

# TRIPS and the PHILIPPINES:

Pharmaceutical patents and the right to health on access to  
essential medicines



Candidate number:

Supervisor: Malcolm Langford

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UNIVERSITY OF OSLO

Faculty of Law

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## **ACRONYMS**

AIDS	Acquired Immunity Deficiency Syndrome
BFAD	Bureau of Food and Drugs
CEDAW	Convention on the Elimination of Discrimination Against Women
CERD	Convention on the Elimination of All Forms of Racial Discrimination
CRC	Convention on the Right of the Child
ICESCR	International Convention on Economic, Social and Cultural Rights
CESCR	Committee on Economic, Social and Cultural Rights
DFID	Department for International Development
DSU	Dispute Settlement Understanding
FTA	Free Trade Agreement
HB	House Bill
HIV	Human Immune Virus
IP	Intellectual Property
MGD	Millennium Development Goals
MNC	Multinational Corporation
PITC	Philippine International Trading Corporation
SB	Senate Bill
TRIPS	Trade Related Aspects of Intellectual Property Rights
WHO	World Health Organisation
WTO	World Trade Organisation
UDHR	Universal Declaration of Human Rights
UNDP	United Nations Development Programme
USA	United States of America

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# 1 Introduction

## 1.1 Overview

The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) was concluded as an international intellectual property rights agreement in 1994 within the framework of the World Trade Organisation (WTO) system resulting from the Uruguay Round Negotiations. One of the fundamental characteristics of the TRIPS Agreement is that it makes protection of intellectual property rights an integral part of the multilateral trading system as embodied in the WTO. It provides a uniform framework for international intellectual property standards and gives protection to innovations such as inventions of pharmaceutical products through a minimum of 20 years patency period and serves as an incentive to invention of new products and designs. This incentive gives the pharmaceutical industry the opportunity to recover the investments used in the development of medicines, and reasonable time to be benefit from their inventions.

Since TRIPS was being implemented, new threats to public health were emerging, specifically HIV/AIDS.<sup>1</sup> In addressing HIV/AIDS crisis, many developing countries were providing affordable medicines through exhaustion of compulsory licenses or parallel importation of generic equivalents.

But some of these efforts were limited due to the implications of the TRIPS Agreement, particularly on patents, with regard to access to drugs. The prohibition of production of generic equivalents by pharmaceutical industry, and a suit filed by the USA against Brazil for exhaustion of compulsory licenses, were manifestations of the existence of legal conflicts between the recognition of intellectual property rights and the right on access to affordable medicines thereby leading to the realisation of the right to health.<sup>2</sup>

This conflict between patent rights and right on access to essential medicines became an eye-opener and led to the birth of the Doha Declaration on the TRIPS Agreement and

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<sup>1</sup> Oxfam International, "Patents versus Patients: Five years after the Doha Declaration", November 2006

<sup>2</sup> Carlos M. Correa "Implications of the Doha Declaration on the TRIPS Agreement and Public Health, June 2002

Public Health in 2001. The Doha Declaration serves as an interpretation to the TRIPS Agreement. It indicates that TRIPS should not prohibit states from addressing crisis on public health.

In 2003, an agreement on the implementation of Paragraph 6 of the Doha Declaration was issued by the General Council of the WTO.<sup>3</sup> This agreement loosened the domestic market requirement, and allows developing countries to export to other countries where there is a national health problem, as long as drugs exported are not part of commercial or industrial policy.<sup>4</sup>

In support to the promotion of public health on access to affordable medicines, the Millennium Development Goals (MDGs) also affirmed the necessity of global cooperation with pharmaceutical companies to provide access to affordable essential medicines in developing countries.<sup>5</sup>

Another threat to the right to access to affordable medicines is Free Trade Agreements (FTAs). These agreements are usually entered into by the developed countries with developing countries. FTAs set higher standards of intellectual property protection that exceed the TRIPS Agreement. There are pressures also from the pharmaceutical industry on developing countries not to use the flexibilities on TRIPS and to enact stricter (Intellectual Property) IP rules.<sup>6</sup>

But despite of these pressures, some countries like the Philippines took promising steps to promote public health and access on essential drugs. The Philippines introduced a new law, adopting the TRIPS flexibilities, including provisions legalising parallel importation and government-use licenses. The new legislation on medicines confirmed the existing right of

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<sup>3</sup> WTO, WT/L/540 September 2003

<sup>4</sup> See <http://en.wikipedia.org/wiki/TRIPS>

<sup>5</sup> MDG Goal 8 Target 17

<sup>6</sup> See Footnote 1



the government to use the Bolar provision to test and register a medicine before the expiration of patent.<sup>7</sup>

There were contentions that the incentive rights guaranteed by the TRIPS were the reasons why the pharmaceutical industry monopolizes the pricing of their products. The monopoly on pricing of medicines by the pharmaceutical industry, it was contended, constitutes a major hindrance in the realization of the right to essential drugs and ultimately realisation of the right to health. On the other hand, pharmaceutical industry denies that patents are the cause of inaccessibility of affordable medicines, but rather other barriers like failure of the states to implement effective related measurements. Inaccessibility of affordable medicines hinders developing countries in their endeavour towards realization and fulfilment of the right to health of the people.

## ***1.2 Research Questions***

This work shall endeavour to answer the following questions;

1. What are the key provisions of the TRIPS agreement and what are their effects on the realisation of the right to health on access to essential medicines?
2. What is the relationship between the commercial right to intellectual property and the fundamental human right to health on access to affordable medicines and how can such be reconciled?

## ***1.3 Significance of the Study***

The Significance of this study is informed on the imperative need to balance private commercial interests such as intellectual property rights on the other hand and the realisation of fundamental human rights such as the right to health on access to affordable medicines. It is hoped that this study will contribute towards the call for multilateral trading institutions such as the WTO and its Dispute Settlement Understanding (DSU) be

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<sup>7</sup> The draft Filipino law: permits parallel importation, narrows patent rules to exclude new indications and uses of existing substances already patented and simplifies government use licences. See Manuel Roxas, “ A just cause: Quality Affordable Medicines for all”, sponsorship speech of Senator Roxas, 16 August 2006, Senate of the Philippines.

informed by human rights imperatives, firstly in the agreements which they enter into, and secondly in the resolution of trade and investment disputes.

### ***1.4 Methodology***

This work will entirely depend on library materials. Both primary and secondary sources of law will be used. This will include Treaties, judicial decisions, legislative enactments, books and journals. The Vienna Convention on the Law of Treaties will be used as an interpretive instrument.

### ***1.5 Delimitation***

The limited nature of this study will not permit for a comprehensive study of the entire provisions of the TRIPS and related agreements but will limit itself to those provisions which in the author's view have a potentially deleterious effect on the realisation of the right to health as provided in international human rights instruments.

## **2 International Patent Protection Regime**

### ***2.1 The TRIPS Agreement***

#### **2.1.1 Overview**

The TRIPS Agreement is a global agreement under the rubric of the WTO which was concluded in 1994. To date it is the most comprehensive multilateral agreement on intellectual property. It provides global minimum standards for the protection and enforcement of intellectual property rights (IPR), including those for patents. Every member state of the WTO has to adhere to the non-discrimination principle encapsulated in the TRIPS agreement. International conventions entered into before the TRIPS did not specify minimum standards for patents. At the time the negotiations began, more than 40 countries did not grant patent protection for pharmaceutical products.<sup>8</sup> The TRIPS Agreement now requires all WTO Members, without prejudice to few exceptions, to pattern their laws to the minimum standards of IPR protection. Further, the Agreement on TRIPS also introduced detailed obligations for the enforcement of intellectual property rights.

The TRIPS Agreement further introduced provisions that allow a degree of flexibility and sufficient latitude for countries to adapt their own patent and intellectual property systems and development needs. This means that the countries have a certain amount of freedom to modify their regulations in formulating their national legislation to ensure a proper balance between the goal of providing incentives for the future inventions of new drugs and the goal of ensuring affordable access to essential medicines.<sup>9</sup>

#### **2.1.2 TRIPS Flexibilities**

The agreement provides certain flexibilities to address the health concerns of the States Parties. Article 7 states that “the protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and

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<sup>8</sup> WHO, *WTO and the TRIPS Agreement*, See [http://www.who.int/medicines/areas/policy/wto\\_trips/en/index.html](http://www.who.int/medicines/areas/policy/wto_trips/en/index.html)

<sup>9</sup> See Footnote 8

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.”

Article 8 of the Agreement states that “Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition and to promote the public interest in sectors of vital importance to their socio-economic and technological development... Appropriate measures...may be needed to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology.”

The IPR should be protected and enforced in a manner conducive to social and economic welfare. According to its provisions, it allows member states to adopt measures necessary for the protection of public health and nutrition. It further allows promotion of public interest in sectors of vital importance to socioeconomic and technological developments.

