.

The top 20 vaccine brands account for 77% of total vaccine sales. 20 new vaccine brands have been filed or approved recently, and another 31 are in phase III trials.⁹⁴ The emergence and re-emergence of new diseases in the last 20 years encouraged vaccine development.⁹⁵ With the better understanding of the immune system and the emergence of the recombinant DNA technologies, new vaccines are developed by conjugate vaccines, recombinant DNA technology for subunit vaccines and improved delivery vaccines.

New vaccines have been introduced with significant results. Some vaccines have been licensed or are at advanced stages of development. The illnesses targeted are rotavirus

⁹³ WHO, 'Immunization against diseases of public health importance', 2005, available at www.who.int/mediacentre/factsheets/fs288/en/print.html (last accessed on March 19, 2009)

⁹⁴ IMS, 'Vaccines: An Antidote to Sluggish Pharma Sales?', available at www.imshealth.com/web/content/0,3148,64576068_63872702_70515404_82367711,00.html (last accessed on March 19, 2009)

The big hitters in the vaccine world, e.g. GlaxoSmithKline, sanofi pasteur and Merck & Co, are anticipating vaccines becoming one of their major drivers of growth going forward. As a result, they are upping their commitment to the area. GSK Bio, GSK's vaccines arm, accounted for 8.4% of GSK's pharmaceutical turnover in 2006, reporting sales up 23% to \$3.4 billion. GSK Bio is set to become an increasingly important part of GSK's business and has been transformed from a tiny company with one product and \$3 million in revenues, into a \$2 billion behemoth with six vaccines in late-stage development - GSK's vaccines business has doubled in growth over the past five years and the company expects it to double again over the coming five years

⁹⁵ Marina Lattanzi and Rino Rappuoli, 'Vaccination: Past, Present, and Future', Guido Grandi edited, *Genomics Proteomics and Vaccines*, P.6, Wiley, 2004

In the past two or three decades, diseases were emerge or reemerge, such as HTVL, HIV, Staphylococcal toxins, Esherichia coli O157, Borrelia burgdorferi, Helicobacter pylori, Human herpesvirus type 6 during the year of 1980-1990 and Hepatitis C, Vibrio cholerae O139, Bartonella sp., Hantavirus, Nipah virus, West Nile virus, TT virus and SARS coronavirus during the year of 1990-2000.

diarrhoea, pneumococcal disease, and cervical cancer (as caused by human papilloma virus). Progress is being made on a vaccine for the regional menace posed by meningococcal meningitis serogroup as well. Intensive efforts are underway to develop effective vaccines for AIDS, malaria, tuberculosis, dengue, leishmaniasis, and enteric diseases, and to adapt new technologies to improved formulation and delivery.⁹⁶ Very recently, the concept of reverse vaccinology has been applied to viruses as well in the hope that this approach might be able to create new vaccines in the fight against AIDS.⁹⁷

2.3.2 Vaccine Industry

The vaccine industry is small but growing⁹⁸ compared to the pharmaceutical industry overall. The revenue of vaccine companies mainly comes from sales of the product. The vaccine business has relatively low profitability in comparison with chemical-compound pharmaceutical industry. Worldwide, vaccine sales are estimated to be approximately US\$6.5 billion, representing only 2% of global pharmaceutical market sales, roughly equaling the sales of one successful chemical compound medicine; therefore, industrial interest in vaccines is limited.⁹⁹ In addition, the cost of putting a new vaccine into a commercialized product is also as high as putting a new medicine on the market, which represents US\$850 million. Moreover, the growing concern of liability costs, regulatory costs, intellectual property rights costs, and other

⁹⁶ WHO, 'Development of New Vaccines', 2006, available at <http://www.who.int/mediacentre/factsheets/fs289/en/print.html> (last accessed on March 18, 2009)

⁹⁷ Marina Lattanzi and Rino Rappuoli, 'Vaccination: Past, Present, and Future', Guido Grandi edited, *Genomics Proteomics and Vaccines*, P.12-13, Wiley, 2004

⁹⁸ IMS, 'Vaccines: An Antidote to Sluggish Pharma Sales?', available at www.imshealth.com/web/content/0,3148,64576068_63872702_70515404_82367711,00.html (last accessed on March 18, 2009)

The vaccine market is expected to double by 2012, from the current level of Euro 9.7 billion, to more than Euro 18 billion.

⁹⁹ Marina Lattanzi and Rino Rappuoli, 'Vaccination: Past, Present, and Future', Guido Grandi edited, *Genomics Proteomics and Vaccines*, P.14, Wiley, 2004

economic factors might provide incentives for withdrawing vaccine products or discontinuing old vaccine production.

As a result, vaccine companies have started to shut down or merge with one another similarly to the chemical compound pharmaceutical industry.¹⁰⁰ The chemical compound pharmaceutical companies even plan to have their own vaccine companies. Larger vaccine companies are more attracted by pharmaceutical business than vaccine business, because the pharmaceutical industry has grown in size and number.¹⁰¹ As a result, the vaccine industry is now dominated by only a few companies. The larger vaccine companies have annual sales of vaccine products of \$1 billion or greater.¹⁰² Some of the mergers are due to the creation of one stronger and larger company, like the merger of Lederle Laboratories, Inc. and Wyeth Laboratories, Inc.; some are due to the departure from vaccines business, e.g., Eli Lilly & Co. and E.R. Squibb & Sons.

The US is extraordinary successful¹⁰³ in vaccine R&D due to the delicate fabric of public and private collaboration involved in interwoven scientific, public health and economic concerns. More than two-thirds of the vaccines approved in the past 25 years have been developed in the

¹⁰⁰ Amie Batson, Sarah Glass, and Erica Seiguer, 'Economic of Vaccines: From Vaccine Candidate to Commercialized Product', Barry R. Bloom and Paul-Henri Lambert edited, *The Vaccines Book*, P.349, Academic Press, 2002

Of the 20 internationally active vaccine companies in the 1960s' less than 12 remained by the early 1990s.

¹⁰¹ Stanley A. Plotkin and Walter A. Orenstein edited, *Vaccines*, 4th Ed., P. 51, Saunders, 2004

¹⁰² Stanley A. Plotkin and Walter A. Orenstein edited, *Vaccines*, 4th ed., P.47, Saunders, 2004

¹⁰³ Amie Batson, Sarah Glass, and Erica Seiguer, 'Economic of Vaccines: From Vaccine Candidate to Commercialized Product', Barry R. Bloom and Paul-Henri Lambert edited, *The Vaccine Book*, P.347-352, Academic Press, 2002

The American companies, such as Wyeth-Lederle Vaccines, Anventis Pasteur, GlaxoSmithKline and Merck have shared the vaccine market and have seen it rise from approximately 50% in 1998 to about 80% today. Small to medium sized companies, notably Chiron and Baxter, as well as the emerging companies in Korean, India, Indonesia, and other sites, vie for the remaining revenues.

US.¹⁰⁴ Currently, the vaccine industry can be found in 50 countries, and is concentrated in the US and Europe. Five multinational producers dominate global vaccine sales.

Estimates of the total world market revenues are US\$6 billion, the top five accounting for 80% of the sales or US\$4.8 billion US, with the remainder coming from the regional vaccines companies located in countries such as India or Brazil. By contrast, the same top five companies supply only approximately 52% of the doses, or 2.8 million of 5.4 billion doses worldwide, with the remainder coming from regional vaccine companies.¹⁰⁵ The vaccine companies have emerged, but the investment in the vaccine industry is shrinking, and compared to the pharmaceutical companies, the vaccine business is less attractive with its low profits and higher costs.¹⁰⁶

2.3.3 Challenges of Vaccine

Safety, Efficacy, Quality and Delivery of Vaccine

Vaccines are usually administered on healthy people to generate immunization. The safety standards are higher for vaccines, which are usually administered on infants or children, than for medicines which are usually used to treat diseases, because a slight adverse effect could result in substantial population-attributable risks.¹⁰⁷ The adverse effect of vaccines could be caused by

¹⁰⁴ Stanley A. Plotkin and Walter A. Orenstein, *Vaccines*, 4th Ed., P. 47, Saunders, 2004 and The Committee on the Evaluation of Vaccine Purchase Financing in United States Board of Health Care Services, *Financing Vaccine in the 21st Century: Assuring Access and Availability*, P. 116, 2004

¹⁰⁵ Maureen Birmingham and Claudia Stein, 'The Burden of Vaccine Preventable Diseases', Stanley A. Plotkin and Walter A. Orenstein, *Vaccines*, 4th Ed., P. 51, Saunders, 2004

¹⁰⁶ Maureen Birmingham and Claudia Stein, 'The Burden of Vaccine Preventable Diseases', Stanley A. Plotkin and Walter A. Orenstein edited, *Vaccines*, 4th Ed., P.51, Saunders, 2004

The vaccine industry has concentrated since 1967, when 26 different companies held vaccine licenses in the US. In 1980, 17 companies held vaccine license. In 2002, only 12 companies held vaccine licenses. Some of the concentration was due to mergers, but some was due to the departure of the vaccine business.

¹⁰⁷ Neal A. Halsey, 'Vaccine Safety: Real and Perceived Issue', Barry R. Bloom, Paul-Henri Lambert edited, *The*

the injection process, incomplete inactivation of the vaccine agent, replication of live vaccine agents, inadvertent contamination of the vaccine with other live agents, the direct effects of the vaccine components, and host immune response to vaccine components.¹⁰⁸

Vaccines are traditionally divided into two main groups: a live organism that is in an attenuated (weakened) or inactivated (killed) form and that is either whole or fractionated. The latest vaccine technology has moved towards new dimensions in recombinant vaccines that have been developed through genetic manipulation and, for later DNA vaccines, cellular vaccines and other novel vaccines. Whereas vaccines are deemed to prevent infection, many vaccines actually prevent or minimize the consequences of infection.¹⁰⁹

The development of vaccines first started with the identification and characterization of antigens. Vaccine science, innovation, and manufacturing are critical components in developing safe and efficacious vaccines. Licenses of new vaccines, and all other information concerning vaccine formulation, vaccine manufacturing, stability and sterility test and results of animal testing, are required by the Food and Drug Administration.

The safety issues are not limited to the safety, quality and side-effects of the vaccine itself, but also to injection safety in order to avoid the transmission of blood-borne pathogens. To provide immunization safety is to ensure vaccine safety and quality at every stage, from the

Vaccine Book, P.371, Academic Press, 2002

¹⁰⁸ Neal A. Halsey, 'Vaccine Safety: Real and Perceived Issue', Barry R. Bloom, Paul-Henri Lambert edited, *The Vaccine Book*, P.375, Academic Press, 2002

¹⁰⁹ Kenrad E. Nelson and Carolyn Masters Williams, *Infectious diseases Epidemiology: theory and Practice*, 2nd ed., P.347-355, Jones & Bartlett Publishers, 2006

There are novel approaches in vaccine development, including the identification of new targets, new adjuvants and new vaccine delivery methods, as well as the development of new vaccine types and combination vaccines.

development stage through clinical trials, vaccine production, quality control and distribution, and up to the point of use. Likewise, the trials of chemical-compound medicines are quite rigorous. The vaccine candidate undergoes multiple trials, and the decision to progress to the next phase is based upon the results from the previous studies. A successful vaccine development normally takes about 10 or more years, but only a small proportion of the candidates will end up as licensed products.¹¹⁰

The manufacturing of vaccines often involves complex transformation of live biologic organisms into active, safe and stable immunization components. The vaccine must be controlled in a certain condition to maintain its safety and activities. The factors have to be controlled in each and every process, including manufacturing, storage and delivery.¹¹¹ Time, sterility and temperature are essential in each manufacturing process; any change will result in a different vaccine.

Each batch of vaccine must be tested and approved individually prior to release. Vaccines require both a product license application and an establishment license application, while new chemical entities require only a product license application. The vaccine companies have to obtain a facility license for a vaccine, which requires full capacity for that vaccine.¹¹²

¹¹⁰ Jens-Peter Gregsen, 'Scientific, Technical and Economic Aspects of Vaccine Research and Development', Oliver Kayser and R.H. Müller edited, *Pharmaceutical Biotechnology: Drug Discovery and Clinical Applications*, P.66, Wiley-VCH, 2004

The vast majorities of the candidates remain stuck in the early development phases or is abandoned.

¹¹¹ The Committee on the Evaluation of Vaccine Purchase Financing in the United States Board on Health Care Services, *Financing Vaccine in the 21st Century: Assuring Access and Availability*, P.109, 2004

The temperature-controlled environments are needed at each manufacturing step, and many vaccines must be maintained with in a narrow temperature range during storage and delivery –referred to as the “cold chain.”

¹¹² The Committee on the Evaluation of Vaccine Purchase Financing in the United States Board on Health Care Services, *Financing Vaccine in the 21st Century: Assuring Access and Availability*, P.109, 2004

An establishment license application certificates for that facilities, equipment and personnel involved in the

Development of Vaccine

Because of the emergence and re-emergence of diseases, the vaccine companies are working co-operatively with partners, including the governmental research branches, the Food and Drug Administration, the governmental disease control branches, other biotechnology companies, international organizations, and NGOs.¹¹³

In order to have sustainable development of vaccines, vaccine companies need to have a rich environment of sponsoring by government-funded institutions and academic universities to carry out the R&D, strong intellectual property rights protection, and freedom to price the products at a fair level in relation to the value of a product to society.¹¹⁴

Vaccine development is difficult, complicated and costly both in clinical studies and process components, and it usually takes more than 10 years to develop a fully licensable product. The production of new vaccines is costly. The vaccine industry receives their revenue from the sale of vaccine products. The cost of vaccine production includes the R&D costs; cost related to the regulatory process; the ongoing regulatory costs; and vaccine plants costs¹¹⁵, including the

manufacturing process meet food and drug administrative regulations and current good manufacturing practices.

¹¹³ B. Bret Finlay, 'Understanding Microbial Pathogenesis as a Basis for Vaccine Design', Barry R. Bloom and Paul-Henri Lambert edited, *The Vaccine Book*, P. 186, Academic Press, 2003

By discouraging the production of vaccine, possible ways to increase the production to meet the demands include: increased construction of facilities by the four majors; growth of regional small manufacturers in countries such as Brazil, Cuba, India, Korea, and Japan; partnerships between regional and major manufacturers' and development of new institutions to make vaccines and Stanley A. Plotkin and Walter A. Orenstein edited, *Vaccines*, 4th Ed, P. 50, Saunders, 2004

Vaccine development starts with basic research, which is usually done in universities, biotechnology firms or the vaccine department of the pharmaceutical company. Funding for vaccine R&D is basically from government¹¹³, profits of the sales of vaccine and risk capital. Large vaccine companies, nowadays, usually is the subdivision of pharmaceutical companies in average reinvest approximately 18% of their profit into R&D. Vaccine R&D has to face the competition with other pharmaceutical product of the budgets and resources.

¹¹⁴ Stanley A. Plotkin and Walter A. Orenstein edited, *Vaccines*, 4th Ed., P. 51, Saunders

¹¹⁵ Stanley A. Plotkin and Walter A. Orenstein edited, *Vaccines*, 4th Ed., P.47-48, Saunders, 2004

The manufacturing plants for vaccines are very expensive, ranging from \$50-200 million US, depend on the dose

depreciation and the marketing costs, variable costs of labor, production, equipment and facility for vaccines and the liability costs. The total costs to bring a vaccine to market are roughly similar to those for other drugs and, in some cases, can be higher. The estimated expense for development of a new vaccine is around US\$500-800 million per year and often takes a period of 12-15 years.¹¹⁶ As a result, vaccine manufacturers charge prices to recoup the costs for each new vaccine while the vaccine is still under the protection of patent.¹¹⁷

As mentioned above, even though the production costs of vaccines have been increasing, the revenue from vaccine sales remains generally constant. The market of one vaccine may be prosperous or slow depending on demand.¹¹⁸ The potential revenue from the vaccine is relatively small compared with chemical compound medicines. Whereas other types of medicine are usually taken for years, a vaccine is usually administered one or four times to gain immunity for a lifetime. The commercial realities usually impact the R&D of those vaccines that are used in developed countries, leaving little investment for the R&D of vaccines to diseases that predominantly touch upon the poor and neglected populations.

Donating vaccines or selling vaccines at a discounted price could help little in solving the enormity of the health problems worldwide. Developed countries generate about 82% of vaccine revenues but represent only 12% of the doses. This economic reality is pushing R&D

requirement and manufacturing complexity.

¹¹⁶ Stanley A. Plotkin and Walter A. Orenstein edited, Vaccines, 4th Ed., P.47-48, Saunders, 2004 and The Committee on the Evaluation of Vaccine Purchase Financing in United States Board of Health Care Services, Financing Vaccine in the 21st Century: Assuring Access and Availability, 2004, P. 114-116

Another estimated that a new vaccine costs \$700-750 million from initial research to commercial production.

¹¹⁷ WHO, State of the World's Vaccines and Immunization, P.9, 2003, available at www.who.int/vaccines-documents/DocsPDF04/wwwSOWV_E.pdf (last accessed on March 18, 2009)

¹¹⁸ Vaccines help the body to have immunizations, once had the vaccination, maybe the immunization can last for a long time and the life time, sometimes. It is the major difference from chemical compound pharmaceuticals.

towards the infectious diseases in developed countries, leaving little investment for infectious diseases which affect mostly poor and neglected populations in developing countries. It is hard to expect that companies will engage in R&D for diseases that only, or predominately, impact the poorer regions of the world without special incentives.¹¹⁹

2.3.4 Concluding Summary

With new vaccine strategies, the revolution in biotechnology also made more powerful tools to make new vaccines' development and research possible. Growing recognition and understanding of human immunity and the importance of immunization also help to accelerate vaccine development.

After an efficient vaccine is developed and is able to be licensed, the work does not stop. The post-marketing surveillance, cost-effectiveness, bridging studies to expand the immunization to larger populations, impact, evaluation of different target populations and possible improved vaccine delivery systems or manufacturing processes to reduce costs are keys of providing safer, more efficient and affordable vaccination¹²⁰ to contribute to the global goal of reducing poverty.

Cooperation by non-profit organizations, non-governmental organizations, and research-based and private-public partnerships helps to focus R&D on the diseases predominately plaguing developing countries. Yet, a number of diseases still lack the leadership, funding and partnership to encourage the development of vaccines.

¹¹⁹ Stanley A. Plotkin and Walter A. Orenstein edited, *Vaccines*, 4th Ed., P. 51, Saunders, 2004
¹²⁰ WHO, The Initiative For Vaccine Research, Strategic Plan 2006-2009, P.1, P.5, 2006, available at:
www.who.int/vaccines-documents/DocsPDF06/854.pdf (last accessed on March 18, 2009)

2.4 Traditional Medicine (TM)

2.4.1 Current State of TM

TM is becoming more and more popular around the world, the global market stands at US\$60 billion per year¹²¹, and it is steadily growing through international trade and cultural exchanges under globalization. The use of TM remains the primary health care in developing countries because chemical compound medicines and vaccines, for most developing countries, remain unaffordable or inaccessible.¹²² In developed countries, the growing trend of using botanical products, traditional, alternative and complementary medicines have attracted a great deal of attention lately as an alternative approach to health care.¹²³

Yet, TM is currently at a critical stage¹²⁴, with the lack of validation, lack of reorganization,

¹²¹ WHO, 'Essential Drug in Brief', P.1, 2002, available at www.who.int/medicines/publications/brief/en/edb07.pdf (last accessed on March 18, 2009)

¹²² WHO, *WHO Traditional Medicine Strategy 2002-2005*, P.1, 2002, available at http://whqlibdoc.who.int/hq/2002/WHO_EDM_TRM_2002.1.pdf (last accessed on March 18, 2009)
In Africa, up to 80% of the population use traditional medicine. In Asia and Latin America, populations continue to use traditional medicine in accordance to historical circumstances and cultural beliefs. In China, traditional medicine accounts for around 40% of all health care delivered. Also, the distribution of traditional medicine is not uniform as well and WHO, 'Guidelines on Developing Consumer Information on Proper Use of Traditional, Complementary and Alternative Medicine', P.1, 2004, available at www.paho.org/spanish/ad/ths/ev/PM-WHO-Traditional-Medicines-Consumer.pdf (last accessed on March 18, 2009)

In many developed, high income countries, traditional and complementary medicine is becoming increasingly popular, with up to 65% of the population reporting that they have used this form of medicine.

¹²³ WHO, *WHO Traditional Medicine Strategy 2002-2005*, 2002, P.2, available at http://whqlibdoc.who.int/hq/2002/WHO_EDM_TRM_2002.1.pdf (last accessed on March 18, 2009)

The concern about the adverse effect of chemical compound drugs fuels the popular use of traditional medicine. In addition, accompanying the aging population and the increasing population with chronic diseases, traditional medicine appears to be a gentler and more affordable method to manage disease. For those seeking this treatment at least once, the use of traditional medicine is 48% in Australia, 70% in Canada, 42% in USA, 38% in Belgium and 75% in France. People in developed countries are concerned about the adverse effects of chemical drugs.

¹²⁴ WHO, 'Report of the Inter-Regional Workshop on Intellectual Property Rights in the Context of Traditional Medicine', Bangkok, Thailand, 6-8 December 2000, P.20, 2001, available at http://whqlibdoc.who.int/hq/2001/WHO_EDM_TRM_2001.1.pdf (last accessed on March 18, 2009)

According to the report, the participants have concluded the problem areas and gaps for the protection of traditional medicine knowledge:

- Lack of a national policy to develop traditional medicine and lack of organizational infrastructure to utilize traditional medicine in the national health care systems;
- Lack of any system for traditional medicines protection and equitable sharing of benefits;

The importance and prioritization of traditional medicine has not been fully recognized and explicitly mentioned by

lack of standardization, lack of protection, lack of delivery infrastructure and lack of integration into national health care systems. With delays in developing TM and the impediments to conserving necessary biological diversity and genetic resources, TM is swiftly losing much of its efficacy.¹²⁵ Although many understand the potential of TM to successfully reduce the burden of diseases and contribute to public health, TM is still struggling with protection and development issues.¹²⁶

TM covers a wide variety of therapies and practices, which vary greatly from country to country.¹²⁷ TM is not only a system of treatment, but it also has its unique methods of assessing health and diagnoses. It is also a way of living, which takes into account the interactions between the internal states of the body and the external environment.

-
- various international health organizations;
 - Absence of formal or informal mechanisms for the participation of traditional healers in policy making and intellectual property development;
 - Lack of mechanism or strategy for equitable benefit sharing among all stakeholders;
 - Lack of policy and regulations for the protection of biodiversity and traditional medicine knowledge;
 - Lack of understanding of intellectual property rights system among stakeholders;
 - Lack of mechanism for developing linkages between traditional medicine of different countries;
 - Lack of appreciation of the potential of traditional medicine to solve the health problems of developing countries
 - Lack of understanding , awareness, communication and respect between traditional medicine and intellectual property rights offices;
 - Difference between the concepts and fundamentals of traditional medicine and modern medicine;
 - Limited applicability of existing intellectual property rights laws to protect traditional medicine knowledge from biopiracy; and
 - Inability to meet the cost of requiring, exercising and enforcing intellectual property rights for the holders of traditional medicine knowledge.

¹²⁵ UNCTAD Commonwealth Secretariat, UNCTAD-Commonwealth Secretariat Workshop on Elements of National Sui Generis Systems for the Preservation, protection and Promotion of Traditional Knowledge, Innovations and Practices and Options for an International Framework, P. 5, 2004, available at www.unctad.org/en/docs/ditcted200518_en.pdf (last accessed on March 18, 2009)

Traditional knowledge is diminishing in importance around the world. It is estimated that 90% of the traditional lifestyle could be lost within the next 100 years. The loss is accelerated by modernization/urbanization and the influence of western education, which also erodes the support of TK.

¹²⁶ Questions concern safety, efficacy, quality, access and rational use.

¹²⁷ Due to the independent development of the traditional medicine in different geographic areas and cultures, several well-known traditional medicine systems, for example Ayurveda, Unani and Chinese Medicines have developed separately.

The term "TM" is a comprehensive term that refers to medicines and therapies that have been used over generations that stem from theories, beliefs and experiences in different cultures. Much of TM is not "ancient" or inert, but articulates a vital, dynamic part of everyday life for many groups or communities today. TM includes medication therapies and non-medication therapies. TM can be codified, taught openly, practiced widely and systematically outlined in written or oral form.

TM is usually comprised of herbal medicines, animal parts, and/or minerals. There are some famous TM systems such as Traditional Chinese Medicine, Indian Ayurveda medicine, Arabic Unani medicine, African Traditional Medicine and other various forms of indigenous medicines.¹²⁸ Non-medication TM therapies are also very popular, such as acupuncture and related techniques, chiropractics, osteopathy, manual therapies, qigong, yoga, tai-ji, Chinese cupping, naturopathy, thermal therapy, and other manual therapies and spiritual therapies.

There is no formulated definition for TM, but the World Health Organization (WHO) and World Intellectual Property Organization (WIPO) have suggested definitions for TM. WHO defines TM as "including diverse health practices, approaches, knowledge and beliefs incorporating plant, animal and/or mineral based medicines, spiritual therapies, manual techniques and exercises applied singularly or in combination to maintain well-being, as well as to treat, diagnose or prevent illness."¹²⁹ WIPO defines TM as one part of the traditional medicinal knowledge, which is generally transmitted from generation to generation; these

¹²⁸ A variety of indigenous TM systems also developed throughout history by Asian, African Arabic, Native American, Oceanic, Central and South American and other cultures.

¹²⁹ WHO, 'WHO Traditional Medicine Strategy 2002-2005', P7, 2002, available at http://whqlibdoc.who.int/hq/2002/WHO_EDM_TRM_2002.1.pdf (last accessed on March 18, 2009)

medicines are generally regarded as pertaining to a particular people or its territory; and are constantly evolving in response to a changing environment.¹³⁰

In TM, the term, “traditional” does not necessarily mean “ancient,” but refers to the creation and use of such medicine and medical knowledge as part of the cultural traditions of communities or groups.¹³¹ TM is a living organic form of thoughts that grew out of the everyday experience of life in a particular place and within a particular community. There are many terms often related to TM, such as “alternative medicine,” “complementary medicine,” “natural remedies,” “herbal medicines,” and “indigenous medicines.” Some of these terms are used interchangeably with TM, but some of them refer to a more specific concept.

¹³⁰ WIPO, ‘Intellectual Property Needs and Expectation of Traditional Knowledge Holder, WIPO Report on Fact-Finding Missions on Intellectual Property and Traditional Knowledge 1998-1999’, P.25, 2001, available at <http://www.wipo.int/tk/en/tk/ffm/report/final/pdf/part1.pdf> (last accessed on March 18, 2009)

The Term, “traditional knowledge” under WIPO refers to tradition-based literary, artistic or scientific works; performances; inventions; scientific discoveries; designs; marks, names and symbols; undisclosed information; and all other tradition-based innovations and creations resulting from intellectual activity in the industrial, scientific, literary or artistic fields. “Tradition-based” refers to knowledge systems, creations, innovations and cultural expressions which have generally been transmitted from generation to generation; are generally regarded as pertaining to a particular people or its territory; and, are constantly evolving in response to a changing environment. Categories of traditional knowledge can include: agricultural knowledge; scientific knowledge; technical knowledge; ecological knowledge; medicinal knowledge, including related medicines and remedies; biodiversity-related knowledge; “expressions of folklore” in the form of music, dance, song, handicrafts, designs, stories and artwork; elements of languages, such as names, geographical indications and symbols; and, movable cultural properties. Excluded from this description of TK would be items not resulting from intellectual activity in the industrial, scientific, literary or artistic fields, such as human remains, languages in general and other similar elements of “heritage” in the broad sense. In summation, TK was created, originated in, developed and practiced by traditional knowledge holders. Indigenous knowledge is knowledge of indigenous people; expressions of folklore are a subset of traditional knowledge; traditional knowledge is in turn a subset of the broader concept of heritage.

¹³¹ Richard Wilder, ‘Protection of Traditional Medicine’, CMH Working Paper Series, P.9, 2001, available at www.emro.who.int/cbi/PDF/TraditionalMedicine.pdf (last accessed on March 18, 2009)

Commonly used TM/CAM therapies and therapeutic techniques

	Chinese medicine	Ayurveda	Unani	Naturopathy	Osteopathy	Homeopathy	Chiropractic	Others
Herbal medicines	●	●	●	●	■	●		● ^a
Acupuncture/acupressure	●				■			■ ^b
Manual therapies	Tuina ^c	●	●	■	●		●	Shiatsu ^d
Spiritual therapies	●	●	●	●				Hypnosis, healing, meditation
Exercises	Qigong ^e	Yoga		Relaxation				

● – commonly uses this therapy/therapeutic technique

■ – sometimes uses this therapy/therapeutic technique

■ – uses therapeutic touch

^a for example, many informal TM systems in Africa and Latin America use herbal medicines.

^b for example, in Thailand, some commonly used TM therapies incorporate acupuncture and acupressure.

^c type of manual therapy used in traditional Chinese medicine.

^d refers to manual therapy of Japanese origin in which pressure is applied with thumbs, palms, etc., to certain points of the body.

^e component of traditional Chinese medicine that combines movement, meditation and regulation of breathing to enhance the flow of vital energy (qi) in the body to improve circulation and enhance immune function.

^a Accordingly, in this document, "traditional medicine" is used when referring to Africa, Latin America, South-East Asia, and/or the Western Pacific, whereas "complementary and alternative medicine" is used when referring to Europe and/or North America (and Australia). When referring in a general sense to all of these regions, the comprehensive TM/CAM is used.

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There are a variety of forms of TM in different systems as shown in the chart above from the WHO. Interestingly, they have different names, but the treatments are similar from one to the other.

These terms "CAM" and "TM" are often used interchangeably. In countries where TM is not part of the country's own tradition or is not covered by the health care system, TM therapies are usually termed as "alternative, complementary" or "non-conventional medicine."¹³³ WHO Traditional Medicine Strategy 2002-2005 points out that the term TM is usually used when referring to Africa, Asia, Latin America, South-East Asia and or Western Pacific, whereas "complementary medicine" is used when referring to Europe and/or North American (and Australia). When referring in a general sense to all of these regions, the comprehensive designation of TM/CAM is used.¹³⁴

¹³² WHO, WHO Traditional Medicine Strategy 2002-2005, P.8, 2002, available at http://whqlibdoc.who.int/hq/2002/WHO_EDM_TRM_2002.1.pdf (last accessed on March 18, 2009)

¹³³ WHO, WHO Traditional Medicine Strategy 2002-2005, 2002, P.1, available at http://whqlibdoc.who.int/hq/2002/WHO_EDM_TRM_2002.1.pdf (last accessed on March 18, 2009)

¹³⁴ WHO, WHO Traditional Medicine Strategy 2002-2005, P.8, 2002, available at

When considering indigenous medicines, "indigenous" should be understood in at least two different ways. First, it is used to describe knowledge held and used by communities, peoples and nations that are "indigenous" to a particular region or area. The Convention on Indigenous and Tribal Peoples of 1989 (ILO Convention No.169) mentioned some commonly used criteria, such as aboriginality, cultural distinctiveness and self-identification as attributes to "indigenesness."¹³⁵ The description of the concept "indigenous" in the Study of the Problem of Discrimination against Indigenous Populations is regarded as an acceptable working definition by many indigenous peoples and their representative organizations. It explains that indigenous peoples are "pre-invasion and pre-colonial societies." Professor Sompong Sucharitkul points out that there is no general accepted definition of "indigenous peoples."¹³⁶ For the purpose of this dissertation, "indigenous knowledge" refers to the traditional knowledge of indigenous peoples and a part of a traditional knowledge category, but traditional knowledge is not necessarily indigenous.¹³⁷

TM is a traditional strategy for remedying diseases and a theory about mental, spiritual and physical health. For people who cannot afford to purchase modern chemical compound pharmaceuticals, TM remains the primary resource for health care, especially in Africa, Asia and Latin America. Interestingly, TM is also as a resource of health care when other pharmaceutical

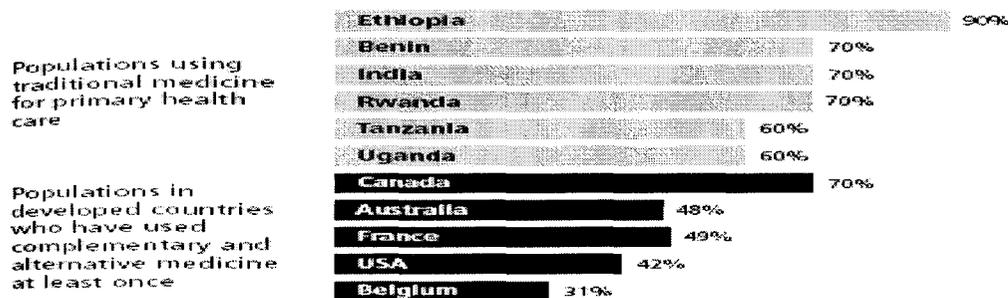
http://whqlibdoc.who.int/hq/2002/WHO_EDM_TRM_2002.1.pdf (last accessed on March 18, 2009) and Bhushan Patwardhan, 'Traditional Medicine: Modern Approach for Affordable Global Health: Traditional Medicine: Could more effective use be made of them in providing affordable treatments?', P. 34, 2005, available at www.who.int/intellectualproperty/studies/B.Patwardhan2.pdf (last accessed on 22 Mar 2008)

¹³⁵ Sompong Sucharitkul, 'The Inter-temporal Character of International and Comparative Law Regarding the Rights of the Indigenous Populations of the World', 50 Am. J. comp. L. 3, 2002

¹³⁶ Sompong Sucharitkul, 'The Inter-temporal Character of International and Comparative Law Regarding the Rights of the Indigenous Populations of the World', 50 Am. J. comp. L. 3, 2002

¹³⁷ WIPO, 'Intellectual Property Needs and Expectation of Traditional Knowledge Holder, WIPO Report on Fact-Finding Missions on Intellectual Property and Traditional Knowledge 1998-1999, P.23-24, 2001 available at <http://www.wipo.int/tk/en/tk/ffm/report/final/pdf/part1.pdf> (last accessed on March 18, 2009)

products pharmaceuticals cannot offer effective treatments or to prevent diseases. For example, in Australia, Europe and North America, “complementary and alternative medicine” (CAM) is increasingly used in conjunction with chemical compound medicine and vaccines, particularly for treating and managing chronic disease.¹³⁸



Sources: Eisenberg DM et al. 1998; Fisher P & Ward A. 1994; Health Canada 2001; World Health Organization, 1998; and government reports submitted to WHO.

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The status of TM is different from country to country. Some countries have established frameworks of laws and regulations to recognize and regulate TM as pharmaceuticals (both as prescription medicines and over the counter medicines). In some other countries, TM is considered self-medication, dietary supplements, health food, functional food, etc., in no need of further regulation. In some countries, the use of TM is just followed as it has been by generations without a “traditional medicine” industry. In countries where the traditional medicine developed more (for example, in China or India), the industry of TM is relatively small compared to modern pharmaceutical companies.

¹³⁸ WHO, Traditional Medicine Fact Sheet, 2008, available at www.who.int/mediacentre/factsheets/fs134/en/print.html (last accessed on March 18, 2009). In some Asian and African countries, 80% of the populations depend on traditional medicine for primary health care. In many developed countries, 70% to 80% of the population has used some form of alternative or complementary medicine (e.g. acupuncture). Herbal treatments are the most popular form of traditional medicine, and are highly lucrative in the international marketplace. Annual revenues in Western Europe reached US\$ 5 billion in 2003-2004. In China, the sales of TM products totaled US\$ 14 billion in 2005. Herbal medicine revenue in Brazil was US\$ 160 million in 2007.

¹³⁹ WHO, Traditional Medicine-Growing Needs and Potential, P.1, 2002, available at http://whqlibdoc.who.int/hq/2002/WHO_EDM_2002.4.pdf (last accessed on March 18, 2009)

2.4.2 Challenges

Some modalities of TM (for example, acupuncture, some herbal medicines and manual therapies) do gain some scientific validity from random clinical trials; however, most TM is still struggling with the challenge of great prejudice and ignorance.

Due to the variation of TM systems, which are developed in different countries and cultures, there is no parallel development of international standards and appropriate methods of evaluation. The lack of research data, the lack of acceptable standards for clinical trials, the lack of support from health care policies, the lack of adequate or acceptable methodology¹⁴⁰ for evaluating TM, and the lack of international laws and regulations have given inadequate protection and discouraged the development of TM.

Countries might have different regulations on TM/CAM and herbal medicine based on the difference in definition of TM/CAM and herbal medicines. In addition, in some countries, animal and mineral materials may be present in herbal medicines.¹⁴¹ TM is unregulated in most countries.¹⁴² WHA also points out that the major challenges to the use of TM include the lack of organized networks of traditional practitioners, and of solid evidence of the safety, efficacy and

¹⁴⁰ The need for having standards and methodologies is so TM might become more acceptable by the scientific community.

¹⁴¹ WHO, National Policy on Traditional Medicine and Regulation of Herbal Medicines, Report of a WHO Global Survey, P.1, 2005, available at <http://whqlibdoc.who.int/publications/2005/9241593237.pdf> (last accessed on March 18, 2009)

Some countries have different regulations or laws on TM/CAM or herbal medicines. TM/CAM often refers to a broad set of health-care practices that are not party of a country's own traditional and are not integrated into the dominant health-care system. Other terms sometimes used to describe there health care practices include "natural medicine," "non-conventional medicine" and "holistic medicine." Herbal medicine often refers to plant-derived materials or preparations with therapeutic or other human health benefits, which contain either raw or processed ingredients from one or more plants. In some traditions, material of inorganic or animal may also be present.