Some existing writings provide a political and economic analysis of TRIPS and conclude that its intellectual property policy is closely connected to the economic development requirements of developed countries. Thus, having in mind consideration of the economic, cultural and legal reality in developing countries, their development needs may be overlooked and it becomes necessary for developing countries to design diversified intellectual property laws that take care of their own interests.<sup>10</sup>

## ***2.2 The TRIPS Agreement and Public Health***

### **2.2.1 The Doha Declaration on TRIPS and Public Health**

In June and September 2001, the WTO Council for TRIPS held sessions specifically devoted to issues which concern access to medicines. The WTO members at the Doha Ministerial Conference of the TRIPS Agreement recognized the gravity of the public health problems afflicting many developing countries hence they attempted to integrate the TRIPS Agreement as part of the international action to address public health problems.

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<sup>10</sup> 3 See Christopher May, *A Global Political Economy of Intellectual Property Rights: The New Enclosure?* (Routledge, 2000).

The Declaration on the TRIPS Agreement and Public Health was adopted after extensive negotiations based on a compromise text prepared by the WTO Secretariat.<sup>11</sup> The Doha Declaration helps to prevent situations where developing country members could not avail themselves fully to the flexibilities provided in the TRIPS Agreement due to pressure from interested groups, though there were some conflicting positions with regard to the status under which the flexibilities of the TRIPS Agreement could be used.<sup>12</sup>

The Doha Declaration on the TRIPS Agreement and Public Health affirms the rights of the member states to take full measures to protect their public health. The Declaration also reaffirms the right of the members of the WTO to use all the flexibilities provided by the Agreement. The Declaration likewise gives each member country the freedom to choose the grounds upon which a compulsory license could be granted. Member states also have the right to determine what constitutes a national emergency, or other circumstances of extreme urgency.

The amendment to the TRIPS Agreement will allow certain countries to export patented drugs to other countries with no manufacturing capacity in the pharmaceutical industry through effective use of compulsory licensing. The amendment includes safeguards against abuse and trade diversion and rules to ensure transparency.

Under Paragraph 6 of the Doha Declaration on TRIPS Agreement and Public Health, it abolished the barrier for import-export of generic medicines. The purpose of this paragraph is to nullify the Agreement on TRIPS requirement that the drugs manufactured under compulsory license should be “predominantly for the supply of the domestic market.”<sup>13</sup>

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<sup>11</sup> WT/MIN(01) DEC/2, WTO Ministerial Conference Fourth Session, November 2001

<sup>12</sup> See Haochem Sun, *A wider Access to Patented Drugs Under the TRIPS Agreement*, Boston University International Law Journal, Boston University Press, 2003, p102

<sup>13</sup> The Doha Declaration on the TRIPS Agreement and Public Health Article 6 provides “We recognize the WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement. We instruct the Council for TRIPS to find an expeditious solution to this problem and to report to the General Council before the end of 2002”.

## 2.2.2 The implication of the Doha Declarations

The Doha Declaration states: “Protection of intellectual property is important for the development of new medicines, however, the TRIPS Agreement does not and should not prevent States Parties from taking measures to protect public health.”

The Doha Declaration is the turning point for legal and political relations at the WTO. The Agreement should be interpreted and implemented to support the right of the States Parties of WTO to protect public health, especially to promote access to medicines for everyone.<sup>14</sup>

The outlined key flexibilities available in the TRIPS Agreement include:

- The right of States Parties to use compulsory licensing and to determine the grounds upon which such licenses are granted.
- The right of State Parties to determine what constitute national emergency or other circumstances of extreme urgency, which can ease the granting of compulsory licenses.
- The right of State Parties to determine their own parallel import regimes and the right of the least developed Members to postpone providing pharmaceutical patents until at least 2016, and possibly longer.<sup>15</sup>

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<sup>14</sup> The Doha Declaration on the TRIPS Agreement and Public Health Article 6 provides “We agree that the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members’ right to protect public health and, in particular, to promote access to medicines for all.

In this connection, we affirm the right of WTO Members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose”.

<sup>15</sup> The Doha Declaration on the TRIPS Agreement and Public Health Article 6 provides “We reaffirm the commitment of developed-country Members to provide incentives to their enterprises and institutions to promote and encourage technology transfer to least-developed country Members pursuant to Article 66.2. We also agree that the least-developed Members will not be obliged with respect to pharmaceutical products, to implement or apply Sections 5 and 7 of Part II of the TRIPS Agreement or to enforce rights provided for under these Sections until 1 January 2016, without prejudice to the right of least-developed country Members to seek other extensions of the transition periods as provided for in Article 66.1 of the TRIPS Agreement. We instruct the Council for TRIPS to take the necessary action to give effect to this pursuant to Article 66.1 of the TRIPS Agreement”.

### **2.2.3 Parallel Importation**

Parallel importation is the purchase of a patented drug from an approved source in an exporting country where it is sold more cheaply, without seeking the consent of the patent holder, as defined by the WTO.

The TRIPS Agreement, reinforced by the 2001 Doha Declaration, leaves it to national governments to decide for themselves when a patent may be exhausted, such as with parallel imports.

The underlying concept of parallel importation is based on the principle of exhaustion of rights. This principle is premised on the fact that where the patent holder has been rewarded through the first sale or distribution of the product, such patent holder has no longer the right to control the use or resale of the product. This would also be in conjunction with WTO's trade liberalization objective that from the moment a product is marketed, the patent holder can no longer control its subsequent circulation.

Parallel imports are adopted and implemented by many countries, especially in developing countries which have no capacity to manufacture. It is a useful policy tool by which developing countries will be able to provide a quick access to life-saving medicines, and to respond speedily to a health crisis or need. For this reason, the parallel importation is considered a legitimate measure which WTO Members are authorized to adopt and implement for the protection of public health.

### **2.2.4 Compulsory Licensing**

Compulsory licensing is when a government allows someone else to produce the patented drugs or process without the consent of the patent holder. It is one of the flexibilities on patent protection included in the WTO's Agreement on TRIPS. The flexibilities on TRIPS have always existed in the TRIPS Agreement since it took effect in 1995.

The Doha Declaration on TRIPS and Public Health Sub-paragraph 5(b) affirms that every member of the WTO has the right to grant compulsory license and the freedom to determine the grounds upon which such licenses are granted. It deals with an issue which focuses on the benefits of developing countries. It is a clarification on the TRIPS flexibilities and assures that governments can use the flexibilities, because some of the governments were unsure about how the flexibilities would be interpreted.

Generally, compulsory licensing is granted when the generic copy is produced mainly for the domestic market and not for export. The patent owner still has the rights over the patent and the right to be paid for the authorized copies of the products.

Though Article 31<sup>16</sup> of the Agreement on TRIPS provides the conditions for the granting of compulsory licensing, it does not limit the grounds on which such licenses can be granted. The TRIPS Agreement does not specify the reasons that might be used to justify compulsory licensing. But under the Doha Declaration on TRIPS and Public Health, it confirms that countries are free to determine the grounds for granting compulsory licenses. Further, compulsory licensing has to meet additional requirements. For example, the patent holder can still continue to produce but it should be subject to judicial review in the country.

But as exception to the general rule, compulsory licensing is granted without the need to first obtain a voluntary license. This case is recognized when an emergency arises, be it national emergencies or other circumstances of extreme urgency. This is also recognized for public non-commercial use or governmental use. This is the only situation when the TRIPS Agreement specifically links emergencies to compulsory licensing. The purpose is to escape the step of negotiation in order to save time and attend to the emergency needs without delay. The patent holder still retains its right to be paid regardless of the type of the grant of such compulsory licensing.

Under the 2001 Doha Ministerial Conference, they decided to change the Article 31 (f)<sup>17</sup> of the TRIPS Agreement in order to give the countries which have no capacity to manufacture pharmaceutical products, a chance to obtain cheaper copies elsewhere if necessary.

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<sup>16</sup> The TRIPS Agreement does list a number of conditions for issuing compulsory licenses, in Article 31.

<sup>17</sup> The TRIPS Agreement Article 31, Other Use Without Authorization of the Right Holder

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

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



Based on the implementation of paragraph 6 of the Doha Declaration on TRIPS Agreement and public health adopted in August 2003, it allows generic copies made under compulsory licenses to be exported to countries that lack production capacity but subject to some conditions. All WTO members have the right to import under this decision, though some countries have already expressly waived their rights.

The Doha Declaration emphasizes the term “compulsory license”, which is not found in the Agreement on TRIPS itself. The purpose of this terminology is to create awareness about the possible use of compulsory licenses to carry the right to public health and other objectives.

### **2.2.5 Early working of patents of drugs**

The practice of early registration in many IP regulations, referred to as Bolar provision, allows a company to import samples of a product and develop and test it in order to prepare for an early registration while the product is still under patent. What is at stake is a new twist on the issue of early working of a patent.

In the United States, there was a dispute in 1983 between Roche and Bolar Pharmaceuticals.<sup>18</sup> Bolar was in possession of small quantities of a generic version of a sleeping pill marketed by Roche as Dalmane. The Bolar Company wanted to register a generic version, so it could promptly enter the market when the Roche patent expired. Roche successfully sued Bolar and its officers and importers, claiming that the effort to register the generic product violated the Roche patent. In 1984, the US Congress changed the US patent law to allow the early working of a patent when preparing a generic drug registration which effectively overturned this decision hence the origin of the Bolar provision.

The Bolar provision is widely adopted as exception in national patent laws. It is an exception under which use of the patented product for scientific experimentation, during the term of the patent and without consent, is not a violation of the intellectual property protection.

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<sup>18</sup> The so- called “early working” of a patent or “Bolar” provision. To overturn a controversial judicial decision (Roche Products, Inc. vs. Bolar Pharmaceutical Co., 733 F.2d 858 (Fed.Cir.1984))

The Bolar provision can be found also in Argentina, Canada and some European countries, but it is not explicitly expressed in the Philippine law. But according to the Consumer Project on Technology (Catechu), this “has been part of the Philippine regulatory practice for several years and it has never been challenged before.”

### ***2.3 The Impact of TRIPS and TRIPS-Plus***

TRIPS-Plus refers to laws that go beyond the requirements of the TRIPS Agreement to protect Intellectual Property. TRIPS-Plus are normally incorporated in FTAs. FTAs are bilateral or regional trade agreements signed between contracting countries that include provisions in IP and deepen the process of harmonization initiated by the Agreement on TRIPS. TRIPS Plus may restrict the utilization of exports of drugs made under compulsory licenses or parallel importation of patented drugs, or it could extend the patents beyond the standard 20 years term as provided by TRIPS Agreement. Such laws are usually drawn up as part of bilateral free trade agreements. The TRIPS Plus will usually include promises of more investments of the investing country and it will enhance trade with a particular nation. In return, the country will guarantee the introduction of strong legislation to protect Intellectual Property Rights.

When the rules of the TRIPS Agreement were introduced in the international trading system in 1994, it was largely patterned from US Intellectual property regime that, among others, grants drug patent protection for 20 years. Apprehensions by developing countries over the agreement’s impact on public health led to a development round of negotiations of new trade rules that later produced the Doha Declaration.

In recent years, significant issues have been raised with regard to the potential adverse impact of FTAs between developed and developing countries on the latter group’s ability to utilize the TRIPS flexibilities for public health purpose and for promoting innovation on targeting diseases that affect them disproportionately.<sup>19</sup>

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<sup>19</sup> See Roffe (2007)

The Philippines attempted to consider various trade negotiations, especially a possible US-Philippine FTA. Aside from ASEAN, the Philippines first formal attempt was the recently concluded economic partnership agreement with Japan.<sup>20</sup>

In the proposed Philippine-US FTA, particularly for the Philippines, one of the major issues was on Intellectual Property Rights. This is a key issue for USA. But due to awareness of the impact of the TRIPS Plus, it is highly likely the negotiators were concerned and mindful enough about the IPR provisions on the FTA, hence, a potential TRIPS plus on the Republic of the Philippines (RP)-US FTA was not included. As it stands no TRIPS Plus issue has been raised in the adoption of the Cheaper Medicines Law of 2008.

Although the RP-US FTA was finally entered into<sup>21</sup>, the question of a possible TRIPS provision was not included in the proposals for a third stage of the FTA between the Republic of the Philippines and the USA.<sup>22</sup>

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<sup>20</sup> See <http://www.atimes.com/atimes/Japan/IA25Dh02.html>

<sup>21</sup> See [http://www.bilaterals.org/article.php3?id\\_article=12443](http://www.bilaterals.org/article.php3?id_article=12443) GMA News, June 17, 2008

<sup>22</sup> RP-US FTA 3 Stages; under phase 1 of the package, the two parties must agree on common products like garments and textile and possibly, electronics. Phase 2 would cover the granting of additional concessions on ore sensitive products, while Phase 3 would delve into a comprehensive coverage of products and services. see Note 11.

## 3 The Right to Health

### 3.1 General

The human right to health is embedded in the preamble of the World Health Organization (WHO) and repeatedly recognized in many subsequent instruments. It is a fundamental right which cannot be dispensed with for the exercise of other human rights.<sup>23</sup> Health is one of the components of an adequate standard of living.<sup>24</sup>

The human right to health is a “state of complete physical, mental and social well being, and not merely the absence of disease or infirmity.”<sup>25</sup> This means that all human rights, civil and political rights, and social and cultural rights are on equal footing and interdependent.<sup>26</sup> Rights relating to discrimination, information, autonomy, education and participation are an integral and indivisible part of the achievement of the highest attainable standard of health, just as the enjoyment of health is inseparable from that of other rights, whether categorized as civil and political, economic, social or cultural. Though the right to health has been recognized in a number of legal instruments, there is a grey area in the definition of a state’s obligations under this right. For example, in the International Convention on Economic, Social and Cultural Rights (ICESCR), the right to health is defined only as “the right to the highest attainable standard of physical and mental health,” with obligations based on the underlying preconditions necessary for health and the provision of medical care.<sup>27</sup>

The definition of the right to health under the WHO includes notion of social well-being. It projects a vision of the ideal state of health as an eternal and universal goal to constantly strive for. The ICESCR defined right to health by differentiating physical health and well-being, and particularly concerned with imposing specific responsibilities to the

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<sup>23</sup> CESCR General Comment No. 14 para. 1

<sup>24</sup> See <http://cesr.org/health>

<sup>25</sup> WHO 1946

<sup>26</sup> Toebes 1999; Kirby 1999

<sup>27</sup> Sofia Gruskin and Daniel Tarantola, *Health and Human Rights* p7

governmental health sector. It also assigns state's obligations relevant to social well-being. Article 12 of the ICESCR is the principal framework to understand state's obligations under the right to health.

### ***3.2 The Right to Health in International Law***

The right to health can be found in different international legal instruments. In the preamble of the Charter of the United Nations, the States Parties are to employ international machinery for the promotion of the economic and social advancement of all people. Likewise, the Universal Declaration of Human Rights (UDHR) confirmed the right to health. In accordance with Article 25 of the UDHR, "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."

The ICESCR also recognized the right to health and it provides in Articles 12 and provides that "The States Parties to the present Covenant recognize the right of everyone to the enjoyment of the highest attainable standard of physical and mental health... The 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 provision for the reduction of the stillbirth-rate and of infant mortality and for the healthy development of the child... The improvement of all aspects of environmental and industrial hygiene...The prevention, treatment and control of epidemic, endemic, occupational and other diseases... The creation of conditions which would assure to all medical service and medical attention in the event of sickness..."

Additionally, the obligation to fulfil right to health is recognized in articles 11.1 (f) and 12 of the Convention on the Elimination of All Forms of Discrimination Against Women (CEDAW), Article 5 (e) (iv) of the International Convention on the Elimination of All Forms of Racial Discrimination (CERD) and Article 24 of the Convention on the Rights of the Child (CRC). Some regional human rights instruments also recognize the right to health, e.g. the European Social Charter of 1961.

Similarly, the Constitution of the WHO is entirely relevant to the right to health. In its preamble, it states that "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."

Finally, in the General Comment No. 14 of the Committee on Economic, Social and Cultural Rights (CESCR), it widely explained the coverage of the right to health. It interpreted that article 12.1 of the Convention to "the highest attainable standard of physical and mental health" is not confined to the right to health care. Article 12.2 acknowledges that the right to health embraces a wide range of socio-economic factors that promote conditions in which people can lead to a healthy life, and extends to the underlying determinants of health, such as food and nutrition...<sup>28</sup>

Further, the Committee explained that the right to health in all its forms and at all levels must be available, accessible and acceptable and must be of good quality for the people. Every state party must ensure that health care facilities, goods and services, and health programmes, have to be available in sufficient quantity. Though the precise nature of the facilities, goods and services will vary depending on State party's developmental level, the underlying determinants on health such as essential drugs, as defined by the WHO Action Programme on Essential Drugs, must be considered.<sup>29</sup> Health facilities, goods and services must be affordable for all.<sup>30</sup> Likewise, all health facilities, goods and services must be respectful of medical ethics and culturally appropriate<sup>31</sup> and scientifically and medically appropriate and of good quality.<sup>32</sup>

### **3.2.1 Access to affordable medicines as a right to health**

Health is a fundamental human right indispensable for the exercise of the other human rights.<sup>33</sup> The ICESCR affirms the full range of economic, social and cultural rights. Human

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<sup>28</sup> CESCR General comment No. 14 paragraph 4

<sup>29</sup> CESCR General comment No. 14 paragraph 12 (a)

<sup>30</sup> CESCR General comment No. 14 paragraph 12 (b)

<sup>31</sup> CESCR General comment No. 14 paragraph 12 (c)

<sup>32</sup> CESCR General comment No. 14 paragraph 12 (d)

<sup>33</sup> General Comment No. 14 on the "right to the highest standard of health", Article 12 of the ICESCR

rights likewise include the right to education, to adequate food and to the highest attainable standard of living.