¹⁴² WHO, National Policy on Traditional Medicine and Regulation of Herbal Medicines, Report of a WHO Global Survey, P.25, 2005, available at http://whqlibdoc.who.int/publications/2005/9241593237_part3.pdf (last accessed on March 18, 2009)

quality of traditional medicines. The need for measures to ensure proper use of traditional medicine and to protect and preserve the traditional knowledge and natural resources is necessary for its sustainable application, and for training and licensing of traditional practitioners.¹⁴³

The legal situation of TM varies from country to country. There are some possible regulatory categories for herbal medicine: prescription medicines, over-the-counter medicines, self-medication, dietary supplements, health food, functional foods, and others.¹⁴⁴

In some countries where TM status is well established, TM can be sold as either medicine or food/dietary medicine, while in other countries, TM is regarded as a food or dietary supplement and therapeutic claims are not allowed. In some developing countries, where TM has been widely used as more folk-knowledge, there is hardly any legislative criteria to conform TM into formal drugs legislation.¹⁴⁵

¹⁴³ WHO, Resolution of the Executive Board of the WHO, 111th Session, Agenda Item 5.7, Traditional Medicine, Jan 24, 2003, available at

http://whqlibdoc.who.int/eb/2003/EB111_R12.pdf (last accessed on March 18, 2009)

¹⁴⁴ WHO, National Policy on Traditional Medicine and Regulation of Herbal Medicines, Report of a WHO Global Survey, P.29, 2005, available at

http://whqlibdoc.who.int/publications/2005/9241593237_part3.pdf (last accessed on March 18, 2009)

- Prescription medicines: medicines/drugs that can only be purchased with a prescription.
- Over the counter medicines: medicines/drugs that can be purchased without a prescription from a physician.
- Self medication only: medicines/drugs permitted for self medication purposes only.
- Dietary supplements: a dietary supplement is a substance which contains, for instance, a vitamin, a mineral, a herb or other botanical or an amino acid. A dietary supplement may be intended to increase the total daily intake of a concentrate, metabolite, constituent, extract or combination of these ingredients.
- Health food: health foods could be products that are presented with specific health claims and therefore regulated differently from other foods.
- Functional foods: like health foods, functional foods may be products which are offered with specific health claims and therefore regulated differently from other foods.
- Other: products classified differently from the above mentioned categories.

¹⁴⁵ WHO, Regulatory Situation of Herbal Medicines: A Worldwide Review, P.1, 1998, available at:

http://whqlibdoc.who.int/hq/1998/WHO_TRM_98.1.pdf (last accessed on March 18, 2009)

The various legislative approaches for herbal medicines fall into one or other following categories:

- Same regulatory requirement for all products;

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Countries might adopt different approaches and definitions toward TM herbs and TM products containing herbs, mineral or animal parts, to regulate their use.¹⁴⁶ The lack of an internationally recognized standard in legislation and regulation of TM makes the protection of TM and the TM users more difficult.

In order to promote R&D in TM, recognition of the role and importance of TM will be the first step. Then, after standardizing the safety, efficacy and quality control, guidelines for rational use will be the second step to gaining public trust that TM is effective as medicine. Thirdly, the nation states shall establish national policy in regulating TM and the TM practitioners.

Standardization

Inadequate standardization of medicinal plants, unacceptable preclinical toxicology studies and inappropriate and poorly designed clinical trials have held back the research and development of TM and consequently have delayed the use of TM and medicinal plants to host new drugs.

Countries might adopt different approaches towards licensing, dispensing and marketing herbs, medicinal plants and products in order to ensure their safety, quality and efficacy.

-
- Same regulatory requirements for all products, with certain types of evidence not required for herbal/traditional medicines;
 - Exemption from all regulatory requirements for herbal/traditional medicines;
 - Exemption from all regulatory requirements for herbal/traditional medicines concerning registration or marketing authorizations;
 - Herbal/traditional medicines subject to all regulatory requirements; and
 - Herbal/traditional medicines subject to regulatory requirements concerning registration or marketing authorizations.

¹⁴⁶ WHO, 'National Policy on Traditional Medicine and Regulation of Herbal Medicines, Report of a WHO Global Survey', P.51, 2005, available at http://whqlibdoc.who.int/publications/2005/9241593237_part4.pdf (last accessed on March 18, 2009)

Although 25% of modern medicine is made from the same plants that make up TM, a relatively small number of TM materials, especially plant species, have been studied in detail. With the growing demand to develop traditional medicine and therapies, getting the best evidence for safety, efficacy, quality and rational use has been the most challenging task for TM.

Standardization is necessary for TM and herbal preparations in order to ensure that they contain the correct amount of the right substances without impurities. Only then can the medicine claim a therapeutic effect and not induce any toxic effects due to possible contamination.

Safety

TM is comprised of about 90% medicinal plants, animals and minerals. Without ensuring the safety of TM, the credibility of TM cannot be built. Medicinal plants comprise thousands of species of plants. Besides the extracts from botanicals, the active ingredients and the chemical interaction between them in TM, especially in multiple substances formulas, have not been clinically proven.¹⁴⁷

Nevertheless, some TM, such as manipulative therapies and behavioral stress-reduction techniques, can effectively provide relief for chronic diseases. For example, acupuncture and some herbal medicines and manual therapies were proven to help patients in studies.

¹⁴⁷ Bhushan Patwardhan, 'Traditional Medicine: Modern Approach for Affordable Global Health: Traditional Medicine: Could more effective use be made of them in providing affordable treatments?', 2005, available at www.who.int/intellectualproperty/studies/B.Patwardhan2.pdf (last accessed on March 18, 2009)
Some of the chemicals are directly responsible to contain several chemical ingredients while others are directly responsible for therapeutic activities, some are responsible for balancing toxicity, and some are required as carriers. Although some of the ingredients and/or chemical reactions might be harmful or not effective as they are claimed to be, because TM has been practiced and continually used for generations, the harm might not be clinically significant.

Acupuncture has been scientifically proven to relieve some pain and nausea. *Artemisia annua*, one Chinese medicine which has been used in China for almost 2000 years, has been found effective in resisting malaria. Plant *Sutherlandia Microphylla* is used to treat HIV/AIDS patients, and is used as a tonic, to increase energy, appetite and body mass in people living with HIV/AIDS.¹⁴⁸

In general, there is a lack of research data, a lack of adequate acceptable research methodology and a lack of clinical evidence to support the widespread claims of TM.¹⁴⁹ Because TM systems are developed in different cultures, within different regions, and have no parallel development standards and methods, problems arise regarding interpretation and application of TM.

As Professor Chaudhury indicates, “the challenge of the twenty-first century will be to carry out clinical evaluation of herbal remedies within the framework of rigid clinical pharmacological principles without trampling on the concepts of the traditional systems of medicine.”¹⁵⁰ This should be the goal to furthering the development of TM.

Evaluating the active ingredients in TM is extremely difficult because some of the species do not exist today.¹⁵¹ In order to maximize the benefit of TM, consumers have to overcome the

¹⁴⁸ WHO, ‘Traditional Medicine’ Fact Sheets’, 2008, available at <http://www.who.int/mediacentre/factsheets/fs134/en/print.html> (last accessed on March 18, 2009) and WHO, *Traditional Medicine Strategy 2002-2005*, P.22, 2002, available at

http://whqlibdoc.who.int/hq/2002/WHO_EDM_TRM_2002.1.pdf (last accessed on March 18, 2009)

¹⁴⁹ WHO, *Traditional Medicine Strategy 2002-2005*, P.3, 2002, available at http://whqlibdoc.who.int/hq/2002/WHO_EDM_TRM_2002.1.pdf (last accessed on March 18, 2009)

¹⁵⁰ Ranjit Roy Chaudhury, ‘Research and Evaluation of Traditional Medicine’, P.5, 2005, available at http://www.searo.who.int/LinkFiles/Meetings_document15.pdf (last accessed on March 18, 2009)

¹⁵¹ The most difficult task in validating TM in Western eyes is the biodiversity issue. The identity of plants and

policy, safety, efficacy, quality, access and rational use issues. This needs to be done on both a national and an international level. On a national level, nations should have regulations and registration systems for TM in order to adopt policies and funds to support research and development. Furthermore, countries and communities should exchange and share the information and results of existing TM knowledge. Networking and having an international registration system worldwide will aid the development of international standards for safety, efficacy and quality of TM.

Efficacy

Efficacy is one of the most debated issues in the TM, which is at the core of the pharmaco-economics of TM. Evaluation of efficacy may be affected by philosophical, cultural, technical, methodological and practical aspects. Some of the TM and therapies have been demonstrated and acknowledged worldwide (for example, acupuncture, herbs like *Artemisia annua* and St. John's wort). Plant extracts¹⁵² have a variety of pharmacological effects, including anti-inflammatory, vasodilatory, anti-microbial, anti-convulsant, sedative and anti-pyretic effects; however, very few randomized, controlled studies have been carried out to investigate the effects of TM practitioners' everyday work.¹⁵³ Recently, many countries and

animals is necessary to understand the active ingredients. The crucial problem is some plants and animals, which used in TM, do not exist nowadays. Moreover, the proprieties of plants and animals could vary the active ingredients, which are influenced by time, weather, and environmental factors as well. Even a single medicinal plant could have more than several hundred natural constituents. Therefore, in order to ensure the safety, quality, efficacy and rational use, the need to set up methodologies and evaluation on TM is urgent.

¹⁵² Bhushan Patwardhan, 'Traditional Medicine: Modern Approach for Affordable Global Health: Traditional Medicine: Could more effective use be made of them in providing affordable treatments?', P.46-50, 2005., available at

www.who.int/intellectualproperty/studies/B.Patwardhan2.pdf (last accessed on March 18, 2009)

Ginkgo biloba, *Uncaria tomentosa*, *Echinacea Spp.*, *Withania somnifera*, Traditional species, including black pepper, long pepper, ginger and turmeric.

¹⁵³ Bhushan Patwardhan, 'Traditional Medicine: Modern Approach for Affordable Global Health: Traditional Medicine: Could more effective use be made of them in providing affordable treatments?', P. 45, 2005, available at www.who.int/intellectualproperty/studies/B.Patwardhan2.pdf (last accessed on March 18, 2009)

organizations have started creating new mechanisms to induce and regulate quality control and standardization of botanical medicine.¹⁵⁴ Aside from evaluating the adverse effects in preparation, post-marketing surveillance will provide useful information.

In order to commercialize TM, correctly identifying and supplying the raw materials without altering the claimed active ingredients has become challenging. In addition to biodiversity issues¹⁵⁵, the standardization for assurance of the “active marker” is a prominent part of quality control.

Efforts are underway to have standardized TM to establish evidence that proves the safety, efficacy, good quality and rational use of TM. Some of the randomized control clinical trials have established clinical efficacy in Rheumatoid and Osteoarthritis, Hapatoprotectives, Diabetes, Hypolipedemic agents, Asthma, Parkinson’s disease and many other disorders.¹⁵⁶

Quality Control

The assurance of quality in TM is another safeguard against the risks of using TM. The growth, cultivation, collection, storage, distribution, processing and marketing of the materials are important, as each part of the process has a great impact on the quality of the product. Not only

Including the World Health Organization, European Scientific Cooperation of Phytomedicine, US Agency for Health Care Policy and Research, European Pharmacopoeia Commission, Department of Health UK, Common Wealth of Australia, Department of Indian System of Medicine.

¹⁵⁴ Bhushan Patwardhan, ‘Traditional Medicine: Modern Approach for Affordable Global Health: Traditional Medicine: Could more effective use be made of them in providing affordable treatments?’, P.63, 2005, available at www.who.int/intellectualproperty/studies/B.Patwardhan2.pdf (last accessed on March 18, 2009)

¹⁵⁵ Due to the time and environmental factors, a lot of species in plants and animals do not exist nowadays. How to ensure the biodiversity is for the sustainable development of TM. How to find the substitutes for TM formula is another block for TM development.

¹⁵⁶ Bhushan Patwardhan, ‘Traditional Medicine: Modern Approach for Affordable Global Health: Traditional Medicine: Could more effective use be made of them in providing affordable treatments?’, P.115, 2005, available at www.who.int/intellectualproperty/studies/B.Patwardhan2.pdf (last accessed on March 18, 2009)

is it necessary to ensure the identity of the right raw material, but the right quality of the elements that compose the material must be considered so that contamination, alteration or spiking does not occur. However, only a few countries have regulations, national policies or registration systems for TM. Due to the extensive use of botanicals and other raw materials in TM, quality control has become a tough task. The quality of TM products may be contaminated or vary tremendously in the context of safety and quality.¹⁵⁷ Addressing the needs for standardization and quality control is the next step to assure the safety of TM.

The lack of passport data for raw materials, identification, and pharmacology is another problem related to quality control. There is no clear labeling standard or requirement for TM, and many of the herbal medicines, which are sold as over-the-counter medicines or food supplements, have little or no advice about the adverse effects or appropriate uses.

The safety and quality control of raw medicinal plant materials and finished products depends on many factors, such as the genetic factors or extrinsic factors of the environment, collection methods, cultivation, harvest, post-harvest processing, transportation and storage practices. This can be ensured by following the WHO guidelines on good agricultural and collection practices (GACP) for medicinal plant materials.¹⁵⁸ Quality control of TM has to

¹⁵⁷ Bhushan Patwardhan, 'Traditional Medicine: Modern Approach for Affordable Global Health: Traditional Medicine: Could more effective use be made of them in providing affordable treatments?', P.63, 2005, available at www.who.int/intellectualproperty/studies/B.Patwardhan2.pdf (last accessed on March 18, 2009)

While in the most part of the use of TM, the main sources of the botanicals and raw materials are from nature and not from planned cultivations.

¹⁵⁸ WHO, 'WHO Guidelines on Good Agricultural and Collection practices (GACP) for Medicinal Plants', P.2, 2003, available at

<http://whqlibdoc.who.int/publications/2003/9241546271.pdf> (last accessed on March 18, 2009)

The guidelines will contribute to the quality assurance of medicinal plant materials used as the source for herbal medicines, which aims to improve the quality, safety and efficacy of finished herbal products; guide the formulation of national and/or regional GACP guidelines and GACP monographs for medicinal plants and related standard

ensure the Good Manufacturing Practice (GMP) of starting materials, including correct identification of species of medicinal plants, special storage, special sanitation and cleaning methods for various materials.¹⁵⁹

Rational Use

There are considerably more regulations and laws regarding the safety, efficacy and quality control of TM than provisions on rational use. Besides information accessible by the consumers, nation states should be the gate-keepers for safeguarding and providing regulations and legislation related to the medicine itself and TM practitioners.¹⁶⁰ Rational use is correlated to safety and assured quality, and one cannot neglect the risk associated with the use of TM. The interaction between TM and other pharmaceutical products is another important issue as well. Measures are needed to avoid chemical conflict when consumers combine the two forms of treatment. Therefore, proper use is another important factor when developing and researching TM to provide the scientific information and guidance for the public to get more rational use of TM.

operating procedures; and encourage and support the sustainable cultivation and collection of medicinal plants of good quality in ways that respect and support the conservation of medicinal plants and the environment in general.

¹⁵⁹ Quality control of finished herbal medicinal products, particularly mixed herbal products, is more difficult.

¹⁶⁰ WHO, Guidelines on Developing Consumer Information on Proper Use of Traditional, Complementary and Alternative Medicine, 2004, P.7-9, available at

<http://www.paho.org/spanish/ad/ths/ev/PM-WHO-Traditional-medicines-Consumer.pdf> (last accessed on March 18, 2009)

To ensure the proper use of TM, there are some general consideration should be addressed on:

- Quality control of herbal medicines;
- Development of reliable treatment guidelines;
- Training and qualified practice for TM practitioners
- Collaboration between health care providers and TM practitioners;
- Communication between TM consumers and their health care providers and TM practitioners;
- Organization of TM practitioners; and
- Regulatory and Mechanisms for Information and Advertisement.

Development of TM

TM has been the primary health care for many people in the world. There are many difficulties to overcome for further development in TM. The lack of recognition of the value of TM has presented obstacles to its advancement. Moreover, the lack of bio-diversity and stability of the TM materials contributes to the slow development of TM. Although intellectual property rights also offer protection to TM, TM has difficulties in passing clinical trials, businesses have little incentive to invest in TM, and the treatments consequently fail to obtain market approval. Or for some other medicines, the products do not fit into the requirements of patent protection. Thus, there are few financial sources investing in TM, and little incentive for R&D and personnel.

2.4.3 Concluding Summary

TM has been widely used and has many positive features in its diversity, flexibility, accessibility, affordability, and the individualization. 80% of the population in most developing countries regularly uses TM. The development of TM will benefit populations in developing countries the most, because of the accessibility and affordability of the pharmaceuticals to fulfill their health care needs. Furthermore, researchers might be able to use TM to invent and develop more efficient and effective pharmaceuticals to benefit the world's population.

2.5 Pharmaceutical Prices

2.5.1 Introduction

Health is something you cannot put a price on, and yet money still determines health in the context of pharmaceuticals. Pharmaceuticals account for a major portion of health expenditures,

and although it has been argued that medicine-as-commerce is at the heart of the problem, many factors contribute to the problems surrounding access to pharmaceuticals.

Access to pharmaceuticals depends heavily on the availability and affordability of pharmaceutical products. Pharmaceuticals are as goods for trade, so the pharmaceutical prices are most affected by globalization. Although global trade increases the trade in pharmaceuticals, most of the pharmaceutical products are traded internationally with protection under intellectual property rights across countries. There are vast disparities between the developed and developing countries in this regard.¹⁶¹

2.5.2 Chemical Compound Pharmaceuticals

The reproduction of chemical compound pharmaceuticals is not difficult for personnel in the field. The cost of the ingredients is not high and the manufacturing processes are not difficult. It is the discovery, development, testing, and gaining regulatory approval for a new medicine that is time-consuming, risky and costly. Pharmaceutical companies represent one of the most research-intensive industries among the many industries.

The North and the South

The worldwide pharmaceutical market is divided into the North and the South when it comes to the accessibility and affordability of pharmaceuticals. The worldwide pharmaceutical marketplace is composed of four geographic areas: the US, Europe (European Union), Asia

¹⁶¹ WHO, Medicines Price Information, available at <http://www.who.int/medicines/areas/access/ecofin/en/print.html> (last accessed on March 18, 2009)

In response to the World Health Assembly Resolution WHA54.11, WHO is working with partners to make existing drug price information more widely available in order to improve equity in access to essential medicines in health systems and to provide support to member states.

(Japan, China, Australia) and the rest of the world. Currently, the developed countries account for 11-12% of the global burden from all causes of death and disability, but just under 90% of health expenditure.¹⁶² 80% of the world's medicines are consumed by populations concentrated in the US, Europe and Japan.¹⁶³ By contrast, developing countries account for just 17% of imports and 6% of exports of pharmaceutical products.

* Pharmaceutical Sales by Region in 2003¹⁶⁴

Region	Sales (\$billion)	% Global Sales
North American	229.5	49
European Union	115.4	25
Rest of Europe	14.3	3
Japan	52.4	11
Asia, Africa, and Australia	37.3	8
Latin America	17.4	4
Total	466.3	100

Among the competitive therapeutic markets, large pharmaceutical companies possess more ability to price their products above the marginal costs of production and generate economic profits. In addition, because of the first-mover advantages, even after the patent expires, the companies will still have a brand-name, which they price above costs to dominate the market over generics. Meanwhile, promotions and advertisements from large companies also help to reinforce the habit of buying such a product by both physicians and patients.¹⁶⁵

2.5.3 Vaccines

Immunization has revolutionized the world, especially when it comes to the health of children.

¹⁶² Anand S Dutta, 'Discovery of New Medicines', John P. Griffin and John O'Grady edited, *The Textbook of Pharmaceutical Medicine*, 5th ed., P.7, BMJ Books, 2006

¹⁶³ Kelley Lee edited, *Globalization and Health: An Introduction*, P.72, Palgrave Macmillan, 2003

¹⁶⁴ C. Ralph Buncher and Jia-Yeong Tsay edited, *Statistics in the Pharmaceutical Industry*, 3rd ed., P.346, CRC, 2005

¹⁶⁵ Goodwill established during the period of patent protection extends the physician and/or patients continue to favor higher-priced products, even after the patent has expired.

Immunization can help prevent childhood death and reduce the toll of disability and illness. Despite the overall success of immunizations, almost 11 million children under the age of five die each year because of the lack of vaccination to prevent diseases. Immunization has not been sustained in most of the developing countries. In some countries, fewer than one in three children are immunized during their first year of life.

The accessibility and affordability of vaccines varies both among regions and among products. The off-patent vaccines, such as the traditional vaccines like measles, bacilli Calmetter-Guérin (BCG), diphtheria-pertussis-tetanus (DPT), Tetanus toxoid (TT), and oral polio vaccine (OPV), are widely accessible by an average 50~80% of infants each year. Due to increasingly efficient production resulting from time, economics, and competition, off-patent vaccines are sold at very low prices and provide low marginal rates of return to producers.¹⁶⁶

Newer vaccines, such as hepatitis B and Haemophilus influenza type B (Hib), which have been available in developed countries for many years, have been introduced into developing countries very slowly due to the price of the vaccines. Although these vaccines were provided at a far lower price¹⁶⁷ to developing countries than to developed countries, the vaccine prices are still making the drugs prohibitively expensive to people in developing countries.¹⁶⁸

¹⁶⁶ Amie Batson, Sarah Glass, and Erica Seiguer, 'Economic of Vaccines: From Vaccine Candidate to Commercialized Product', Barry R. Bloom and Paul-Henri Lambert edited, *The Vaccines Book*, P.350, Academic Press, 2002

¹⁶⁷ The vaccine prices introduced in developing countries have been contained by measures by differential pricing.

¹⁶⁸ Amie Batson, Sarah Glass, and Erica Seiguer, 'Economic of Vaccines: From Vaccine Candidate to Commercialized Product', Barry R. Bloom and Paul-Henri Lambert edited, *The Vaccines Book*, P.350, Academic Press, 2002

When comparing with the traditional or off patent vaccines, which range from \$0.05~0.15/dose, the prices of newer vaccines are still unaffordable to the majority of the population.

The accessibility and affordability of these drugs are big problems in both developed and developing countries. The vaccine industries are just like any other business sectors; the market demand dictates the potential earnings from a product. The price of vaccines is a critical component of accessibility and affordability of a vaccine. If the vaccine price is too high, the higher price will cause problems to government budgets, clinicians, hospitals and consumers. Immunization will surely decrease if the payers are unable to afford the treatments. By contrast, if the vaccine price is too low, due to government discounts¹⁶⁹, price caps or the purchasing power of consumers or small markets, it will discourage investment by vaccine companies. The economics of vaccines have become the major obstacle to vaccine development. Nevertheless, vaccines prices are just like any other goods, affected by the volume, market demand, and the purchasing power of the buyer.

The high profit of vaccines is influential for large companies and for venture funding of small companies because potential sales determine the desirability of an investment decision. The public expectation is for low vaccine prices.

Nonetheless, the gaps between those who have and who do not have access to vaccines has widened in the past two decades. The main reason for the lack of access to live-saving vaccines is that they are unaffordable; however, there are other factors that contribute to the problem. In many developing countries, lack of an adequate health care service to provide medical services¹⁷⁰,

¹⁶⁹ Large group or government can usually negotiate discounts to up to 15% and for the small clinics and hospitals pay for the list price. Historically, the discount was up to 75%.

¹⁷⁰ WHO, State of the World's Vaccines and Immunization, P.14, 2003, available at www.who.int/vaccines-documents/DocsPDF04/wwwSOWV_E.pdf (last accessed on March 18, 2009)
Developing countries account for 93% of the world burden of diseases, but only 18% of its income and only 11% of global spending on health.

lack of the capacity to deliver the vaccines, the inadequacy of diseases surveillance and reporting systems cause the burden of diseases and application of the cost-effective vaccines to fight against the diseases—these all factor into the complexity of the problem.¹⁷¹

It is true that developing countries are in tremendous need of vaccines, but from the point of view of the companies, the demand is relatively small.¹⁷² Low and uncertain demand for a product discourages the industry from investing.

Because the vaccine development and manufacturing are very costly, the decision makers in developed countries have to appropriate the budget in the interests of the people for vaccine purchase. The licensed pneumococcal conjugate vaccine provides an example. Four recommended doses exceed \$200 if purchased in a private retail market. The vaccine price is beginning to impinge on decisions of those who do the recommending of the vaccination. Therefore, even though the vaccine is effective, the vaccine price makes people more reluctant to purchase it.¹⁷³

Accessibility and affordability of vaccines are even worse for developing countries. Those most in need of the vaccines are the least able to afford or develop them. Developing countries

¹⁷¹ WHO, State of the World's Vaccines and Immunization, P.7, 2003, available at www.who.int/vaccines-documents/DocsPDF04/wwwSOWV_E.pdf (last accessed on March 18, 2009)

¹⁷² Amie Batson, Sarah Glass, and Erica Seiguer, 'Economic of Vaccines: From Vaccine Candidate to Commercialized Product', Barry R. Bloom and Paul-Henri Lambert edited, The Vaccines Book, P.347, Academic Press, 2002

The terms of market and demand is usually used very differently. The potential market for vaccines in developing countries is very large; however, the actual market is the portion of this need that translates into demand or purchased doses at a give price. Thus, the market for a manufacture is the revenue generated by sales of products. Although the potential need of vaccine may be large in developing countries, the actual demand is much smaller because of those who need the vaccine are often least able to pay for it.

¹⁷³ B Brett Finlay, 'Understanding Microbial Pathogenesis as a Basis for Vaccine Design', Barry R. Bloom and Paul-Henri Lambert edited, The Vaccine Book, P. 186, Academic Press, 2003

are mostly haunted by infectious disease. With limited health budgets and poor infrastructure, governments are unable to purchase the vaccine for their peoples.

Even though transnational pharmaceutical companies sell vaccines through a two-tiered pricing system (prices in developed countries are high, as in Western Europe and the US, and a large volume of vaccines is sold to developing countries at a significantly lower price), immunization is still not sustainable in most developing countries.

The lack of demand¹⁷⁴ is the cause of both the inaccessibility and unaffordability of vaccines. From the perspective of the industry, the freedom to price vaccines is restrained. Most of the vaccines are sold to governments at discounted prices. Prices for developed countries are high.¹⁷⁵ Setting the price of vaccines is even tougher in countries with price controls, such as in Western Europe and Japan. Controls are even more pressured regarding the sales to developing countries, or sometimes the vaccine donations. The downward price pressures discourage investment.

Even though vaccines have given important benefits to the population, the vaccine supply system is surprisingly fragile. At the moment, only four major vaccine manufacturers are able to adhere to modern standards and their total capacity is inadequate for future demand. Currently,

¹⁷⁴ From the perspective of the vaccine industry, the need for vaccines is different than the demand for vaccines. The market is located at the consuming capacity. When the market can cover up the costs and generate profits, then there is a demand.

¹⁷⁵ The Committee on the Evaluation of Vaccine Purchase Financing in United States Board of Health Care Services, *Financing Vaccine in the 21st Century: Assuring Access and Availability*, P. 108-109, 2004
Trying to strike a balance between multinational pharmaceutical companies and developing countries, large, multinational pharmaceutical companies sell the vaccine in a two-tiered pricing system. Means, prices in developed countries are higher than the vaccines sell to developing countries. For those vaccines revenue generate from developed countries around 82% but only represent 12% of doses.

the new vaccines sell for dramatically high prices.¹⁷⁶ On the other hand, prices of the old vaccines are more stable; this stable pricing may be disrupted by the development of new combinations of individual vaccines and of existing vaccine combinations.

2.5.4 TM

In many developing countries, TM is the primary health care. The considerable use of TM can be shown by statistics: 40% of people in China and Colombia, 71% of people in Chile and up to 80% of those living in some African countries use TM. In some developed countries, TM has also been regularly used by about 70~75% of the population.¹⁷⁷

TM should be the most accessible and affordable pharmaceutical in countries where TM is the primary health care¹⁷⁸, when compared with the chemical compound medicines and vaccines. TM is usually harvested from plants, animals or minerals on a national level. However, it cannot be assumed that TM is always a cheaper option. In some countries, governments subsidize the chemical compound medicines and vaccines used by the pharmaceutical industry, but not the TM industry. As a result, some TM is more expensive than the chemical compound medicines and vaccines.¹⁷⁹

¹⁷⁶ The Committee on the Evaluation of Vaccine Purchase Financing in the United States Board of Health Care Services, *Financing Vaccine in the 21st Century: Assuring Access and Availability*, P. 128, 2004
Varicella vaccine is at a federal contract price of \$32.70 per dose. One new pediatric pneumococcal vaccine is at \$43.50 per dose and the list price is \$58.00 in the US.

¹⁷⁷ Gerard Bodeker, Fredi Kronenberg, and Gemma Burford, 'Policy and Public Health Perspectives on Traditional, Complementary, and Alternative Medicine: An Overview', Gerard Bodeker and Gemma Burford edited, *Traditional, Complementary and Alternative Medicine: Policy and Public Health Perspectives*, P.10, World Scientific Publishing, 2006

¹⁷⁸ Primary health care in most countries in African region, Latin America and several Asian countries.

¹⁷⁹ Gemma Burford, Gerard Bodeker, and Chi-Keong Ong, 'Financing Traditional, Complementary, and Alternative Health Care Services and Research', Gerard Bodeker and Gemma Burford edited, *Traditional, Complementary and Alternative Medicine: Policy and Public Health Perspectives*, P.42, World Scientific Publishing, 2006

Moreover, the problem of biodiversity of the raw material of TM, has posed problems to reproducing TM, making the TM inaccessible and unaffordable in some situations.

In most countries, TM services are not insured, so patients and consumers have to pay out of pocket. According to the survey for Global Atlas among the WHO members, only 58 out of 121 surveyed states (27%) are known to have public financing for TM, whether full or partial. The reimbursement of the TM services is often restricted to specific therapies or certain categories of practitioners.¹⁸⁰

2.5.5 Factors Contributing to Pharmaceutical Prices

There are a number of factors that contribute to the price when pharmaceuticals become internationally traded goods. In addition to the R&D and the market approval and other marketing expenses, tariffs and taxes, as well as the global intellectual property protection on pharmaceuticals, are key factors in driving up the market price.

2.5.5.1 Tariffs and Other Charges

Tariffs and other charges are revenue sources for governments, though at the same time they are barriers to trade. Sometimes governments may use tariffs or other charges to protect their domestic pharmaceutical industries against foreign competition; however, the tariffs and charges add to pharmaceutical prices for the end-users—the patients. The WHO recommends that the listed essential medicines should not be subject to tariffs, but some countries still levy tariffs and

¹⁸⁰ Gerard Bodeker, Fredi Kronenberg, and Gemma Burford, 'Policy and Public Health Perspectives on Traditional, Complementary, and Alternative Medicine: An Overview', Gerard Bodeker and Gemma Burford edited, Traditional, Complementary and Alternative Medicine: Policy and Public Health Perspectives, P.16, World Scientific Publishing, 2006

other charges on essential medicines.

2.5.5.2 Global Intellectual Property Protection

Intellectual property rights protection, as the safeguard of and incentive for the investment in pharmaceutical products, plays an important role in both the domestic and global trade of pharmaceutical products.

Due to the enormous loss of profits as a result of off-patent pharmaceuticals, pharmaceutical companies face considerable countervailing pressures to maintain and promote their sales with patent protection to recoup their costs and make profits. Pharmaceutical companies adopt measures to prolong patent life or delay the generic products entering the markets, measures that wind up driving the command prices well above the manufacturing costs.¹⁸¹

TRIPS ensures the minimum patent protection of pharmaceutical products globally. There are also concerns about how the TRIPS agreement affects pharmaceutical prices, because with the implementation of TRIPS, all WTO member states have to provide patent protection for product and processes following the content in TRIPS. Since the patent offers the patent holders (primarily the pharmaceutical companies) exclusive rights, the pharmaceutical prices then will be set according to the market.

2.5.5.3 Cost Containment Measures

In facing the problems of unaffordable pharmaceuticals, governments use cost-containment

¹⁸¹ WHO, The World Medicines Situation, P.38, 2004, available at www.searo.who.int/LinkFiles/Reports_World_Medicines_Situation.pdf (last accessed on March 18, 2009)

measures to ensure the availability of pharmaceutical products.

Parallel Imports

Parallel imports or grey market pharmaceuticals are genuine pharmaceutical products imported into one country without the authorization of the patent holder. National governments may have different policies regarding parallel imports. The pharmaceutical prices from the grey market are much cheaper than those sold under license.

Compulsory Licensing

Governments may use compulsory licensing to allow the use of patented pharmaceutical products without the patent holder's consent on the ground of public interest; for example, national emergency, anti-competitive practices or non-commercial use may qualify for a public interest exception to the patent rules.

Drug Donation

Some large pharmaceutical companies engage in the support of health development through private-public partnerships. In a number of cases, international corporations and foundations have contributed drugs or products free of charge to help in disease eradication.

SmithKline Beecham has made a US\$500 million commitment to WHO of its drug albendazole, used to treat lymphatic filariasis (elephantiasis). American Home Products has provided a non-toxic larvicide and the DuPont Company have contributed free cloth water filters for the eradication of guinea-worm disease (dracunculiasis). The Japanese Nippon Foundation

has enabled the WHO to supply blister packs containing the drugs needed for multi-drug therapy (MDT) of TB in sufficient quantities to treat about 800,000 patients a year in some 35 countries.¹⁸² Novartis, in a framework established with the WHO, offers public sector purchases in developing countries a special price for its anti-malarial medicine Coartem (artmether+lumefantrine).¹⁸³

Differential Pricing (Tiered Pricing)

The term “different,” “tiered,” “preferential,” “discounted pricing” and “market segmentation” is used to describe the practice of charging lower prices in different markets.¹⁸⁴ By using differential pricing, companies can charge a low price in developing countries to promote accessibility and affordability, while still charging developed countries higher prices to recoup their expenditures. However, the different pricing measures do not necessarily result in greater affordability or availability. The measure of differential pricing has been applied in other sectors for years. It is often integral to widespread use of products, but safeguards must be instituted in order to prevent the importation of grey market goods.

Price Controls

Price control is a government policy that intervenes directly with the pharmaceutical industry in order to control costs. Usually, with a nationally run healthcare system, the government acts like a monopolist in selecting which pharmaceuticals will be subject to reduced prices¹⁸⁵, a

¹⁸² WHO, ‘Pharmaceutical Industry’, available at www.who.int/trade/glossary/story073/en/print.html (last accessed on March 18, 2009)

¹⁸³ WHO, The World Medicines Situation, P.70, 2004, available at www.searo.who.int/LinkFiles/Reports_World_Medicines_Situation.pdf (last accessed on March 18, 2009)

¹⁸⁴ WHO, ‘Access to Medicines’, available at www.who.int/trade/glossary/story002/en/print.html (last accessed on March 18, 2009)

¹⁸⁵ Kevin A. Hassett, Price Control and the Evolution of Pharmaceutical Markets, P.4, 2004, available at

decision based on national health budgets by implementing pharmaceutical price controls. Pharmaceutical companies strongly oppose the government price control and claim that the price control policies discourage the investment in new R&D, and may in certain cases negatively impact the interests of consumers and patients.¹⁸⁶

Pharmaceutical pricing is free in a few countries such as the US, Germany and Denmark. Some countries apply the individual price fixing systems, such as Australia, Austria, Belgium, Finland, France, Greece, Hungary, Italy, Japan, Korea, Mexico, Norway, Spain, Sweden and Switzerland.¹⁸⁷

2.5.6 Concluding Summary

The market of pharmaceuticals is led by the invisible hands of self-interest.¹⁸⁸ From the perspective of the pharmaceutical industries, profits guide the markets. Whenever the market price of pharmaceuticals exceeds their costs, there are profits. The market force is the mechanism driving the R&D of pharmaceuticals. The profits provide an incentive for the current companies or others to produce more pharmaceuticals to enter into the market. As a consequence, more pharmaceuticals will be invented or produced to provide for their priority markets (those places where consumers or patients are willing to pay the most).

www.who.int/intellectualproperty/news/en/Submission-Hassett.pdf (last accessed on March 18, 2009)

The government interventions in the control of pharmaceutical prices usually include price, volume, and spending controls.

¹⁸⁶ Phrma, What Goes into the Cost of Prescription Drugs, P.10-11, 2005, available at

www.phrma.org/files/Cost_of_Prescription_Drugs.pdf (last accessed on March 18, 2009)

¹⁸⁷ Jaume Puig-Junoy edited, The Public Financing of Pharmaceuticals: An Economic Approach, Edward Elgar Publishing, 2005

¹⁸⁸ Jack Hirshleifer, Amihai Glazer and David Hirshleifer, Price Theory and Applications: Decisions, Markets, and Information, 7th Ed., P.18-19, Cambridge University Press, 2005

2.6 Conclusion

Pharmaceutical products work wonders in improving the quality of human life. Pharmaceuticals not only extend human life but also contribute in many ways to making human life more enjoyable. So although pharmaceuticals can be seen as preventing disease or as life-saving instruments, whether or not the market-based theory shall be applied to pharmaceuticals as a commodity is an important question in need of resolution.

However, the pharmaceutical companies need financial resources to work these wonders. The human capital and productivities are one main factor in the competition in the international marketplace, and in attracting investments. Healthy populations make for a better working force, higher household income and increased domestic savings. Globalization can have a positive influence, making the pharmaceuticals accessible and affordable. It is essential to make the economic benefits extend to all countries, especially those in need. The possible adverse effects on globalization must be minimized. "Globalization will have a positive impact only if a country can successfully compete in the global environment."¹⁸⁹

Meanwhile, the pharmaceutical products and R&D processes need protections to safeguard the interests of producers and consumers. As a result of lobbying to safeguard pharmaceutical products, the system of global intellectual property has succeeded in protecting investment by the pharmaceutical companies and, as the companies claim, to offer incentives for the development of new and better pharmaceuticals. The extension of TRIPS to define pharmaceutical products as goods in trade turns a new page in the complicated history of the global trade of

¹⁸⁹ WHO, Globalization, Trade and Public Health: Tools and Training for National Action: Report of an Inter-country Expert Group Meeting, P.4, 2001, available at http://whqlibdoc.who.int/searo/2001/SEA_HSD_244.pdf (last accessed on March 18, 2009)

pharmaceuticals.

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Chapter Three: Intellectual Property Rights Protection and

Pharmaceutical Products

3.1 Intellectual Property Rights Protection on Pharmaceutical Products

Long before the legal definition of intellectual property rights, these rights were understood as being conferred on creations or inventions of intelligence. The protections are usually given to the creators or owners of an exclusive right over the use for a period of time, with some exceptions in a variety of cases.

The protection of intellectual property has progressed over time. The evolution of the protections given to such property can be divided into three periods: the territorial, international and global response to the needs for protection of scientific and technological development.