There are some human rights cases which are related to the right to health. One is the Treatment Action Campaign vs. Minister of Health case in South Africa in 2002. In this case, it was held that the Constitution guarantees the right of access to healthcare services, hence the government is required to devise and implement a comprehensive and coordinated program to progressively realize the right of pregnant women and their newborn children to have access to treatment for the prevention of mother-to-child transmission of HIV.

Based on the decided human rights cases like the one mentioned earlier, right to health can be justiciable. It can lead to the actual change in government policy and eventually improve the welfare of the people. Article 12.2 paragraphs b, c and d<sup>34</sup> of the ICESCR specifically commands States Parties to take actions to protect the right to health progressively by adopting measures that suggest that states have the obligation to provide essential drugs.

### ***3.3 State's obligations for health under Human Rights Law***

States' governments have the responsibility not to violate rights, but also to ensure the conditions which enable individuals to realize their rights to the fullest. This obligation means as an obligation to respect, protect and fulfil rights and governments have the legal obligations to comply with this range of obligations for every right in every human right they ratified.

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<sup>34</sup> The most relevant State obligations on right to health; Article 12.2 of the ICESCR states “ The steps to be taken by the State Parties to the Present Covenant to achieve the full realization of the right to health shall include those necessary for;

(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

### **3.3.1 Minimum core obligations**

The CESCR General Comment No. 14 asserts that all states have immediate obligations, including minimum core obligations. Core obligations are intended to ensure that people are provided with, at the very least, the minimum conditions under which they can live in dignity; enjoy the basic living conditions needed to support their health; and be free from avoidable mortality. They serve, in other words, as a minimum or bottom line for responsibilities of states. They require governments to take the basic measures that are needed to enable people to achieve minimum standards of health, including the provision of essential primary health care. They also take into account the fact that health problems associated with poverty and inequity pose the main obstacles to attaining minimal standards of health and well-being for most of the world's population.

The minimum core obligations cannot be subjected to progressive realization. All states, regardless of their level of development, are required to take immediate action to implement them. This can include legislation; the regulation, design and enforcement of policies; and mobilization of the necessary resources.

The core obligations identified under CESCR GC 14 includes the obligation of the states “to provide essential medicines, as defined by WHO’s Action Programme on Essential Medicines.” The states, when formulating a national policy in relation to health must “adopt and implement a national public health strategy and plan of action, which is based on epidemiological evidence, and which takes into account the health concerns of the whole population. The strategy and plan of action must be developed through a participatory and transparent process and subject to regular review. Specific objectives and a cost-effective strategy must be adopted for using available resources, as well as methods such as right to health indicators and benchmarks, by which progress can be closely monitored. The process, by which the strategy and plan of action are formulated, as well as their content, shall pay particular attention to all the vulnerable or marginalized groups in the population.”

As to the implementation of the state’s obligations, particularly to the right to affordable medicines, the CESCR states that essential drugs, as defined by the WHO Action programme on essential drugs, must be available. It must be economically accessible or



affordable for all. In order to fulfil the right to health-affordable medicines, the state must ensure that the medicines must improve the health status of those concerned. It must be ensured also by the state that the available medicines must be scientifically and medically appropriate and of good quality.

### **3.3.2 Obligation to respect, protect and fulfil rights**

Obligation to ensure the right to health requires State Parties to refrain from obstructing action taken by an individual in pursuit of their health goals. State parties should report on how public and private healthcare providers meet their duties to respect people's right to have access to healthcare. An example of obligation to respect is that State Parties should refrain from denying or limiting access to health care services and from marketing unsafe drugs. Also in the General comment No. 14 of the CESCR, State Parties have to respect the enjoyment of the right to health in other countries.

Obligation to protect right relating to healthcare requires State Parties, their agents and officials to take action to prevent and impose sanctions for violation of rights by private persons and organizations. States Parties should adopt legislation or other measures to ensure that private actors conform to the human rights standards in the exercise of their duty to provide health care and other services. States should control the marketing of medical equipment and medicines by private actors. States should ensure that privatization does not constitute a threat to the availability, accessibility, acceptability and quality of healthcare facilities, goods and services. The states should protect individuals from acts by third parties that may be harmful to the right to health.

Based on the GC No. 14 of the CESCR, it stressed that States parties should prevent third parties from violating the rights to health in other countries. States Parties should take steps to ensure that these instruments do not have an adverse impact on the right to health when negotiating international or multilateral agreements.<sup>35</sup>

The obligation to fulfil right to health places an obligation on State Parties to take appropriate legislative, judicial, administrative, budgetary, economic and other measures to

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<sup>35</sup> See <http://www.ohchr.org/Documents/Publications/Factsheet31.pdf>

the maximum extent of their available resources to ensure that the individuals realize their rights to healthcare.

The State Parties are obliged to act to achieve an objective result, and the legislative measures will invariably have to be supported by appropriate, well-directed policies and programs implemented by the Executive. These policies and programs must be reasonable both in their conception and their implementation. The formulation of a program is only the first stage in meeting the State's obligations. The program must also be reasonably implemented.

The States Parties, for instance, should adopt a national health measure or a national health plan which covers the public and private sectors. They should ensure provision of health care. There should be assurance of equal access for all to the underlying determinants of health and they should provide information and counselling on health related issues such as HIV/AIDS. Specifically relevant to access to essential drugs is the obligation of the state to fulfil the right to health of the people.

The GC 14 defines the obligation to provide essential drugs as a core obligation. If a state is not providing such essential medicines available, it is in breach of its duty to fulfil its international legal responsibility pertaining the realisation of the right to health. It further specifies that State Parties have an obligation to promote medical research and health education as part of their duty to fulfil the right to health care.

### ***3.4 The Application of Human Rights to Intellectual Property Rights***

#### **3.4.1 Human Rights and Trade**

Does trade policy liberalization enhance or undermine human rights? Should trade agreements do more or nothing to promote human rights? These issues have been raised in the last few years by many human rights advocates who are watchful to ensure non derogation of the enjoyment of human rights by trade policies. These concerns were also raised by actors who believe in free trade and by developing countries who fear that human rights standards might be applied in a way that works against free trade and thus undermine economic well-being. Some development campaigners also claim that trade

sanctions should be used as tools to ensure respect for minimum standards of human rights.<sup>36</sup>

Trade policy lacks transparency and participation and it is inconsistent to human rights. They stand in contrast to human rights principles, like participation of everyone in their governments, embedded in article 19 of the ICCPR, and in the citizens' rights to participate in the conduct of public affairs embodied in article 25 of the ICCPR.

The lack of transparency gives a stronger role to business than public interest groups because governments may tend to consult business groups and prioritize their interest more than the interest of society.<sup>37</sup>

### **3.4.2 Human Rights and Intellectual Property**

Human rights and intellectual property rights were two independent rights. But now they are becoming unified. Concluded international standards setting activities have started to reconcile the gap between intellectual property laws on the one hand and human rights law, specifically the right to access to affordable medicines, on the other.

Human rights and intellectual property rights are first viewed as being in fundamental conflict. This means that strong intellectual property protection is undermining - and therefore incompatible with human rights obligation, especially in the area of economic, social and cultural rights. On the other hand, the conflict between human rights and intellectual property protection sees both areas of human rights law and intellectual property laws as concerned in defining the appropriate scope of private monopoly power. This gives innovators a sufficient incentive to create, while ensuring that the consumers have adequate access to the progress of their innovations. This means that human rights law and intellectual property law are essentially compatible, although they often disagree on how to balance incentives on the one hand and access on the other.<sup>38</sup>

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<sup>36</sup> Dommen, Caroline, *Trade & Human Rights: Towards Coherence*, See <http://www.surjournal.org/eng/index3.php>

<sup>37</sup> Ibid

<sup>38</sup> Laurence R. Helfer, *Human Rights and Intellectual Property: Conflict or Coexistence?* Vol.5,2003, No.1

### **3.4.3 Upholding Human Rights in Intellectual Property**

Human rights are inherent while intellectual property rights are a mere privilege. The former cannot be derogated from, while the latter can be limited or terminated. According to the CESCR, “The right of everyone to benefit from the protection of the moral and material interests resulting from any scientific invention... of which he or she is the author is a human right, which derives from the inherent dignity and worth of all persons ...Human rights are fundamental, inalienable and universal entitlements belonging to individuals and, under certain circumstances, groups of individuals and communities. Human rights are fundamental as they are inherent to the human person as such, whereas intellectual property rights are first and foremost means by which States seek to provide incentives for inventiveness and creativity, encourage the dissemination of creative and innovative productions, as well as the development of cultural identities, and preserve the integrity of scientific invention... for the benefit of society as a whole.”<sup>39</sup>

Human right derives from Article 15 (1) ( c ), which states that “ The States Parties to the present Convention recognize the right of everyone...to benefit from the protection of the moral and material interests resulting from any scientific invention...of which he is the author”, and other human rights are distinguished from most legal entitlements provided in the intellectual property rights.

The CESCR further interprets the distinction between human rights and intellectual property rights. Intellectual property rights, in contrast to human rights, are generally of limited nature. It can be revoked, licensed or assigned to someone else. Often with the exception of moral rights, it may be allocated, limited in time and scope, traded, amended and even forfeited. Its purpose is just to protect primarily business and corporate interests and investments. On the other hand, human rights are unlimited expressions of fundamental entitlements of the human person. To benefit from the protection of the moral and material interests resulting from one’s scientific invention... human rights safeguards the personal link between authors and their creations and between peoples, communities,

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<sup>39</sup> CESCR GC No. 17 para. 1

or other groups and their collective cultural heritage, as well as their basic material interests which are necessary to enable authors to enjoy adequate standard of living.<sup>40</sup>

Based on the given definitions, it is therefore clear that human rights and intellectual property rights are not of equal footing. The intellectual property rights can be limited by applying human rights. Thus, in the case of realizing the right to affordable medicines as against the claim of the multinationals for non-infringement of their patent rights, the right to affordable medicines is paramount over the right to patent.

There are concerns about the impact of the implementation of the Agreements on TRIPS. Despite of these concerns, strict standards continue to increase. These strict standards are known as TRIPS-Plus standards. They have emerged in the trade and investment agreements through multilateral, bilateral, or regional agreements.

The strict standard of protection provided by IP rules is increasingly affect the development policies, human rights and other international political commitments such as Millennium Development Goals (MDGs). These standards have had a negative effect on the capacity of many states to fulfil their obligations on human rights – obligations to ensure access to affordable medicines, educational goods and adequate food.

Further, if states are required to effect the strict IP standards sought through multilateral or bilateral agreements, they risk violating their legal obligations provided by international human rights instruments, including the right to life, the right to health, the right to education, the right to food, the right to adequate standard of living, the right to access to information, the right to take part in cultural life, and to enjoy the benefits of scientific progress.

Similarly, human rights law requires States Parties to take steps “individually and through international assistance and cooperation especially economic and technical<sup>41</sup> to fulfil their human rights obligations.<sup>42</sup> The States Parties, as members of international organizations,

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<sup>40</sup> CESCR GC No. 17 para. 2

<sup>41</sup> *ibid*

<sup>42</sup> The scope of this obligation is further reinforced by the principle of good faith in international law which requires States to refrain from taking actions that defeat the object and purpose of a treaty. See Article 18 of the Vienna Convention on the Law of Treaties.

including financial institutions such as the International Monetary Fund (IMF) and the World Bank, must do all they can to ensure that the policies and decisions of those organizations are in conformity with the obligations of State Parties under the treaty, in particular the obligations concerning international assistance and cooperation.<sup>43</sup>

Human rights law likewise requires assessment of the development impacts of State activities, including state activities as part of international organizations. Reporting by States has the objective to ensure comprehensive review of legislation, rules and procedures, and to ensure that States Parties monitors the situation with respect to the rights in their countries.<sup>44</sup>

#### **3.4.4 Effects of TRIPS on Right to Health in relation to the Perspective of Millennium Development Goals (MDG)**

The millennium goals are benchmarks for a vision of development, peace and human rights guided by fundamental values including freedom, equality, solidarity, tolerance, respect for nature and shared responsibility.<sup>45</sup>

The MDG 8 Target 17 deals with the provision, in co-operation with pharmaceutical companies, of access to affordable, essential drugs in developing countries. The cost of drugs is an important concern for developing countries for the reason that most poor people in those countries pay out-of-pocket for their own drugs, and state provision is normally selective and resource constrained. One of the main reasons of high prices of drugs is patents.

Imports for pharmaceutical products have to be relied upon by most developing countries that have no capacity to produce their own drugs. The WTO on its 2003 Doha Declaration, gives WTO members with no sufficient or no production capacity for generic medicines, the possibility to import those pharmaceutical products under compulsory licensing.

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<sup>43</sup> The CESCR, Concluding observations, Ireland, E/C.12/1/Add.77, 5 June 2002.

<sup>44</sup> See CESCR, General Comment No. 1 (1989), Reporting of States Parties, 24 February 1989.

<sup>45</sup> The UN General Assembly adopted the Millennium Development Goals (MDGs) on 8 September 2000 (General Assembly Resolution 55/2). They include the commitment to making the right to development a reality for everyone and to freeing the entire human race for want.

This decision is an important step towards affordable drugs for developing countries. This compulsory licensing must be implemented by all WTO members swiftly and effectively. This WTO decision also needs to be integrated with the TRIPS Agreement by means of amendments. Its objective is to let developing countries be able to import cheap medicines without facing overcomplicated procedures and conditions.

Based on the Factsheet (January 2006) issued by the Department for International Development (DFID), it provides the following facts and figures;

- A third of the world's population lack access to the medicines they need – rising to 50% in parts of Asia and Africa;
- Up to 50% of medicines are inappropriately prescribed, dispensed or sold, leading to wasted resources and potentially resulting in patient harm;
- Patients improperly use up to 50% of medicines, resulting in reduced treatment efficacy and potentially leading resistance.
- In developing countries, medicines account for 60% - 90% of household expenditures on health. Inappropriate prescription, high prices, low quality and improper use mean that the poor often receive little health benefit for their spending on drugs.

Further, on the same Factsheet by DFID, access to medicines as Target 17 of the Millennium Development Goal 8 has the mission to inform the concerned that:

- Properly used, essential medicines save lives, reduce suffering and improve health;
- By improving access to essential drugs and vaccines, up to 10.5 million lives could be saved every year worldwide: 4 million in Africa and South-East Asia alone;
- Concerted action is needed to ensure fair and sustainable financing, affordable prices, reliable health and supply systems, and the rational use of medicines. Efforts are also needed to develop new vaccines, drugs and other health technologies that meet developing country needs.
- This requires partnership between developing country governments and healthcare providers, donors, international agencies, non-governmental organizations,

pharmaceutical and biotechnology companies and the broader private sector, as well as consumers and health researchers.

To achieve the millennium goals is not without challenges and obstacles. Unaffordable medicines, irrational use of medicines, unfair health financing mechanisms, unreliable medicines supply, the quality of medicines, and the need for new medicines are the challenges identified by WTO which must be addressed to improve access to medicine.<sup>46</sup>

Every country needs to develop policies to improve access to medicines. In many countries there is a critical need to strengthen health and procurement systems, and to improve poor people's access to health services. Awareness of providers, communities and patient rising about medicines is equally important to address poor prescribing, overpricing, lack of quality and use issues.<sup>47</sup>

The majority of medicines in many countries are accessed through the private or informal sectors. The poor may rely on drug sellers whether trained or untrained for both diagnosis and prescription where access to health services is low.<sup>48</sup>

Emerging challenges include increased resistance to key drugs, such as those for malaria. The growing trade in substandard and counterfeit medicines is also a major problem, contributing to an increase in drug resistance and resulting in ineffective and often unsafe treatment.

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<sup>46</sup> WHO, *The WHO Medicines Strategy: Countries at the Core 2004-2007*, WHO 2004

<sup>47</sup> WHO, *The World Medicines Situation*, 2004 pp29

<sup>48</sup> See the WHO factsheet



## **4 Health Situation in the Philippines**

### **4.1 General**

The protection of public health is of primordial importance. The Philippine Constitution mandates for the State to protect the health of the people: The Constitution further mandates that the State must adopt an integrated and comprehensive approach to health development, which shall endeavour to make essential goods, health and other social services available to all the people at affordable cost. Further, the State must prioritize the needs of the underprivileged, sick, elderly, disabled, women and children.<sup>49</sup> Based on the foregoing, it is clear that the protection of public health with priorities over the interests of the marginalized and vulnerable is a top State objective which is an overriding parameter to the manner by which the State, through Congress, regulates the acquisition, ownership, use and disposition of property and its increments.<sup>50</sup>

The Philippines has a current population of about 83 million people. The high population growth rate is a serious challenge to the delivery of public health services. The inequalities in the access of health between the urban and rural areas, and between the poor and the rich, are still present. Compared to the neighbouring countries, the infant mortality rate is still high. The country's social and economic development is hindered by the burden of both communicable and non-communicable diseases.

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<sup>49</sup> Philippine Constitution, Sec. 11, Art. XIII Social Justice and Human Rights: “ The State shall adopt an integrated and comprehensive approach to health development which shall endeavour to make essential goods, health, and other social services available to all the people at affordable cost. There shall be priority for the needs of the underprivileged, sick, elderly, disabled, women, and children. The State shall endeavour to provide free medical care to paupers.”

<sup>50</sup> Philippine Constitution, Sec. 1, Art. XIII Social Justice and Human Rights: “The Congress shall give highest priority to the enactment of measures that protect and enhance the right of all the people to human dignity, reduce social, economic, and political inequalities, and remove cultural inequities by equitably diffusing wealth and political power for the common good. To this end, the State shall regulate the acquisition, ownership, use and disposition of property and its increments.”