The territorial period is characterized by the protection of rights within the territory of the nation state. As trade across national borders increased, states sought ways to protect rights to their intellectual property through agreements and treaties. The primary territorial protections were national in nature, and the international protections, such as treaties, tolerated some level of differences among states, and the process of forming international standards for protection was still limited.¹⁹⁰

As globalization emerged as an economic paradigm, there was an urgent need to standardize protection of the interests of scientific and technological developments. Negotiations to more comprehensively set minimum standard protections for intellectual property started during the

¹⁹⁰ Ian Fletcher, Loukas Mistelis and Marise Cremona edited, Foundations and Perspectives of International Trade Law, P.516, Sweet & Maxwell, 2001

GATT, which acknowledged that the ineffective protection of scientific and technological R&D and inventions could pose a barrier to trade.

Since pharmaceutical products are a cornerstone of advancement in science and technology, the pharmaceutical industry was eager to require international or even global protections for pharmaceutical products in order to incentivize continuous R&D as well as sustainable investment. Because of the special essential characteristics of their products, including the ability to prevent and cure diseases, it has been difficult to reconcile these products within the IPR system.

The high cost of R&D coupled with the relatively low cost of manufacturing existing pharmaceuticals has resulted in an industry-wide push to strengthen legal protections for the intellectual property rights underlying these products. This behavior is a rational response by an industry motivated by the need to maximize their return on investment. During the expansion of intellectual property rights in the international arena, these industry players focus to an even greater extent on securing stronger global protections for their interests.

3.1.1 National Era

The concept of a patent system originated in Europe. In Renaissance Italy, 1474, the concept was first used as an incentive to attract foreign engineers with a 10-year monopoly on their works and devices.¹⁹¹ In 1624, the English Statute of Monopolies changed the focus of patent laws, with a goal of granting the true owner a monopoly rather than simply encouraging

¹⁹¹ Graham Dutfield, *Intellectual Property Rights and the Life Science Industries: A Twentieth Century History*, P2-3, Ashgate Publishing, 2003

invention. In the US, the first patent law came about in 1790, implementing Article 1, Section 8 of the Constitution, which empowers Congress to promote the progress of science and useful arts by securing for limited times to inventors the exclusive rights to their inventions.¹⁹² Later, Germany also established its Patent Act in 1877.¹⁹³ At this time, most of the national patent laws were based on several rationales from natural law, contract law, reward and incentive paradigms, and prospect theory.¹⁹⁴

The Industrial Revolution saw growing concerns by inventors seeking to protect their interests to avoid domestic and foreign free riders, and the result was a development trend to base the protection of their scientific and technological intelligence and invention on private property rights. These trends, coupled with the need to protect intelligent labor, have spread across the globe, from Europe to America, and eventually into Asia.¹⁹⁵

During the 19th century, the number of patent applications in each country skyrocketed as the availability of foreign investment and the expansion of trading and markets brought to inventors and corporations the pressure of protecting their interests beyond national boundaries.

Originally, the system for the patent “granting” power was at the discretion of the rulers. The patent was considered to be a “privilege.” The historical accounts of patent protections show that the uses of patent laws have been to balance the interests of both inventors and users of

¹⁹² US Constitution Article 1, Section 8,
<http://www.law.cornell.edu/constitution/constitution.article1.html> (last accessed on March 19, 2009)

¹⁹³ Graham Dutfield, *Intellectual Property Rights and the Life Science Industries: A Twentieth Century History*, P.2-3, Ashgate Publishing, 2003

¹⁹⁴ Holger Hestemeyer, *Human Rights and the WTO: The Case of Patents and Access to Medicines*, P.29-33, Oxford University Press, 2007

¹⁹⁵ Holger Hestemeyer, *Human Rights and the WTO: The Case of Patents and Access to Medicines*, P.27, Oxford University Press, 2007

the products on a public policy basis. However, the later international and global development of patent systems has shifted the conceptual basis for patent protection from that of a "privilege" to that of a "right;" in this emerging system, countries have lost their discretion to grant protections within their sovereign territories, but instead are obligated to protect patents under the treaties and international laws.¹⁹⁶ This fundamental shift in the nature of patent protections turned the system on its head, and along the way it has created obstacles and problems that are still not fully resolved.

The patentability of pharmaceutical products was different in each nation state. Pharmaceutical products have not been explicitly stated as within the subject matter of national patent laws, but by the interpretation of the laws, the laws give patent protection to some pharmaceutical products. At first the Statute of Monopolies granted patent protection for "the sole working or making of any matter of new manufacture," and this was later interpreted by the courts to include substances formed by chemical compounds or other processes. US patent law under the Patent Act of 1970, 1973 offers patent protection to "any new and useful process, machine, manufacture, or composition of matter, of any new and useful improvement thereof." The pharmaceutical chemical compounds therefore, by interpretation, fit into the definition of "composition" and can be given patent protection. By contrast, the French Patent Act of 1844 explicitly excluded pharmaceutical products from patent protection for public policy reasons.¹⁹⁷

¹⁹⁶ Susan Sell, *Private Power, Public Law: The Globalization of Intellectual Property Rights*, P.5, Cambridge University Press, 2003

¹⁹⁷ Holger Hestemeyer, *Human Rights and the WTO: The Case of Patents and Access to Medicines*, P.28-29, Oxford University Press, 2007

French started to give special patent protection for pharmaceutical products with the compulsory licensing system to balance the interests from the pharmaceutical companies and the interests of the consumers or patients when the quality, quantity and the price is too high.

For the pharmaceutical industry, the 19th century was a truly a breakthrough era, especially in the extraction and purification of the active ingredients of plant-based drugs. The modern pharmaceutical industry emerged in Germany in the late 19th century. The interest groups of the chemical industry lobbied hard for national patent laws to protect their investment.¹⁹⁸

Bayer and Hoechst were the pioneer firms in the application of synthetic chemistry and drug discovery. The German chemical companies became dominant in the pharmaceutical industry prior to World War I. The successful model of the patent system caught the attention of other countries, many of which came to agree that the patent system was necessary and essential to protecting their assets, and could also be used to raise capital and protect inventions by their citizens and companies.¹⁹⁹ The lobbying for international patent protection of pharmaceutical products started in the late 20th century.²⁰⁰

3.1.2 International Era: The Paris Convention

As pressures grew to internationalize protections, many patent abolitionists argued that the patent system would become a barrier to free trade and should therefore be abolished; the supporters of the patent system rejoined that without patent protections, intellectual property theft would deprive inventors of the fruits of their research, development, and labor. After many years of controversy and extensive debates, the policy of adapting rather than abolishing the patent

¹⁹⁸ Intellectual property rights protection can relate to pharmaceutical products in many ways, besides the primary related patent system, other intellectual property rights also relate to pharmaceutical products, including the protection in trademark, copyright, trade secret/knowhow and the recent development of the protection of pharmaceutical test data.

¹⁹⁹ Christopher May and Susan K. Sell, *Intellectual Property Rights: A Critical History*, P.126-131, Lynne Rienner Publishers, 2005

²⁰⁰ Holger Hestemeyer, *Human Rights and the WTO: The Case of Patents and Access to Medicines*, P.29, Oxford University Press, 2007

Many countries adopted the patent protection to pharmaceutical products will the late 20th century, e.g. German in 1968, Japan in 1976, Switzerland in 1977, Italy in 1978, Spain in 1992, Portugal in 1992 and Norway in 1992.

system was favored by policy makers.

Patent law was developed during the 19th century in most economically and technologically advanced countries, such as Great Britain, the U.S., France, and Germany, and the resultant patent laws were different from each other. It was quite difficult for inventors to secure effective protection of their interests once the invention crossed international boundaries or was sold in foreign countries. At the same time, the industrial revolution brought a resultant increase in trading between countries, exacerbating the need to prevent piracy with strong international standards for patent protections.

The proposal of having an international patent protection system encountered much opposition. Nevertheless, the Paris Convention of 1883 was signed and became the first major international treaty on the protection of industrial property. The controversy over patent protection temporarily ended in compromise, by the terms and perspective of the powerful national states and the influences of non-state actors in this multinational treaty.²⁰¹ The institution merged with the Berne Convention in 1970, and was transformed and administered by the World Trade Intellectual Property Organization (WIPO).

The Paris Convention has been revised six times since 1883, with the intent to progressively promote and strengthen the rights of intellectual property despite the anti-patent trend moving from Europe to the rest of the world. Again, the commercial interests and political pressure

²⁰¹ Christopher May and Susan K. Sell, *Intellectual Property Rights: A Critical History*, P.95, Lynne Rienner Publishers, 2005

In the negotiation of Paris Convention, non-state actors, private sectors, had played a prominent role. The private sectors used the influences and lobby nation states to provide a more protective regime.

emerged triumphant. The Paris Convention requires the signatory states to offer certain explicit fundamental intellectual property protections to comply with a set of international norms. Substantively, the most important achievements of the Paris Convention are the national treatment, the right of priority, and rules relating to local manufacture.

National treatment requires that a signatory state to grant a foreign patent owner the same rights and remedies offered to the state's own citizens. The right of priority gives an applicant six months from the date a patent is first filed in a member country to seek patent protection in other signatory states.

Until that time, there was no international standard or harmonizing of national laws for the granting of patents, and each nation state applied its own patent law to the granting or denying of patent protection. The Paris Convention made no reference to compulsory licensing, contained no standards addressing the gap between the patent laws in each country, and left to each country to decide to which industrial sectors they wanted to extend patent protections.

In the case of pharmaceutical products, the Paris Convention has never explicitly required giving patent protection to chemical substances, including pharmaceutical products, nor has it specified the duration of the protection to be offered. Due to the concern of the states, pharmaceutical products remained as an area which many countries generally excluded from patentability, for public policy reasons.²⁰²

²⁰² Pedro Rofee, Geoff Tansey and David Vivas-Eugui edited, *Negotiating Health: Intellectual Property and Access to Medicines*, P.9, Earthscan Publications Ltd., 2006

Moreover, although the Paris Convention has been supported by some countries, many developing countries were particularly reluctant to sign the convention. The signatory states of WIPO were far from constituting global participation.

As mentioned above, the pharmaceuticals industry has been developed rigorously since the 19th century. The industry has been defined by mergers and acquisitions among the top companies in the industry in the 20th century. The resulting market is dominated by transnational pharmaceutical corporations based in the U.S. and Western Europe.

As the demand for pharmaceutical products grew, the transnational pharmaceutical industry and pharmaceutical industry-based countries lost confidence in the patent protection of pharmaceuticals under the Paris Convention, because it contained no explicated international standard protection to include pharmaceutical products, weak enforcement, and no dispute settlement mechanisms. As late as 1988, 49 Paris Convention signatories still excluded pharmaceutical products, and 10 signatories excluded pharmaceutical processes from patent protection.²⁰³

To protect their interests, pharmaceutical industry-based countries used bilateral, regional agreements or sanctions to make other countries compromise to offer more similar patent protection to secure their interests, or used investment agreements to encourage other nation states to bargain their right to refuse protections away. For example, the U.S. used Special 301

²⁰³ Christopher May and Susan K. Sell, *Intellectual Property Rights: A Critical History*, P.154~155 Lynne Rienner Publishers, 2005

40 out of 98 signatory states of WIPO, excluded pharmaceutical products, animal varieties, methods of treatment, plant varieties, and biological processes for producing animal and plant varieties; over 30 excluded food products and computer programs and further 22 excluded chemical products.

as a threat of trade sanction on those countries which did not offer efficient protection of their products. The purpose of this tactic was to influence other states to modify their inefficient intellectual property rights systems to be more consistent with the American approach. Disregarding all the measures and still dissatisfied with the result, the pharmaceutical and chemical industries went further to lobby for stronger intellectual property protections from an international level towards a global level.

3.1.3 Global Era: The TRIPS Agreement

As global trade increases, the pharmaceutical industry claims that it has lost growing amounts of its prospective profits by putting more investment in R&D without a corresponding increase in its legal protections. The pharmaceutical industry seeks to use its power to influence a more efficient global system to protect its profit in the global market.

After the successful negotiation of the General Agreement on Tariffs and Trade (GATT), the negotiations turned to addressing new issues, such as investment, trade in services, and protection of intellectual property rights, driven almost exclusively by private actors. In the negotiations, pharmaceutical industry representatives took a leading role, along with other private actors such as the software and entertainment industries. As these industries influenced the evolution of patent protections, they created a system of stronger protections that help their bottom line, but may become an obstacle to free global trade.²⁰⁴

The intellectual property system was finally incorporated into formal trade negotiation at

²⁰⁴ Susan Sell, *Private Power, Public Law: The Globalization of Intellectual Property Rights*, P.7, Cambridge University Press, 2003

the 1986 Punta del Este Ministerial Declaration. Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) was introduced in the 1994 to establish minimum standard requirements for intellectual property protection rather than harmonization of each member state's national law. The TRIPS Agreement came into effect on January 1, 1995. Though it establishes minimum standards of protection, it has allowed countries some latitude in defining the scope and duration of their protections, but it has helped to narrow the differences and gaps that created tension in cross-borders trading.

Another breakthrough concept in TRIPS was to recognize that intellectual property rights are private rights and TRIPS regulations are minimum standards set for public policy reasons to balance the interests of the inventors and the users. All WTO member states are fully bound by the TRIPS agreement. However, TRIPS allows countries to have different transitional periods of time to fully comply with the TRIPS provisions depending on the status of the countries.²⁰⁵

During the negotiation, pharmaceutical industries-based countries, as one of the major negotiating groups, used their influential powers to persuade others that the counterfeiting of pharmaceutical products and the lack of protection for pharmaceutical products have become barriers to international trade. The international patent protection for pharmaceutical products, they argued, is insufficient and ineffective.

As mentioned above, the Paris Convention did not require any specific field to be covered

²⁰⁵ For developed countries, the transitional period is one year following the entry of the WTO, i.e. until 1 Jan 1996. Developing countries are allowed to delay their transitional period for four years, which is 1 Jan 2000. Least developed countries are granted a longer transitional period of a total of eleven years, i.e. till 1 Jan 2006, with the possibility of an extension.

by the rights of patent protections, nor did it specify a minimum durational requirement. Therefore, the field and duration of protection was determined by the signatory states.

TRIPS sets minimum requirements for positive legislative action, but it does not bar member states from taking certain actions.²⁰⁶ TRIPS obligated member states to implement patent protection to at least the minimum standard set forth in the agreement. It is considered a major boon to the pharmaceutical industry by providing protection to technology in any field, including pharmaceutical science and technology. Moreover, patent protection in the technology field was set at a minimum duration of 20 years, with effective enforcement mechanisms.

3.1.4 Concluding Summary

The development of intellectual property has progressed from the national and international levels to the global level. TRIPS is only the latest step in an ongoing political process by which intellectual property law is becoming increasingly standardized across the globe. There is not yet a fundamental agreement on how to protect “knowledge-based property.”

The role of the industry, as non-state actors, in influencing the development of these treaties and norms demonstrates that law is not based on science, but on normative ideology, tightly tied to power.²⁰⁷ The pharmaceutical industry will be one of the private sectors which benefit the most from TRIPS. The relationship between intellectual property rights, innovation and public

²⁰⁶ Christopher May and Susan K. Sell, *Intellectual Property Rights: A Critical History*, P.163, Lynne Rienner Publishers, 2005

²⁰⁷ Paul Farmer, *Pathologies of Power: Health, Human Rights and the New War on the Poor*, P.235, University of California Press, 2003

health has always been the focus of debate. The primary goal of pharmaceutical industry is to protect and maintain the funding and incentive mechanisms for the development of new pharmaceutical products. The pharmaceutical industry asserts that the system of intellectual property rights is to safeguard the end-product, pharmaceuticals, in the return on investment rather than the amount invested.²⁰⁸

With the development of technology and international law, the emerging dominant themes in intellectual property law- privatization, deregulation, expansion of incentives to entrepreneurial behavior, structure adjustment programs, and related pressures from international financial institutions and developed countries- have had mixed, and sometimes adverse, effects on the enjoyment of economic and social rights.²⁰⁹

3.2 TRIPS, Public Health and Pharmaceutical Products

The greatest achievement made by the pharmaceutical industry in its efforts to secure international protection for its products came when TRIPS obligated WTO member states to extend patent protection to all field of technology, which included pharmaceutical products, within their national intellectual property protection laws. TRIPS defines minimum standards for the core elements of these protections, including subject matter, definitions of rights, permissible exceptions, and a minimum durational period.

²⁰⁸ Jaume Puig-Junoy edited, *The Public Financing of Pharmaceuticals: An Economic Approach*, P.22, Edward Elgar Publishing, 2005

The pharmaceutical industry claims that the contribution of pharmaceutical patents should be evaluated as a function of how they have helped to developed new medicines that have improved the public health, and in particular from a perspective of opportunity cost.

²⁰⁹ Paul Farmer, *Pathologies of Power: Health, Human Rights and the New War on the Poor*, P.244, University of California Press, 2003

TRIPS adds a substantial number of obligations on each member state dealing with areas of the law which are not addressed or specified from prior international agreements, and in some cases replaced provisions that were inadequate or ineffective. Moreover, it included a set of enforcement procedures and dispute resolution practices to give teeth to these new obligations.

TRIPS binds member states as part of the single package of the WTO Agreement, and imposes minimum standards of protection. It also mandates that citizens of different states be given equal treatment by law to that given to the nation's own citizenry. However, TRIPS offered transitional arrangements for developing countries, and built in some flexibility in reaching the minimum standards, tolerating some variations by member states.

3.2.1 General Provisions

The TRIPS Agreement also embraces the three general provisions under GATT: national treatment, most-favored-nation (MFN) status, and transparency. TRIPS provides its members with fundamental rules for national treatment in Article 3²¹⁰ and most-favored-nation treatment of foreign nationals in Article 4.²¹¹

In its scheme of national IP protections, WTO member states cannot discriminate against foreigners by offering them less favorable protection than it accords its own nationals with regards to the incorporation of the minimum protections for intellectual property rights from

²¹⁰ WTO, TRIPS, 1994, Article 3, available at http://www.wto.int/english/docs_e/legal_e/27-trips.pdf (last accessed on March 19, 2009)

²¹¹ WTO, TRIPS, 1994, Article 4, available at http://www.wto.int/english/docs_e/legal_e/27-trips.pdf (last accessed on March 19, 2009)

TRIPS into their national laws, policies and regulations.²¹² Member states must provide both the substantive standards for protection and the availability, acquisition, scope, maintenance, enforcement and use of the intellectual property.

The most-favored nation provision forbids discrimination between member states as stated in Article 4²¹³. With regard to the protection of intellectual property, any advantage, favor, privilege or immunity granted by a WTO member state to the nationals of another member state should be accorded immediately and unconditionally to the nationals of all other member states.

The enforcement of intellectual property rights related to pharmaceutical products has to be effective in preventing infringement by member states under the WTO law, providing that the procedures are fair and equitable, not complicated, costly, or entailing unreasonable time limits or unwarranted delays; each case must be decided on merits, supported by evidence, and available to parties without undue delay; and the parties shall have opportunity to ask for judicial review of the administrative decision or lower court's ruling. The details of the enforcement provisions are in Article 41 - Article 62, including the rules to obtain evidence, injunctions, provisional measures, damages, other remedies, and penalties.²¹⁴

3.2.2 Patent Protection for Pharmaceutical Products

Before the round of TRIPS negotiations, more than 50 countries did not offer patent protection to

²¹² WTO, TRIPS, 1994, Article 3.2, available at http://www.wto.int/english/docs_e/legal_e/27-trips.pdf (last accessed on March 19, 2009)

²¹³ WTO, TRIPS, 1994, Article 4, available at http://www.wto.int/english/docs_e/legal_e/27-trips.pdf (last accessed on March 19, 2009)

²¹⁴ WTO, TRIPS, 1994, Article 41, available at http://www.wto.int/english/docs_e/legal_e/27-trips.pdf (last accessed on March 19, 2009)

pharmaceuticals.²¹⁵ It was a major achievement of the pharmaceutical industry to extend patent protection to pharmaceutical products in these countries.

Besides the general obligations of national treatment and most favored nation standards, TRIPS sets minimum standards for intellectual property protections in copyright, trademarks, geographic indications, industrial designs, patents, layout-designs (topographic) of integrated circuits, undisclosed information, and the anti-competitive practices in contractual licenses. For pharmaceutical products, the most relevant and essential protection is the patent protection in Article 27 - Article 34.

The key breakthrough for pharmaceutical products is in TRIPS Article 27, which defines patentable subject matter.²¹⁶ Article 27.1 requires member states to make patents available for any inventions,

...[P]atents shall be available for any inventions, whether products or processes in all field of technology, provided they are new, involve an inventive step and are capable of industrial application... patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether the product is imported or locally produced.

Article 27.1 makes patent protection available to inventions of products and processes in all field of technology. The absence of exclusion for pharmaceutical products and processes established these products and processes as within the scope of patentability, provided they meet

²¹⁵ Pedro Rofee, Geoff Tansey and David Vivas-Eugui edited, *Negotiating Health: Intellectual Property and Access to Medicines*, P.9, Earthscan Publications Ltd., 2006, and

²¹⁶ Patent protection offers the patent from unauthorized use of the right, but not the permit to market the pharmaceutical product. Patented pharmaceuticals still have to pass the testing and approval by food and drug administration before put into the market.

all other requirements for patentability.²¹⁷

The standard for patentability reflects and mirrors the terms in national patent laws in some member states; however, the provision does not define the terms of “inventions,” “new,”²¹⁸ involvement of “inventive steps” and “capable of industrial application.” The intention might be for a future change in science and technology. Some countries have a more liberal²¹⁹ interpretation of the terms. Some scholars suggest that member states can interpret these terms to restrict the number of patents issued.

Despite this perceived victory for the pharmaceutical industries, TRIPS Article 27.1 was one of the major concessions made to developing countries during the negotiation. The exchange that established IPR protection will actually help the economy of these countries, and in the case of pharmaceutical products, the patent regime should have offered more incentives for R&D to benefit consumers or patients, especially for people in developing countries. However, the application of the global patent systems has not had the intended results. Patent systems

²¹⁷ There are other patentability requirements, such as novelty, inventive steps (non-obviousness), utility (capable of industrial application), disclosure in state of the art (best mode) and capable if carrying out by a person skilled in the art.

²¹⁸ Carlos M. Correa, *Trade Related Aspects of IPR: A Commentary on TRIPS Agreement*, P.274-275, Oxford University Press, 2007

Member states have different interpretation of novelty. The universal novelty, which applied in most countries, prevent pharmaceutical products from patentability which belong to prior art. The issue of ‘second indication’ of pharmaceutical products, which are the same known chemical compound, is used for a new use for different treatment. Article 27.1 did not address to this issue. Some countries allow patentability for second indication pharmaceuticals by using the so called ‘Swiss formula’ in patent claim, whereas, for some other countries, prevent the patentability. US, adopts liberal concept of patent standards. In US, patent can be granted by new chemical entities, the so called NCES, but are also granted secondary patent, if the existing chemical entities have taken new formulas, new combination or new uses. It has been on debated for those “Me too” or “evergreen” drugs, when the pharmaceutical companies use the strategies to prolong their patent protection to dominate the market.

²¹⁹ Holger Hestemeyer, *Human Rights and the WTO: The Case of Patents and Access to Medicines*, P.54-55, Oxford University Press, 2007

The interpretation of the term “invention” is different in countries. Where the distinction on things which exist, is discovery, should not be invention. However, many developed countries adopted narrower definition of discovery, by not allowing patentability on the discovered substance, but allowing patentability on the processed substance by purified or extracting. In some developing countries, do not allow mere purification of the substances.

offer incentives to profitable markets, but do not stimulate more R&D for diseases existing in developing countries. The pharmaceutical products have become even more inaccessible and unaffordable ever since.

TRIPS Article 29 requires that patent application be disclosed by the state of the art, in other words, the best mode of the invention. The language of that article requires disclosure in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art and may require the applicant to indicate the best mode for carrying out the invention known to the inventor at the filing date or, where priority is claimed, at the priority date of the application.

TRIPS allows member states to exclude patentability from an invention when it is necessary to protect order or mortality within their territory, including to protect human, animal or plant life or health, or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law.

TRIPS Article 27.2 provides flexibilities to WTO member states in their possible interpretation to structure their national patent system for pharmaceutical products. Some argue that pharmaceutical products should be excluded from patent protection under Article 27.2, for reasons to protect human health, but others argue that Article 27.2 should be read into two parts. First, it says that member states can exclude patentability from commercial exploitation of the invention, when it is necessary to protect order public or mortality; it then provides examples as including to protect human, animal, or plant life or health.

Pharmaceutical products have essential impacts on human health, and the legitimate commercial exploitation of pharmaceutical products does not necessarily pose a threat to public order, but it is the exclusionary effect of the pharmaceutical patent system and the marketing strategies of the pharmaceutical invention for profit which results in inaccessible and unaffordable pharmaceutical products, and which leads to the impacts on human health. Professor Carlos M. Correa agrees that TRIPS Article 27.2 is a sub-provision of public order and morality, but it does not provide grounds to refuse the application of a patent system to pharmaceuticals.²²⁰

Moreover, in TRIPS Article 27.3, member states may also exclude patentability from diagnostic, therapeutic and surgical methods for the treatment of human and animals, plants and animals other than micro-organisms, and essential biological processes for the production of plants or animals other than non-biological and microbiological processes. However, members shall provide for the protection of plant varieties either by patent or other effective sui generis systems, or the combination thereof.

TRIPS Article 28, Article 30 and Article 33 confer on the patent owner exclusive rights for at least 20 years, but subject to exceptions. The product patent owner has the right to prevent third parties from making, using, offering for sale, selling or importing these products without his consent. The process patent owner has the right to prevent third parties without consent from using the process, and from the acts of using, offering for sale, selling or importing for these purposes the product obtained directly by that process. Additionally, the patent owner has

²²⁰ Carlos M. Correa, Trade Related Aspects of IPR: A Commentary on TRIPS Agreement, P.289, Oxford University Press, 2007

the right to assign, or transfer by succession, the patent, and to conduct licensing contracts.

WTO member states are bound by the WTO laws as a single package when they become members. Each WTO member state is required to provide patent protection for all inventions in any field of technology by fully complying with the TRIPS agreements, with no different treatment based upon the development status of the member states, only allowing transitional arrangements for states in Article 65 and Article 66.²²¹

In the case of pharmaceutical patent, generally, new members joining WTO after 1995 have agreed to fully comply with TRIPS as soon as they join. For developing countries not providing product patents in pharmaceutical products, a transition period in which to comply was extended from January 1, 2000 through January 1, 2005. The transitional period had a big impact on developing countries, including India, Brazil, South Africa, Thailand and Egypt, which are most important producers of the pharmaceutical products still under patent protection in other developed countries.

Least-developing countries were given a transitional period until January 1, 2006. It was later agreed by members on November 30, 2005 to extend the deadline for patent protection for pharmaceutical products until January 1, 2013, or the date a country is no longer considered a least-developing country, whichever occurs first. The Doha Declaration on TRIPS and Public Health extended the deadline for least-developing countries to fully comply with the patent

²²¹ WTO, TRIPS, 1994, Article 65 Transitional Arrangements, available at http://www.wto.int/english/docs_e/legal_e/27-trips.pdf (last accessed on March 19, 2009) and WTO, TRIPS, 1994, Article 66.1 Least Developing Country Members, available at http://www.wto.int/english/docs_e/legal_e/27-trips.pdf (last accessed on March 19, 2009)

protection in pharmaceuticals until 2016.

3.2.3 Parallel Import/Grey Market and Exhaustion of Rights ²²²

Parallel import/grey market goods are product sold by the patent owner or with the permission of the patent owner more cheaply in one country and imported and sold into another country without the patent holder's permission. Though it is an unauthorized distribution of a good or service, such goods are not illegal per se, and are not considered counterfeit, but they are an unauthorized exportation, which may create problems when traded beyond borders. The parallel importation of pharmaceutical products was one of the major issues in accessibility and affordability of pharmaceutical products.

Applying the legal principle of "exhaustion" to parallel imports is important here, because once a protected product has been sold, the patent holder generally has exhausted his right to control the product. There are three exhaustion schemes: national, regional and international. Under a national exhaustion scheme, the exclusive right is exhausted when the product is sold under the authority of the right holder. In a regional exhaustion scheme, the effect of exhaustion extends beyond the borders to other countries which have agreements.

The most complicated issue arises in the situation of exhaustion in the international scheme, when the pharmaceutical products are involved in the parallel trade from one country into another with no agreement between the countries. Pharmaceutical industries, especially transnational pharmaceutical corporations, argue that the prevalence of grey market

²²² Grey market is different from black market, which involves the distribution of product or service that is illegal to distribute.

pharmaceuticals reduces their profits and has adversely affected the R&D of new drugs and sustainable price controls as well as the administrative regulation to ensure the safety of the pharmaceutical products. State governments, public health administrations and patients will buy the pharmaceutical products from the cheapest available source. Grey market pharmaceutical products thus increase the accessibility and affordability of pharmaceuticals. Therefore, some countries still allow parallel importing of pharmaceuticals. On this issue, each WTO member state has different laws and regulations on whether they allow parallel importation.

TRIPS has addressed this issue in a specific provision in Article 6²²³, which states the exhaustion of right: “[f]or the purpose of dispute settlement under this Agreement, subject to the provisions of Art 3 and 4 nothing in this Agreement shall be used to address the issue of the exhaustion of intellectual property rights.” This language provides that TRIPS simply does not deal with the issue of parallel importation, except for those overlaps with the violation of national treatment and most-favored-nation treatment which can raise the issues of exhaustion of intellectual property rights in the WTO dispute mechanism. It is up to each member’s discretion whether or not to have a national exhaustion regime, under which right holders can take action against parallel imports, or an international exhaustion regime, under which they cannot take action against parallel imports.

The current practice of parallel importation depends on the national law of each country. Some countries allow parallel importation if the products are sold domestically and then sold into

²²³ WTO, TRIPS, 1994, Article 6, available at www.wto.org/english/docs_e/legal_e/27-trips.pdf (last accessed on March 19, 2009)

foreign markets only by the consent of the patent holder. Other countries have adopted the theory of 'implied license,' that a purchaser of the pharmaceutical products has an implied license from the patent holder for reasonably contemplated purposes. Exhaustion of rights is presumed if the patent holder abstained from imposing restrictions in the original sales contract.²²⁴

3.2.4 TRIPS Exceptions/Flexibilities

TRIPS requires minimum standards for IPR protection, but at the same time offers flexibilities to WTO member states as the result of compromise during the negotiation. During the negotiation of TRIPS, several exceptions and flexibilities were established in order to balance the private interests by offering incentives for R&D and the public interest in accessibility and affordability of inventions. In addition, the use of the exceptions/flexibilities cannot unreasonably prejudice the legitimate interests of the patent owner and the legitimate interests of third persons.

TRIPS Article 30 states that

[m]embers may provide limited exceptions to the exclusion rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties."²²⁵

The wording of the flexibilities was general, which reflects the difficult compromise during the negotiation of this provision. According to Article 30, referred exceptions must be 'limited,' 'not unreasonably conflict with a normal exploitation of the patent,' 'not unreasonably prejudice the legitimate interests of the patent owner,' and '[take] into account the legitimate interests of

²²⁴ Carlos M. Correa, Trade Related Aspects of IPR: A Commentary on TRIPS Agreement, P.82-83, Oxford University Press, 2007

²²⁵ WTO, TRIPS, 1994, Article 29 Exceptions to Rights Conferred, available at www.wto.org/english/docs_e/legal_e/27-trips.pdf (last accessed on March 19, 2009)

third parties.’

In TRIPS Article 30, the most relevant flexibilities to the pharmaceutical products are the legitimate acts done privately and for a non-commercial purpose; use for experimental or teaching purposes; seeking regulatory approval for marketing before the expiration of the patent (usually refers as BOLAR exceptions); and compulsory licensing.²²⁶

The experimental exception is to permit a person to invent, perform, test or improve on the existing pharmaceutical patented product. In the US, the experimental exception is only allowed without authorization from the pharmaceutical patent owner when it is limited to scientific purposes. In Europe or other countries, the experimental exception is even allowed for commercial purposes. By contrast, many developing countries have not explicitly referred to this exception.²²⁷

The regulatory exception, usually called the ‘BOLAR exception’ or ‘early working exception,’ is another exception for pharmaceutical products which allows the exceptional use of patented pharmaceutical products for regulatory purposes, mostly by the generic pharmaceutical companies for the purposes of obtaining market approval before the patent expires so they will be able to put their products into the market as soon as the patent expires. In order to compensate the loss of the exclusion rights of years due to the administration process for pharmaceutical products, the original pharmaceutical patent could be extended up to five years

²²⁶ Carlos M. Correa, Trade Related Aspects of IPR: A Commentary on TRIPS Agreement, P.302-303, Oxford University Press, 2007

²²⁷ Carlos M. Correa, Trade Related Aspects of IPR: A Commentary on TRIPS Agreement, P.304-305, Oxford University Press, 2007

from the time they processed their products for market approval.²²⁸

Many countries have adopted this 'BOLAR' concept into their national laws to benefit the consumers, who are able to purchase accessible and affordable pharmaceutical products from generic drug companies as soon as the patent expires.

Compulsory licensing is another exception/flexibility related to pharmaceutical products. The term of 'compulsory licensing' is not used in the TRIPS provisions. TRIPS Article 31, Other Use Without Authorization of the Right Holder, describes the application of compulsory licensing as "[w]here the law of a Member allows for other use of the subject matter of a patent without authorization of the right holder, including use by the government or third parties authorized by the government."²²⁹ In other words, compulsory licensing is one of the uses under

²²⁸ Carlos M. Correa, Trade Related Aspects of IPR: A Commentary on TRIPS Agreement, P.304-305, Oxford University Press, 2007

The exception is called after a US case of Roche Products Inc v. BOLAR Pharmaceutical Co, which US court denied BOLAR's right to use of the pharmaceutical product for the purpose to obtain FDA approval process before the patent expiry of the patent. This issue was settled in a later US Drug Price Competition and Patent Term Restoration Act, 1984, which allow the non-patent owner, usually generic drug companies to use of the patented pharmaceutical product for the purposes of initiation of procedures for the marketing approval from FDA before the patent expired. Generic drug companies then can place their product into the market as soon as the patent expired. In the compensation of the lost patent term protection of the patented pharmaceutical product, the patent protection for the original patent owner could be extended up to five years.

²²⁹ WTO, TRIPS, 1994, Article 31 Other Use Without Authorization of the Right Holder, available at www.wto.org/english/docs_e/legal_e/27-trips.pdf (last accessed on March 19, 2009)

Where the law of a Member allows for other use⁷ of the subject matter of a patent without the authorization of the right holder, including use by the government or third parties authorized by the government, the following provisions shall be respected:

(b) such use may only be permitted if, prior to such use, the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time. This requirement may be waived by a Member in the case of national emergency or other circumstances of extreme urgency or in cases of public noncommercial use. In situations of national emergency or other circumstances of extreme urgency, the right holder shall, nevertheless, be notified as soon as reasonably practicable. In the case of public non-commercial use, where the government or contractor, without making a patent search, knows or has demonstrable grounds to know that a valid patent is or will be used by or for the government, the right holder shall be informed promptly;

(c) the scope and duration of such use shall be limited to the purpose for which it was authorized, and in the case of semi-conductor technology shall only be for public noncommercial use or to remedy a practice

Article 31 when the government allows the use of the patented invention without the patent holder's permission or authorization under some conditions for protecting the patent right holder's interest.

The concept of compulsory licensing is aimed at striking a balance between the rights holder and the user. Compulsory licensing is used to promote the accessibility and affordability of pharmaceutical products and to offer incentives for R&D in pharmaceutical products. Compulsory licensing of pharmaceutical products is only applicable when several conditions are met.

The person or company must first make efforts to obtain voluntary licensing under reasonable commercial terms; if it fails with reasonable efforts within a reasonable period of time, then the person or company can pursue compulsory licensing,²³⁰ limiting the scope, duration and use of the authorization²³¹ to domestic markets only.²³² If a compulsory license is issued, adequate remuneration must still be paid to the patent holder.²³³

determined after judicial or administrative process to be anti-competitive;

(f) any such use shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use;

(k) Members are not obliged to apply the conditions set forth in subparagraphs (b) and (f) where such use is permitted to remedy a practice determined after judicial or administrative process to be anti-competitive. The need to correct anti-competitive practices may be taken into account in determining the amount of remuneration in such cases. Competent authorities shall have the authority to refuse termination of authorization if and when the conditions which led to such authorization are likely to recur;

²³⁰ WTO, TRIPS, 1994, Article 31 (b), available at www.wto.org/english/docs_e/legal_e/27-trips.pdf (last accessed on March 19, 2009)

²³¹ WTO, TRIPS, 1994, Article 31 (c), available at www.wto.org/english/docs_e/legal_e/27-trips.pdf (last accessed on March 19, 2009)

²³² WTO, TRIPS, Article 31 (f), available at www.wto.org/english/docs_e/legal_e/27-trips.pdf (last accessed on March 19, 2009)

²³³ WTO, TRIPS Article 31 (h), available at www.wto.org/english/docs_e/legal_e/27-trips.pdf (last accessed on March 19, 2009)

However, the pre-requisite of first attempting to get voluntary license may be waived temporarily in the situations of national emergency, other extreme urgent conditions, public non-commercial/government use, or anti-competitive practices. However, in emergency and urgency conditions, the patent holder must still be notified as soon as is practicable. In the case of public non-commercial or government use with knowledge of a valid patent, the government or contractor should inform the right holder promptly.²³⁴

3.2.5 Concluding Summary

The global patent regime in TRIPS has opened the door to patent protections for the pharmaceutical industry. TRIPS introduces norms and standards for all member states to follow. Though the norms and standards will be monitored and enforced by the WTO dispute settlement mechanism, the application is difficult and the effects of the patent system to pharmaceuticals have impacted the accessibility to affordable pharmaceutical products.

3.3 TRIPS Issues in Pharmaceutical Products

WTO member states, especially states with no patent protection for pharmaceutical products, were concerned about the accessibility of affordable pharmaceutical products during the TRIPS negotiation. However, in order to join the WTO and take advantage on the free trade agreement to promote their domestic economies, WTO member state has to agree to be bound by TRIPS. As a compromise based on those concerns, the negotiation included a balancing principle for the protection of intellectual property rights which is reflected in TRIPS Article 7, with the goal that TRIPS can balance the interests.