Based on a WHO report, the Philippines is ranked 126<sup>th</sup> out of 191 countries in terms of “level of health”.<sup>51</sup> Likewise, according to WHO, Philippines is classified as among countries where less than 30 percent of the population have regular access to essential drugs.<sup>52</sup> An estimated 40% of the Filipinos never get to see a doctor in their lives. United Nations Development Programme (UNDP) said that the Philippines is ranked 84<sup>th</sup> out of 177 countries in their Human Development Index 2003.

The country’s main causes of illnesses are pneumonia, diarrhoea, bronchitis, influenza, hypertension, respiratory tuberculosis and heart diseases, wherein vascular system diseases, malignant neoplasm, pneumonia, accidents and tuberculosis are the leading causes of deaths on the other hand.

The market of pharmaceutical companies in the Philippines has grown into an 80-100 Billion pesos industry. According to the Statistics held in 2004, the average annual growth rate of drug sales has grown by 14 percent, with multinational companies (MNCs) accounting for 70 percent of total sales.

In the Philippines, 80-90 percent of essential drugs sold are already off-patent. The contribution of true generic drugs in the Philippine market is a measly 3 percent compared to US which has a market share of 50 percent. In relation to per capita income, the Philippines has probably the highest drug prices in the world. According to the PITC, the contributing factors to why drugs prices in the Philippines are expensive include the following;

- “Cartelized system” of drug marketing and distribution
- Underdeveloped market for generic products
- Present patent system inimical to general consumer interest
- Lack of safeguards against certain trade practices that inflate cost of medicines
- No price control even for off-patent products

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<sup>51</sup> WHO, *The WHO Health Development Report*, 2000

<sup>52</sup> WHO, *The World Drug Situation*, 2000

- Heavy dependence on imported raw materials

Before the passing of the Cheaper Medicines of 2008, the Philippines, through the Philippine International Trading Corporation (PITC), launched a program called “Half Price Medicines Program” as a solution to the problems in engendered by high prices of drugs. The program was part of the Medium Term Philippine Development Plan. The aim of the program was to reduce costs of medicines commonly bought by the poor, to half of their 2001 prices by 2010. The program also involves parallel importation, strengthening the pharmaceutical industry, combating the proliferation of fake medicines, and forging strategic alliances with key stockholders.

PITC was also supporting other initiatives for the success of the program, like:

- Maximising flexibilities available under the TRIPS Agreement including compulsory licensing, parallel importation/exhaustion of patent rights, early working exceptions or the so called Bolar provisions and government use licenses
- Instituting selective and time-bound price control or regulation for off-patent medicines
- Exploring the possibility of instituting spending controls on pharmaceutical marketing and advertising
- Stronger enforcement of the Generics Act 1988
- Amendment of the Intellectual Property Code through the passing of a bill for cheaper medicines<sup>53</sup>

After the legislation of the Cheaper Medicines Law of 2008, the Filipino people were hoping for a solution to their long agony of not affording the high prices of drugs in the Philippines.

#### **4.1.1 Health and children’s rights**

As alluded to above, Philippines is a state party to the CRC. Its obligation as state party is to give primary consideration to the best interests of the child in all its decision making.<sup>54</sup>

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<sup>53</sup> see [www.pcij.org/blog/?p=958](http://www.pcij.org/blog/?p=958)

As a signatory to the Convention, it has an obligation to protect and promote the child's right to the enjoyment of the highest attainable standard of health<sup>55</sup> and child's inherent right to life, survival and development.<sup>56</sup>

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<sup>54</sup> Article 3 of the CRC provides "1. In all actions concerning children, whether undertaken by public or private social welfare institutions, courts of law, administrative authorities or legislative bodies, the best interests of the child shall be a primary consideration.

2. States Parties undertake to ensure the child such protection and care as is necessary for his or her well-being, taking into account the rights and duties of his or her parents, legal guardians, or other individuals legally responsible for him or her, and, to this end, shall take all appropriate legislative and administrative measures.

3. States Parties shall ensure that the institutions, services and facilities responsible for the care or protection of children shall conform with the standards established by competent authorities, particularly in the areas of safety, health, in the number and suitability of their staff, as well as competent supervision."

<sup>55</sup> Article 24 of CRC provides "1. States Parties recognize the right of the child to the enjoyment of the highest attainable standard of health and to facilities for the treatment of illness and rehabilitation of health. States Parties shall strive to ensure that no child is deprived of his or her right of access to such health care services.

2. States Parties shall pursue full implementation of this right and, in particular, shall take appropriate measures:

(a) To diminish infant and child mortality;

(b) To ensure the provision of necessary medical assistance and health care to all children with emphasis on the development of primary health care;

(c) To combat disease and malnutrition, including within the framework of primary health care, through, inter alia, the application of readily available technology and through the provision of adequate nutritious foods and clean drinking-water, taking into consideration the dangers and risks of environmental pollution;

(d) To ensure appropriate pre-natal and post-natal health care for mothers;

(e) To ensure that all segments of society, in particular parents and children, are informed, have access to education and are supported in the use of basic knowledge of child health and nutrition, the advantages of breastfeeding, hygiene and environmental sanitation and the prevention of accidents;

(f) To develop preventive health care, guidance for parents and family planning education and services.

3. States Parties shall take all effective and appropriate measures with a view to abolishing traditional practices prejudicial to the health of children.

4. States Parties undertake to promote and encourage international co-operation with a view to achieving progressively the full realization of the right recognized in the present article. In this regard, particular account shall be taken of the needs of developing countries".

As a signatory to the ICESCR, the Philippines has to fulfil its obligation to ensure that every child has to enjoy the benefits of scientific progress. Article 15 states that “The States Parties...recognize the right of everyone...b) to enjoy the benefits of scientific progress and its applications....”

This State’s obligation is also embedded in the Philippine Constitution. The Constitution mandates the State to adopt measures to health development and ensure that essential goods, health and other social services are available to all the people at affordable prices. The state shall prioritize the needs of the underprivileged, sick, elderly, disabled, women and children.<sup>57</sup>

Children are future contributors to and beneficiaries of development. In order to realize the fundamental rights of the children, the states must fulfil their obligations under CRC by taking into account the best interest of the children in the adoption of measurements and trade policies. Access to affordable medicines and health care services, under the child’s right to health<sup>58</sup> and the child’s right to life<sup>59</sup>, are part of these obligations.

States Parties, in negotiating trade agreements, must take into account their human rights obligations at all times.<sup>60</sup> The Philippines was heavily warned about the possible violation on its obligations as a State Party to the CRC in its potential US-Philippines FTA. So far, no TRIPS Plus has been agreed upon between the US and the Philippines and a Cheaper Medicines Law has been recently passed and approved as a law. This law is an amendment to the IP rules of the Philippines while adoption of the TRIPS flexibilities as confirmed by the Doha Declaration on the Agreement on TRIPS.

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<sup>56</sup> Article 6 of CRC provides “1. States Parties recognize that every child has the inherent right to life. 2. States Parties shall ensure to the maximum extent possible the survival and development of the child”.

<sup>57</sup> Sec. 11, Article XIII of the Philippine Constitution

<sup>58</sup> Article 24 of the CRC

<sup>59</sup> Article 6 of the CRC

<sup>60</sup> See <http://lists.essential.org/pipermail/ip-health/2005-June/007984.html>

### **4.1.2 Children's Medicine in the Philippines**

In the passage of the cheaper medicines bill in the Philippines, it was pointed out heavily that expensive medicines have a heavy impact to the elderly. The elderly are more vulnerable to chronic ailments. This is the reason why they are seriously dependent on medicines. It is also noteworthy that every year, approximately 100,000 Filipino children die from diseases that can be prevented and cured. Vaccines can prevent many of these deaths. There are important vaccines that are necessary and must be given to children. Fortunately, some of them, like for tuberculosis, diphtheria, tetanus, polio and hepatitis B, are being given free by the government. But some other important vaccines for such diseases like chickenpox, measles, mumps and rubella, have to be shouldered by the people personally.

Acute respiratory infections are the main reasons of illness and death among children in the Philippines and their infections cannot be prevented by vaccines. They are also at risk for gastrointestinal infections that lead to life threatening, diarrhoea. A lot of Filipino children are also suffering from chronic ailments or asthma. The bulk of medicines and vaccines against children's infections can barely be afforded by the majority of the Filipino people. Inaccessibility of affordable medicines for children is tougher than for adults because the range of generic alternatives for children is actually smaller than that for adults. The costs differences with branded may not always matter whether or not they are available to the market.<sup>61</sup>

### ***4.2 Context of Access to medicines in the Philippines***

Compared to the prices in neighbouring countries like Thailand, Malaysia and Indonesia, pharmaceutical products are expensive in the Philippines. The prices of drugs increased faster compared to the consumer price index since 1985. Advocates of public intervention have rallied the need to reform the international and local monopolistic practices. On the other hand, in the policy debate, drug companies have stressed cost and quality differences to explain price differences.