²³⁴ WTO, TRIPS Article 31 (b), available at www.wto.org/english/docs_e/legal_e/27-trips.pdf (last accessed on March 19, 2009)

TRIPS Article 7 states²³⁵,

The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.

TRIPS Article 7 spells out that the object of TRIPS is to balance both rights and obligations of the inventors and users of technological knowledge in a manner conducive to social and economic welfare. TRIPS tries to strike a balance between encouraging creation and invention and the interests people have in accessing the intellectual property. Several TRIPS flexibilities were offered to balance these interests during the negotiation; nevertheless, the application of flexibilities to pharmaceutical products has proven difficult.

3.3.1 Exclusive Effect of Patented Pharmaceutical Products

Tracing its history, the concept of intellectual property has shifted in the twentieth century from a “privilege” to a “right.” In the old patent system, it was recognized as a “grant of privilege” and the sovereign states had the discretion to determine the grant.²³⁶ The later shifting from “privilege” to “right” changed the formal concept and left the sovereign states obligated to recognize these protections as a right, and the shifting character of the patent system increases the tension between competition and rights.

The patent system has often been criticized for its exclusive character. The exclusive

²³⁵ WTO, TRIPS, 1994, Article 7, available at http://www.wto.int/english/docs_e/legal_e/27-trips.pdf (last accessed on March 19, 2009)

²³⁶ Susan Sell, *Private Power, Public Law: The Globalization of Intellectual Property*, P.5, Cambridge University Press, 2003

aspect of patent protection especially affects pharmaceutical products. The term monopoly²³⁷ might not really apply to the patent system, but the nature of the pharmaceutical products, which is very different from that of other industrial property, makes the patented pharmaceutical products more exclusive than other industrial property.

This is because every pharmaceutical product is unique and not replaceable by other products, and sometimes it is the uniqueness and inability to be replaced which makes its use a life or death decision for the patient. Products differ from others in their pathology, chemical reactions, and suitable intake for patients. Due to the patent protections given to pharmaceutical products, many new pharmaceuticals are still under patent protection, and the pharmaceutical companies make every effort to extend that protection²³⁸. The new pharmaceuticals are deemed to be more effective in one way, so are construed as better than existing products.²³⁹ Not only the physicians but also patients are hoping to have more effective treatments, but because of the cost and inaccessibility of the pharmaceutical products, physicians and patients are excluded from access to the products and choose other products, or give up treatment.

²³⁷ Philip Grubb, *Patent for Chemicals, Pharmaceuticals and Biotechnology: Fundamentals of Global Law Practice and Strategy*, 4th Ed., P.7, Oxford University Press, 2005

Philip Grubb points out that, monopoly should not be used to patent system because patent as a new invention, cannot take any right from public which public previous had.

²³⁸ Carlos M. Correa, 'Protection and Promotion of Traditional Medicine implications for Public Health in Developing Countries', P. 111, 2002

http://www.southcentre.org/index.php?option=com_content&task=view&id=74&Itemid=67 (last accessed on March 19, 2009)

This dilemma is particularly serious in the area of public health, as increased prices mean reduced access to medicines which in some cases determines life or death.

²³⁹ Patent expired pharmaceutical products, or so called generic drugs, are more accessible compare with the drugs still under the patent protection in the term of affordability. But most of the patented drugs are newer drugs (which are created or invented recently), and most of the time, more effective drugs. In most of the criticism on the unaffordable and inaccessible of pharmaceutical products, patients are really in hush needs for patented drugs mostly, but not for the generic drugs. And those patented drugs may cure or decrease the pain for the new disease, SARS, AIDS or cancer. However, these drugs are all still under patent protection, in other words, still very expensive.

The protection of the patent system does create exclusive effects, but it is also the temporary exclusive character which gives the incentives to investment. Cornish also agrees that “the exclusive rights to prevent other people from doing things are at least monopolistic in a legal sense, if not necessary in an economic one.” Sell also points out that intellectual property rights per se do not constitute a monopoly, but the effect of the application of the exclusive rights raises monopoly power in a form of monopoly rent to the innovator. The patent right owners have the opportunity to raise the price.²⁴⁰

The use of the patent system to foster R&D in new drugs and balance the access of medicine has become an important task. With no effective patent protection and enforcement, pharmaceutical companies would be unable to insure their investment and unwilling to spend capital to do R&D; without ongoing R&D, fewer new drugs will be created and invented. However, many consumers and patients cannot afford the pharmaceutical products, and are forced to buy gray market medicine or counterfeited medicine. The gray market and counterfeited pharmaceutical products might be much cheaper, but some of the products might not have the same ingredients and some of the ingredients might damage the health. Moreover, the grey market pharmaceutical products are not examined by the Food and Drug Administration, and there is little consumer protection if damages occur. Therefore, there has to be a balance between the enjoyment of the right and the fair application of the right.

²⁴⁰ Susan Sell, *Private Power, Public Law: The Globalization of Intellectual Property*, P.13-14, Cambridge University Press, 2003

3.3.3 The Use of TRIPS Flexibilities: DOHA Declaration on TRIPS and Public Health and Later Development

Due to the need to clarify the use and interpretation of TRIPS flexibilities as it relates to the goal for the citizens of WTO member states to benefit from increased opportunities and welfare²⁴¹, the DOHA Declaration on TRIPS had stepped forward to settle some important parts of the TRIPS at the DOHA Ministerial Conference in 2001 in recognition that "...no country should be prevented from taking measures for the protection of human, animal or plant life or health or of the environment..."²⁴²

In the DOHA Declaration, members adopted a separate declaration on TRIPS and Public Health in recognition of the public problems.²⁴³ The WTO member states agreed on the need for and the importance of implementing and interpreting TRIPS' role in supporting public health. The WTO members also recognized that intellectual property is important to the development of new medicines, but at the same time, they were also concerned about the effects on the prices of pharmaceutical products. It was agreed that TRIPS does not and should not prevent members from taking measures to protect public health. It was affirmed that TRIPS should be interpreted and implemented in a manner supporting members' right to protect public health, and in particular to promote both the access to existing medicines and the creation of new medicines for all.²⁴⁴

²⁴¹ WTO, Doha Declaration, 2001, Paragraph 2, available at www.wto.int/english/thewto_e/minist_e/min01_e/mindecl_e.pdf (last accessed on March 19, 2009)

²⁴² WTO, Doha Declaration, 2001, Paragraph 6, available at www.wto.int/english/thewto_e/minist_e/min01_e/mindecl_e.pdf (last accessed on March 19, 2009)

²⁴³ WTO, Doha Declaration, 2001, Paragraph 17, available at www.wto.int/english/thewto_e/minist_e/min01_e/mindecl_e.pdf (last accessed on March 19, 2009)

²⁴⁴ WTO, Declaration on the TRIPS Agreement and Public Health, 2001, available at www.wto.int/english/thewto_e/minist_e/min01_e/mindecl_trips_e.pdf (last accessed on March 19, 2009)

Some of the TRIPS flexibilities have been clarified. Each member has the right to grant compulsory licenses and is free to determine the grounds for granting such licenses, including what constitutes national emergency or other extreme urgency. Moreover, the issue of parallel importing in exhaustion was also affirmed in that each member state is free to determine the scope of exhaustion of rights and exhaustion of rights decisions cannot be challenged under the WTO dispute panel unless the issue is subject to the MFN and national treatment provisions of TRIPS Article 3 and Article 4. The transitional period was extended for the least developed countries until 2016.

The remaining question was how to promote accessibility to existing pharmaceuticals by adopting TRIPS flexibilities regarding compulsory licenses for countries that do not have the manufacturing ability to produce pharmaceutical products and offer them domestically.

This issue was partially resolved on August 30, 2003, when the General Council decided to allow countries with no manufacturing capacity to import patented pharmaceutical products from other countries under compulsory licenses provided certain conditions were met.²⁴⁵

TRIPS Article 31 (f)²⁴⁶, “the compulsory licensing for domestic supply only” provision will be waived by application of the August 30, 2003 decision to the extent that the production of pharmaceutical products and export to eligible importing countries.

²⁴⁵ WTO, Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, Decision of the General Council of 30 August 2003, 2003, available at www.wto.int/english/tratop_e/trips_e/implem_para6_e.htm (last accessed on March 19, 2009)

²⁴⁶ WTO, TRIPS, 1994, Article 31 (f), available at http://www.wto.int/english/docs_e/legal_e/27-trips.pdf (last accessed on March 19, 2009)

The decision contains three waivers. First, the exporting countries' obligations to supply the compulsory licensed pharmaceutical products to domestic use only are waived. Second, the importing countries' obligations for remuneration to the patent holder are waived. Exporting countries will pay the remuneration. Third, exporting constraints are waived for developing countries, so they can export within a regional trade agreement.²⁴⁷

The application of the August 30, 2003 decision is that the eligible importing countries have to provide notification to the TRIPS Council of information of the specific names and quantities of the pharmaceutical products and the exporting countries which have been issued compulsory licenses, regarding the specific requirements by the importing countries and the distinguishable features of exporting compulsory licensed-pharmaceutical productions from the original patented pharmaceutical products. The importing and exporting country governments are also required to post all the information on the designated website²⁴⁸ on which the licensor will post additional information, such as the quantities being supplied to each destination and the products' distinguishing features, in order to prevent these pharmaceutical products from being diverted into the wrong markets.²⁴⁹ The posting on the webpage is an informational notification to other member states of the use of the "paragraph 6" system; WTO's approval is not required.

²⁴⁷ WTO, TRIPS and Pharmaceutical Patents, 2006, available at www.wto.int/english/tratop_e/trips_e/factsheet_pharm00_e.htm (last accessed on March 19, 2009)

During the time for Aug 30 2003's decision, at least half of the WTO member states were categorized as developing countries at that time.

²⁴⁸ WTO, TRIPS and Public Health: Dedicated Webpage for Notification, available at www.wto.int/english/tratop_e/trips_e/public_health_e.htm (last accessed on March 19, 2009)

This webpage is dedicated for notification of the 30 August 2003's decision for members using the Doha "Paragraph 6" system for using compulsory licensing of pharmaceutical products.

²⁴⁹ WTO, Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, Decision of the General Council of 30 August 2003, 2003, available at www.wto.int/english/tratop_e/trips_e/implem_para6_e.htm (last accessed on March 19, 2009)

When a compulsory license is granted under the “paragraph 6 system,” adequate remuneration in accordance with TRIPS Article 31 (h)²⁵⁰ shall be paid to the exporting member, taking into account the economic value to the importing member. The remuneration of the pharmaceutical products shall be waived by the eligible importing member to the patent owner when the remuneration is paid by the exporting member.²⁵¹ In this case of two compulsory licenses, it is suggested that double payment to the patent right holder be avoided by considering that the potential importing member is usually short of resources; therefore, it is preferable for the exporting member to make payment of the adequate remuneration, taking into account the economic ability of the importing member.²⁵²

All WTO member countries are eligible to import under this decision, but 23 developed countries are listed in the decision as announcing voluntarily that they will not use the system to import.²⁵³ Another 10 countries about to join the EU said they would only use the system to import in national emergencies or other circumstances of extreme urgency, and would not import once they had joined the EU.²⁵⁴ Additionally, 11 countries said they would only do so in national emergencies or other circumstances of extreme urgency.²⁵⁵

²⁵⁰ WTO, TRIPS, 1994, Article 31, Other Use of the Authorization of the Right Holder, available at http://www.wto.int/english/docs_e/legal_e/27-trips.pdf (last accessed on March 19, 2009)

²⁵¹ WTO, Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, Decision of the General Council of 30 August 2003, 2003, available at www.wto.int/english/tratop_e/trips_e/implem_para6_e.htm (last accessed on March 19, 2009)

²⁵² Katharina Gamharter, Access to Affordable Medicines: Developing Responses under the TRIPS Agreement and EC Law, P.192-193, Springer, 2004

²⁵³ Australia, Austria, Belgium, Canada, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Japan, Luxembourg, Netherlands, New Zealand, Norway, Portugal, Spain, Sweden, Switzerland, United Kingdom and the US.

²⁵⁴ As to the countries are Czech Republic, Cyprus, Estonia, Hungary, Latvia, Lithuania, Malta, Poland, Slovak Republic and Slovenia.

²⁵⁵ As to the countries are Hong Kong China, Israel, Korea, Kuwait, Macao China, Mexico, Qatar, Singapore, Chinese Taipei, Turkey, and United Arab Emirates.

The August 30, 2003 decision created the so called “paragraph 6 system” which was later incorporated into the amendment of the TRIPS in 2005.²⁵⁶ Several workshops to help officials of WTO member states learn about the use of patent flexibilities for the health purposes have been held Geneva since 2005.²⁵⁷

Canada is the first member state to notify the Council of Information of its use of the special provisions of the paragraph 6 system’s compulsory license to export patented pharmaceutical products to Rwanda in 2007.²⁵⁸

The Doha Declaration and the August 30, 2003 decision did confirm the public health concepts and solve some technical problems regarding the application of the TRIPS flexibilities; however, these are difficult in practice.

3.3.4 TRIPS, Traditional Medicine (TM), Traditional Medical Knowledge (TMK), Vaccines and New Pharmaceutical Technology

As previous mentioned, most of the TRIPS patent-related provisions were adapted from WIPO and other IPR conventions, especially designated to apply to industrial property. In pharmaceutical products, the application fits properly with the new chemical compound entities pharmaceutical products, but there are problems when applying one system to various pharmaceutical products, including TM, TMK, vaccines, and new pharmaceutical technology,

²⁵⁶ WTO, Amendment of the TRIPS Agreement, 2005, available at www.wto.int/english/tratop_e/trips_e/wtl641_e.htm (last accessed on March 19, 2009)

²⁵⁷ WTO, 3rd Geneva Workshop Helps Officials Use Health Patent Flexibilities, 2007, available at www.wto.org/english/news_e/news07_e/trips_wp_7dec07_e.htm (last accessed on March 19, 2009)

²⁵⁸ WTO, Patent and Health: WTO Receives First Notification Under “Paragraph 6” System, 2007, available at www.wto.org/english/news_e/news07_e/public_health_july07_e.htm (last accessed on March 19, 2009) and WTO, Canada is First to Notify Compulsory License to Export Generic Drugs, 2007, www.wto.int/english/news_e/news07_e/trips_health_notif_oct07_e.htm (last accessed on Dec 3, 2008)

due to the different nature of these pharmaceutical products.

The protection of TM and TMK has been a very difficult issue for TRIPS. The main problem is that the patent system is designated to protect novel invention, whereas the TM and TMK are old wisdom from traditions. The current concept of IPR is not applicable to TM and TMK.

First, there is the composition issue: there are varieties of forms of TM. 90% of TM is composed of biological ingredients, including plants and animal parts, as well as minerals. The natural materials may be made and used in their original wild form or processed into preparations or mixtures. In this context, intellectual property right protection for products based on generic resources may pose problems, because the natural materials are usually not patentable, though depending on national law, some countries do allow patents on the discovery of natural materials.²⁵⁹

Also, TM and TMK encompass great varieties of methods for diagnosis and treatment, including physical, mental and spiritual therapies. The treatment and diagnosis methods are not patentable in most countries, and many countries do not even apply patent law to intangible mental and spiritual therapies.

²⁵⁹ WTO, TRIPS, 1994, Article 27.3 (b), available at http://www.wto.int/english/docs_e/legal_e/27-trips.pdf (last accessed on March 19, 2009)
Allows governments to exclude some kinds of inventions from patenting, i.e. plants, animals and "essentially" biological processes (but micro-organisms, and non-biological and microbiological processes have to be eligible for patents). However, plant varieties have to be eligible for protection either through patent protection or a system created specifically for the purpose ("sui generis"), or a combination of the two.

Secondly, the ownership or possession rights to TM/TMK pose an additional problem. Without the prior consent of the owner/holder of the TM/TMK, the appropriation will be biopiracy. However, by its nature most TM/TMK may be possessed by individuals without others' contributions, or by people's knowledge collectively possessed and asymmetrically distributed among individuals within a group, even though such individuals may not be aware that others share the same knowledge.

TM is usually developed and held collectively, and often the original holders of the TM inventors are not determinable. Sometimes, this knowledge may be kept as confidential and passed to certain people or certain classes of people within the group, and may be accessed by restrictions; some of the knowledge may be shared with others, and become public domain.

By contrast, the current patent law seeks to protect one or a small discrete number of inventors. Determining who is legally entitled to the right of TM/TMK or the use of genetic resources can be a difficult task. Some of the generic resources, TM, and TMK have been transferred from the countries of origin by the trade of goods, the movement of people, colonization and war, and even globalization.

Moreover, most TM/TMK has been disclosed in written or oral forms and widely used, documented or researched for generations. It does not fit the novelty requirement in the current concept of patent system.

One major problem with the development of TM is that most of the TM/TMK relies on

living traditions rather than upon second-hand accounts of the value and use of certain methods or treatments. Upon the lack of conservation, some of the generic resources have become scarce or disappeared entirely. This makes protection and development of TM/TMK more difficult.

The United Nations Convention on Biological Diversity (CBD) in 1992 was the first convention recognizing the need for international cooperation towards the important goal of conservation and the sustainable use of biological diversity for meeting the needs for food, health and the future. Member states started trying to set up principles defining these bio-resources as the sole property of sovereign states, which should have the freedom to use and trade them, but in a sustainable manner to prevent destruction, extinction, or alienation of biological resources.

CBD Article 8 (j)²⁶⁰ states as its goal the in-situ conservation and protection of traditional knowledge. It also provides a scheme for granting incentives at the local level to encourage indigenous and local communities to have rights to knowledge, innovations and practices, subject to national legislation. State governments must provide participatory mechanisms for the exercise of these rights so that communities can share the benefits from the commercialization of their resources.

Regarding access to biological resources, CBD Article 15²⁶¹, Access to Genetic Resources,

²⁶⁰ Convention on Biological Diversity, Art 8 (j), 1992, available at <http://www.cbd.int/convention/articles.shtml?a=cbd-08> (last accessed on March 19, 2009)

Each Contracting Party shall, as far as possible and as appropriate...

(j) Subject to its national legislation, respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity and promote their wider application with the approval and involvement of the holders of such knowledge, innovations and practices and encourage the equitable sharing of the benefits arising from the utilization of such knowledge, innovations and practices.

²⁶¹ Convention on Biological Diversity, Art 15, 1992, available at

establishes property rights, from open access to materials at the international level, to a common property resource at the national level, for genetic resources. Sub-provisions of Article 15 provide the designing mechanisms to regulate access.

Though CBD has provided some legal recognition for traditional knowledge, there are problems with its provisions.²⁶² The major problem of CBD is that the provisions impose a weak, fragile obligation on the proprietors, mostly pharmaceutical companies, to ensure the exchange of genetic resources and the associated traditional knowledge are acquired under the auspices of the Convention with payment of guaranteed equitable returns. The convention lacks contextualization to local eco-political circumstances and its integration across local, regional, commercial and environmental frontiers has been lax.²⁶³ The lack of clarity of the

<http://www.cbd.int/convention/articles.shtml?a=cbd-15> (last accessed on March 19, 2009)

²⁶² Padmashree Gehl Sampath, *Regulating Bioprospecting: Institutions for Drug Research, Access, and Benefit-Sharing*, P. 36, United Nations University Press, 2005

CBD Article 8(j) calls for respect, preservation and maintenance of traditional knowledge that is associated to biodiversity at the national level and contains an obligation to support and further advance TK in the context of conserving biological diversity. It does not contain a legal basis for creating individual rights nor any legal protection in the sense of establishing, exclusive, enforceable proprietary rights over the traditional knowledge. Though CBD has recognized TK and provided mechanisms and broad-based measures on biological diversity, it does not specifically prioritize the measures nor does it provide details, thus leaving member states with a lot of flexibility to implement its framework.

Moreover, the CBD embodies the concept of benefit sharing in both general and specific ways through several provisions, but there are still big gaps in between. Although countries will be compensated for the use of genetic resources, the Convention does not codify the relationship between the generation of revenues through such activities and biodiversity conservation in a direct way. Secondly, the Convention does not define "appropriate" compensation for the use of genetic resources. Lastly, though specific forms of benefit-sharing are mentioned, the Convention does not provide guidelines as to which form of benefits should be shared under what circumstances, which leave a lot of rooms for countries to deliberate amongst themselves and Sohpia Twarog and Promila Kapoor edited, UNCTAD, *Protecting and Promoting Traditional Knowledge: Systems, National Experiences and International Dimensions*, P. 99, 2004

www.unctad.org/en/docs/ditcted10_en.pdf (last accessed on March 19, 2009)

Another major difficulty in CBD and so do to other international treaties lies in the fact that, CBD obligations bind states as contracting parties but confer no rights and obligations on private entities such as research institutes, pharmaceutical companies and indigenous communities and without specific and effective national laws and regulations, governments have little power to enforce the provisions in the Convention. Currently, the access and benefit sharing left to contracts between the bioprospectors, mostly firms and scientific institutes, and public authorities in the sources countries. This contractual approach has several disadvantages which against the original purpose of the Convention.

²⁶³ Padmashree Gehl Sampath, *Regulating Bioprospecting: Institutions for Drug Research, Access, and*

terms in CBD and the diverse political ambitions of member countries has led to reduced implementation of the provisions.²⁶⁴ The biodiversity issues are made even more complicated due by the relationship between TRIPS and CBD.

In the case of vaccines, vaccines may be protected by patent, trade-secret/know-how, or undisclosed information.²⁶⁵ The traditional way to patent vaccines is by patenting the vaccine itself in the form of organism with specific modification; antigen by the sequence, DNA, or purified form; or in conjugate, in the adduct, linkage method or carrier protein.²⁶⁶ In order to prolong the exclusive benefits of patents, just as with chemical pharmaceutical products, the vaccine companies patent new vaccines using methods to extend the life of patents on vaccines by patenting the expression system of organisms, the regulatory sequences, and the fusion partners; the platform technology, such as DNA vaccines and vectors; other purification process; the formulation in adjuvant, excipients, and process to boost up the immunogenicity, stability, reactogenicity; and the delivery devices, such as nasal, aerosol, flapulette, patch or cartridge, to provide efficient and comfortable drug delivery.²⁶⁷

There are several problematic issues in the application of TRIPS provisions to vaccines.

Benefit-Sharing, P.3, United Nations University Press, 2005

²⁶⁴ Padmashree Gehl Sampath, *Regulating Bioprospecting: Institutions for Drug Research, Access, and Benefit-Sharing*, United Nations University Press, P.45, 2005

“One of CBD’s problems lies in the way in which its worthwhile goals are to be implemented. They are vague, ambiguous or impotent. As a result, it is very ambitious attempt to integrate ‘previously distinct policy goals’ in the CBD is on the verge of a failure. Key provisions such as Article 8 (j), Article 15 and Article 16 are being used out of context and in isolation from the rest of the Convention. Many of reasons lie in the politics that divide genetic-resource-rich source (yet developing) countries and technology-rich (but developed) countries.”

²⁶⁵ The knowhow/trade secret and undisclosed information have problems on how to securely protect the IPRS during transfer of technology.

²⁶⁶ WHO, Martin Friede, ‘IP Parameters to Vaccines’, 2004, available at www.who.int/intellectualproperty/events/en/WHO-Friede.pdf (last accessed on March 19, 2009)

²⁶⁷ WHO, Martin Friede, ‘IP Parameters to Vaccines’, 2004, available at www.who.int/intellectualproperty/events/en/WHO-Friede.pdf (last accessed on March 19, 2009)

WTO member states have different views on vaccines with regards to TRIPS. Some countries believe vaccines are pharmaceutical products under TRIPS, but some countries do not treat vaccines as pharmaceutical products under TRIPS.²⁶⁸ Additionally troublesome, vaccines have more biological substance than chemical compound pharmaceutical products. Vaccines either involve live or killed bacteria, live attenuated virus, or genetically manipulated antigens.²⁶⁹ If TRIPS allows biological substances to be covered by the patent system, it may be contrary to the basic concept of patentable subject matter.²⁷⁰

Another issue involved is the ownership of the vaccine, since the vaccines are mostly biological substances, and whether anyone is eligible to claim as the patent holder is an open question. Dr. Jonas Salk was interviewed on the evening on April 12, 1955 when he announced the development of a polio vaccine, as to the question of who owns the patent of the vaccine, he responded, "Well, the people, I would say, there is no patent. Could you patent the sun?"²⁷¹

3.3.5 Concluding Summary

Patent law is not incompatible with pharmaceutical products, but the application of the patent system affects their distribution and supply. TRIPS was negotiated based on the balancing principle, and also provides some balanced flexibilities, but some of the flexibilities are difficult

²⁶⁸ Dr. SS. Jodhav, 'Intellectual Property Rights & Vaccines in Developing Countries', 2004, available at www.who.int/intellectualproperty/events/en/S.Jadhav.pdf (last accessed on March 19, 2009)

For example, Japan insisted that the Doha declaration about pharmaceutical products did not cover vaccines and vaccine should not be included. However, EU agreed that vaccine were very much covered under pharmaceutical products. Sri Lanka argued strongly that vaccines were not part of the pharmaceutical sectors; therefore, Doha declaration should not apply to it. India argued that vaccine should be included in pharmaceutical sectors.

²⁶⁹ Dr. SS. Jodhav, 'Intellectual Property Rights & Vaccines in Developing Countries', 2004, available at www.who.int/intellectualproperty/events/en/S.Jadhav.pdf (last accessed on March 19, 2009)

²⁷⁰ WTO, TRIPS, 1994, Art 27, available at http://www.wto.int/english/docs_e/legal_e/27-trips.pdf (last accessed on March 19, 2009)

²⁷¹ Dr. SS. Jodhav, 'Intellectual Property Rights & Vaccines in Developing Countries', 2004, available at www.who.int/intellectualproperty/events/en/S.Jadhav.pdf (last accessed on March 19, 2009)

to practice in reality. Additionally, it is difficult to apply the concept of patent provisions to other pharmaceutical products, such as TM/TMK, vaccines, or other new technology.

3.4 Conclusion

The trade framework in global patent protection has progressed from preventing free riding to providing incentives for R&D, and benefitting the population as a whole by allowing them to enjoy the fruits of pharmaceutical science and technology. Applying global patent systems to pharmaceutical products should further new innovation of drugs and promote the public health. However, the application of the patent system has made it difficult to realize this goal due to the conflicts between the accessibility and affordability of pharmaceutical products, lack of R&D in diseases predominantly in developing countries, and in those pharmaceutical products which are not fully protected under the current patent law system. The precious value of pharmaceutical products and their unique function of preventing, curing and improving the health and life of human beings must be taken into account, as the application of global patent systems is causing impacts on human health and life. Health should not be jeopardized by money, but by applying the global patent system, money has taken a dubious role in determining the bounds of the human right to health.

Chapter Four: Right to Health as a Basic Human Right

4.1 The Development of Human Rights

Human rights are the rights that every human being in the world possesses irrespective of race, religion, political belief, legal status, economic status, language, color, national origin, gender, or ethnicity, and which are applicable to all individuals and groups on the basis of equality and non-discrimination. Human rights are freedoms and entitlements that protect the inherent dignity and equality of every human being. Professor Sompong Sucharitkul states that there are at least three dimensions of legal order or systems in promoting, protecting and preserving human rights as universal or global, regional or interregional, and internal or national.²⁷² The human rights norms were first developed at the national level, and then progressed towards the international level. The international human rights principle and norms are the result of negotiation and compromise among nation states, and were later embodied in international legal instruments on various fundamental issues as minimum international standards.

The development of human rights has transitioned from civil and political rights to economic, social and cultural rights. The civil and political rights are typically referred to as first generation rights, whereas the economic, social and cultural rights are usually referred to as second generation rights. Today, the development of human rights is moving towards new dimensions, to the so-called third and fourth or later generations of human rights. This classification²⁷³ scheme has been criticized as misleading, since a generation typically implies a type of revolution in which a new generation is the offspring of another. The term "generation"

²⁷² Sompong Sucharitkul, 'A Multi-Dimensional Concept of Human Rights in International Law', 62 Notre Dame L. Rev. 305, 1987

²⁷³ The human rights have been categorized into generations as first, second, third generation of human rights or even fourth generation rights recently.

also suggests a hierarchy in international human rights norms, but the human rights norms are universal, indivisible, interdependent, interrelated, co-existent and mutually supportive of each wave of rights without hierarchy.

Nevertheless, the classification is still used for common understanding of different categories of human rights. The classification of a generation of human rights describes different categories of the human rights in terms of the time in which they developed. The later-developed human rights remain indivisible, interdependent and interrelated to the previous generations of human rights in the progressive steps to respect, fulfill and protect the rights.²⁷⁴

4.1.1 The Development of Human Rights in Nation States

These rights originated and were codified from the human rights protection in nation states during the eighteenth and nineteenth centuries.²⁷⁵ The developed substance of human rights at the national level was later strengthened by a complementary international set of rules.

Accordingly, the civil and political rights are usually referred to as “negative” human rights or civil liberties, which enjoin nation states to abstain from interfering with individual rights, such as the freedom of security of person or freedom of speech. The civil and political rights have been included in most of the constitutional texts since eighteenth century.²⁷⁶

²⁷⁴ Christian Tomuschat, *Human Rights: Between Idealism and Realism*, P.2425, Oxford University Press, 2003
Without enjoying the right of the first generation, the human being would remain subject to the whims and fancies of the rulers by whom he/she is confronted. Likewise, rights of the second generations, such as the right to social security, do not become superfluous on account of the emergence of rights of the third generation. On the contrary, it may be said from the very outset that step by step, the next generation leaves the path of legal entitlement becoming heavily enriched with political elements.

²⁷⁵ Christian Tomuschat, *Human Rights: Between Idealism and Realism*, P.24~25, Oxford University Press, 2004

²⁷⁶ Christian Tomuschat, *Human Rights: Between Idealism and Realism*, P.24~25, Oxford University Press, 2004
The development of human rights which is originated or codified to nation level, for example, the Virginia

From the beginning of the twentieth century, a number of rights have developed as another class of fundamental rights in the constitution at a national level.²⁷⁷ The economic, social and cultural rights are usually referred to as “positive” human rights, which compel societies and nation states to assume the responsibility for social questions and problems.

Governments have been charged to respect, fulfill and protect civil and political rights as well as social, economic and cultural rights. Governments were more willing to commit themselves to the civil and political rights and abstain from violating those rights. However, as to the economic, social and cultural rights, due to available resources, nation states were more reluctant to commit themselves to incorporating positive social welfare benefits into their constitutions²⁷⁸ because the steps of progression are not mandatory and there is no strong infrastructure to ensure the development of rights.

4.1.2 International Development of Human Rights Norms

With the development of national human rights protection norms, nation states formed a consensus on the necessity of codifying the human rights norms for a minimum international human rights standard. The international human rights norms are protected by a variety of methods, including international human rights treaties and instruments and customary international law.

Declaration of Rights of 1776, first 12 Constitutional Amendment of United States, the Déclaration des Droits de l'Homme et du Citoyen of 1789, Belgian constitution of 1831, which had a considerable influence on constitutional developments.

²⁷⁷ Christian Tomuschat, *Human Rights: Between Idealism and Realism*, P.26, Oxford University Press, 2004

The Soviet Constitution of 1917 paved the way by setting a number of social and economic rights, and the German Weimar Constitution of 1919 are examples to entrenching furtherance new rights during the twentieth century.

²⁷⁸ Christian Tomuschat, *Human Rights: Between Idealism and Realism*, P.27~29, Oxford University Press, 2004

Based on the trend of constitutional human rights development in nation states, the United Nations embarked upon drafting international human rights instruments to strengthen human rights norms. The UN first drafted the Universal Declaration of Human Rights (UDHR) in 1948 as a common standard of achievement for all peoples and nation states, and planned to engage in negotiations for more human rights protections in depth. However, during the time following the Second World War, due to the tension between the western and socialist countries, there arose a question of whether to unite the civil and political rights and the economic, social and cultural rights into one convention or let them remain as two sets of conventions. Moreover, there was the question of whether the unity between the civil and political rights and economic and social rights should be split into two or more separate pieces.

The western states and the socialist states insisted on their own standards, while the socialist countries favored the inclusion of economic and social rights in the text first because of mistrust of the civil and political rights, the western states insisted on the inclusion of civil and political rights first while favoring non-inclusion of economic and social rights.²⁷⁹

The two sides tried to find ways to codify human rights protection in their list of priorities. At the result, the two sides came up some concessions²⁸⁰ for the International Covenant on Civil and Political Rights (ICCPR) 1966 and its two Optional Protocols, and the International Covenant on Economic, Social and Cultural Rights (ICESCR) 1966. The compromise between

²⁷⁹ Christian Tomuschat, *Human Rights: Between Idealism and Realism*, P.28, Oxford University Press, 2004

²⁸⁰ Christian Tomuschat, *Human Rights: Between Idealism and Realism*, P.28, Oxford University Press, 2004

The compromise solution was much damaged to the socialist countries, but not the western countries. For the socialist countries, but accepting the civil and political rights which undermined the bases of the communist dictatorships; for the west countries, no one was against providing the economic and social services to the populations, but the problems remain on the essentially the legal method of regulation.

the western states and socialist states has been criticized as one of the major political pitfalls while the full recognition of the civil and political rights and the economic and social rights remained unchanged until the definitive adoption of the two Covenants.²⁸¹ The two international covenants together with the UDHR formed into the so-called “International Bill of Human Rights.”

After the adoption of the International Bill of Human Rights, a series of international human rights treaties or instruments have adopted and conferred the protections and developments in more specific areas or groups, regional human rights protections²⁸² and non-binding instruments. International human rights instruments lay down obligations and duties for state parties and some non-state actors²⁸³ to assume under international law.

Through the ratification of international human rights treaties, state parties have to undertake domestic measures and legislation compatible with their treaty obligations and duties. State parties are accountable for the violation of the human rights obligations by non-state actors within their jurisdictions, while the human rights obligations and duties of non-state actors is another issue which needs further research.

Some international human right norms are developed from multitude of non-binding

²⁸¹ Christian Tomuschat, *Human Rights: Between Idealism and Realism*, P.31~32, Oxford University Press, 2004

²⁸² Christian Tomuschat, *Human Rights: Between Idealism and Realism*, P.34, Oxford University Press, 2004

There are several regional human rights protection instruments in the America Continent. For example, the American Declaration of the Rights and Duties of Man, the American Convention on Human Rights (ACHR), 1969; African Charter of Human and People's Rights (Banjul Charter, AFCHPR), 1981, but there is no regional human rights instrument in Asia so far, due to the political complexities and difficulties

²⁸³ Andrew Clapham, *Human Rights Obligations of Non-State Actors*, P.91, Oxford University Press, 2006

When European Union may yet become a party to the European Convention on Human Rights and Protocol 14 to that treaty has already been adopted by the state of the Council of Europe in order to make it possible.

recommendations or resolutions. Though the soft laws are non-binding, they are often used for some specific human rights guarantees and influences on the development of law. Under some circumstances, soft law may form into customary international law and may be given firmer binding power.

Aside from international human rights instruments, international human rights are protected under the international customary law. According to the Statute of the International Court of Justice Article 38²⁸⁴, the source of international law includes international conventions, international custom, as evidenced by a general practice accepted as law, the general principles recognized in civilized nations, judicial decisions, and the teachings of the most highly qualified publicists of the various nations, as subsidiary means for the determination of rules of law.

There are two essential criteria which must be fulfilled to form customary international law. First, there must be some unambiguous and consistent practice by states; secondly, the state must have followed that practice out of legal obligations. In the landmark case of customary international law, the North Sea Continental Shelf case did not identify the application of customary international law into the field of human rights. However, the Nicaragua judgment points out that in the formation of customary international law, the methodology must closely

²⁸⁴ Statute of the International Court of Justice, Article 38, available at http://www.icj-cij.org/documents/index.php?p1=4&p2=2&p3=0&PHPSESSID=cd318d9c693d2ae6ec2c3963fc64acf2#CHAPTER_II (last accessed on March 19, 2009)

1. The Court, whose function is to decide in accordance with international law such disputes as are submitted to it, shall apply:
 - a. international conventions, whether general or particular, establishing rules expressly recognized by the contesting states;
 - b. international custom, as evidence of a general practice accepted as law;
 - c. the general principles of law recognized by civilized nations;
 - d. subject to the provisions of Article 59, judicial decisions and the teachings of the most highly qualified publicists of the various nations, as subsidiary means for the determination of rules of law.
2. This provision shall not prejudice the power of the Court to decide a case *ex aequo et bono*, if the parties agree thereto.

verify to what extent states should present their practices as fully corresponding to the international rule of law or whether they can simply deny charges brought against them while possibly hiding or concealing conduct when there is violation or abuse under customary rules.

In the field of international human rights protection, customary international law must have primary, universal characteristics proclaimed in various international instruments. The practice of human rights protection and the implementation and development of international human rights instruments have formed the backbone of customary international law in human rights protection. The protection of civil and political rights has formed into customary international law because more nation states have adopted them into the text of their constitutions. For example, the rules of prohibiting arbitrary killing, slavery, torture, detention, and systematic racial discrimination are now recognized as customary international law. Other rights, including the right to self-determination, freedom of opinion, equality rights, and the right to fair trial have now entered the realm of customary international law.

Due to the special characteristic of economic, social and cultural rights as positive rights, governments are reluctant to include them into their constitutional texts. Until now, there have been some potential candidates for the rights recognized under international law: the right to free choice of employment, the right to form and join trade unions, and the right to free primary education, subject to a state's available resources.²⁸⁵ Whether the human rights protections in economic, social and cultural rights have formed into customary international law often receives little attention.

²⁸⁵ Andrew Clapham, *Human Rights Obligations of Non-State Actors*, P.86, Oxford University Press, 2006

An interesting facet of customary international law is that it binds every one within the international community. It usually applies to hold non-state actors accountable. Obligations arise due to the general application and the international legal order considering certain rights and duties important for the legal order to follow.

4.1.3 Concluding Summary

The protection of international human rights is a trend of progression. Although there are different kinds of human rights, the ultimate goal of the protections is to respect, fulfill and protect human dignity. With the codification of international human rights, the international community has taken steps towards further realization of these rights.

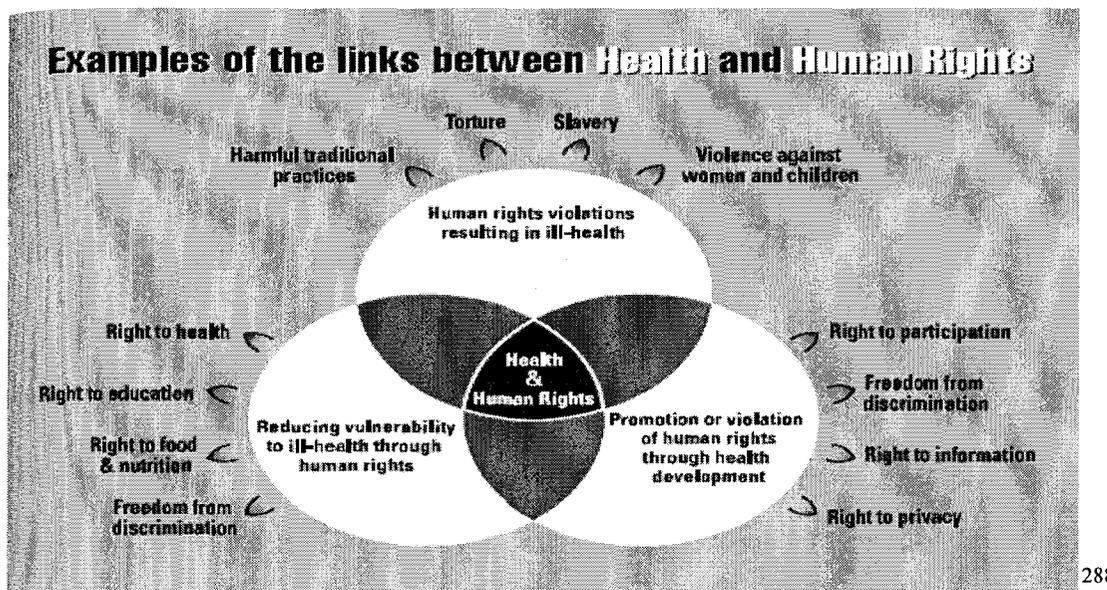
4.2 The Development of the Human Right to Health

Health is among the most pressing concerns facing decision-makers in countries across the world. The concept of health is very broad and subjective. The definition is always cultural and affected by many socio-economic factors. The term "right-based approach to health"²⁸⁶ is now being used to characterize a wide range of activities. A human rights perspective on health could generate new insights and effective measures as guidance at the global level. Nevertheless, health is the most fundamental right and is indispensable from other human rights. Without health, other human rights would be difficult to realize.

Health and human rights have rarely been linked in an explicit manner, but the linkage between health and human rights is so closely interrelated, complex and essential that as the

²⁸⁶ WHO, 25 Questions & Answers on Health & Human Rights, P.16~17, 2002, available at <http://www.who.int/hhr/NEW37871OMSOK.pdf> (last accessed on March 19, 2009)

WHO observed “[w]ithout health, other rights have little meaning.”²⁸⁷



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As shown in the diagram, human rights have a particularly close relationship with health, and their overlap includes the right to health, non-discrimination, privacy, water, education, information, food, housing, and the right to enjoy scientific progress and its applications. Violation or neglect to any one of these human rights could have serious, negative health consequences, such as harmful traditional practices, slavery, torture, inhuman and degrading treatments, and violence against women and children.²⁸⁹

The recognition of the relationship between public health and human rights can lead to more effective policies. The establishment of health policies and programs can either promote or violate human rights protection²⁹⁰, so governments have to be careful when designing and

²⁸⁷ James G. Hodge, Jr., Nicole Valentine and Helena Nygren-Krug, 'The Domain of Health Responsiveness-A Human Rights Analysis', P.4, 2003, available at http://www.who.int/hhr/Series_2%20Responsiveness.pdf (last accessed on March 19, 2009)

²⁸⁸ WHO, 25 Questions & Answers on Health & Human Rights, P.8-9, 2002, available at <http://www.who.int/hhr/NEW37871OMSOK.pdf> (last accessed on March 19, 2009)

²⁸⁹ WHO, 'Linkage between Health and Human Rights', available at <http://www.who.int/hhr/HHR%20linkages.pdf> (last accessed on March 19, 2009)

²⁹⁰ For example, lack of protection in freedom from discrimination, right to participation, individual autonomy,

implementing policies and legislations.²⁹¹

Promoting and protecting health requires explicit and concrete efforts to promote and protect human rights by everyone, including individuals, groups, nation states, and international communities.

4.2.1 International Development of Health as Human Right

Before the 19th century, health and human rights were scarcely a part of the international dialogue. The first health legislation was adopted in the 19th century, and the trend towards adoption of a right to health in the 20th century was marked by slow progress.

The public health movement of the 19th century started over the outrage at unhealthy working conditions and living environments during the industrial revolution, and the spread of epidemic diseases. Realizing that sickness would load the social burden and good health would relieve the burden of social and economic concerns, policy makers became aware of the fact that public health measures and policies should be implemented to fight against diseases and ensure healthy living conditions.

International health organizations have taken steps toward public health. A series of International Sanitary Conferences was held in the 19th century.²⁹² In 1907, founded by the Rome Agreement, an international office of public health was created, the Office International

rights to participation, privacy and information.

²⁹¹ WHO, 'Linkage between Health and Human Rights', available at <http://www.who.int/hhr/HHR%20linkages.pdf> (last accessed on March 19, 2009)

²⁹² Brigit C.A. Toebes, *The Right to Health as a Human Right in International Law*, P.13-14, Intersentia Publishers, 1999

d'Hygiene Publique (OIHP). The main function of the OIHP was to disseminate information on public health matters, particularly on communicable diseases. The OIHP did not work well due to insufficient funding, and because it had to work with the health organization of the League of Nations until the creation of the UN²⁹³. Later, the International Labor Organization (ILO) of 1919 dealt with work-related health issues in the field of occupational health. The ad hoc Committee defined problems relating to workers' health to which international regulation was to be directed.²⁹⁴

Since this historic evolution, the issue of public health has been focused on the recognition of health as a human right on the national level. The national health policies were focused on improving the health of the public, and sanitary conditions were its first priority. However, in order to have sustainable public health, the issue of poverty should also be combated by providing accessible and affordable health related products and services.

The notion of health as one of the social and economic rights was initiated at the United Nations Conference on International Organization held in San Francisco in 1945. Article 55 of the UN Charter stipulates that "the United Nations shall promote: b. solutions of international economic, social, health, and related problems; and international cultural and educational cooperation...."²⁹⁵ Later, the formulation of health as a human right was initiated and incorporated into various international human rights instruments, regional human rights

²⁹³ Brigit C.A. Toebes, *The Right to Health as a Human Right in International Law*, P.13-14, Intersentia Publishers, 1999

²⁹⁴ Brigit C.A. Toebes, *The Right to Health as a Human Right in International Law*, P.13-14, Intersentia Publishers, 1999

²⁹⁵ Article 55 of Charter of the United Nation, available at www.un.org/aboutun/charter/ (last accessed on March 19, 2009)

protections and customary international law.

4.2.1.1 Sources

The international human right to health can be found in large numbers of international human rights instruments, regional human rights instruments, customary international laws, and non-binding soft laws.

4.2.1.1.1 Primary International Human Right Instruments

Constitution of the WHO 1946²⁹⁶

The Preamble of the Constitution of the WHO states:

Health is a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity. The enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social condition....

Though it is striking to see the absolute, broad and idealistic character of the text, the WHO's definition of the right to health is still a breakthrough in the field of international human rights and a milestone in the further refinement and implementation of the right to health.

Universal Declaration of Human Rights (UDHR) 1948²⁹⁷

Article 25.1 of Universal Declaration of Human Rights (UDHR) 1948 affirms:

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.

²⁹⁶ WHO, WHO Constitution, 1946, available at http://www.who.int/governance/eb/who_constitution_en.pdf (last accessed on March 19, 2009)

²⁹⁷ UDHR, 1948, available at <http://www.un.org/Overview/rights.html#a25> (last accessed on March 19, 2009)

Article 25 of the UDHR has not adopted in the WHO's text. There is no separate article for the human right to health, but instead this right is combined with other social issues in very broad terms. Nevertheless, the UDHR is still a universally known and recognized human rights document.

International Covenant on Economic, Social and Cultural Rights (ICESCR) 1966

The right of health has been outlined in Article 12²⁹⁸ as follows:

1. The States Parties to the present Covenant recognize the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.
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 still birth-rate and of infant mortality and for the healthy development of the child;
 - (b) The improvement of all aspects of environmental and industrial hygiene;
 - (c) The prevention, treatment and control of epidemic, endemic, occupational and other diseases;
 - (d) The creation of conditions which would assure to all medical service and medical attention in the event of sickness.

There was considerable debate over whether to include the WHO definition in the covenant.

Ultimately, it was decided not to include the definition so the terms of the right to health remain unclear. Questions as to the extent of the right to health still remain. The second part of Article 12 does mention health but as a broad concept, and establishes steps to achieve a right to health.

The Committee on Economic, Social and Cultural Rights elaborated on the right to health in General Comment No.14 in 2000. General Comment No.14 described in more detail on the normative content of the right to health, including health care and the health determinant, the

²⁹⁸ International Covenant on Economic, Social and Cultural Rights (ICESCR), 1966, available at <http://www2.ohchr.org/english/law/cescr.htm> (last accessed on March 19, 2009)

precondition of human health, the individual rights and the nation states' and even non-state actors' obligations towards the right to health.²⁹⁹

Some of the preconditions of health determinants are also indirectly linked to the right to health and affect the enjoyment of that right. The ICESCR aims to ensure the protection of economic, social and cultural rights including the right to self-determination of all peoples in Article 1; the right to non-discrimination based on race, color, sex, language, religion, political or other opinion, national or social origin, property, birth or other status in Article 2; the equal right of men and women to enjoy the rights in the ICESCR in Article 3; the right to work in Articles 6 and 7; the right to form and join trade unions in Article 8; the right to social security in Article 9; the right of protection and assistance to the family in Article 10; the right to an adequate standard of living in Article 11; the right to health in Article 12; the right to education in Articles 13 and 14; and the right to cultural freedoms in Article 15.³⁰⁰

4.2.1.1.2 Regional Human Right Protection

The most famous regional human rights protection is laid out by three organizations: the Council of Europe, the Organization of American States (OAS) and the Organization of African Unity. These organizations have adopted human rights principles in the documents in which a right to health is set forth.

²⁹⁹ Committee of Economic, Social and Cultural Rights General Comment on The right to the highest attainable standard of health, 2000, available at <http://www.unhchr.ch/tbs/doc.nsf/%28symbol%29/E.C.12.2000.4.En?OpenDocument> (last accessed on March 19, 2009)

³⁰⁰ International Covenant on Economic, Social and Cultural Rights, 1966, available at <http://www2.ohchr.org/english/law/cescr.htm> (last accessed on March 19, 2009)

Article 11 of the European Social Charter (ESC)

The right to protection of health³⁰¹

With a view to ensuring the effective exercise of the right to protection of health, the Parties undertake, either directly or in cooperation with public or private organisations, to take appropriate measures designed *inter alia*:

1. to remove as far as possible the causes of ill-health;
2. to provide advisory and educational facilities for the promotion of health and the encouragement of individual responsibility in matters of health;
3. to prevent as far as possible epidemic, endemic and other diseases, as well as accidents.

Though the language in the provision is narrow and weak, the text of ESC describes clear state obligations requiring states to take measures as far as possible to protect health.³⁰²

Convention on Human Rights and Biomedicine³⁰³

The Convention contains specific provisions regarding the right to health as to consent, privacy and the right to information, the human genome, scientific research, organ and tissue removal from living donors for transplantation purposes, and prohibition of financial gain and disposal on parts of the human body.

Article 3 of the Convention stipulates State obligations to ensure equitable access to health care, as “[p]arties, taking into account health needs and available resources, shall take appropriate measures with a view to providing, within their jurisdiction, equitable access to health care of appropriate quality.”³⁰⁴

³⁰¹ European Social Charter Article 11, 1996, available at <http://conventions.coe.int/Treaty/EN/Treaties/Html/163.htm> (last accessed on March 19, 2009)

³⁰² European Social Charter Article 11, 1996, available at <http://conventions.coe.int/Treaty/EN/Treaties/Html/163.htm> (last accessed on March 19, 2009)

³⁰³ Convention on Human Rights and Biomedicine, 1997, available at <http://conventions.coe.int/Treaty/en/Treaties/Html/164.htm> (last accessed on March 19, 2009)

³⁰⁴ Convention on Human Rights and Biomedicine, 1997, available at <http://conventions.coe.int/Treaty/en/Treaties/Html/164.htm> (last accessed on March 19, 2009)

This provision does not include a broad base of the right to health, but focuses on access to health care instead. The provisional text also includes the state parties' obligation regarding health care which depends on the "health needs and available resources" of the state parties.

American Convention on Human Rights and Protocol San Salvador, 1988

The protocol that was adopted as the "Additional Protocol to American Convention on Human Rights in the area of Economic, Social and Cultural Rights" since 1988, is called the "Protocol of San Salvador."

Article 10 states that

1. Everyone shall have the right to health, understood to mean the enjoyment of the highest level of physical, mental and social well-being.
2. In order to ensure the exercise of the right to health, the States Parties agree to recognize health as a public good and, particularly, to adopt the following measures to ensure that right:
 - a. Primary health care, that is, essential health care made available to all individuals and families in the community;
 - b. Extension of the benefits of health services to all individuals subject to the State's jurisdiction;
 - c. Universal immunization against the principal infectious diseases;
 - d. Prevention and treatment of endemic, occupational and other diseases;
 - e. Education of the population on the prevention and treatment of health problems, and
 - f. Satisfaction of the health needs of the highest risk groups and of those whose poverty makes them the most vulnerable.³⁰⁵

Article 10 (1) derived the term "physical, mental and social well-being" from the preamble of the WHO Constitution. This provision also states the obligations to undertake in the protection of the right to health.

³⁰⁵ Additional Protocol to the American Convention on Human rights in the Area of Economic, Social and Cultural Rights "Protocol of San Salvador", 1998, available at <http://www.oas.org/juridico/english/Treaties/a-52.html> (last accessed on March 19, 2009)

In addition, Article 11 proclaimed the right to a healthy environment:

Article 11 states that

1. Everyone shall have the right to live in a healthy environment and to have access to basic public services.
2. The States Parties shall promote the protection, preservation, and improvement of the environment.³⁰⁶

The African Charter on Human and Peoples' Rights

The African Charter of Human and Peoples' Rights originally dealt with individual human rights, and collective rights, civil and political rights, and also a limited number of economic and social rights, such as the right to work, the right to health, and the right to education.³⁰⁷

Article 16 of the Charter contains the protection with regards to health:

1. Every individual shall have the right to enjoy the best attainable state of physical and mental health.
2. State Parties to the present Charter shall take the necessary measures to protect the health of their people and to ensure that they receive medical attention when they are sick.³⁰⁸

The language in the provision is similar to Article 12 (1) of the International Covenant on Economic, Social and Cultural Rights; however, the article does not enumerate steps in state obligations regarding the right to health.

4.2.1.1.3 Customary International Law

Customary international law, described in Article 38 of the Statute of the International Court of

³⁰⁶ Additional Protocol to the American Convention on Human rights in the Area of Economic, Social and Cultural Rights "Protocol of San Salvador", 1998, available at <http://www.oas.org/juridico/english/Treaties/a-52.html> (last accessed on March 19, 2009)

³⁰⁷ African Charter on Human and People's Rights, 1986, available at www.achpr.org/english/info/charter_en.html (last accessed on March 19, 2009)

³⁰⁸ African Charter on Human and People's Rights, 1986, available at www.achpr.org/english/info/charter_en.html (last accessed on March 19, 2009)

Justice, is one source of international law, which is understood as consisting of general practices accepted as law and binding on everyone, including individuals, groups, nation states and non-state actors³⁰⁹ in the international community without exceptions and irrespective of express consent. From this perspective, if the international human right to health norms go beyond human rights treaties and have become customary international law, this would broaden its application to non-state actors.

Professor Andrew Clapham and Mariano Garcia Rubio confirm the existence of an opinio juris within the international community and consider the customary international human right to health using four criteria: (a) the wide acceptance of non-binding instruments dealing with the right to health; (b) the wide participation in multilateral treaties that establish the right to health; (c) the reference to such a right in national legislation, mainly at the constitutional level; and (d) the implementation of the right to health before municipal courts.³¹⁰

4.2.1.2 Scope and Content of the Right to Health

Human rights have a long history. "Health" is usually one of the first rights recognized as a human right. Health is a very broad and subjective concept. Health is influenced by cultural, geographic, and most importantly, socio-economic factors.

The right to health is usually addressed in the negative, in other words, in violation, neglect

³⁰⁹ Processor Andrew Clapham and Mariano Garcia Rubio, 'The Obligation of State with Regard to Non-State Actors in the Context of the Right to Health', P.20, 2002, available at www.who.int/hhr/Series_3%20Non-State_Actors_Clapham_Rubio.pdf (last accessed on March 19, 2009)

³¹⁰ Processor Andrew Clapham and Mariano Garcia Rubio, 'The Obligation of State with Regard to Non-State Actors in the Context of the Right to Health', P.22, 2002, available at www.who.int/hhr/Series_3%20Non-State_Actors_Clapham_Rubio.pdf (last accessed on March 19, 2009)

or abuse of other human rights which cause a health impact, such as torture. The actual basic concept of "health" in human rights has been generally absent from human rights discourse.

Scope

The scope of the right to health is usually divided into individual health and public health.³¹¹ Individual health usually refers to medicine and health care. Public health usually refers to the health of population, including the underlying precondition for health or health-related factors shared by the population as a whole. The term "public" health should be understood as "shared," or "use in common." When the conditions, situations, mediums or things shared or used in common are not healthy and pose a threat to the health of people, this should raise the protections due to public health.

Content

The traditional concept of human rights protection is to ensure that all people are born to be free and equal in dignity and rights.³¹² There are different perspectives over the term "the right to health." Different terms have been used, such as "right to health care," or "the right to health protection." But what does "health" mean in connection with the right to health? It is agreed that the right to health does not mean the right to have perfect health or to be healthy. Health is a broad and highly subjective matter; how then should health be defined in the right to health?

³¹¹ Jonathan M. Mann, Sofia Gruskin, Michael A. Grodin, George J. Annas edited, Health and Human Rights: A Reader, P.8, Routledge, 1999

Modern concept of health usually derives from two related disciplines: medicine and public health. While medicine generally focuses on the individual health, which concerns to medical and other health care services in the physical, mental and disability, in the contrast, public health has been focus in ensuring healthy conditions which emphasis mostly in the prevention of diseases, disability and premature death.

³¹² Jonathan M. Mann, Sofia Gruskin, Michael A. Grodin, and George J. Annas edited, Health and Human Rights: A Reader, P.9, Routledge, 1999

In the Preamble of the Constitution of the WHO, the term of health is still nebulous and left undefined. This definition has been criticized as too idealist and inappropriate.³¹³

There are other international agreements, regional human right instruments, and even national constitutions directly or indirectly recognizing and the right to health. Yet, the practice of the right to health is still waiting for further development.

Human rights advocacies are trying hard to push for the realization of the right to health. Recently, they have challenged policy makers to gradually define the right to health and then to extend the concept³¹⁴ of the right to health in various aspects.

Brigit C. A. Toebes believes that the right to health underlies the economic, social rights safeguarding individuals from suffering social and economic injustices with respect to his/her health. She also points out that the right to health, as with other human rights such as civil and political rights and economic, social and cultural rights, are interdependent and indivisible from all human rights.³¹⁵ Some issues exerting health impacts are not part of the scope of the right to health.³¹⁶ Toebes observes that the right to health can be divided into elements of health care

³¹³ David P. Fidler, *International Law and Public Health: Materials on and Analysis of Global Health Jurisprudence*, P.302, Transnational Pub, 2000

³¹⁴ Jonathan M. Mann, Lawrence Gostin, Sofia Gruskin, Troyen Brennan, Zita Lazzarini, and Harvey Fineberg, 'Health and Human Right', Jonathan M. Mann, Sofia Gruskin, Michael A. Grodin, and George J. Annas edited, *Health and Human Rights: A Reader*, P.10, Routledge, 1999

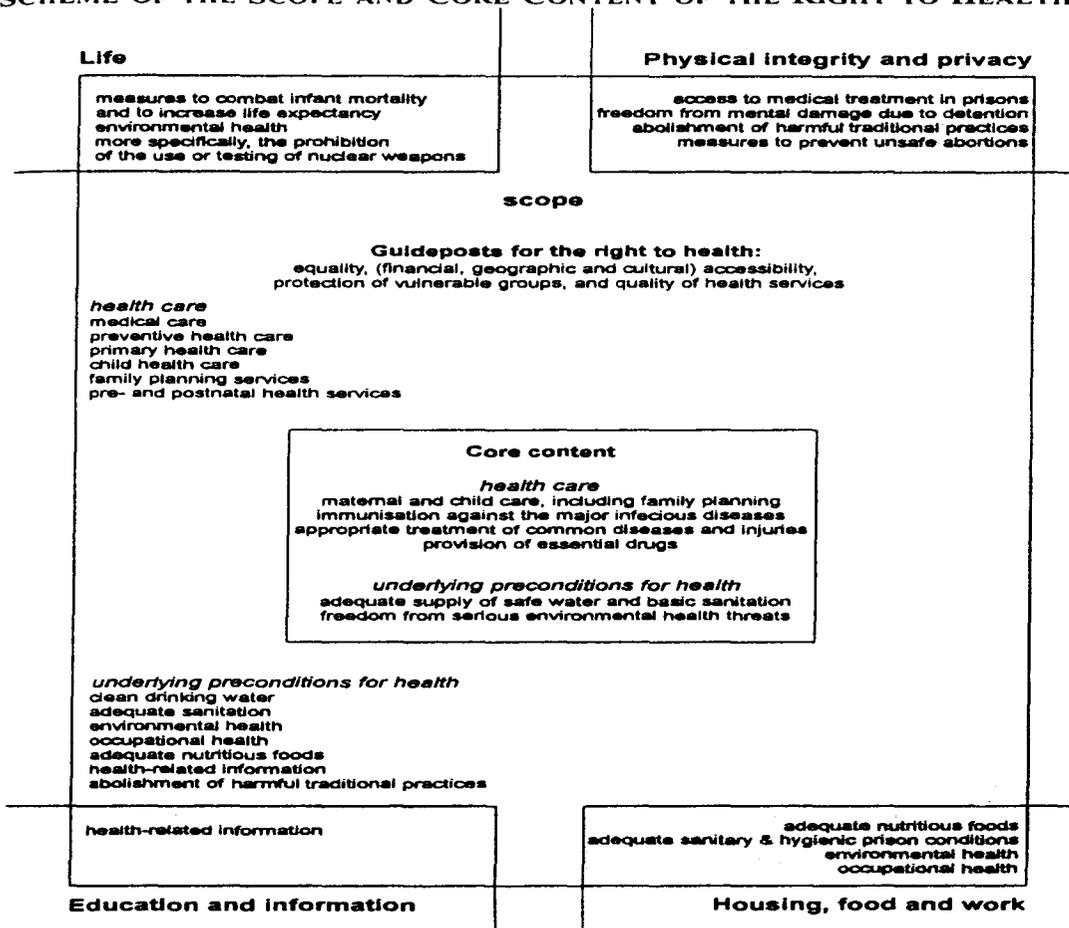
The modern concept of human rights has extended into concerns about the environment and global socioeconomic development, the practice into wider social involvement and participation to broaden the language and human rights concepts, the expansion of the protection from individuals v. states to other non-state actors, such as transnational business, and to combine the promotion and protection of human rights altogether.

³¹⁵ Asbjørn Eide, Catarina Kause and Allan Rosas Edited, *Economic, Social and Cultural Rights*, 2nd Ed., P.170-171, Springer, 2001

³¹⁶ Asbjørn Eide, Catarina Kause and Allan Rosas Edited, *Economic, Social and Cultural Rights*, 2nd Ed., P.175, Springer, 2001

and of underlying preconditions affecting health.³¹⁷ The scope and core content of the right to health from Toebes is as follows chart:³¹⁸

SCHEME OF THE SCOPE AND CORE CONTENT OF THE RIGHT TO HEALTH



Professor David P. Fidler argues for the right to health illustrated in the concentric circles below. He conceptualizes this right as it pertains to violations of civil and political rights, such as torture;³¹⁹ regulatory failure, involving failures by governments to regulate activities within

For example, the right to health probably does not encompass a prohibition of torture per se, protection against arbitrary execution or the right to adequate housing per se, not to mention normal education at schools.

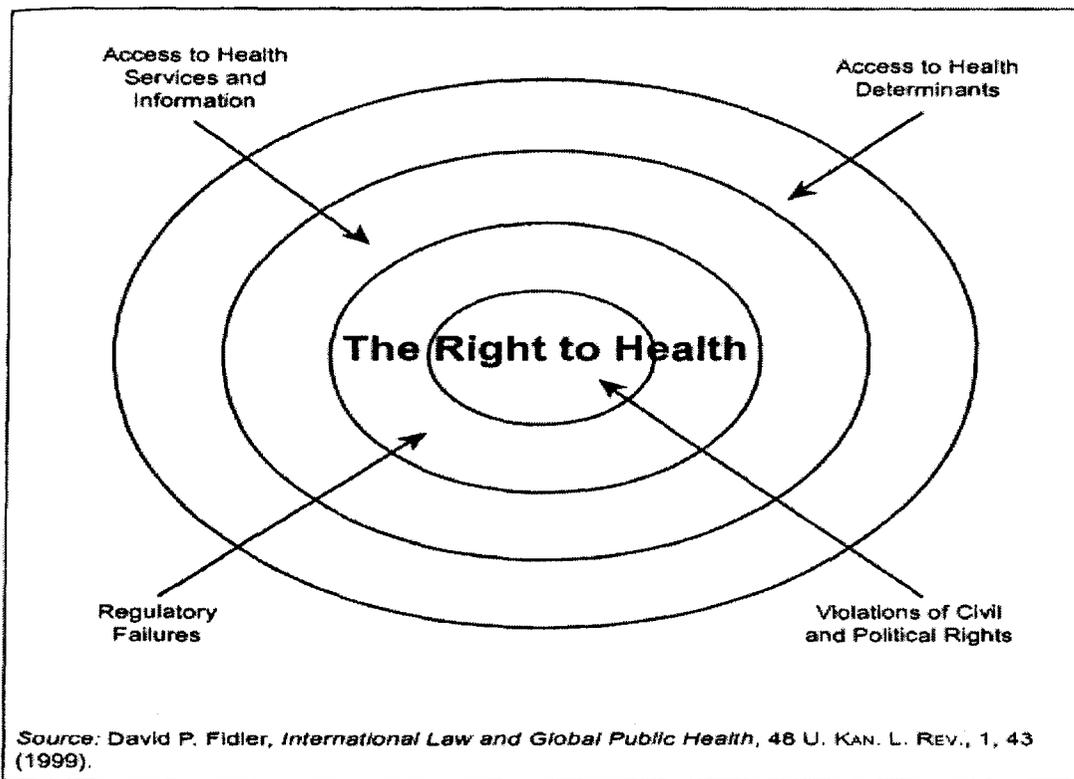
³¹⁷ Brigit C. A. Toebes, *The Right to Health as a Human Right in International Law*, P.245, Intersentia Publishers, 1999

³¹⁸ Brigit C. A. Toebes, *The Right to Health as a Human Right in International Law*, P.288-289, Intersentia Publishers, 1999

³¹⁹ David P. Fidler, *International Law and Public Health: Materials on and Analysis of Global Health Jurisprudence*, P.304, Transnational Pub, 2000

Not all international experts concur. For example, the study of Toebes in the right to health in international law excludes the prohibition against torture and cruel, inhuman, or degrading treatment or punishment from the scope of

their boarders that can cause serious and foreseeable harm to health; access to health services and information, including supplies of safe water and basic sanitation; and access to health determinants, such as adequate food, housing, education and employment. The fact that the scope of the right to health remains uncertain in international terms, however, is one of the basic obstacles to its implementation.



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Some assert that the right to health means access to health care services. This argument raised a suggestion that in order to achieve a state of complete physical, mental, spiritual, and social well-being, an individual needs access to health care services. This concept is also reinforced by the WHO's concept of "health for all," meaning that nation states provide health care³²¹ and protect the right to such care with no discrimination on any ground. Professor

the right to health.
³²⁰ David P. Fidler, *International Law and Public Health: Materials on and Analysis of Global Health Jurisprudence*, P.305, Transnational Pub, 2000
³²¹ David P. Fidler, *International Law and Public Health: Materials on and Analysis of Global Health Jurisprudence*,

David P. Fidler believes that the right does not address health services. Moreover, he points out that the progressive realization of health care service as a health right will have difficulties involving the questions of the economic resources of each country.³²²

The UN adopts the broader term of the right to health. The term is defined with treaty provisions which proclaim not only as to the right to health care, but also the right to underlying preconditions for health. In the General Comment No.14 (2000) of the ICESCR is established clearer normative content of the right to health contained in Article 12. The Committee contends that the right to health is not a right to be healthy, but rather takes into account the individual's biological and socioeconomic precondition and a nation state's available resources. The right contains both freedoms and entitlements regarding health. The freedom of the right to health includes the right to control one's health and body, including sexual and reproductive freedom and the right to be free from interference, such as free from torture, non-consensual medical treatment and experiments. The entitlements of the right to health, which are proposed in this dissertation, are to include a system of health protection which provides equality of opportunity for people to enjoy the highest attainable level of health.³²³

The core content of the right to health refers to the minimum essential level of the right. The key elements are set out in guidance for nation states. The comment underscores that the right to health is an inclusive right which not only obligates nation states to provide health care

P.302, Transnational Pub, 2000

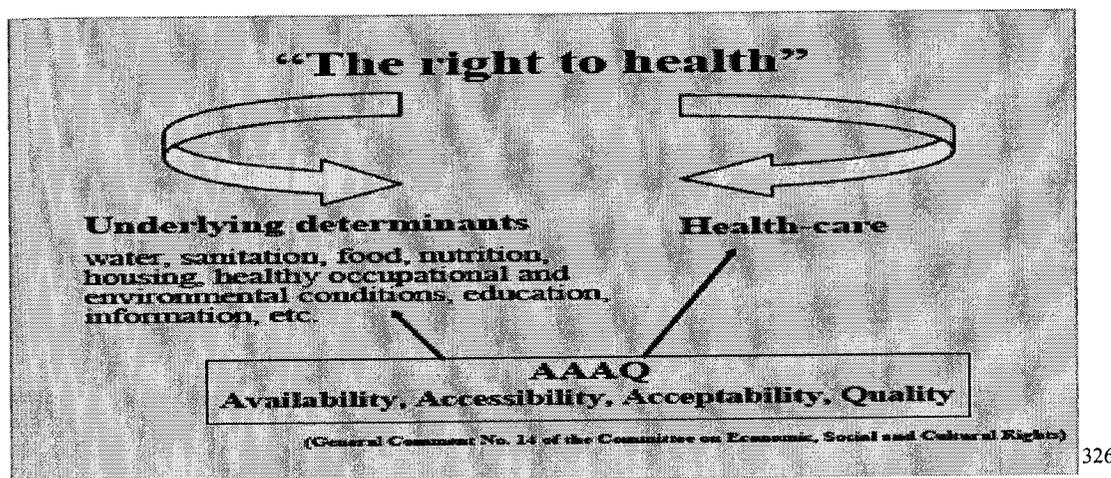
The issue on the definition on the right to health as to a right to access health services remains controversial and even more challenging when the issue involves with the scarcity of economic resource of each country.

³²² David P. Fidler, *International Law and Public Health: Materials on and Analysis of Global Health Jurisprudence*, P.302, Transnational Pub, 2000

³²³ CESCR, General Comment No. 14, 2000, available at

[www.unhcr.ch/tbs/doc.nsf/\(symbol\)/E.C.12.2000.4.En?OpenDocument](http://www.unhcr.ch/tbs/doc.nsf/(symbol)/E.C.12.2000.4.En?OpenDocument) (last accessed on March 19, 2009)

based on their resources, but also to address the preconditions which closely relate to human health, such as access to safe and potable water and adequate sanitation, an adequate supply of safe food, nutrition and housing, healthy occupational and environmental conditions, access to health-related education and information, including information on sexual and reproductive health, and also participation in the health related decision making at the community, national and international levels³²⁴ and conditions which are necessary for the realization of the highest attainable level of health.³²⁵



The committee also outlines elements for nation states as guidelines to protect and fulfill the right. The elements are AAAQ: availability, accessibility, acceptability and quality.

“Availability” means that functioning public health and healthcare facilities, goods, services and programs, including the underlying determinants of health, such as safe and potable drinking water and adequate sanitation facilities, hospitals, clinics and other health-related buildings,

³²⁴ CESCR, General Comment No. 14, P.3, 2000, available at www.unhchr.ch/tbs/doc.nsf/%28symbol%29/E.C.12.2000.4.En?OpenDocument (last accessed on March 19, 2009)

³²⁵ CESCR, General Comment No. 14, P.2, 2000, available at www.unhchr.ch/tbs/doc.nsf/%28symbol%29/E.C.12.2000.4.En?OpenDocument (last accessed on March 19, 2009)

³²⁶ WHO, ‘The Right to Health’, Fact Sheet, available at www.who.int/entity/hhr/Right_to_health-factsheet.pdf (last accessed on March 19, 2009)

trained medical and professional personnel receiving domestically competitive salaries, and the availability of essential drugs³²⁷ in sufficient quantity within the nation state.

“Accessibility” means that health facilities, goods and services must be accessible to everyone without discrimination, including water, pharmaceuticals, and shelter. Accessibility also encompasses physical accessibility, economic accessibility and information accessibility. Physical accessibility includes the physical accessibility of underlying determinants of health such as safe and potable water and sanitation facilities, whereby all health services must be within safe physical reach for all sections of the population. Economic accessibility means that all health services are affordable to all. Information accessibility refers to the right to seek, receive and impart information and ideas concerning health issues. “Acceptability” refers to state parties’ obligation to ensure that all health facilities, goods and services are respectful of medical ethics and are culturally appropriate. Lastly, referring to “quality”, the Committee specifies that states have to guarantee that all services are scientifically and medically appropriate and of good quality.³²⁸

Availability, accessibility, acceptability and quality of pharmaceuticals and medical services are the core content of the international human right to health which can solve and manage the disease burden caused by the ill preconditions of health determinants. In the fight against diseases, the lack of accessible and affordable pharmaceuticals and medical services, including medicines, vaccines, medical equipments and services, is urgently in need of attention.

³²⁷ CESCR Council, The Right to Highest Attainable Standard of Health, General Comment 14, 2000, available at [www.unhchr.ch/tbs/doc.nsf/\(symbol\)/E.C.12.2000.4.En?OpenDocument](http://www.unhchr.ch/tbs/doc.nsf/(symbol)/E.C.12.2000.4.En?OpenDocument) (last accessed on March 19, 2009)

³²⁸ WHO, ‘International Covenant on Economic, Social and Cultural Rights, Health and Human Rights’, available at www.who.int/hhr/Economic_social_cultural.pdf (last accessed on March 19, 2009)

Professor Paul Hunt, a Special Rapporteur of the Commission of Human Rights, divides the contour and content of the right to health into health care and the underlying determinants of health, freedoms and entitlements, which is very similar to and overlaps with the General Comment No.14 of the CESCR.

Hunt states that the right to health is an inclusive right which includes not only timely and appropriate health care, but also the underlying determinants of health. The right to health also contains both freedoms and entitlements. Freedoms include the right to control one's health, including the right to be free from non-consensual medical treatment and experimentation. Entitlements include the right to a system of health protection that provides equality of opportunity for people to enjoy the highest attainable standard of health.³²⁹

Judith Asher agrees that the right to health should not be seen as a right to be healthy. Nor should the right to health be viewed as a limitless right to receive medical care for any and every illness or disability. Instead, the right to health should be understood as a right to enjoyment of a variety of facilities and conditions which the state is responsible for providing as necessary for the attainment and maintenance of good health.³³⁰

4.2.2 Right to Health in Accessible and Affordable Pharmaceutical Products

Given these considerations, I believe that the right to health should be based on a foundation

³²⁹ Commission on Human Rights, The Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health, E/CN.4/2003/58, available at <http://daccessdds.un.org/doc/UNDOC/GEN/G03/109/79/PDF/G0310979.pdf?OpenElement> (last accessed on March 19, 2009)

³³⁰ Judith Asher, The Right to Health: A Resource Manual for NGOs, 2004, available at http://shr.aaas.org/pubs/rt_health/rt_health_manual.pdf (last accessed on March 19, 2009)

invested in the protection of civil and political rights.³³¹ Civil and political rights are associated with ensuring people's liberties whereas economic, social and cultural rights are concerned with ensuring the basic needs in accordance with social justice; the right to health is an overlapping area between the two.³³² Not only will the violation, neglect, and abuse of civil and political rights have impacts on the right to health, but in order to respect, fulfill and protect the right to health, the nation states must be able to ensure the protection and promotion of civil and political rights, then to implement and enforce economic, social and cultural rights.³³³ This does not mean that the protection of civil and political rights is a prerequisite and priority for the right to health, but without the respect and recognition of civil and political rights, there can be no respect and recognition of human rights, and no nation states to provide for the protection, promotion and fulfillment of human rights.³³⁴ As Jack Donnelly puts it, "civil and political rights, by providing accountability and transparency, can help to channel economic growth into national development rather than private enrichment."³³⁵ Amartya Sen has also observed that, "among the most important freedom we can have is freedom from avoidable ill-health and from escapable mortality." Sen concludes that health improvement requires improvements in participatory politics in which "the public must see itself not merely as a patient, but also as an

³³¹ International Covenant of Civil and Political Rights, 1966, available at <http://www2.ohchr.org/english/law/ccpr.htm> (last accessed on March 19, 2009) and Andrew Clapham, Human Rights Obligations of Non-State Actors, P.10, Oxford University Press, 2006
Though state dominated role of the international community has failed, development without an effective state is impossible.

³³² The UDHR 1948, a primary source of international human rights, does not make any distinction between the civil and political rights and economic, social and cultural rights.

³³³ It seems that I fell into the debate after the Universal Declaration of Human Rights, on the issues on whether countries shall first have civil and political rights or economic, social and cultural rights.