The Generic Act of 1988 was implemented to require the use of generic labelling, advertising and prescriptions. But it has not led to a limited discernment of generic

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<sup>61</sup> See <http://www.asianjournal.com/?c=193&a=21793>

medicines in the market, estimated at 5 percent based on current statistics. This status is absolutely attributed to the poor public perception of generic medicines by both consumers and providers reinforced by aggressive promotion of branded products by the pharmaceutical industry. According to WHO, Philippines is among the countries where less than 30 percent of the population have regular access to essential drugs.

When the National Health Insurance Program was implemented, the problem of national drug use and management got another face of challenge. Under the Health Program, it institutes the quality assurance procedures for health care providers and limits for drugs and medicines for claims to the national health insurance. The problem lies in the limitation of the coverage of the health insurance of 70 percent of the 83 million population, hence, leaving 30 percent of the Filipino people out from drug quality assurance protection from the insurance program of the National Health.

#### ***4.3 Obligation to provide essential drugs***

The Philippines has taken measures to reduce the cost of medicines for the Filipino people, especially the vulnerable and marginalized groups, including children. Some of the enacted measures are the Generics Act of 1988 and the importation of generic equivalents from India. But despite of these notable actions, the majority of the Filipinos cannot afford the ever-increasing cost of drugs.

The Philippines, as a State party to the ICESCR, has the obligation to fulfil the required minimum core obligations defined under GC No. 14 of the CESCR. The government must ensure the availability, economic accessibility and good quality of medicines. The drugs must be adequately available in quantity within nations which are in need.

The Philippines is also a state party to the CRC. As a member state, it is enjoined to take into account the best interests of the child in all its decision-making<sup>62</sup> Further, the Philippines has an obligation to promote and protect the child's right to the enjoyment of the highest attainable standard of health<sup>63</sup> and the child's inherent to life, survival and

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<sup>62</sup> CRC, Article 3

<sup>63</sup> CRC, Article 24

development<sup>64</sup> The CRC GC No. 3 on HIV/AIDS and CRC GC No. 4 on Adolescent Health interpreted that intrinsic to the right to health and the right to life is the child's right to "sustained and equal access" to comprehensive treatment and affordable medicines without discrimination.

The fulfilment of these human rights obligations are at risk of being undermined by the monopoly of drugs pricing by the multinationals in the Philippines. There was no provision in the Philippine IP Code about TRIPS flexibilities. This is the reason why the multinationals control the pricing of pharmaceutical products. Pfizer, a multinational pharmaceutical company in the Philippines, even sued the Philippine government when the latter tried to import some drugs from India as exhaustion of its right to early working of drugs, as provided for in the TRIPS Agreement.

Due to this obstacle in fulfilling right to access to affordable medicines, it is necessary for the Philippines to undertake a human rights assessment impact of its existing laws such as the Philippine IP Code, in order to ensure the fulfilment of its obligations on right to health- specifically the right of access to essential drugs

Nevertheless, the Philippines has made promising steps as part of its obligation to realize the right to essential drugs of the Filipino people by amending and incorporating TRIPS flexibilities to the Philippine IP law. In fact, a quality and cheaper medicines law has been concluded and is now enforceable.<sup>65</sup>

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<sup>64</sup> CRC, Article 6

<sup>65</sup> See Chapter 5.5 of this thesis



## **5 The Philippine Patent Law and Access to Affordable Medicines**

### ***5.1 The Philippine Intellectual Property Rights Regime***

Based on the Philippine Constitution, the Philippine state is mandated to protect inventors' rights to their intellectual property and creations. The State has the obligation to "protect and secure the exclusive rights of scientists, inventors, artists and other gifted citizens to their intellectual property and creations particularly when beneficial to the people, for such period as may be provided by law".<sup>66</sup>

Intellectual property protection provides social and technological benefits. It is designed to encourage inventors and creators so they can benefit in the future from their creativity, like in the case of new medicines. But the State has a legitimate concern about the effect of the intellectual property protection on prices, especially of drugs. On the other side, the State has also the obligation to "protect and promote the right to health of the people"<sup>67</sup> and to adopt an integrated and comprehensive approach to health development which shall endeavour to make essential goods, health and other social services available to all the Filipino people at affordable cost."<sup>68</sup> Hence, there is the need to balance the right of the people to health and the protection of property rights of the patent owners.

### ***5.2 Proposed amendments to the Philippine Intellectual Property Code***

In response to its obligation to protect and promote the right to health of the Filipino people and instil health consciousness among them, the Philippine government have taken promising steps to promote public health and increase access to affordable medicines, by adopting legislative amendments and incorporate public health flexibilities.

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<sup>66</sup> Philippine Constitution, Article XIV, Section 13, 1987

<sup>67</sup> Philippine Constitution, Article II, Section 15, 1987

<sup>68</sup> Philippine Constitution, Article XIII, Section 11, 1987

On September 30, 2004, an Administrative Order was issued to establish the policies and guidelines governing intellectual property rights in relation to the registration of pharmaceutical products.<sup>69</sup> The government later decided to make an amendment to the previously issued administrative order. As a result, a new administrative, Patent Registration Linkage Administrative Order was issued on January 03, 2005. The purpose of this order is to establish and revise the previous policies and guidelines governing intellectual property rights and the registration of pharmaceutical products.<sup>70</sup>

On June 04, 2005, the Philippine government also affirmed the power of some governmental bodies to undertake procurement, sourcing and marketing of quality essential and low-priced generic medicines needed by the Filipino consumers through parallel importation<sup>71</sup>

On the 13<sup>th</sup> Philippine Congress in June 2006, a committee report was submitted, introducing Senate Bill 2139, authored by Senator Manuel Roxas. This bill proposed recommendations on the issue of amending the IP Code of the Philippines to achieve the objectives of broadening the access and lowering the prices drugs and medicines.<sup>72</sup>

After these struggles in addressing public health crisis on affordable medicines, finally, the two legislative bodies, the Senate and the House of Representatives, passed their own version, a Senate Bill<sup>73</sup> and House Bill,<sup>74</sup> of medicines bill on February 21, 2007.

The proposed amendments, based on the passed House and Senate bills would balance the health interest of the Filipinos on one hand and the rights of the holder of patents on the other hand. The amendments would update the 6 decades old patent regime in order that the law is more responsive to the right of the people to healthcare. The bill sought to amend provisions pertaining to non-patentable inventions, limitation of patent rights, use

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<sup>69</sup> RP-Department of Health (DOH) Administrative (A.O.) No. 170, series of 2004

<sup>70</sup> RP-DOH A.O. No. 2005-001

<sup>71</sup> RP Executive Order 442

<sup>72</sup> RP Senate Committee Report 79, introducing Senate Bill 2139, June 07, 2006

<sup>73</sup> Senate Bill 2263, January 31, 2007

<sup>74</sup> House Bill 6035, February 20,2007

of invention by governments, and limitation on rights conferred to trademark owners in cases of importation of drugs.

Some of the proposed provisions would allow importation of medicines that are cheaper than their counterparts in the Philippines, which is in conformance with the TRIPS Agreement. It would allow to parallel importation of more affordable drugs from other countries. It would support the generic industry through the adoption of early working principle. It would disallow the grant of new patents on grounds of new use and to allow for government use and compulsory licensing.

The progress of these bills will be fully discussed below.

### **5.2.1 Reactions from the Multinational Pharmaceutical Industry**

The multinational pharmaceutical industry (multinationals) justifies their dominance of the Philippine pharmaceutical market because the drugs or medicines that they produce are of good quality with their efficacy and safety assured. In relation to the alleged high prices that they impose, they justify for the reason that the quality and the need to recoup their research and development costs in relation to each successful patent which is given exclusive rights by the intellectual property law of the Philippines. This means that the strength of the multinationals lies in the patents of the drugs.

In the proposed amendments to the IP Code of the Philippines, it seeks to, among other things, exclude certain types of pharmaceutical inventions from patent protection, expand the concept of experimental use, allow early working of pharmaceutical patents, institutionalize parallel importation of drugs and medicines covered by existing patents and trademark registrations, and liberalize use of pharmaceutical inventions by the government. The aim of the proposed amendments is to lower the price of medicines and hoping this will ensure availability and accessibility of essential medicines to the Filipino people and eventually improve the healthcare system in the nation.

But regardless of the aim presented in the proposed amendments to the IP Code of the Philippines, the multinational pharmaceutical industry through Pharmaceutical and Healthcare Association of the Philippines (PHAP)<sup>75</sup> argued that the proposed amendments

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<sup>75</sup> PHAP is composed of 65 member companies and all multinational pharmaceutical companies are part of it.

will weaken the patent system and it will not transform or improve general access to medicines.