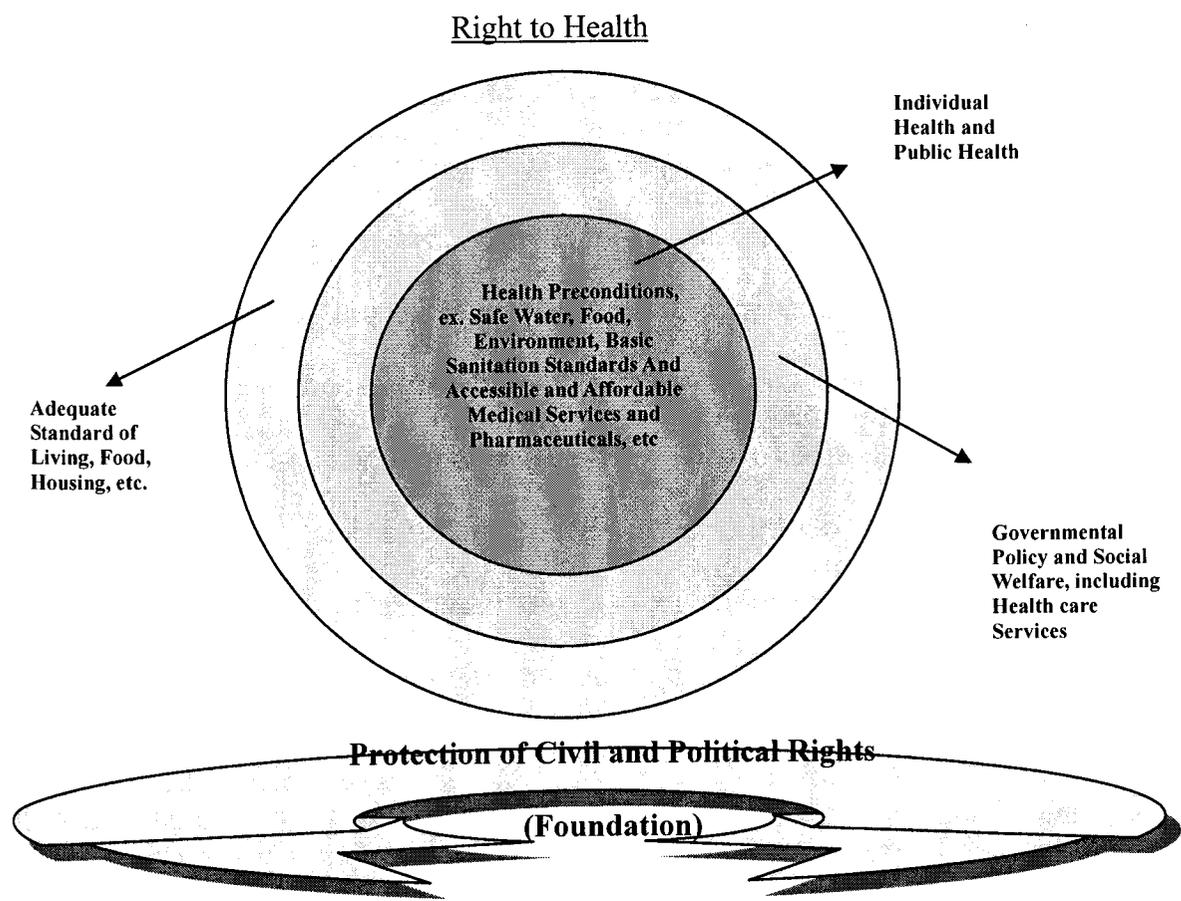
³³⁴ The violations of civil and political rights, such as lack of protection of the right to life, liberty, security of persons, freedom of movement, and not to torture or to cruel and unusual punishment, or arbitrary arrest and detention, usually, are accompanying with the violation of right to health.

³³⁵ Debra L. Delaet, The Global Struggle for Human Rights: Universal Principles in World Politics, P. 107, Wadsworth Publishing, 2005

Jack Donnelly continues to note that the interdependence between economic and social rights and civil and political rights is not inevitable. Human rights need to make conscious efforts to like these rights to foster interdependence.

agent of change.³³⁶ Thus, the protection of the right to health depends on the protection of civil and political rights, but the civil and political rights are outside the circle of the right to health. Without the protection of civil and political rights, the right to health will be difficult to recognize and implement.

Though many international legal experts have different views regarding the right to health, the definition of health should not be too restrictive. The international human right to health is a growing area of the law which adapts to the changing world and adjusts to its need. This dissertation suggests that the scope and content of the right to health should be clarified if we are to proceed with its development and effectively approach the problems it presents.



³³⁶ Sofia Gruskin, Michael A. Grodin, George J. Annas, Stephen P. Marks edited, Perspectives on Health and Human Rights, P.1, Routledge, 2005

Both health care and social conditions are important determinants of health issues in practical terms; however, this dissertation proposes different views of the core of the right to health. The approach of the right to health is diagramed above. The core content of the right is divided into two categories: individual health and public health. Individual health is related to diseases, medical services and pharmaceuticals. Public health is related to the essential elements shared in common, such as the water, air, environment, disease and viruses. In the content of the right to health, there should not be divisions between each aspect of the right. The link between individual health and population health is closely interrelated. The traditional boundaries of the two have blurred due to a closer understanding of the links between them.

Many scholars suggest that the right to health equals the right to health care, but this dissertation relegates health care to the secondary status as this research believes that the health care system is the tool or policy which nation states uses to provide available, accessible, acceptable and good quality care, mostly in the pharmaceutical and medical services to promote individual and public health. The health of the population can be strengthened by the increasing accessibility and affordability of medicines through health care.³³⁷ The health care services, the second circle, may overlap with individual health, but they are outside the core content of the right. Such a health care service should be one of the infrastructures of a social welfare policy. Having the health care system will be more effective and efficient for populations to use to seek treatments, to maintain their health, to prevent and treat diseases, and

³³⁷ Jonathan M. Mann, 'Medicine and Public Health, Ethics and Human Rights', Jonathan M. Mann, Sofia Gruskin, Michael A. Grodin, and George J. Annas edited, *Health and Human Rights: A Reader*, P. 441, Routledge, 1999
It suggests that medicine and health care have limited influence of the right to health. Jonathan M. Mann points out that the major problem of the accessibility and affordability of the medicine arising from the socioeconomic status which effect greatly in the health gradient. It might be true, but the gap of socioeconomic status has vigorous impact on the accessibility and affordability of medicine and health care.

to increase the accessibility and affordability of health care services and pharmaceuticals. The health care services will have the goal of affecting the right to health more efficiently and effectively in the second concentric circle, but the benefit will still depend on each nation's resources and economic conditions.

Nonetheless, above all the debates and discussions, the most critical components of the right to health are non-discrimination and equal treatment in the access to health care, the underlying determination of health, and other internationally prohibited grounds which impair the equal enjoyment of the right to health.

4.2.3 Concluding Summary

The right to health has been firmly embedded in a substantial number of UN human rights treaties. The UN treaties construe the right to health in broad terms. There are still many human right to health instruments which built their provisions upon the foundation of the earlier text but focus on specific groups, and these are characterized by more detail than the general human rights instruments.

The above-mentioned regional human rights organizations have included a right to health in their instruments, some defining the right to health and some referring more generally to the right to health as the right to health care or to a healthy environment. In other cases, regional agreements do not explicitly recognize the right to health, but offer indirect protections through other health-related rights.³³⁸ However, the scope and content of the international human right to

³³⁸ Commission on Human Rights, The Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health, E/CN.4/2003/58, 2003, available at

health remains unconfirmed.

Health is one of the main concerns of a human being. The health issue has been a priority for decision makers; however, comparing the right to health to other human rights, progress towards developing rigorous standards for international human rights to health has been relatively slow.

Due to the political sensitivity of the health issue, the right to health has begun to be firmly embedded into a number of international treaties, declarations and national constitutions, but the universal right to health is still waiting to be realized. As former United Nations Secretary General Kofi Annan once stated, “[i]t is my aspiration that health will be finally seen not as a blessing to be wished for, but as a human right to be fought for.”³³⁹

4.3 Benefit of Pharmaceutical Science & Technology as Human Right

Scientific and technological development and progress has become one of the most important factors in the development of human society. This development and progress has brought better conditions of life to the world population.

Pharmaceutical science and technology has brought enormous benefits to human life and social progress. Benefits of pharmaceutical science and technology are a critical component of

<http://daccessdds.un.org/doc/UNDOC/GEN/G03/109/79/PDF/G0310979.pdf?OpenElement> (last accessed on March 19, 2009)

There are indirect protections of human rights to health, such as the American Declaration on the Rights and duties of Man, the American Convention on Human Rights, the Inter-American Convention on the Prevention, Punishment and Eradication of Violence against Women, and the European Convention for the Protection of Human Rights and Fundamental Freedoms and its protocols.

³³⁹ WHO, 25 Questions & Answers on Health & Human Rights, 2002, available at <http://www.who.int/hhr/NEW37871OMSOK.pdf> (last accessed on March 19, 2009)

the right to health. As a result of the burden of diseases and conditions described above, there is an urgent need to make full recognition of the enjoyment of pharmaceutical science and technology a part of the right to health.

The privatization and commercialization of pharmaceutical science and technology does contribute to R&D in science and technology; however, they also change the focus of pharmaceutical-related science and technology from the life-saving and diseases-curing and prevention to pure capitalism. As one industry insider bluntly put it, “[i]’s about the consumers, not the diseases”.³⁴⁰

The right to protect the pharmaceutically-related inventions and the right to the enjoyment of the benefit of pharmaceutical science and technology both fall within the scope of human rights, but balancing the two interests has become a difficult task.

The current international intellectual property rights³⁴¹ system has provided some forms of protection on the supply side. The system ensures that the rights of the inventors, corporations

³⁴⁰ Conference of Commercialization of Biotechnology R&D Results in Taipei, 15 Feb, 2008

³⁴¹ 3dthree Organization, ‘Intellectual Property and Human Rights: Is the Distinction Clear Now?: An Assessment of the Committee on Economic, Social and Cultural Right’ General Comment No.17 (2005) on “The Right of Everyone to Benefit From the Protection of the Moral and Material Interest Resulting from any Scientific, Literary or Artistic Production of Which he is the Author”, P.1~2, 2006, available at www.3dthree.org/pdf_3D/3D_GC17_IPHR.pdf (last accessed on March 19, 2009)

There are arguments on whether intellectual property rights are protected in the scope of the human rights in Art15 of ICESCR and Art 27 of UDHR. These debates have been partly resolved by General Comment no. 17 (2005) by the Committee on Economic, Social and Cultural Rights. The General Comment No.17 (2005) points out that, “while under most intellectual property systems, intellectual property rights, often with the exception of moral rights, can be allocated, limited in time and scope, traded, amended and even forfeited, human rights are timeless expressions of fundamental entitlements of the human person.”. It goes one and add “it is therefore important not to equate intellectual property rights with the human rights recognized in article 15 (c), but for some protection as long as available is suited to secure authors’ moral and material interests from their productions. Commentators have argued that General Comment No.17 is focusing on individual author’s rights to scientific or literary production and fails to look at the current reality that most of the scientific inventions and literary products are almost wholly owned by corporation which might cause a problem when it comes to Art 15 (b) later.

or investors of the pharmaceutical products benefit from the protection of the moral and material interests resulting from their scientific, technological products are protected.³⁴² By contrast, there is little attention on the demand side. The consumers or patients are not guarded by the right to enjoy the benefits of scientific and technological progress and its applications.

The epidemic of SARS and HIV/AIDS, the terrorists' use of anthrax in 2002, and the increasing burdens of chronic diseases have awakened attention to the importance of the right to health. Though there are other factors that affect health, the accessibility and affordability of pharmaceutical-related products are surely on the list of priority for treating the sick and preventing diseases.

4.3.1 Sources

The first attention given to the link between human rights, science and technology appeared in Article 27 of the Universal Declaration of Human Rights (UDHR), 1948 and Article 15 of the International Covenant on Economic, Social and Cultural Rights (ICESCR), 1966.

Article 27³⁴³ of UDHR reads:

- (1) Everyone has the right freely to participate in the cultural life of the community, to enjoy the arts and to share in scientific advancement and its benefits.
- (2) Everyone has the right to the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author.

Article 15 of ICESCR³⁴⁴, which elaborates ideas parallel to Article 27 of UDHR with minor

³⁴² Some scientific or technological products; however, have been left out of the concept and scope of the protection, such as traditional medicine, medical knowledge, etc.

³⁴³ Universal Declaration of Human Rights, Article 27, 1948, available at www.un.org/Overview/rights.html (last accessed on March 19, 2009)

³⁴⁴ International Covenant on Economic, Social and Cultural Rights, 1966, available at www2.ohchr.org/english/law/cescr.htm (last accessed on March 19, 2009)

differences, reads as follows:

1. The States Parties to the present Covenant recognize the right of everyone:
 - (a) To take part in cultural life;
 - (b) To enjoy the benefits of scientific progress and its applications;
 - (c) To benefit from the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author.
2. The steps to be taken by the States Parties to the present Covenant to achieve the full realization of this right shall include those necessary for the conservation, the development and the diffusion of science and culture.
3. The States Parties to the present Covenant undertake to respect the freedom indispensable for scientific research and creative activity.
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.

4.3.2 Scope and Content

The drafting history of Article 27 of UDHR 1948 alluded to the lesson from the misuse of science and technology by the Hitler regime.³⁴⁵ The provision also recognizes rights and claims related to science and technology in the human rights framework. Article 27 (1) recognized a right to benefit from scientific applications and the right to share in scientific advancement and its benefits.³⁴⁶

ICESCR 1966 was created with the same issue in mind, but it articulated more specific and binding human rights norms than UDHR 1948. ICESCR made the most relevant provisions of human rights analysis and IPRs in the context of pharmaceuticals in Article 12 and 15.

Article 12 of ICESCR established a foundation of international human rights to health as mentioned in chapter 2.3, and Article 15 of ICESCR binds state parties to having a system to

³⁴⁵ International Covenant on Economic, Social and Cultural Rights, 1966, available at www2.ohchr.org/english/law/cescr.htm (last accessed on March 19, 2009)

³⁴⁶ International Covenant on Economic, Social and Cultural Rights, 1966, available at www2.ohchr.org/english/law/cescr.htm (last accessed on March 19, 2009)

balance between interests of the general public in accessing science and technology and the interests of authors and inventors of such science and technology.

4.3.3 Concluding Summary

The Committee of Economic, Social and Cultural Rights (CESCR) recognizes the broad significance of the creation, ownership and control of knowledge-based science and technology that is protected in the form of IPRs. The allocation of IPRs has significant consequences that can affect the enjoyment of human rights in the commercialization and privatization of science and technology and the emergence of international IPR protections in the global trading system.

The balancing of public and private interests works in favor of the IPRs protection of pharmaceuticals. Pharmaceutical science and technology were first invented to facilitate the innovations into the application of science to broadly benefit members of society from individuals, peoples, states and international communities in order to restore the physical and mental health of all people. However, due to commercialization and privatization, the international IPRs protection has led pharmaceutical science and technology into capitalism. Today, the human right to enjoyment of the benefit of pharmaceutical science and technology is judged by social and economic factors. The IPRs protection has traditionally offered incentives to inventors, but now, the system has become a safeguard mechanism for the returns on investment by pharmaceutical corporations, mostly by transnational pharmaceutical corporations.

General Comment No.17 of CESCR in 2005 considers that the right to enjoyment of the benefit from the invention by authors, in the form of IPRs, must be balanced with the enjoyment

of the benefits of scientific progress and its application,³⁴⁷ which is stated in Article 15.1 (b). However, this provision still lacks clarity in its definition, and the narrow scope of the right suggests slow progress. General Comment No.17 only focuses on Article 15 (c), rather than the Article as a whole. There has been criticism of commentators for failing to take into account the complex nature of the relationship between science and technology with IPRs and cultural rights.³⁴⁸

4.4 Disputed Hierarchy of International Law

There has been vast discussion around whether the international trade laws have to comply with international human rights norms. The most important task under international human rights norms is to ensure the protection of the rights and applicable standards.

In the case of pharmaceutical science and technology, the international trade laws in intellectual property rights create new opportunities for human beings to become and remain healthy; however, the intent to protect the interest of the pharmaceutical products has brought unforeseen problems and even threats and undesirable outcome to the international community.

³⁴⁷ Committee on Economic, Social and Cultural Rights, Human Rights and Intellectual Property: Statement by the Committee on Economic Social and Cultural Rights, E/C.12/2001/15, 2001, available at <http://www2.ohchr.org/english/bodies/cescr/docs/statements/E.C.12.2001.15HRIntel-property.pdf> (last accessed on March 19, 2009)

³⁴⁸ 3rdthree Organization, 'Intellectual Property and Human Rights: Is the Distinction Clear Now?: An Assessment of the Committee on Economic, Social and Cultural Right' General Comment No.17 (2005) on "The Right of Everyone to Benefit From the Protection of the Moral and Material Interest Resulting from any Scientific, Literary or Artistic Production of Which he is the Author", P.3-4, 2006, available at www.3dthree.org/pdf_3D/3D_GC17_IPHR.pdf (last accessed on March 19, 2009)

The Chair of the Committee on Economic, Social and cultural Rights, Ms Dandan states the reasons for choosing Art.15 (c): Art 15 (c) was most urgent as there was a need to identify the human rights dimensions of IP policy. And the work of general comment on Art15 (a) and (b) has begun but is progressing slowly.

4.4.1 International Human Rights Norms and International Trade Laws

The issue of the hierarchies between the international human rights law and international trade law has been vigorously discussed.³⁴⁹ Arguments arise as to whether the international trade law system can be and should be applied and interpreted in compliance with of the international human rights law obligations. The arguments are resolved by some commentators on the issue of whether the given human rights norms have achieved the status of jus cogens or obligations erga omnes.³⁵⁰

The obligations erga omnes and jus cogens are the obligations which are so important in the value that state actors have to honor the protection under international law. Obligations erga omnes, which mean "towards everyone"³⁵¹ are a broader general principle which embraced jus cogens. In the case of Barcelona Traction (1970), ICJ defines the obligations erga omnes as those in which state actors owe a duty to the international community as a whole. "In the view of the importance of the rights involved, all States can be held to have a legal interest in their protection; they are erga omnes."³⁵² The Barcelona Traction case gives some examples of the types of rights which reached the status of erga omne to obligate the all states including "the outlawing of acts of aggression, and of genocide, as also from the principles and rules concerning basic rights of the human person, including protection from slavery and racial

³⁴⁹ James Harrison, *The Human Rights Impact of the World Trade Organization*, P.57, Hart Publishing, 2007
This issue has draws much scholarly attention in recent times in ILC in the "Fragmentation of International Law: Difficulties Arising from the Diversification and Expansion of International Law

³⁵⁰ James Harrison, *The Human Rights Impact of the World Trade Organization*, P.56, Hart Publishing, 2007

³⁵¹ Andrew Clapham, *Human Rights Obligation of Non-State Actors*, P.96, Oxford University Press, 2006

³⁵² Barcelona Traction, Light and Power Company, Limited (Belgium v. Spain)(New Application: 1962), available at

<http://www.icj-cij.org/docket/index.php?sum=292&code=bt2&p1=3&p2=3&case=50&k=1a&p3=5> (last accessed on March 19, 2009)

discrimination”³⁵³ by giving separate right which gives rise to another to complain about the violation. Thus the International Court of Justice (ICJ) specifically confirms that every state can complain about the violation of international law when an obligation, which “owed to the international community as whole” or “owed to a group of states,” is breached³⁵⁴; indicating examples as of the obligations erga omnes from slavery, genocide, racial discrimination. Although the ILC special Rapporteur, James Crawford, points out that human rights obligations are either the obligations which are “owed to the international community as whole” or those which are “owed to a group of states”.³⁵⁵ He notes that, the classification of obligations is depends on the “the universality and significance” and moreover, he adds, human rights treaties are plainly, even if not always explicitly designed to protect a general common interests.”³⁵⁶ However, the content of “the principles and rules concerning basic right so f human rights” is not very clear.

There are certain rights and obligations which have very important value to be protected under international law. The status of these rights and obligations are high above the international legal regime, and are referred to as “jus cogens”. Jus Cogens obligations are a

³⁵³ Barcelona Traction, Light and Power Company, Limited (Belgium v. Spain)(New Application: 1962), available at <http://www.icj-cij.org/docket/index.php?sum=292&code=bt2&p1=3&p2=3&case=50&k=1a&p3=5> (last accessed on March 19, 2009)

³⁵⁴ Andrew Clapham, Human Rights Obligation of Non-State Actors, P.96, Oxford University Press, 2006, and International Law Commission, Draft Articles on Responsibility of States for Internationally Wrongful Act, 2001, available at http://untreaty.un.org/ilc/texts/instruments/english/draft%20articles/9_6_2001.pdf (last accessed on March 14, 2009)

Article 48 Invocation of responsibility by a State other than an injured State

1. Any State other than an injured State is entitled to invoke the responsibility of another State in accordance with paragraph 2 if:

(a) The obligation breached is owed to a group of States including that State, and is established for the protection of a collective interest of the group; or

(b) The obligation breached is owed to the international community as a whole.

³⁵⁵ Andrew Clapham, Human Rights Obligation of Non-State Actors, P.97, Oxford University Press, 2006

³⁵⁶ Andrew Clapham, Human Rights Obligation of Non-State Actors, P.97, Oxford University Press, 2006

subset of obligations erga omnes, which address to the hierarchically superior than obligations in obligations erga menes.³⁵⁷

The Vienna Convention on the Law of Treaties 1969, Article 53³⁵⁸ “Treaties conflicting with a peremptory norm of general international law (‘jus cogens’)” provides,

[A] peremptory norm of general international law is a norm accepted and recognized by the international community of States as a whole as a norm from which no derogation is permitted and which can be modified only by a subsequent norm of general international law having the same character.

The principle of jus cogens is given the highest effect of the international legal norms, which binds every member of the international community. Any provision in treaties or convention is void when contradicting jus cogens. Any actor breaching the jus cogens norms cannot claim that he/she is acting pursuant to underlying valid treaty obligations, in the proposed issue, the international trade law. Thus, when any human right norms achieve jus cogens status, they will trump international trade laws.³⁵⁹

Unlike obligations erga omnes, examples of obligations jus cogens are not clearly identified. The settled lists of human rights norms which achieved the status of jus cogens may include:

³⁵⁷ James Harrison, *The Human Rights Impact of the World Trade Organization*, P.59, Hart Publishing, 2007
In other words, all obligations jus cogens are obligations erga omnes, but not all the obligations erga omnes are obligations jus cogens,

³⁵⁸ The Vienna Convention on the Law of Treaties, Article 53, 1969, available at http://untreaty.un.org/ilc/texts/instruments/english/conventions/1_1_1969.pdf (last accessed on March 19, 2009)

³⁵⁹ James Harrison, *The Human Rights Impact of the World Trade Organization*, P.58, Hart Publishing, 2007
As the author indicated that in theory, if the WTO obligations have reached jus cogens, WTO obligations will trump human rights. However, it will be dangerous in the international law practice, especially in the case of WTO law. When the WTO law was negotiated by the influence of powerful non-state actors and certain powerful state actors and accompany with strong enforcement mechanism, it is difficult to say that once the trade norm will become jus cogens, when the norm has being accepted and recognized by the international community.

genocide, prohibition of slavery and slave trade, the murder or causing the disappearance of individuals, torture, prolonged arbitrary detention, systematic racial discrimination, or a consistent pattern of gross violation of international recognized human rights. Lacking consensus in the content of human rights in obligations jus cogens has diminished its value to solve conflicts and impact of the principle and leaves indeterminate its legal effect.³⁶⁰

4.4.2 TRIPS and International Human Right to Health

Article 3.2 of the WTO Understanding the Rules and Procedures Governing the Settlement of Dispute³⁶¹ demands that the WTO agreement to interpret the exiting agreement in accordance with customary rules of public international law.³⁶² In addition, according to the Vienna Convention on the Law of Treaties (1969), Article 53, when there is a conflict with a peremptory norm of general international law ('jus cogens')", general international law will prevail.

Whether the human right norms in health have achieved the status of jus cogens is another heavily debated argument. In the most settled list of jus cogens, the recognized obligations are limited to individual or state negative conducts including stated genocide, torture, and slavery. By contrast, the human right norms in health which are beyond the relationship of one individual or state actor to another encourage all actors in the international community to protect human rights in a positive way, which has been slow to progress. The positive realization of human rights is progressing and depends on a state actor's resources to inject the norms into the international community. It is very difficult to determine whether the human rights norms

³⁶⁰ James Harrison, *The Human Rights Impact of the World Trade Organization*, P.58-59, Hart Publishing, 2007

³⁶¹ WTO, *Understanding on Rules and Procedures Governing the Settlement of Disputes*, Article 3.2, available at http://www.wto.org/english/docs_e/legal_e/28-dsu_e.htm (last accessed on March 19, 2009)

³⁶² Andrew Clapham, *Human Rights Obligation of Non-State Actors*, P.166, Oxford University Press, 2006

depends on state resources to gradually realizing the right has been achieved in the status of jus cogens or not.

Harrison provides a similar argument in application to WTO laws. He states that human rights norms are obligations which are collective, i.e. owed to all parties in the treaty; but the WTO law obligations are reciprocal, i.e. bilateral or multilateral treaties among the member states. Some scholar suggests that when these two norms conflict, the human rights norm should prevail, but no consensus has been reached.³⁶³

Some commentators argue that international human rights are the most unique norms under international law; thus, at least there are some “core contents” which cannot be violated, even with insufficient agreement on the content of some international human rights norms.³⁶⁴

Though there are still arguments regarding which human right norms have achieved the status of jus cogens, there are certain international human rights which should have be viewed as having reached this higher level of global recognition. The content of jus cogens grows just as human rights law, and with time and environmental changes, its content and protection expands.

4.4.3 TRIPS and Convention of Biological Diversity

The United Nations Convention on Biological Diversity marks the beginning of international cooperation in recognizing the importance of conservation and sustainable use of biological diversity for meeting the needs for food, health and other needs of future generation to access to

³⁶³ James Harrison, *The Human Rights Impact of the World Trade Organization*, P.60 Hart Publishing, 2007

³⁶⁴ James Harrison, *The Human Rights Impact of the World Trade Organization*, P.60 Hart Publishing, 2007

and share both the genetic resources and essential technologies.³⁶⁵ Biological diversity is essential to TM, because 90% of TM and TM knowledge involves the use of plants. In order to have sustainable use, research and development of TM, there must also be biological diversity of genetic resources.

Convention on Biological Diversity, 1992

The Earth Summit for the adaptation of the Convention on Biological Diversity (CBD) was held in Rio de Janeiro in 1992. CBD embodies the international recognition and acceptance of the importance biological diversity. Members started trying to set up principles as to the bio-resources as the sole property of sovereign states and to establish that they have the freedom to use and trade them, but in a sustainable manner. The Convention also embodies how national governments can play a role in ensuring sustainable biodiversity regimes within which commerce, resources management and environmental institutions are utilized to prevent destruction, extinction, or alienation of biological resources.³⁶⁶

The recognition of “property rights” is one such set of incentives under the Convention and is aimed at encouraging beneficiaries to continue efforts of conservation and sustainable use of biological resources. The “sharing of benefits” that arise from commercialization of genetic resources in source countries is another incentive to encourage conservation efforts.³⁶⁷

³⁶⁵ Regulatory Situation of Herbal Medicines: A Worldwide Review, by WHO, P.1, 1998, available at http://whqlibdoc.who.int/hq/1998/WHO_TRM_98.1.pdf (last accessed on March 19, 2009)

³⁶⁶ CBD, Historical perspectives on the occasion of the 10th Anniversary of the entry into force of the Convention on Biological Diversity, available at <http://www.cbd.int/doc/publications/CBD-10th-anniversary.pdf> (last accessed on March 19, 2009)
CBD, 1992, Article 15, Access to Genetic Resources, available at <http://www.biodiv.org/convention/articles.shtml?a=cbd-15> (last accessed on March 19, 2009) and Padmashree Gehl Sampath, Regulating Bioprospecting: Institutions for Drug Research, Access, and Benefit-Sharing, P.35-36, United Nations University Press, 2005

CBD implicitly recognize the existence, value and importance of TK in Article 8 (j)³⁶⁸, In
Situs Conservation, which reads as follows:

Each Contracting Party shall, as far as possible and as appropriate...

Subject to its national legislation, respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity and promote their wider application with the approval and involvement of the holders of such knowledge, innovations and practices and encourage the equitable sharing of the benefits arising from the utilization of such knowledge, innovations and practices.

The CBD also provides a scheme of granting incentives at a local level suggesting that indigenous and local communities have a right over knowledge, innovations and practices, subject to national legislation. It includes that national governments have to provide participatory mechanisms for the exercise of the right so that communities can share the benefits

The CBD reinforces the concept of national sovereignty of genetic resources within country's territory. CBD Article 15 also requires national governments to identify the priority in biodiversity conservation and set up legal rules and institutions to govern the bioprospecting.

³⁶⁸ Including the following provisions:

- Preamble, paragraph 12: Recognition of the close dependence of indigenous and local communities on biological resources and the desirability of sharing equitably benefits arising from the use of traditional knowledge, innovations and practices relevant to the conservation of biological diversity and the sustainable use of its components (
- Preamble, paragraph 13: Recognition of the vital role that women play in the conservation and sustainable use of biological diversity and the need for their full participation at all levels of policy-making and implementation
- Article 1: The objectives of the Convention, namely, the conservation of biological diversity, the sustainable use of biological resources and the equitable sharing of benefits from the use of these resources
- Article 8 (j): The undertaking of Parties to respect, preserve and maintain TK, innovations and practices relevant to the conservation and sustainable use of biological diversity; to promote their wider application with the approval and involvement of the holders of such knowledge; and to encourage the equitable sharing of benefits arising from the application of such knowledge, innovations and practices
- Article 10 (c) Protecting and encouraging customary use of biological resources in accordance with traditional cultural practices
- Article 17.2: The exchange of information relevant to the conservation and sustainable use of biological diversity to include, inter alia, indigenous and traditional knowledge
- Article 18.4: In cooperation for the development and use of technologies, the inclusion of indigenous and traditional technologies relevant to the pursuit of the objectives of the Convention

from the commercialization of their resources. Many countries are now implementing Article 8 (j) through their national plans, strategies and programs. A number of governments have adopted specific laws, policies and administrative arrangements for protecting traditional knowledge, emphasizing that prior informed consent must be obtained before bio-prospecting.³⁶⁹

CBD also refers to traditional knowledge as including “indigenous and traditional technologies” in Article 18.4, which reads as follows:

The Contracting Parties shall, in accordance with national legislation and policies, encourage and develop methods of cooperation for the development and use of technologies, including indigenous and traditional technologies, in pursuance of the objectives of this Convention. For this purpose, the Contracting Parties shall also promote cooperation in the training of personnel and exchange of experts.

Conjoining Article 8(j) and Article 18.4, “traditional knowledge, innovations and practices” means not only the protection of such knowledge, innovation and practices by appropriate legal and administrative means of protections, but also the respecting, preserving and maintaining of such knowledge, innovation and practices in accordance with Article 8 (j).

CBD Article 15 (1), Access to Genetic Resources, establishes property rights, from open access

³⁶⁹ CBD, 1992, Article 8 (j): Traditional Knowledge, Innovations and Practices, Introduction, available at <http://www.biodiv.org/programmes/socio-eco/traditional/default.shtml> (last accessed on March 19, 2009) and CBD, Article 8 (j): Traditional Knowledge, Innovations and Practices, Article 8 (j) after COP 7, available at <http://www.biodiv.org/programmes/socio-eco/traditional/akwe.aspx> (last accessed on March 19, 2009)

In the seventh meeting of the conference of the Parties in 2004, the COP 7 adopted Akwen: kon guidelines for governments to initiate a legal and institutional review. The COP7 also considered using sui generis systems for the protection of traditional knowledge, innovations and practices. The issues are considered as follows:

- Consider non-intellectual-property-based sui generis forms of protection;
- Further develop, as a priority issue, elements for sui generis systems;
- Review the relevance and applicability of the Bonn Guidelines;
- Make recommendations regarding the international regime on access and benefit-sharing;
- Assess the role of databases and registers in the protection of traditional knowledge; and
- Explore, existing as well as new forms of intellectual property protection.

to materials at an international level, to a common property resource at the national level, on genetic resources, stating that “[r]ecognizing the sovereign rights of States over their natural resources, the authority to determine access to genetic resources rests with the national governments and is subject to national legislation.” Some sub-provisions of Article 15 provide the designing mechanisms to regulate the access.³⁷⁰

However, realization of biodiversity conservation is far more complex, because the Convention’s most important points are a departure from earlier international environmental agreements in that they recognize that conservation and the sustainable use of biological diversity can only be tackled when the subject matter is defined within an economic context. CBD Article 8(j) calls for respect, preservation and maintenance of traditional knowledge that is associated with biodiversity at the national level and contains an obligation to support and further advance TK in the context of conserving biological diversity; it does not contain a legal basis for creating an individual right nor any legal protection in the sense of establishing, exclusive, enforceable proprietary rights over the traditional knowledge.³⁷¹ Moreover, the CBD embodies the concept of benefit-sharing in both general and specific ways in several provisions,³⁷² but there are still big gaps in between.³⁷³ Yet, unlike the WTO, the provisions in the CBD impose a

³⁷⁰ CBD, 1992, Article 15, available at

<http://www.cbd.int/convention/convention.shtml> (last accessed on March 19, 2009)

³⁷¹ Padmashree Gehl Sampath, *Regulating Bioprospecting: Institutions for Drug Research, Access, and Benefit-Sharing*, P. 36, United Nations University Press, 2005

Though CBD has recognized TK and provided mechanisms and broad-based measures on biological diversity, it does not specifically prioritize the measures nor it provides nor does it provide details, thus leaving member states with a lot of flexibility to implement its framework.

³⁷² Provisions relate to benefit sharing: Article 1, “fair and equitable sharing of benefits”; Article 16, access and transfer of technology; and Article 19, handling of biotechnology and distribution of its benefits.

³⁷³ Padmashree Gehl Sampath, *Regulating Bioprospecting: Institutions for Drug Research, Access, and Benefit-Sharing*, P. 38-39, P.50-51, United Nations University Press, 2005

Although countries will be compensated for the use of genetic resources, the Convention does not codify the relationship between the generation of revenues through such activities and biodiversity conservation in a direct way. Secondly, the Convention does not define “appropriate” compensation for the use of genetic resources. Lastly,

weak, fragile obligation on the proprietors, mostly pharmaceutical companies, to ensure the exchange of the genetic resources, and the associated traditional knowledge are under the protection of the provisions of the convention and guaranteed equitable returns.

The biggest problem of the CBD is that it “lacks contextualization to local eco-political circumstances and its integration across local, regional, commercial and environmental frontiers has been lax.”³⁷⁴ CBD left optimal national legal frameworks for bio-prospecting. The lack of clarity of the terms in CBD and the diverse political ambitions of countries had led to less than full implementation of its provisions.³⁷⁵ Not only has the policy on the meaning and import of these provisions been polarized among countries of the South and the North, but the issues are made even more complicated by the TRIPS Agreement. TRIPS deals with the intellectual property rights within the Member States, including the pharmaceuticals, public health, access, traditional knowledge and benefit sharing that are the subject of the CBD. The issues fall on the relationship between TRIPS and CBD, the regulation of bio-prospecting on drug research

though specific forms of benefit-sharing is mentioned, the Convention does not provide guidelines as to which form of benefits should be shared under what circumstances, which leave a lot of rooms for countries to deliberate amongst themselves.

The language and interpretation in Article 15 of benefit-sharing is ambiguous, especially the prior informed consent (PIC) and Mutually Agreed Terms (MAT), scholars fear that the PIC process and benefit-sharing provisions may end up as a ‘rent-seeking’ process. Moreover, developing countries ask transfer of technology as reads in CBD Article 16, but developed countries only respond with the obligation to provide or facilitate access of and transfer of technologies related to access, conservation, and sustainable use of the genetic resources or traditional knowledge. Accompanying with the economic value of the drug research based on the genetic resources and traditional knowledge, developing source countries argue for the benefit sharing on the intellectual property rights lead to the exploitation of the resources or traditional knowledge, but developed, user countries tend to think that the payment shall be related to the potential or actual harm caused, which is the use of the genetic resources or traditional knowledge. This issue has not been settled.

³⁷⁴ Padmashree Gehl Sampath, *Regulating Bioprospecting: Institutions for Drug Research, Access, and Benefit-Sharing*, P.3, United Nations University Press, 2005

³⁷⁵ Padmashree Gehl Sampath, *Regulating Bioprospecting: Institutions for Drug Research, Access, and Benefit-Sharing*, P.45, United Nations University Press, 2005

“One of CBD’s problems lies in the way in which its worthwhile goals are to be implemented. They are vague, ambiguous or impotent. As a result, it is very ambitious attempt to integrate ‘previously distinct policy goals’ in the CBD is on the verge of a failure. Key provisions such as Article 8 (j), Article 15 and Article 16 are being used out of context and in isolation from the rest of the Convention. Many of reasons lie in the politics that divide genetic-resource-rich source (yet developing) countries and technology-rich (but developed) countries.”

based on genetic resources and traditional knowledge. There are also splits of stakeholders, the resources rich countries, towards the access and benefit sharing on genetic resources and traditional knowledge. One group of countries stands for the conservation of the genetic resources and traditional knowledge and another group focuses on benefit sharing. How to balance the interests in between and how to reach the needs and expectation of genetic resources or TK holders has become a tough task. The design of successful legal instruments for the protection and realization of the economic potential and economic commercial value of genetic resources and traditional knowledge depends on how to get a consensus between these three main interests groups for the R&D in the pharmaceutical sectors.³⁷⁶

Another major difficulty faced by CBD, in common with many international treaties, is that CBD obligations bind states as contracting parties but confer no rights and obligations on private entities such as research institutes, pharmaceutical companies and indigenous communities.³⁷⁷ Without specific and effective national laws and regulations, governments have little power to enforce the provisions in the Convention. Currently, the access and benefit-sharing are left to contracts between the bio-prospectors, mostly firms and scientific institutes, and public authorities in the sources countries. This contractual approach has several disadvantages which act against the original purpose of the Convention.³⁷⁸

³⁷⁶ Padmashree Gehl Sampath, *Regulating Bioprospecting: Institutions for Drug Research, Access, and Benefit-Sharing*, P.4-5, United Nations University Press, 2005

³⁷⁷ Sohpia Twarog and Promila Kapoor edited, UNCTAD, *Protecting and Promoting Traditional Knowledge: Systems, National Experiences and International Dimensions*, P. 99, 2004, available at www.unctad.org/en/docs/ditcted10_en.pdf (last accessed on March 19, 2009)

³⁷⁸ Sohpia Twarog and Promila Kapoor edited, UNCTAD, *Protecting and Promoting Traditional Knowledge: Systems, National Experiences and International Dimensions*, P. 99, 2004, available at www.unctad.org/en/docs/ditcted10_en.pdf (last accessed on March 19, 2009)

The original right holders of genetic resources and traditional knowledge often is not included in the contract, thus, they have no information and participation in the negotiation in the terms of contract and profit results wherefrom. Moreover the agreements are made as "package", where have little bargaining power on it.

So far, most of the developing countries, mainly TM/TMK holder countries, have not yet enacted laws to implement the resolution passed at the CBD. Although with the recognition of traditional medicine by most countries would help to improve the traditional medicine and knowledge and allow those countries to work closely to tackle some problems of intellectual property rights relating to traditional knowledge and medicine, the majority of the problems still exists.

The purpose of CBD is to promote more equitable use and exchange of genetic resources under ethical and legal norms to share the benefits among interested parties. It tries to reach a balance between the two sides for both the needs of technologically advanced countries and biologically endowed countries. Companies within pharmaceutical, crop-protection, seed and biotechnology industries appear to be the most likely to acknowledge the CBD.³⁷⁹ However, most companies are increasingly using contractual agreements³⁸⁰ to clarify their own rights and

³⁷⁹ Saraha A. Laird, *Biodiversity and Traditional Knowledge: Equitable: Partnerships in Practice*, P.279, Earthscan Pubns Ltd, 2002

Companies are responding the awareness of CBD by changing business practice.

The most common responds include:

- A decrease in corporate collecting activities; consolidation of collecting programmes into fewer countries, or ever solely domestic-collecting activities;
- Greater recourse to material from ex-situ collections, such as culture collections and compound libraries, in place of samples acquired through field-collecting activities;
- An increased role for intermediaries as brokers of access and benefit-sharing relationships, as well as suppliers of samples;
- The increasing use of material transfer agreements to clarify the terms of exchange; and
- The development of basic standards of benefit-sharing best practice to guide staff within companies-for example, through policies and internal guidelines.

³⁸⁰ Saraha A. Laird, *Biodiversity and Traditional Knowledge: Equitable: Partnerships in Practice*, P.286, Earthscan Pubns Ltd, 2002

Most of the contractual agreements are used for identifying parties, define the subject matter, specify uses and compensation, technological or in-kind basis, regulate rights over intellectual property in the event to development and marketing of products and define the period of the agreement and conditions for termination and provision containing breach of contract and the choice of law. The forms and terms of contracts may be varied, for example, contracts for the sale of raw material, material transfer agreements, licensing regimes and memoranda of understanding.

responsibilities.³⁸¹ It is common to see provisions comprising a “package” of monetary and non-monetary benefits, and most of the time the right holders cannot negotiate fair terms for access and benefit-sharing.³⁸²

CBD established the obligation of protection and conservation of genetic resources, but leaves the legislation and content of this obligation to member states. Many member states have ratified the CBD, but do not have national laws governing access to TM/TK and the sharing of benefits from its use, leaving TM/TK and genetic resources in the public domain.³⁸³

The Link and Interaction between TRIPS and CBD

TRIPS Article 27.3 (b) and the provision of the CBD dealing with access to TK and benefit-sharing interact in two major ways. First, the interaction between intellectual property rights and traditional knowledge raises the issue of whether current intellectual property rights system can provide a satisfactory mechanism for protecting TK, and whether current intellectual property rights systems dealing with on biotechnological inventions aid the appropriation of traditional knowledge.³⁸⁴ The second interaction relates to the CBD Article 16, transfer of

³⁸¹ WIPO engages in the works of the Draft Intellectual Property Guidelines for Access and Benefit-Sharing Contracts.

³⁸² Professor Anil K. Gupta prepared, WIPO-UNEP Study on the Role of Intellectual Property Rights in the Sharing of Benefits Arising from the Use of Biological Resources and Associated Traditional Knowledge, P.64, available at

www.wipo.int/tk/en/publications/769e_unep_tk.pdf (last accessed on March 19, 2009)

Mgbeoji states that the contract model neglects the immense asymmetry in the negotiating power of commercial firms and local people, accompanying by the problems of privacy of contract and places undue trust in the bureaucracy overseeing licensing arrangements.

³⁸³ Sophia Twarong and Promila Kapoor edited, UNCTAD, Protecting and Promoting Traditional Knowledge: Systems, National Experiences and International Dimensions, P.99, 2004, available at www.unctad.org/en/docs/ditcted10_en.pdf (last accessed on March 19, 2009)

CBD established the obligation of protection and conservation of genetic resources, but leaves the legislation and content of obligation to member states. Many member states have ratified fir the CBD, but do not have national legislations governing the access to TK and the sharing of benefits from its use, the TK and genetic resources, then remains in the public domain.

³⁸⁴ Padmachree Gehl Sampath, Regulating Bioprospecting: Institutions for Drug Research, Access, and Benefit-Sharing, P.43, United Nations University Press, 2005

Some of the genetic sources countries, communities and NGOs have been concerned about that intellectual property

technology, including biotechnology. It is unclear whether transfer of technology is a form of benefit sharing as defined in CBD Article 16 (1)³⁸⁵.

The intellectual property protection on some potential medicinal plants or some other genetic resources may make possible capitalization and provide incentives to some groups of users, but not as to the rest of genetic resources which has less economic value. In the mean time, CBD Article 16 (5)³⁸⁶ does recognize that cooperation to ensure the protection of intellectual property, but the protection of intellectual property cannot undermine the objectives of the CBD. The most discussed potential conflicts involve the relationship between the demands of drug research, compensation, and the prohibition on unsustainable use of genetic resources. Groups, communities, or source countries have different perceptions on whether genetic resources or traditional knowledge based on medicinal products should be protected under the intellectual property rights system and to what extent.

Without resolving these issues, such as the roles, the rights and responsibilities for the users and providers of TM, it will be more difficult to protect and promote TM systems, hindering their ability to contribute to drug research and public health.

system, especially TRIPS, encourages privatize and patent the genetic resources itself or traditional knowledge without any obvious intellectual contribution, and not even compensation. Cases are many, the famous misappropriation ones such as, patent on traditional knowledge on the uses of turmeric, ayahuasca and neem.

³⁸⁵ CBD, 1992, Article 16 (1), available at

<http://www.biodiv.org/convention/articles.shtml?a=cbd-16> (last accessed on March 19, 2009)

Each Contracting Party, recognizing that technology includes biotechnology, and that both access to and transfer of technology among Contracting Parties are essential elements for the attainment of the objectives of this Convention, undertakes subject to the provisions of this Article to provide and/or facilitate access for and transfer to other Contracting Parties of technologies that are relevant to the conservation and sustainable use of biological diversity or make use of genetic resources and do not cause significant damage to the environment.

³⁸⁶ CBD, 1992, Article 16 (5), available at

<http://www.biodiv.org/convention/articles.shtml?a=cbd-16> (last accessed on March 19, 2009)

The Contracting Parties, recognizing that patents and other intellectual property rights may have an influence on the implementation of this Convention, shall cooperate in this regard subject to national legislation and international law in order to ensure that such rights are supportive of and do not run counter to its objectives.

The relationship between TRIPS and CBD is defined by three interpretations. The first holds that there is inherent conflict between the two. Another view perceives no such conflict, finding instead mutual support for each framework's provision. Finally, a third interpretation views no inherent conflict, but sees the potential for conflict in implementation, requiring international action to ensure that TRIPS and CBD are implemented in a mutually-supportive fashion.³⁸⁷

CBD Article 8 contains the general principle that the sui generis right should not interfere with the minimum standards of intellectual property rights and should not result in the complications that may result in less compliance with the terms of the Agreement. Sampath believes that CBD Article 8 (a)³⁸⁸ includes the general accepted "public interest" principle, which allows the member states to adopt laws, regulations and measures necessary to the protection of public health.³⁸⁹

Many source countries propose that TRIPS can implement the CBD in the content of genetic resources and TK protection. Because the TRIPS Agreement was adopted after CBD and is more specific in its terms regarding intellectual property protection, under Article 30 of the Vienna Convention of the Law of Treaties, 1969, it will prevail if there is a conflict in intellectual

³⁸⁷ Padmachree Gehl Sampath, *Regulating Bioprospecting: Institutions for Drug Research, Access, and Benefit-Sharing*, United Nations University Press, 2005

³⁸⁸ CBD, 1992, Article 8 (a), available at

<http://www.biodiv.org/convention/articles.shtml?a=cbd-08> (last accessed on March 19, 2009)

Each Contracting Party shall, as far as possible and as appropriate:

(a) Establish a system of protected areas or areas where special measures need to be taken to conserve biological diversity;

³⁸⁹ Padmachree Gehl Sampath, *Regulating Bioprospecting: Institutions for Drug Research, Access, and Benefit-Sharing*, United Nations University Press, 2005

property protection.³⁹⁰

4.4.4 Concluding Summary

Since there is no content addressed to issues of the right to the enjoyment of the benefit of scientific progress and its application directly, the enjoyment of the benefit and application of pharmaceuticals remains untouched by international instrument.

Due to difficulties in formulating these rights, the international community has consistently delayed developing a system for the specific definition, scope, and enforcement of the right to enjoy the benefits of scientific progress and the application of pharmaceutical research.

With economic globalization and the increasing privatization and commercialization of pharmaceutical-related science and technology, it has become more difficult to achieve the goal of accessibility and affordability of pharmaceuticals.

The IPRs system is turning away from its original intent to encourage R&D in order to have more inventions to benefit the human populations, and today the system has evolved to serve the commercial and economic interests of global pharmaceutical corporations. IPR system should include human rights norms to safeguard the benefit of the inventors and the users of the inventions and the sustainable development of bio-prospering and benefit sharing of bio-diversity. The type and level of protections should be applied in a manner that will broadly benefit members of society both individually and collectively, especially in the context of

³⁹⁰ Vienna Convention of the Law of Treaties, 1969, available at http://untreaty.un.org/ilc/texts/instruments/english/conventions/1_1_1969.pdf (last accessed on March 19, 2009)

pharmaceuticals. A right to benefit from science and technology assumes that both individuals and communities will have to be easy access.³⁹¹

Dr Margaret Chan, Director-General of the WHO, has noted that “[p]ublic health cannot move forward without innovation. The need for innovation is constant.” She also notes that “the price of medicines and other products can be prohibitive, effectively blocking access to care.”³⁹² She acknowledges that the price of medicines is one of the several factors which influence the availability, accessibility, acceptability and quality of pharmaceuticals. Appropriate funding and incentive mechanisms are needed to research and develop accessible, available, acceptable and quality pharmaceuticals, especially for the diseases disproportionately affecting the populations of developing countries. The international human right to health will be difficult to realize without equitable access to life-saving and health-promoting interventions for the price of medicine.³⁹³

4.5 Conclusion

“Health” is a human rights issue that covers a very wide range of other issues. The definition of ‘the right to health’ has been seen in many international treaties, declarations and documents, however, how to recognize, respect, protect and fulfill the right to health in the availability, accessibility of pharmaceuticals still remains complex and contentious.

³⁹¹ Audrey R. Chapman, WIPO Panel Discussion on Intellectual Property and Human Rights, 1998, available at www.wipo.int/tk/en/hr/paneldiscussion/papers/pdf/chapman.pdf (last accessed on 1 Mar 2008)

³⁹² WHO, Dr. Margaret Chan, Director-General of the World Health Organization, Opening Remarks at the second session of the Intergovernmental Working Group on Public Health, Innovation and Intellectual Property, 2007, available at www.who.int/dg/speeches/2007/20071105_igwg/en/print.html (last accessed on March 19, 2009)

³⁹³ WHO, Dr. Margaret Chan, Director-General of the World Health Organization, Opening Remarks at the second session of the Intergovernmental Working Group on Public Health, Innovation and Intellectual Property, 2007, available at www.who.int/dg/speeches/2007/20071105_igwg/en/print.html (last accessed on March 19, 2009)

While the conceptual uncertainty and political sensitivity of the international human right to health has left the sick and the needy behind, we, as actors in the international community, should give consideration to both the protections of R&D and the human right to accessible, available, acceptable and good quality pharmaceutical-related products. The IPRs system serves a social function. The IPRs protection should serve the objective of protecting individual well-being to the extent of the highest attainable level of health.

Chapter 5: Change

5.1 The Changing World and the Expansion of International Human Rights Law

The global economy has influenced the status of health and also affects many human rights and health issues. Globalization promotes the transnational activities of individuals, nation states and non-state actors. As this process occurs, international human rights are also developing to adapt to this globalized world.

5.1.1 Expanding Scope of International Human Rights Law

The traditional concept of human rights is that they are universal, indivisible and interdependent, interrelated,³⁹⁴ and cultural.³⁹⁵

³⁹⁴ WHO, 25 Questions & Answers on Health & Human Rights, P.7, 2002, available at <http://www.who.int/hhr/NEW37871OMSOK.pdf> (last accessed on March 19, 2009)

Human rights protection is universal regardless of cultural differences,³⁹⁶ and applies to all human being around the world, regardless of whom they are or where they live. Human rights inhere in each human being. The rights protect individuals and groups from violation and interference by acts or omissions. They treat all people as equal by following the principle that all human beings are born free and equal in rights and dignity.³⁹⁷

The principle of indivisibility recognizes that no human being is inherently inferior to any other. Economic, social and cultural rights must be respected and recognized as being on the same footing as civil and political rights. The principle of interdependence recognizes the difficulty of realizing human rights when any human right is neglect, isolated, or discriminated against without justification. Human rights are interrelated to one another. The right to a safe and healthy life is more important to most people than others, and efforts to realize international human rights should be made only after considering all rights as a whole, but allowing for prioritization as necessary in accordance with human rights principles.³⁹⁸

Due to the positive character of economic and social rights, the civil and political rights protections are included in most nation states' constitutions; by contrast, the economic, social and

³⁹⁵ Sompong Sucharitkul, 'A Multi-Dimensional Concept of Human Rights in International Law', 62 Notre Dame L. Rev. 305, 1987

³⁹⁶ United Nations, Frequently Asked Questions on a Human Rights-Based Approach to Development Cooperation, P.5, 20066, available at <http://www.ohchr.org/Documents/Publications/FAQen.pdf> (last accessed on March 19, 2009)

International human rights are universally recognized and cannot allow culture difference in the respect, protection and fulfillment, but in the practical implementation and adaptation to different cultural contexts.

³⁹⁷ Sompong Sucharitkul, 'A Multi-Dimensional Concept of Human Rights in International Law', 62 Notre Dame L. Rev. 305, 1987

³⁹⁸ Sompong Sucharitkul, 'A Multi-Dimensional Concept of Human Rights in International Law', 62 Nortre Dame L. Rev. 305, 1987

cultural rights are generally framed in much softer terms.³⁹⁹ Some parts of economic, social and cultural rights have not yet established internationally-recognized measures and steps to be included in the constitutional contexts. Socio-economic factors influence this process to a great extent, and even though some human rights have been recognized, often nation states cannot move forward because of a lack of resources.

5.1.2 The Expanding Right Holders of International Human Rights

Traditionally, human rights protection is between the individual and state governments. Human rights are primarily the rights of individuals.⁴⁰⁰ Each nation state should be responsible for respecting and promoting human rights. By ratifying the international human rights treaties, nation states will be obligated under international law to enrich their domestic national laws. International and national obligations require transparent, effective and accessible mechanisms of accountability for the protection of human rights.⁴⁰¹

On the other hand, human rights primarily create obligations on nation states. The Vienna Declaration and Programme of Action adopted at the World Conference on Human Right, "...it is the duty of States, regardless of their political, economic and cultural systems, to promote and protect all human rights and fundamental freedoms."⁴⁰²

Within the context of globalization, human rights protection should not be limited to only

³⁹⁹ Christian Tomuschat, *Human Rights: Between Idealism and Realism*, P.38, Oxford University Press, 2004

⁴⁰⁰ Sompong Sucharitkul, 'A Multi-Dimensional Concept of Human Rights in International Law', 62 *Notre Dame L. Rev.* 305, 1987

⁴⁰¹ Paul Hunt, 'Neglected Diseases, Social Justice and Human Right: Some Preliminary Observations', 2003, P.5, 2003, available at

http://www.who.int/hhr/working_paper4_neglected%20diseases.pdf (last accessed on March 19, 2009)

⁴⁰² WHO, 25 Questions & Answers on Health & Human Rights, P.7, 2002, available at <http://www.who.int/hhr/NEW37871OMSOK.pdf> (last accessed on March 19, 2009)

individuals but should also include collective groups of people.⁴⁰³ When the violation of individual rights cumulates into the violation of peoples' rights, there should be collective or group's right⁴⁰⁴ to hold the state actors or non-state actors responsible and/or accountable.

Applying this principle to the right to health, the right should not be limited to individual human rights only, but when the health problems or conditions have become so pervasive as to constitute a violation against an entire group, collective rights should exist to combat the violation. When a threat to individual health may cumulate into a threat to public health, when the individual's illness has turned into an epidemic or outbreak of infectious diseases or serious chronic diseases or pollution of the health determinants, here, the core of the right to health is violated. Moreover, when the pharmaceuticals or medical services are not affordable and accessible, the issue will then become a public health concern. The individual problems can add up to collective problems.

5.1.3 The Expanding Subjects of International Human Rights Law

As mentioned, human rights primarily focus on the relationship between individuals and nation states. Globalization has affected not only state actors but also non-state actors, particular transnational corporations.⁴⁰⁵ The promotion and protection of human rights should not be

⁴⁰³ The term collective or group rights usually refer to the rights of peoples and groups. Human rights claims are more effective by peoples and groups.

⁴⁰⁴ The later developed concept of collective, groups' or peoples' rights have been reflected in some regional human rights regimes⁴⁰⁴, but not yet in international human rights instruments.

⁴⁰⁵ Office of the United Nations High Commissioner for Human Rights, Globalization—Business and Human Rights, available at

<http://www2.ohchr.org/english/issues/globalization/business/index.htm> (last accessed on 1 Mar 2008)

The international community intervenes of the human rights protection mostly in the situations of natural disasters to make the goods and services available under the special conditions. And also

Andrew Clapham, Human Rights Obligations of Non-State Actors, 2006, P.8

As Professor Andrew Clapham emphasis, “[a]nalyzing globalization highlights change and developments in various

bounded by the frontiers of national states. Both state actors and non-state actors should be responsible and accountable for creating, promoting and maintaining international human right norms.

As the promotion and realization of international human right norms progresses, greater international cooperation is required⁴⁰⁶. The international cooperation of every actor in this international community might be able to progressively achieve realization the right on a global scale.

5.1.4 Concluding Summary

The emerging global economy has brought explosive changes and challenges to the world. The process of globalization has changed the interaction of individuals and groups across certain boundaries. The most problematic issue might be that the application and practice of the current international human rights does not meet with the demands of the globalized world.

The former Secretary-General of the United Nations, Kofi Annan, has underscored that

the pursuit of development, the engagement with globalization, and the management of change must all yield to human rights imperatives rather than the reverse. Respect for human rights, as proclaimed in the international instruments, is central to our mandate. If we lose sight of this fundamental truth, all else will fail.⁴⁰⁷

sectors- but human rights abuses are committed by legal entities, not by an abstract phenomenon named globalization.”

⁴⁰⁶ WHO, 25 Questions & Answers on Health & Human Rights, 2002, P.15, available at <http://www.who.int/hhr/NEW37871OMSOK.pdf> (last accessed on 1 Mar 2008)

As reflected in Article 2 of ICESER, which states that nation states need to “take steps, individually and through international assistance and cooperation, especially economic and technical, to the maximum of its available resources, with a view to achieving progressively the full realization of the rights recognized [herein]???” Additionally, “international action for the achievement of the rights ... includes such methods as ... furnishing of technical assistance and the holding of regional meetings and technical meetings for the purpose of consultation and study organized in conjunction with the Governments concerned.”

⁴⁰⁷ WHO, 25 Questions & Answers on Health & Human Rights, P.24,2002, available at <http://www.who.int/hhr/NEW37871OMSOK.pdf> (last accessed on March 19, 2009)

Globalization is increasing the flow and movement of money, goods, services and people across national borders. It also has also complicated the relationship between state actors and non-state actors. The process of globalization has brought benefits to many people and countries in the form of a better life and awareness of human rights protection. However, the effect of the process has also been to deny many people equality in the access to markets, information and essential goods, such as life saving pharmaceuticals and medical equipment.

It has been recognized that the development of human rights protection needs a more friendly and favorable environment; however, the expanding scope and application of international human rights protections have not received a very clear profile. Not only must the concept of international human rights be expanded, but new entities or power associations must be included in order to build a proper framework and a network of institutions.

International law is living, growing, and developing, especially in the area of international human rights protection. International human rights protections must prepare to face the changing and challenging globalized world.

5.2 Responsibility and Accountability in the International Human Rights to Health

Legal recognition of the right to health will give rights to the holders and legal responsibility and accountability to the obligors. Legal responsibility is closely linked to the notion of entitlement. Action or omissions done by either state actors or non-state actors which cause harmful consequences or damages could result in responsibility and accountability. The legal recognition of the human right to health is the prerequisite of legal responsibility. With the

legal recognition of the right to health, persons and peoples will be able to claim human rights-based remedies in cases of violations of or neglect to the right to health.

The primary human rights obligation rest with the state actors, as state actors are subjects of international law and the decision makers in international law. State actors have human rights responsibility and accountability to ensure protection and prevent threats from others, including both other state actors and non-state actors. The realization of the international human rights still requires international co-operation between state actors and non-state actors.⁴⁰⁸

5.2.1 State Actors

State actors which ratify the treaties for human rights protection in the right to health assume responsibility and accountability. Article 2 of International Covenant of Economic, Social and Cultural Rights imposes obligations on nation states specify that “states are a party to take steps ... with a view to achieving progressively the full realization of the rights recognized in the present Covenant.”⁴⁰⁹ The provision sets out the general legal obligation of States in relation to the various covenant rights, including the right to health in Article 12. The General Comment No.3 of the Committee of ICESCR in 1990 also confirms that state parties have core obligation to ensure the satisfaction of at the very least, minimum essential level of protection for each of the rights.⁴¹⁰

⁴⁰⁸ Sompong Sucharitkul, ‘The Right to Food and Freedom from Hunger in the Past Sixth of a Century’, P.4, 1993 <http://dialnet.unirioja.es/servlet/articulo?codigo=2021472> (last accessed on March 20, 2009)

The protection of human rights in the common concern and primary responsibility of every State as well as the collective obligation of the international community.

⁴⁰⁹ International Covenant on Economic, Social and Cultural Rights (ICESCR), 1966, available at http://www.unhchr.ch/html/menu3/b/a_cescr.htm (last accessed on March 19, 2009)

⁴¹⁰ ICESCR, General Comment No.3, 1990, available at [http://www.unhchr.ch/tbs/doc.nsf/\(Symbol\)/94bdbaf59b43a424c12563ed0052b664?Opendocument](http://www.unhchr.ch/tbs/doc.nsf/(Symbol)/94bdbaf59b43a424c12563ed0052b664?Opendocument) (last accessed on March 19, 2009)

Nation states' accountability and responsibility based on international human rights is confirmed in the General Comment No.14 of the Committee on Economic Social and Cultural Rights.⁴¹¹ The comment addresses the state governments' obligation first to require state actors to respect, protect and fulfill the obligation. The duty to respect the right to health requires states to refrain from interfering directly or indirectly with the enjoyment of the right to health, both in the context of pharmaceuticals and in other contexts affecting preconditions to health. The duty to protect requires states to take measures in preventing non-state actors from interfering with the right to health in health services such as pharmaceuticals. The duty to fulfill requires states to adopt appropriate legislative and administrative measures in promotion and full realization of the right.⁴¹²

It is obvious that both states and non-state actors must act vigorously in international human rights protection in the context of health. In the neglect or non-compliance with human rights norms, the term "abusing" is usually used instead of "violation."⁴¹³

In the General Comment No.14 of the Committee on Economic Social and Cultural Rights, the term "violation" is used for non-state actors. Moreover, the General Comment makes clear that states' obligation includes omission or failure to regulate the activities of individuals, groups or corporations to prevent them from violating the right to health.

⁴¹¹ ICESCR, General Comment No.14, 2000, available at [http://www.unhchr.ch/tbs/doc.nsf/\(Symbol\)/40d009901358b0e2c1256915005090be?Opendocument](http://www.unhchr.ch/tbs/doc.nsf/(Symbol)/40d009901358b0e2c1256915005090be?Opendocument) (last accessed on March 19, 2009)

⁴¹² CESER, The Right to the Highest Attainable Standard of Health, General Comment No.14, available at [www.unhchr.ch/tbs/doc.nsf/\(symbol\)/E.C.12.2000.4.En?OpenDocument](http://www.unhchr.ch/tbs/doc.nsf/(symbol)/E.C.12.2000.4.En?OpenDocument) (last accessed on March 15, 2009)

⁴¹³ Professor Andrew Clapham and Mariano Garcia Rubio, The Obligation of States with Regard to Non-State Actors in the Context of the Right to Health, 2002, P.1, available at www.who.int/hhr/Series_3%20Non-State_Actors_Clapham_Rubio.pdf (last accessed on March 15, 2009)
"Violation" usually refers to the misconduct by governments, so as to avoid greater recognition and undue status to non-state entities.

State Responsibility held by the State Itself

The right to health requires health policies to ensure the accessibility, availability, acceptability and quality facilities, goods and services related to the underlying determinants of health. The section addressing accessibility (affordability) states in part that payments for health-care services, as well as services related to the underlying determinants of health, has to be based on the principle of equity, ensuring that these services, whether privately or publicly provided, are affordable for all, including socially disadvantaged groups.⁴¹⁴

The accessible, available, acceptable and of quality medicine is the main issue related to trade. Professor Paul Hunt recommends that states are obligated to ensure that pharmaceutical products are:⁴¹⁵

- Available: state has to have health policy in making medicine available within its territory by using, where appropriate TRIPS flexibilities, such as compulsory licenses and parallel imports.
- Accessible: state has to ensure that essential medicine is not only available in the jurisdiction, but also accessible to all. The accessibility has four dimensions: non-discrimination, physical accessibility, economic accessibility (affordability) and information.
- Quality: states need to have monitoring system to ensure good quality of medicines, and to prevent counterfeit, contaminated and sub-standard drugs.⁴¹⁶

⁴¹⁴ CESER, General Comment No.14, available at [http://www.unhchr.ch/tbs/doc.nsf/\(Symbol\)/40d009901358b0e2c1256915005090be?Opendocument](http://www.unhchr.ch/tbs/doc.nsf/(Symbol)/40d009901358b0e2c1256915005090be?Opendocument) (last accessed on March 20, 2009)

⁴¹⁵ Paul Hunt, The Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health, Mission to the World Trade Organization, 2004, P.10-11
[http://www.unhchr.ch/Huridocda/Huridoca.nsf/\(Symbol\)/E.CN.4.2004.49.Add.1.En?Opendocument](http://www.unhchr.ch/Huridocda/Huridoca.nsf/(Symbol)/E.CN.4.2004.49.Add.1.En?Opendocument) (last accessed on March 20, 2009)

⁴¹⁶ ICESER, General Comment No.14, P.3, available at [www.unhchr.ch/tbs/doc.nsf/\(symbol\)/E.C.12.2000.4.En?OpenDocument](http://www.unhchr.ch/tbs/doc.nsf/(symbol)/E.C.12.2000.4.En?OpenDocument) (last accessed on March 19, 2009)

States have an obligation to take steps necessary for the development and diffusion of science for the prevention, treatment and control of diseases. State responsibility in promoting the highest attainable physical and mental health is achieved through the establishment of health care system.

It is individual nation state's responsibility to provide for health care needs through the public sector through adequate funding of health delivery systems. This would substantially enhance the health budget. The share of general government budget expenditure allocated to health care varies. From as low as 5% in several countries in Africa, Asia and the WHO Eastern Mediterranean Region to well over 20% in some countries in Americas, great inequality exists between these health expenditure ratios. One-third of low income countries allocated over 10% of their national budget to health in 2003.⁴¹⁷ The influxes of capital often reach as high as 20% from external sources thorough global health partnerships such as the Global Fund to Fight AIDS, Tuberculosis and Malaria and the Global Alliance for Vaccine and Immunization, and from bilateral donors. However, with no assurance of aid predictability over the long term, sustainability is a major concern.⁴¹⁸

State Responsibility on State-Empowered Non-State Actors

State actors have responsibility and accountability to regulate and enforce international human rights laws on their people or entities. The international law of state responsibility has been

⁴¹⁷ WHO and HAI, *Medicine Prices: A New Approach to Measurement*, 2003, Working Draft for Field Testing and Revision, available at:

http://whqlibdoc.who.int/hq/2003/WHO_EDM_PAR_2003.2.pdf (last accessed on March 19, 2009)

In most developed countries, health insurance covers a major part of medicine costs; however, in some African and Asian countries, because the pharmaceutical price is so high, the medicine and health spending could dominate around 80% of a household's income.

⁴¹⁸ World Health Statistics 2006, P. 16, also available at www.who.int/whosis/whostat2006.pdf

developed to cover state-empowered non-state actors, especially for the privatized state corporations which retain public or regulatory functions.

Article 5 of Articles of State Responsibility of International Law Commission (ILC)⁴¹⁹ refers to the increasing phenomena of non-state actors exercising governmental authority, mostly in the situations of formerly state-controlled corporations which have been privatized but still retain certain public or regulatory functions.⁴²⁰ Article 5 reads as:

The conduct of a person or entity which is not an organ of the State under article 4 but which is empowered by the law of that State to exercise elements of the governmental authority shall be considered an act of the State under international law, provided the person or entity is acting in that capacity in the particular instance.

The Commentary also explained the intended scope of Article 5:

- (2) The generic term 'entity' reflects the wide variety of bodies which, though not organs, may be empowered by the law of a State to exercise elements of governmental authority. They may include public corporations, semi-public entities, public agencies of various kinds and even, in special cases, private companies, provided that in each case the entity is empowered by the law of the State to exercise functions of a public character normally exercised by State organs, and the conduct of the entity relates to the exercise of the governmental authority concerned. For example in some countries private security firms may be contracted to act as prison guards and in that capacity may exercise public powers such as powers of detention and discipline pursuant to a judicial sentence or to prison regulations.

Therefore, states will be responsible for the acts and omission of the non-state actors at the international level when the behavior constitutes an internationally wrongful act and the entity was acting in that capacity in the particular instance. Nation states will be responsible for the

⁴¹⁹ International Law Commission, Draft Articles on Responsibility of States for Internationally Wrongful Acts, 2001, available at http://untreaty.un.org/ilc/texts/instruments/english/draft%20articles/9_6_2001.pdf (last accessed on March 19, 2009)

⁴²⁰ Professor Andrew Clapham and Mariano Garcia Rubio, 'The Obligation of States with Regard to Non-State Actors in the Context of the Right to Health', P.5, 2002, also available at www.who.int/hhr/Series_3%20Non-State_Actors_Clapham_Rubio.pdf (last accessed on March 19, 2009)

acts of the empowered non-state actors where they carry out governmental activities, but not when those activities are un-related to the governance responsibilities of the actors.⁴²¹

Article 5 of the ILC covers entities that have been privatized or granted governmental powers by internal, domestic law. The internal law in question must specifically authorize the conduct as involving the exercise of public authority. Whether the non-state actors are involved with the right to health within the scope of Article 5 depends on the domestic law, history and tradition of the state. For example, when the health care has been considered governmental and empowered by domestic law, then the act or omission of the non-state actors will be considered to be a denial of the right to health attributed to the state under the law of state responsibility.⁴²²

Non-State Actors under State's Control

When the non-state actors is under the state's actual or direct control, there will be state responsibility for all acts or omission of the state-controlled non-state actors if there is evidence that the non-state actors were exercising public powers or the state was using its ownership interest in, or control of the non-state actors to achieve certain result.

The commentary of Article 8 in the ILC Draft Articles on Responsibility of States for

⁴²¹ Professor Andrew Clapham and Mariano Garcia Rubio, 'The Obligation of States with Regard to Non-State Actors in the Context of the Right to Health', P.6, 2002, available at www.who.int/hhr/Series_3%20Non-State_Actors_Clapham_Rubio.pdf (last accessed on March 19, 2009)

⁴²² Professor Andrew Clapham and Mariano Garcia Rubio, 'The Obligation of States with Regard to Non-State Actors in the Context of the Right to Health', P.6, 2002, available at www.who.int/hhr/Series_3%20Non-State_Actors_Clapham_Rubio.pdf (last accessed on March 19, 2009)

However, in the context of a practical approach to the private sector and the right to health, it is unlikely to prove a useful avenue to pursue for an organization such as the World Health Organization. Speculating on whether a particular society has a tradition of governmental provision of health care, and searching for the pertinent internal law which has empowered a large company to operate would clearly distract from the main message of "health for all".

Internationally Wrongful Acts, 2001, reads:

The conduct of a person or group of persons shall be considered an act of a State under international law if the person or group of persons is in fact acting on the instructions of, or under the direction or control of, that State in carrying out the conduct.⁴²³

When the violations or abuses are attributed to the state by the non-state actors, the state might be responsible under international and entitled to sanction, just as when the state is the actor. When state fails to provide or prevent the human rights violation or human rights abuses by the non-state actors, the state might be responsible when human rights bodies exists, such as the six UN human rights treaty bodies, or the regional human rights courts, then the state can be held responsible and failed in its international human rights obligations.⁴²⁴

State Responsibility on Non-State Actors within Its Jurisdiction

State responsibility for health is not only to abstain from violating human rights to health of itself, but also to ensure the conditions which enable individuals and other entities to realize their rights as fully as possible. Every entity, including individuals and organs of society, shall strive to respect, protect and fulfill the international human right to health.

As mentioned, state actors have responsibility and accountability to regulate and enforce international human rights laws. Some countries impose human rights obligations directly on

⁴²³ International Law Commission, Draft Articles on Responsibility of States for Internationally Wrongful Acts, 2001, available at http://untreaty.un.org/ilc/texts/instruments/english/draft%20articles/9_6_2001.pdf (last accessed on March 19, 2009) and Professor Andrew Clapham and Mariano Garcia Rubio, 'The Obligation of States with Regard to Non-State Actors in the Context of the Right to Health', P.7, 2002, available at www.who.int/hhr/Series_3%20Non-State_Actors_Clapham_Rubio.pdf (last accessed on March 19, 2009)

⁴²⁴ Professor Andrew Clapham and Mariano Garcia Rubio, 'The Obligation of States with Regard to Non-State Actors in the Context of the Right to Health', P.7, 2002, available at www.who.int/hhr/Series_3%20Non-State_Actors_Clapham_Rubio.pdf (last accessed on March 19, 2009)
The omission of the human rights obligation, sorts of indirect accountability, is often overlooked as one considers the ability of the human rights regime to deal with the accountability of the non-state actors.

non-state actors, while some others pass legislations for that purpose.⁴²⁵

Non-state actors are increasing their influence in relation to economic, social and cultural rights. It is the obligation of the state actors to ensure that no individual's or people's rights are violated in any way by any discriminatory behavior or undue damage these non-state actors may be causing. State actors should set up laws and regulations to control the conduct of non-state actors, including: multinational corporations, including pharmaceutical companies; national private sector companies; health insurance providers; providers of private health care; medical research institutes; international and national NGOs. However, some problems arise due to a nation state's inability or unwillingness to ensure that non-state actors conform to international human rights.⁴²⁶

5.2.2 Non-State Actors-Transnational Corporations

Nation states' international human rights obligations have been featured and established in international law and international human rights systems. However, the issue of international human rights responsibility and accountability of non-state actors is not totally settled.

In the wake of the global economic downturn, transnational corporations sell their products or services everywhere in the world, and they are able to negotiate with national governments. Their power has been so influential that when the industry is the major industry of nation states,

⁴²⁵ Holger Hestermeyer, *Human Rights and the WTO: The Case of Patent and Access to Medicines*, P.94-95, Oxford University Press, 2007

⁴²⁶ Andrew Clapham, *Human Rights Obligations of Non-State Actors*, P.4, Oxford University Press, 2006
Caroline Thomas suggests that "the globalization is privileging the private over the public sphere and over the commons. It is eroding the authorities of states differentially to set the social, economic and political agenda within their respective political space. It erodes the capacities of states in different degrees to secure the livelihoods of their respective citizens by narrowing the parameters of legitimate state activities".

they influence the negotiation of treaties between nation states. While the non-state actors are exercising their powers and influences on the forming or negotiation on the international law, non-state actors essentially participate in the rule making activities. Acting in tandem with the state actors to exercise negotiation power, the non-state actors are like invisible hand of control behind the veil of the decision making.⁴²⁷ “[I]ndividuals are increasingly as powerless towards big corporations as they are towards the states and that human rights can be violated by both states and corporations.”⁴²⁸ The growing sphere of influence⁴²⁹ and the role of non-state actors in the international community have been more crucial than ever under international law.

The United Nation General Assembly has a Declaration on the Rights and Responsibility of Individuals, Groups and Organs of Society to Promote and Protect Universally Recognized Human Rights and Fundamental Freedoms in 1999. The declaration stresses that the international community shall fulfill human rights protection jointly and separately without any distinction. Individuals, groups, institutions and NGOs also have important roles and responsibilities to use as appropriate to the promotion of the rights of everyone to a social and international order in which the rights and freedom set forth in the Universal Declaration of Human Rights (UDHR) and other human rights instruments are honored. In the UDHR calls on “every individual and every organ of the society” to strive to promote and respect the rights and

⁴²⁷ Holger Hestermeyer, *Human Rights and the WTO: The Case of Patent and Access to Medicines*, P.94-95, Oxford University Press, 2007

⁴²⁸ Holger Hestermeyer, *Human Rights and the WTO: The Case of Patent and Access to Medicines*, P.94-95, Oxford University Press, 2007

⁴²⁹ UN Global Compact Office and the Office of the UN High Commission for Human Rights, *Embedding Human Rights in Business Practice*, P.17, available at

<http://www.ohchr.org/Documents/Publications/Embeddingen.pdf> (last accessed on March 19, 2009)

“The concept of sphere of influence is not defined in detail by international human rights standards; it will tend to include the individuals to whom the company has a certain political, contractual, economic or geographic proximity.” All corporations have sphere of influences, no matter how large or small, local or transnational, though it is obvious that large transnational corporations tend to have more sphere of influences.

freedoms it contains and to secure their effective recognition and observance. The concept of “every organ of the society” covers non-state actors, such as corporations.⁴³⁰ General Comment No.14 also makes clear that non-state actors have responsibilities and can violate those responsibilities due to failure to fulfill their obligations.⁴³¹

The UN Sub-Commission for the Protection and Promotion of Human Rights, states some international human rights to health in these relevant paragraphs:

...
12. Transnational corporations and other business enterprises shall respect civil, cultural, economic, political and social rights and contribute to their realization, in particular the rights to development; adequate food and drinking water; the highest attainable standard of physical and mental health; adequate housing; education; freedom of thought, conscience and religion; and freedom of opinion and expression; and refrain from actions which obstruct the realization of those rights.

...
14. Transnational corporations and other business enterprises shall carry out their activities in accordance with national laws, regulations, administrative practices and policies relating to the preservation of the environment of the countries in which they operate as well as in accordance with relevant international agreements, principles, objectives, responsibilities and standards with regard to the environment as well as human rights, public health and safety; and shall generally conduct their activities in a manner contributing to the wider goal of sustainable development.

Looking at Professor Chris Okeke’s criteria, transnational corporations (TNCs) should be subjected to human rights responsibility and accountability since they enjoy having rights, possess duties and are empowered to vindicate their rights. The most difficult problems remain with how TNCs and other business enterprises shall contribute to the realization of the rights to

⁴³⁰ CESER, ‘Declaration on the Right and Responsibility of Individuals, Groups and Organs of Society to Promote and Protect Universally Recognized Human Rights and Fundamental Freedoms, 1999, available at [http://www.unhchr.ch/huridocda/huridoca.nsf/\(Symbol\)/A.RES.53.144.En?OpenDocument](http://www.unhchr.ch/huridocda/huridoca.nsf/(Symbol)/A.RES.53.144.En?OpenDocument) (last accessed on March 19, 2009) and UN Global Impact Office and UN OHCHR, Embedding Human Rights in Business Practice, P.15, available at <http://www.ohchr.org/Documents/Publications/Embeddingen.pdf> (last accessed on March 20, 2009)

⁴³¹ CESER, General Comment No.14, P.12-13, 2000, available at [www.unhchr.ch/tbs/doc.nsf/\(symbol\)/E.C.12.2000.4.En?OpenDocument](http://www.unhchr.ch/tbs/doc.nsf/(symbol)/E.C.12.2000.4.En?OpenDocument) (last accessed on March 20, 2009)

the highest attainable standard of physical and mental health, human rights and public health.

Pressure from advocates is directed at imposing a duty to corporate entities to respond to the right to health and bear the accountability and responsibility. The most common case is neglect of the human rights violation or omission of non-state actors by the state actor. Lately, there has been a focus on corporate social responsibility in the areas of labor rights and environmental protection⁴³² and trying to extend that responsibility to other areas of human rights.

Nicola Jägers divides this issue into respect, protection and fulfillment in the environmental law, labor law and consumer protection. The draft norms on the responsibility of transnational corporations and other business enterprises with regard to human rights also focus on the right to equal opportunity and non-discriminatory treatment; the right to security of persons; the rights of workers; consumer protection; environmental protection; and economic, social and cultural rights. To fulfill their corporate duty to respect the right to health, a company is required to abstain from operations which may cause environmental problems in the working environment which may cause the health problem to employees and the people residing on the land. Negligence or intentional disregard for these protections, including allowing unsafe or unhealthy products to enter the marketplace, violates this duty. For corporations, the duty to protect the right to health relies on the underlying determinants of the right to health, such as food and nutrition, housing, access to safe and portable water and adequate sanitation, safe and healthy

⁴³² UN Global Compact Office and the Office of the UN High Commissioner for Human Rights, *Embedding Human Rights in Business Practice*, P.99-118, available at <http://www.ohchr.org/Documents/Publications/Embeddingen.pdf> (last accessed on March 20, 2009)

“Human rights and supply chain management in the pharmaceutical sector”, the case study of how Novo Nordisk integrated human rights, including labor rights, into its supply chain management and the human rights dimension of the work.

working conditions and the environment. This duty may require corporations to adopt guidelines⁴³³ in order to ensure the activities of business partners will not lead to violations of other individuals' right to health. For example, a corporation may meet its obligation to fulfill right by providing its employees with health care services and hospitals.⁴³⁴ Nicola Jäger focuses on the duty of a corporation to facilitate realization of the right to health of its employees rather than a general obligation to fulfill the right to health to everyone.

As mentioned, relying on state actors to ensure TNCs comply and non-violate with human rights norms might be more difficult than among all non-state actors because TNCs are often more economically powerful than the state actors in the trading of benefits to attract investment. Some of the state actors are not likely to enforce or regulate TNCs, fearing that it will chill investment. Moreover, though the TNC's home state should bear the responsibility to regulate and enforce the international human rights norms, the enforcement is usually weak, because of the interested relationships between the state and the TNCs.

Furthermore, when there is violation of human rights by TNCs, sanctions on the nationality state of the TNCs will not be effective. The effectiveness of sanctions has been criticized hardily, but over all, it appears that the political gain of sanctions is usually out weighted by the pain of civilian suffering and the wrongdoer TNCs remains untouched while innocent peoples are gratuitously harmed.⁴³⁵

⁴³³ The guidelines are usually referred as "code of conduct".

⁴³⁴ Professor Andrew Clapham and Mariano Garcia Rubio, 'The Obligation of States with Regard to Non-State Actors in the Context of the Right to Health', P.16, 2002, also available at www.who.int/hhr/Series_3%20Non-State_Actors_Clapham_Rubio.pdf (last accessed on March 20, 2009)

⁴³⁵ Sofia Gruskin, Michael A. Grodin, George J. Annas, and Stephen P. Marks edited, *Perspectives on Health and Human Rights*, P. 369-370, Routledge, 2005

TNCs currently favor voluntary codes of conduct, guidelines, and sectoral initiatives to reflect their tackle on the human rights protection.

OECD Code of Conduct

OECD has elaborate Guidelines for TNCs. Transnational corporations shall bear a voluntary heavy moral responsibility when engaging activities, however, the “OECD Code of Conduct” was constituted only as a recommendation.

Moral/Social Responsibility

The classic concept of corporate responsibility⁴³⁶ was composed by Milton Friedman, who famously declared: “The social responsibility of business is to increase its profits.” The primary corporate accountability is to shareholders to maximizing the profit and only constraint the conduct pursuit of profits legally comply the law.⁴³⁷

The Sub-Commission on the Promotion and Protection of Human Rights has adopted a set of draft norms, based on existing international standards that seek to identify which human rights apply directly to companies. The “Norms of the Responsibilities of Transnational Corporations and Other Business Enterprises with regard to Human Rights” focuses on the right to equal opportunity and non-discriminatory treatment; the right to security of persons; the right of

⁴³⁶ The moral obligation of business has been discussed since late 1990s, the term sometimes called, ‘code of conduct’, ‘business ethics’, ‘corporate sustainability’, ‘good corporate citizenship’ or ‘corporate social responsibility’.

⁴³⁷ Doreen McBarnet, ‘Human Rights, Corporate Responsibility and New Accountability’, Tom Campbell and Seumas Miller edited, Human Rights and the Moral Responsibility of Corporate Public Sector Organization, P.64, Springer, 2004

workers; consumer protection; environmental protection; and economic, social and cultural rights.⁴³⁸

However, the norms are not legally binding, but provide a guideline and explanation for companies to understand human rights in the hope that corporations will undertake, embrace and incorporate the norms into their policies.

UN Global Compact

The United Nation' Global Compact is a voluntary initiative asking participating companies to embrace, support and enact, within their sphere of influences, policies concerning human rights, labor rights, environmental protection, and anti-corruption measure, among others.⁴³⁹ Principle one and two of the UN Global Compact focus on human rights protection. However, the measures are voluntary and lack binding power.

Human Rights Guidelines for Pharmaceutical Companies in Relations to Access to Medicines⁴⁴⁰

This guideline confirmed that having accessible and affordable pharmaceutical products is vital to the right to the highest attainable standard of health. It also confirmed state actors as the primary actor to provide health care system to its people, but also addressed non-state actors, such as pharmaceutical corporations, requiring them to share responsibilities to increase access

⁴³⁸ Commission on Human Rights, Sub-Commission on the Promotion and Protection of Human Rights, Norms on the Responsibility of Transnational Corporations and Other Business Enterprises with regard to Human Rights, 2003 [http://www.unhchr.ch/huridocda/huridoca.nsf/\(Symbol\)/E.CN.4.Sub.2.2003.12.Rev.2.En](http://www.unhchr.ch/huridocda/huridoca.nsf/(Symbol)/E.CN.4.Sub.2.2003.12.Rev.2.En) (last accessed on March 20, 2009)

⁴³⁹ UN Global Compact, available at www.unglobalcompact.org/AboutTheGC/TheTenPrinciples/index.html (last accessed on March 20, 2009)

⁴⁴⁰ General Assembly of the UN Special Rapporteur on the Right to the Highest Attainable Standard of Health (UN document:A/63/263. dated 11 August 2008), 2008, available at <http://www2.ohchr.org/english/issues/health/right/docs/Guidelinesforpharmaceuticalcompanies.doc> (last accessed on March 20, 2009)

to medicines.⁴⁴¹

However, although this guideline addresses on the concerns on management, monitoring and accountability, corruption, public policy influence, advocacy and lobbying, clinical trials, neglect diseases, patent and licensing, pricing, discounting and donations and ethical promotion and marketing,⁴⁴² this guideline is only a recommendation to pharmaceutical companies, with no binding power. Moreover, the guideline guides pharmaceutical companies to provide more accessible pharmaceutical products, but does not address what responsibility and accountability pharmaceutical companies have to the international human right to health and the inaccessible and unaffordable pharmaceutical price effects caused by the non-violation of pharmaceutical industry-negotiated TRIPS agreement.

Both the states and non-state actors prefer voluntary initiative to legal binding commitment. However, voluntary initiatives have been criticized as ineffective in the field of human rights protections. Good developments require stakeholders to be accountable for specific result for violation and neglect. Some advocates focus on the need to give “teeth” to international instruments by moving social responsibility towards legal obligations or even accountabilities in some field of protection to uphold international standards, which could have imminent effects on the human population.

⁴⁴¹ CESCR, General Assembly of the UN Special Rapporteur on the Right to the Highest Attainable Standard of Health (UN document:A/63/263. dated 11 August 2008), 2008, available at <http://www2.ohchr.org/english/issues/health/right/docs/Guidelinesforpharmaceuticalcompanies.doc> (last accessed on March 20, 2009)

Pharmaceutical companies, including innovator, generic and biotechnology companies, have human rights responsibility in relationship to access to medicines and enhance shareholder value.

⁴⁴² CESCR, General Assembly of the UN Special Rapporteur on the Right to the Highest Attainable Standard of Health (UN document:A/63/263. dated 11 August 2008), 2008, available at <http://www2.ohchr.org/english/issues/health/right/docs/Guidelinesforpharmaceuticalcompanies.doc> (last accessed on March 20, 2009)

5.2.3 Conclusion

The right to health obligates nation state actors to be responsible and accountable to ensure that there is a health care system delivering right to health outcomes. State actors also acquire responsibility and accountability which fail to ensure the powerful transnational corporations respect human rights responsibilities.

Nation states are also obligated to live up to international obligations in human rights to ensure that their own action, and those of other actors under its control, do not violate or contravene human rights norms.

Trade globalization has brought the world closer, and offers opportunities for access to previous closed markets for products and services. However, it also has an impact on the realization of human rights, especially the right to health, including a healthy environment, labor rights, and access to affordable medicines.

The human rights to health in the context of pharmaceutical products might be an issue for both state actors and non-state actors. As pharmaceutical product expenses also contribute to the health care expenditure, without accessible and affordable pharmaceutical products, state actors will have problem providing accessible and affordable health care to their people.

Moreover, though pharmaceutical transnational corporations might receive subsidies from some nation states, pharmaceutical companies are not empowered or under direct control by state actors in order to impose responsibility and accountability. Even if pharmaceutical companies

are empowered or under direct control by state actors, other state actors are not able to pursue international liability to pharmaceutical companies when there is absent for injuries consequences arising out of Acts not prohibit by international law by acting in compliance of international law, but the effect in inaccessible and affordable pharmaceutical products.⁴⁴³

Furthermore, the existing responsibility and accountability of non-state actors focus on direct violation on human rights by tortious act, environmental pollution and consumer protection. However, when the pharmaceutical prices are so inaccessible and unaffordable, there is an emergent questions of what responsibility and accountability can be imposed on transnational pharmaceutical corporations when there is no direct violation of laws.

5.3 Conclusion

Too often, economic power trumps politics in the development of international norms in response to globalization. There must be new ways to understand transnational justice and global law. Andrea Bianchi suggests that transnational civil society networks and non-governmental organizations create our understanding of human rights.⁴⁴⁴ However, in the legal approach, non-state actors exist as actors within the international community, but operate independently of binding obligations, responsibilities and accountability under international law. International law is lively, growing and expanding, but subject to restrictions. We need to examine all the actors under international law, though not give the same "status" to all actors.

States have obligations not only to their own population, but also have obligations to take

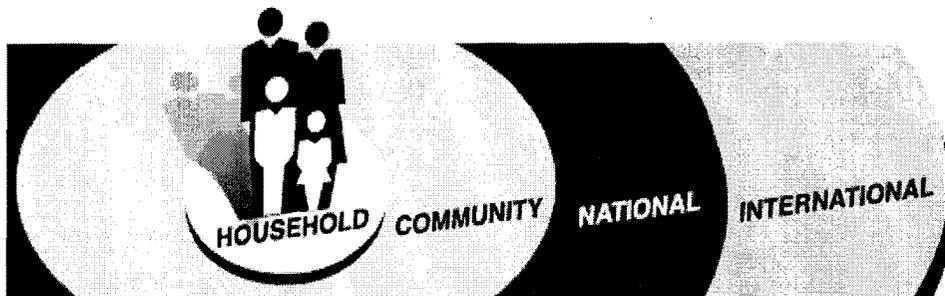
⁴⁴³ Sompong Sucharitkul, 'State Responsibility and International Liability under International Law', 18 *Loy. L.A. Int'l & Comp. L.J.* 821, 1996

⁴⁴⁴ Andrew Clapham, *Human Rights Obligations of Non-State Actors*, P.26, Oxford University Press, 2006

steps through international assistance and cooperation toward the full realization of the right by all people. In the spirit of United National Charter Article 56⁴⁴⁵, the State parties should recognize the essential role of international cooperation and comply with the commitment to take joint and separate action to achieve the right.

The protection of international human rights is a trend of progression. Although there are different kinds of human rights, the ultimate goal of the protections is to respect, fulfill and protect human dignity. The international community has taken steps towards further realization of international human rights and international co-operation in needed by everyone in the international community.⁴⁴⁶

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Although the right to health is sometimes recognized, there are difficulties in implementing

⁴⁴⁵ United Nation, Charter of United Nation, available at <http://www.un.org/aboutun/charter/index.html> (last accessed on March 19, 2009)

Article 56

All Members pledge themselves to take joint and separate action in co-operation with the Organization for the achievement of the purposes set forth in Article 55.

⁴⁴⁶ CESCR Council, The Nature of States Parties Obligations, General Comment 3, 1999, available at [http://www.unhchr.ch/tbs/doc.nsf/\(symbol\)/CESCR+General+comment+3.En?OpenDocument](http://www.unhchr.ch/tbs/doc.nsf/(symbol)/CESCR+General+comment+3.En?OpenDocument) (last accessed on March 19, 2009)

In the General Comment 3 of CESCR, the Committee addressed the attention on the State parties' international obligation to take steps, individually and through international assistance and cooperation, especially economical and technical towards the realization of the right to health.

⁴⁴⁷ Human Rights, 'Health and Poverty Reduction Strategies', P.17, 2005, available at http://www.who.int/hdp/publications/human_rights.pdf (last accessed on March 20, 2009)

and enforcing the right due to the character of the right to health, which unlike other economic, social and cultural rights depends on the state's available resources. There is insufficient attention given to how international law might be implemented within the changing context of globalization with regards to health. The free-market based economy has driven both state actors and non-state actors into more difficulties with the attempts to ensure economic, social and cultural rights in the field of health.

The health of its population is one nation state's responsibility to the extent of its capacity, which depends on its resources, but with the issues of infectious and chronic diseases, the public and individual health become the concerns of everyone. In fighting against diseases, the socioeconomic inequalities have adverse effects on health. In the rapid wake of globalization and privatization, attention must be paid to both nation states and non-state actors⁴⁴⁸ in order to fully grasp the essential influences that contribute to the right to health.

⁴⁴⁸ Sofia Gruskin and Daniel Tarantola, 'Health and Human Rights', Sofia Gruskin, Michael A. Grodin, George J. Annas, and Stephen P. Marks edited, *Perspectives on Health and Human Rights*, P.29, Routledge, 2005
Non-state actors can involve within the right to health by themselves or governments could delegate their roles and responsibilities to non-state actors, for example, biomedical research institutions, international foundations, health insurance companies, care providers, health management organizations and the pharmaceutical industry. In the situations of the delegated responsibilities, the accountability of non-state actors is poorly defined and inadequate monitored in most cases.

Chapter 6: Enforcement

6.1 Implementation and Enforcement

Legal enforcement mechanisms have been the central focus of many human rights advocates. State parties are the primary obligors to safeguard human rights by implementing and enforcing the rights following treaty provisions. International human rights instruments have committees to deal with disputes and violations. Some covenants explicitly state that state parties may use other procedures for the settlement of disputes in accordance with the agreement. Other regional agreements even provide inter-state dispute mechanisms to the relevant regional body or court.⁴⁴⁹

Implementation of international human rights is usually complicated. The codified treaties have stronger binding power on state parties, and declarations typically have weaker binding power, whereas customary international law can have either strong or weak binding power.

6.1.1 International Human Rights Treaties and Regional Agreements

Treaties are binding on the countries that ratify them, but are sometimes subject to reservations. The key international human rights treaties are the International Covenant on Economic Social and Cultural Rights 1966 (ICESCR), and the International Covenant on Civil and Political Rights 1966 (ICCPR),⁴⁵⁰ both of which elaborate on the Universal Declaration of Human Rights 1948 (UDHR). Besides these core documents, other international human rights treaties⁴⁵¹ focus on

⁴⁴⁹ Andrew Clapham, *Human Rights Obligations of Non-State Actors*, P.92, Oxford University Press, 2006

⁴⁵⁰ International Bill of Human Right: After World War II, the international communities adopted Universal Declaration of human Rights 1948 (UDHR). Two separate treaties were created in 1966: the International Covenant on Economic, Social and Cultural Rights (ICESCR) and the International Covenant on Civil and Political Rights (ICCPR). The West argued for civil and political rights prior social and economic rights. The East argued that food, health, education was paramount and civil and political rights should be later.

⁴⁵¹ WHO, International human rights treaties/conventions, available at

either specific groups or categories of populations, such as racial minorities,⁴⁵² indigenous populations,⁴⁵³ women,⁴⁵⁴ children,⁴⁵⁵ disabilities,⁴⁵⁶ migrants,⁴⁵⁷ or on specific issues, such as torture,⁴⁵⁸ genocide,⁴⁵⁹ and victims of crime.⁴⁶⁰

The civil and political rights are generally included in the constitutional text or other legal orders demanding that the state abstain from violating certain rights. Thus, victims of unlawful governmental interference can claim violation under the legal system in which these infractions took place. Nation states have been more reluctant to incorporate economic, social, and cultural rights, though these rights are being incorporated progressively through recognition by an increasing number of countries.

State actors are the primary party responsible for the protection of human rights. State actors must implement and enforce these rights. The international human rights mechanisms monitor, promote and coordinate the rights with the state actors. State actors will be held

<http://www.who.int/hhr/readings/treaties/en/index.html> (last accessed on March 20, 2009)

⁴⁵² International Convention on the Elimination of All Forms of Racial discrimination, 1963, available at

<http://www.unhchr.ch/html/menu3/b/9.htm> (last accessed on March 20, 2009)

⁴⁵³ Convention Concerning Indigenous and Tribal Peoples in Independent Countries, 1989

⁴⁵⁴ Convention on the Elimination of All Forms against Women 1979

<http://www2.ohchr.org/english/law/cedaw.htm> (last accessed on March 20, 2009)

⁴⁵⁵ Convention on the Rights of Child, 1989, available at

<http://www.unhchr.ch/html/menu3/b/k2crc.htm> (last accessed on March 20, 2009)

⁴⁵⁶ Convention on the Rights of Persons with Disabilities, 2007, available at

<http://www.un.org/disabilities/convention/conventionfull.shtml> (last accessed on March 20, 2009)

⁴⁵⁷ International Convention on the Protection of the Rights of All migrant Workers and Members their Families, 1990

<http://www2.ohchr.org/english/law/cmw.htm> (last accessed on March 20, 2009)

⁴⁵⁸ Convention against Torture and other Cruel, Inhuman or Degrading Treatment or Punishment, 1984, available at

<http://www2.ohchr.org/english/law/cat.htm> (last accessed on March 20, 2009)

⁴⁵⁹ Convention on the Prevention and Punishment of the Crime of Genocide, 2003, available at

[http://www.unhchr.ch/Huridocda/Huridoca.nsf/\(Symbol\)/E.CN.4.RES.2003.66.En?Opendocument](http://www.unhchr.ch/Huridocda/Huridoca.nsf/(Symbol)/E.CN.4.RES.2003.66.En?Opendocument) (last accessed on March 20, 2009)

⁴⁶⁰ Convention for the Suppression of the Traffic in Persons and of the Exploitation of the Prostitution of Others, 1949, available at

<http://www2.ohchr.org/english/law/trafficpersons.htm> (last accessed on March 20, 2009)

accountable if they fail to give effect to the rights.

The human rights mechanisms are divided into two categories: charter-based mechanisms and treaty-based mechanisms.

The treaty-based human rights mechanisms are derived from provisions contained in specific legal instruments, and these mechanisms hold more narrow mandates, address unlimited audiences in the countries that have ratified them, and base their decision-making on consensus. This group includes the Committee against Torture, the Committee on Economic, Social and Cultural Rights, the Committee on the Elimination of Racial Discrimination, the Committee on the Protection of the Rights of All Migrant Workers and Members of their Families, and the Committee on the Right of the Child, and Human Rights Committee.⁴⁶¹

State parties are required to submit progress reports to the treaty bodies and their populations. The monitoring bodies meet regularly to review state parties' reports and to engage in a "constructive dialogue" with governments on how to live up to their human rights obligations. At the end of each session, the treaty body makes concluding observations which include recommendations to the government. Other specialized agencies can also facilitate the dialogue between the state parties and treaty monitoring bodies.⁴⁶²

The charter-based human rights mechanisms are derived from the provisions contained in

⁴⁶¹ United Nations Documentation Research Guide, Human Rights, available at <http://www.un.org/Depts/dhl/resguide/spechr.htm> (last accessed on March 20, 2009)

⁴⁶² WHO, 25 Questions & Answers on Health & Human Rights, P.12, 2002, available at <http://www.who.int/hhr/NEW37871OMSOK.pdf> (last accessed on March 20, 2009)

the Charter of the United Nations, and these mechanisms hold broad human rights mandates, address an unlimited audience and take action based on majority voting. This group includes the Human Rights Council, the Commission on Human Rights, and the Sub-commission on the Promotion and Protection of Human Rights.⁴⁶³

The bodies appoint special reporters, independent experts and working groups to monitor and report on human rights issues or human rights conditions in specific countries.⁴⁶⁴

There are other regional arrangements of human rights protection within regional intergovernmental organizations. The organizations monitor, promote, protect and coordinate the human rights in those regions. Examples of the regional human rights protection instruments include the African Charter on Human and People's Rights in African region, the American Convention of Human Rights in American region, and the European Convention on the Protection of Human Rights and Fundamental Freedoms in the European region. The Asian Pacific regional organization is still under development.⁴⁶⁵

While these international mechanisms are monitoring at an international level, they still have limited capacity to ensure effective and systematic monitoring. None of the international treaties contains international monitoring mechanisms for nation states or individual to file complaints. This can be done more easily at the national level. Civil society can reveal and

⁴⁶³ United Nations Documentation Research Guide, Human Rights, available at <http://www.un.org/Depts/dhl/resguide/spechr.htm> (last accessed on March 20, 2009)

⁴⁶⁴ United Nations Documentation Research Guide, Human Rights, available at <http://www.un.org/Depts/dhl/resguide/spechr.htm> (last accessed on March 20, 2009)

⁴⁶⁵ WHO, 25 Questions & Answers on Health & Human Rights, P.13, 2002, available at <http://www.who.int/hhr/NEW37871OMSOK.pdf> (last accessed on March 20, 2009)

highlight problems through coalitions and networks.⁴⁶⁶ However, relying on the nation states to comply with the protections of the right to health poses some obstacles. For those nation states as the obligor for the right, the only monitoring mechanism is the state's own reporting procedure, and if there are failures of implementation and compliance with the right to health, the reports will not be effective in improving compliance with the right. Most of the times, state parties do not file reports or the content of the reports are self-serving, unhelpful or reflect an unwillingness to improve the condition. Therefore, there are proposals suggesting that an individual complaint procedure be added for furtherance of the realization of the right.⁴⁶⁷

6.1.2 Non-Binding International Human Rights Instruments

The non-binding international human right to health instruments are usually in the form of declarations, comments, and resolutions. Even though non-binding, they offer guidelines for actors in the field of international law. With the wide acceptance of the soft laws, sometimes these laws can be seen as initial evidence of the customary character of the norm and may be evidence of customary obligations for all states where there is a degree of state practices⁴⁶⁸ that later might form into part of customary international law.

The main human right declaration is the Universal Declaration of Human Rights 1948. Other declarations⁴⁶⁹ are focused on specific groups, such as women,⁴⁷⁰ disabled persons,⁴⁷¹ or

⁴⁶⁶ WHO, Third Informal Consultation on Health and Human Rights, P.7, 2002, available at http://www.who.int/hhr/information/en/Human_Rights_Day2002report.pdf (last accessed on March 20, 2009)

⁴⁶⁷ David P. Fidler, International Law and Public Health: Materials on and Analysis of Global Health Jurisprudence, P.307, Transnational Pub, 2001

⁴⁶⁸ Professor Andrew Clapham and Mariano Garcia Rubio, 'The Obligation of State with Regard to Non-State Actors in the Context of the Right to Health', P.20, 2002, available at www.who.int/hhr/Series_3%20Non-State_Actors_Clapham_Rubio.pdf (last accessed on 1 March 20, 2009)

⁴⁶⁹ WHO, International declaration, norms and standards, available at <http://www.who.int/hhr/readings/declarations/en/index.html> (last accessed on March 20, 2009)

specific issues on the right to development,⁴⁷² individually recognize human rights,⁴⁷³ and the use of scientific and technological progress.⁴⁷⁴ Consensual policy⁴⁷⁵ and regional documents⁴⁷⁶ are non-binding, and include such formats as declarations and programs of action.

Declarations from international organizations provide guidance on some policy implementation, but declarations are non-binding; however, norms and standards instituted therein could become binding as customary international law.

6.1.3 Customary International Human Rights Law

According Article 38 of the Statute of International Court of Justice, the source of international law include international convention; international custom, as evidenced by general practices accepted as law; the general principle recognized in civilized nations; judicial decisions; and the teachings of the most highly qualified publicists of the various nations.⁴⁷⁷

⁴⁷⁰ Declaration on the Elimination of Violence against Women, 1993, available at [http://www.unhchr.ch/huridocda/huridoca.nsf/\(Symbol\)/A.RES.48.104.En](http://www.unhchr.ch/huridocda/huridoca.nsf/(Symbol)/A.RES.48.104.En) (last accessed on March 20, 2009)

⁴⁷¹ Declaration on the Rights of Disabled Persons, 1975, available at <http://www.unhchr.ch/html/menu3/b/72.htm> (last accessed on March 20, 2009)

⁴⁷² Declaration on the Right to Development, 1986, available at <http://www.unhchr.ch/html/menu3/b/74.htm> (last accessed on March 20, 2009)

⁴⁷³ Declaration on the Right and Responsibility of Individuals, Groups and Organs of Society to Promote and Protect Universally Recognized Human Rights and Fundamental Freedoms, 1999, available at [http://www.unhchr.ch/huridocda/huridoca.nsf/\(Symbol\)/A.RES.53.144.En](http://www.unhchr.ch/huridocda/huridoca.nsf/(Symbol)/A.RES.53.144.En) (last accessed on March 20, 2009)

⁴⁷⁴ Declaration on the Use of Scientific and Technological Progress in the Interests of Peace and for the Benefit of Mankind 1975, available at <http://www1.umn.edu/humanrts/instree/s2dustp.htm> (last accessed on March 20, 2009)

⁴⁷⁵ WHO, International conference documents and follow ups, available at <http://www.who.int/hhr/readings/conference/en/index.html> (last accessed on March 20, 2009)

⁴⁷⁶ WHO, Regional Instruments Related to Human Rights, available at <http://www.who.int/hhr/readings/regional/en/index.html> (last accessed on March 20, 2009)

⁴⁷⁷ Statute of the International Court of Justice, available at http://www.icj-cij.org/documents/index.php?p1=4&p2=2&p3=0&PHPSESSID=cd318d9c693d2ae6ec2c3963fc64acf2#CHAPTER_II (last accessed on March 20, 2009)

Article 38

1. The Court, whose function is to decide in accordance with international law such disputes as are submitted to it, shall apply:

a. international conventions, whether general or particular, establishing rules expressly recognized by the contesting

For the formation of customary international law, objectively there is a state practice, understood as material acts accomplished by states, and subjectively it is believed that such a practice is rendered obligatory by the existence of a rule of law requiring it. The frequency or even habitual character of the acts may be considered to be motivated by consideration of courtesy, convenience, or tradition, but this frequency by itself is not enough to constitute custom.⁴⁷⁸ Customary international obligation may also be evidenced through a normative instrument.⁴⁷⁹

Abi-Saab argues that if a nation state may create custom through practice, it may also generate customary international law through a written instrument that does not necessarily constitute a treaty. Treaties create convention obligations to their member states, but treaties may also create customary obligations for all nation states, for both parties and non-parties to the treaty, through further practice.⁴⁸⁰

Non-binding instruments, such as the resolutions of international organization, may be

states;

b. international custom, as evidence of a general practice accepted as law;

c. the general principles of law recognized by civilized nations;

d. subject to the provisions of Article 59, judicial decisions and the teachings of the most highly qualified publicists of the various nations, as subsidiary means for the determination of rules of law.

2. This provision shall not prejudice the power of the Court to decide a case *ex aequo et bono*, if the parties agree thereto.

⁴⁷⁸ Professor Andrew Clapham and Mariano Garcia Rubio, 'The Obligation of State with Regard to Non-State Actors in the Context of the Right to Health', P.20, 2002, available at www.who.int/hhr/Series_3%20Non-State_Actors_Clapham_Rubio.pdf (last accessed on March 20, 2009)

It is the traditional theory on customary international law developed by the International Court of Justice (ICJ) in the North Sea Continental Shelf case.

⁴⁷⁹ Professor Andrew Clapham and Mariano Garcia Rubio, 'The Obligation of State with Regard to Non-State Actors in the Context of the Right to Health', P.20, 2002, available at www.who.int/hhr/Series_3%20Non-State_Actors_Clapham_Rubio.pdf (last accessed on March 20, 2009)

⁴⁸⁰ Professor Andrew Clapham and Mariano Garcia Rubio, 'The Obligation of State with Regard to Non-State Actors in the Context of the Right to Health', P.21, 2002, available at www.who.int/hhr/Series_3%20Non-State_Actors_Clapham_Rubio.pdf (last accessed on March 20, 2009)

binding on every actor in the international community later, when the standards contained in the resolution have matured into customary international law.⁴⁸¹ Treaties and non-binding international instruments seem to form customary international law in many fields. Through general practices by nation states, treaty obligations may become customary international law and customary obligations applicable to non-party states.⁴⁸²

The key element of the formation of customary international law is the general acceptance that follows the state practices. Generally, a state's acceptance and recognition form customary international law; state practices also help to form the customs in some way. The content and criterion of the custom are also created by the state practices.⁴⁸³

Once the norms form into customary international law, that custom will bind every actor in the international community. If the international human rights norm is mostly practiced between nation states and individuals, once the norms ripen into customary international law, the norms will then bind individuals, groups, nation states and non-state actors. However, this approach requires time to develop, and further discussion is needed regarding the status of non-state actors in international human rights law.

6.1.4 Concluding Summary

⁴⁸¹ Professor Andrew Clapham and Mariano Garcia Rubio, 'The Obligation of State with Regard to Non-State Actors in the Context of the Right to Health', P.21, 2002, available at www.who.int/hhr/Series_3%20Non-State_Actors_Clapham_Rubio.pdf (last accessed on March 20, 2009)

⁴⁸² Professor Andrew Clapham and Mariano Garcia Rubio, 'The Obligation of State with Regard to Non-State Actors in the Context of the Right to Health', P.21, 2002, available at www.who.int/hhr/Series_3%20Non-State_Actors_Clapham_Rubio.pdf (last accessed on March 20, 2009)

⁴⁸³ Professor Andrew Clapham and Mariano Garcia Rubio, 'The Obligation of State with Regard to Non-State Actors in the Context of the Right to Health', P.21, 2002, available at www.who.int/hhr/Series_3%20Non-State_Actors_Clapham_Rubio.pdf (last accessed on March 20, 2009)

International human rights instruments bind the signatory parties through the application of the domestic law of each nation state. International human rights treaties or declarations could form into customary international law and bind all actors, including non-signing parties, individuals and even non-state actors by customary international law, and therefore compel them to abide by the norms of international human rights.

The right to health has been firmly embedded in a substantial number of UN human rights treaties. The UN treaties construe the right to health in broad terms. There are still many human rights to health instruments which built their provisions upon the earlier texts but focus on specific groups, and these are characterized by more detail than the general human rights instruments.

The above-mentioned regional human rights organizations have included a right to health in their instruments, some defining the right to health and some referring more generally to the right to health as the right to health care or to a healthy environment. In other cases, regional agreements do not explicitly recognize the right to health, but offer indirect protections through other health-related rights.⁴⁸⁴ However, the scope and content of the international human right to health remains unconfirmed.

Most of these regional human rights instruments obligate nation states as the parties

⁴⁸⁴ Commission on Human Rights, The Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health, E/CN.4/2003/58, 2003, available at <http://daccessdds.un.org/doc/UNDOC/GEN/G03/109/79/PDF/G0310979.pdf?OpenElement> (last accessed on March 20, 2009)

There are indirect protections of human rights to health, such as the American Declaration on the Rights and duties of Man, the American Convention on Human Rights, the Inter-American Convention on the Prevention, Punishment and Eradication of Violence against Women, and the European Convention for the Protection of Human Rights and Fundamental Freedoms and its protocols.

primarily responsible and accountable for the right to health. Notably, Article 27 to 29 of the African Charter⁴⁸⁵ clearly obligates not only the nation states, but everyone in the international community, including each individual, group and non-state actor, to be responsible and accountable for human rights protection.

The international human right to health is still developing and growing. Once the right is confirmed by customary international law as binding on all actors within the international community, the issue will focus on which parties can claim to hold the right, which parties may be obligated by it, and to what extent.

6.2 Proposed Resolution to Balance the Interests

The imbalance of economic power also greatly affects the realization of the right to health. International cooperation and assistance is crucial. Professor Paul Hunt also points out that it is important to have international cooperation in realization of the right to health. Developing countries have firm obligations arising from the right to health and the developed countries have the responsibility to offer assistance to developing countries to emerge from poverty and the burden of diseases to realize the right to health for their populations.⁴⁸⁶ Non-state actors are also encouraged or imposed obligations and/or accountabilities to the right to health.

In order to balance the interests of both transnational pharmaceutical corporations and patients/consumers of pharmaceutical products, this dissertation concludes that the financial

⁴⁸⁵ African Charter on Human and People's Right, available at http://www.achpr.org/english/_info/charter_en.html (last accessed on March 20, 2009)

⁴⁸⁶ The Right to Health: An Interview with Professor Paul Hunt, 2004, available at <http://projects.essex.ac.uk/ehrr/V2N1/Hunt.pdf> (last accessed on March 20, 2009)

factor is the determinable element underlying this controversy.

This dissertation proposes to use tiered pricing systems for pharmaceutical products according to the gross domestic product (GPD) or gross domestic income (GDI) to set the price of pharmaceutical products in each country, and also a sui generis intellectual property system for pharmaceutical products.

Since TRIPS sets a minimum standard for pharmaceutical products, but not global patent law, pharmaceutical industry-based state actors try to negotiate for stronger protection by bi-lateral agreements, free trade agreement to strengthen and insure their investment.⁴⁸⁷ A sui generis intellectual property system for pharmaceutical products can offer special protection to register, monitor and enforce the intellectual property holder's right in each national state, globally. Since pharmaceutical products are so unique in their ability to determine life or death, there is a need for a special category for the fruits of the R&D, and these fruits must be given special protection. Pharmaceutical companies are not charity, and they need incentives to engage in more R&D. Through the global pharmaceutical products system, pharmaceutical companies could have more protection on their investment, and could save substantial sums of money lost to patent litigation, parallel imports, and grey market pharmaceuticals, and transfer the costs to deduct the pharmaceutical products' price to make them accessible and affordable to populations. The organization will also manage traditional medicine and medical knowledge, to prevent taking of the knowledge without just compensation.

The patients/consumers will be willing and able to pay for the price of such pharmaceuticals,

⁴⁸⁷ It is the so called, "TRIPS-Plus" Agreements.

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