The pharmaceutical industry cited that according to Bibek Debroy, an Indian economist who opined that the problem lies not in patents but in the lack of adequate safe drinking, sanitation, sewage treatment and immunization, which is mainly attributable to state failure and bad governance. India has both an inadequate healthcare system and a weak patent system. Some parts of India have worse rates of infant mortality, maternal mortality, and immunization than such poorer parts of Sub-Saharan Africa or neighbouring Bangladesh. Debroy also said that the corruption-riddled health system in India<sup>76</sup> and the government maintained bureaucratic barriers that prevent the development of medical insurances in the country are also to blame. In his conclusion, he said that if the developing world is to significantly improve its health profile, problems relating to availability of safe drinking water, sanitation, sewage treatment and immunization will have to be primarily addressed.<sup>77</sup>

In reference to Debroy statements, the pharmaceutical industry was criticizing the government of the Philippines in recognizing India as a model of healthcare delivery in Asia for reality speaks otherwise. According to the pharmaceutical industry, the Philippines has a common situation of healthcare with India. The leading causes of morbidity in the Philippines like pneumonia, diarrhoea, malaria, and to name a few are attributable to the lack of safe drinking water, poor sanitation and lack of sewage treatment systems.

In this situation, the pharmaceutical body said that while access to medicines is supported, the government must realize that the general state of health of the Filipinos, especially those in the depressed and marginalized areas, will not be significantly improved unless those other problems are addressed.

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<sup>76</sup> According to a 2005 report by Transparency International, the health system is the most corrupt service sector in India.

<sup>77</sup> See Bibek Debroy, *Patents help the sick, poor globally*, the China Post, October 11, 2007 [www.chinapost.com.tw/editorial/2007/10/11/126199/Patents-help.htm](http://www.chinapost.com.tw/editorial/2007/10/11/126199/Patents-help.htm)

## 5.2.2 Inclusion of non-patentable drugs

In the inclusion of non-patentable drugs<sup>78</sup> as part of the proposed amendments to the IP Code, the pharmaceutical industry argued that it is inconsistent with Article 21, paragraph 1, Section 5 of the Agreement on TRIPS.<sup>79</sup> It was argued that this proposed amendment violates the equal protection clause of the Philippine Constitution as it creates an invalid and unreasonable distinction between new forms or uses of chemicals in the pharmaceuticals field as compared to those chemicals in the industrial and agricultural field. There is no distinction as to the characteristics between pharmaceutical chemicals and agro-industrial chemicals that would guarantee their different treatment under the Philippine Patent Law, awarding patent protection to innovators in one field while withholding it from the other.

## 5.2.3 Adoption of international exhaustion of rights

The adoption of international exhaustion of rights<sup>80</sup> as part of the proposed amendments will allow parallel importation of drugs covered by existing Philippine patents. The multinational pharmaceutical industry objected to the said proposed amendment. They

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<sup>78</sup> The HB 2844 proposes to treat the following inventions as non-patentable subject matter and, thus, incapable of being granted Philippine patents:

- (i) In case of drugs or medicines, mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance;
- (ii) In case of drugs or medicines, mere discovery of any new property or new use for a known substance; or
- (iii) In case of drugs or medicines, mere discovery of a new use of a known process, unless such known process results in a new product that employs at least one new reactant.<sup>78</sup>

<sup>79</sup> Article 27, Section 5, paragraph 1 of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), which provides:

Subject to the provisions of paragraphs 2 and 3 below, patents shall be available for any inventions, whether products or processes, in all fields of technology, provided they are new, involve an inventive-step and are capable of industrial application.

Subject to paragraph 4 of Article 65<sup>79</sup>, paragraph 8 of Article 70<sup>79</sup> and paragraph 3<sup>79</sup> of this Article, patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.

<sup>80</sup> The HB 2844 seeks to amend Sec. 72.1 of the IP Code by adopting the so called “international exhaustion of rights” as regards drugs and medicines, thereby allowing parallel importation of drugs covered by existing Philippine patents.

argued that allowing parallel importation discriminates against patents on drugs and medicines. Parallel importation of drugs and medicines, under patent or not creates serious safety and other concerns especially the following:

- Uncontrolled parallel importation may compromise safety and potency of medicines and may adversely affect patient safety.
- Uncontrolled parallel importation may compromise safety and potency of medicines and may adversely affect patient safety.
- Parallel importation will detract from developing local industry.

#### **5.2.4 Incorporation of early working of patents on drugs**

The pharmaceutical industry also criticized the proposed amendment which allows the early working of patents on drugs or medicines.<sup>81</sup> This early working of patents on drugs is analogous to the “Bolar” provision. They suggested that in order to implement the “early working” of patents on drugs, the government is required to promulgate rules for protecting submitted data related to acts covered by the Bolar-type exception from “unfair commercial use” in a manner consistent with Article 39 (3)<sup>82</sup> of the Agreement on TRIPS, but does not protect such data from disclosure as required by the said article of the TRIPS Agreement.

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<sup>81</sup> The HB 2844 seeks to amend Section 72.3 of the IP Code by expanding the concept of non-infringing use of pharmaceutical patents and Section 72.4 by allowing early working of patents on drugs and medicines.

<sup>82</sup> Article 39(3) of the TRIPS specifically states:

Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilize new chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use. In addition, Members shall protect such data against disclosure, except where necessary to protect the public or unless steps are taken to ensure that the data are protected against unfair commercial use.

### **5.2.5 Additional grounds in granting compulsory licensing**

In the case of providing additional grounds in granting compulsory licensing<sup>83</sup> as part in the proposed amendments, the pharmaceutical industry continually opposed such measure. They pointed out that in the proposed amendments it was not clear whether the government is required to first obtain authorization from the patent owner, or reasonable commercial terms and conditions over a reasonable period of time, as required by Article 31 of the Agreement on TRIPS.

They argued that this amendment appears to be overboard and ambiguous as it gives the Department of Health of the Philippines a wide latitude of discretion in determining the applicability of the additional grounds allowing use of the invention by the government without authorization from the patent holder.

### **5.2.6 Counter reactions from the small- scaled pharmaceutical companies**

The Filipino small-scaled pharmaceutical companies contended that there were a lot of barriers to a level playing field in the Philippine pharmaceutical market. It's not only that they do not have that much capital, but they especially noted that, unlike the intellectual property laws of other countries, the intellectual property laws of the Philippines are designed in favour of heavily protecting the patents of the multinationals. Thus, granting more marketing monopoly in favour of the multinationals. It was manifested by the representative of the local pharmaceutical companies that every time they consider coming up with a generic drug, a significant risk they consider is the possibility and costs of a lawsuit that may be filed by a multinational entity.<sup>84</sup> Also, they noted that their resources are limited in terms of checking which patents were filed by the multinationals. Hence, there is the necessity to amend the Philippine IP Code.

Despite of the different contentions, arguments, positions, or even defences from different organizations, the Philippine government has done what is right in order to ensure

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<sup>83</sup> The HB 2844 also seeks to amend Section 74.1 of the IP Code by providing additional grounds authorizing use of a patented invention by the Government or third person authorized by the Government even without agreement of the patent owner. HB 2844 also introduces a new Section 74.3 and further amends Sections 93, 94, and 95 on the granting of compulsory licenses.

<sup>84</sup> See <http://lists.essential.org/pipermail/ip-health/2006-December/010341.html>

realization of the right to access to affordable medicines of its people, by amending its one sided IP rules.

### ***5.3 The Generics Act of 1988***

The Republic Act No. 6675 euphemistically referred to as the Generics Act of 1988 was enacted by the Philippine government in 1988. The generics law sought to promote, require and ensure the labelling, prescribing and dispensing of drugs using their generic names. It is a measure to reduce the cost of medicines for the Filipino people especially the poorest and most vulnerable groups, and it also allows the importation of cheaper medicines from India.

Despite the passing of the law, the majority of the Filipino population still could not afford the over-pricing costs of drugs in the Philippines. After more than a decade since the enactment, the consensus among stockholders in the healthcare sector, government agencies, manufacturing companies and other covered organizations is that the implementation of the generics law has never been good and has suffered from weak enforcement.

The purpose of the generics law is for the people to have access to affordable medicines, by giving the generic drugs a chance in the local market. In its implementation, drugstores, for instance, were supposed to have a generics menu visible and accessible to customers. They were also to remind customers the availability of generic equivalents of branded medicines. The doctors were supposed to give the generic name of every medicine they prescribe, and drugs advertisements were to carry a brand's generic name.<sup>85</sup>

The United States passed a generic drugs law just four years ahead of the Philippines and at present their share to the market for generic medicines is 50 percent as contrary to the Philippines which has measly a 3 percent share to the nominal drug sale in the country.

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<sup>85</sup> Republic Act 6675 Sec 6(b) provides "All medical, dental, and veterinary practitioners, including private practitioners, shall write prescriptions using the generic name. The brand name may be included if so desired"; and Section 6(d) provides " Drug outlets, including drugstores, hospital, and no-hospital pharmacies and non-traditional outlets such as supermarkets and stores, shall inform any buyer about any and all other drug products having the same generic name, together with their corresponding prices so that the buyer may adequately exercise his option. Within one (1) year after approval of this Act, the drug outlets referred to herein, shall post in conspicuous places in their establishments, a list of drug products with the same generic name and their corresponding prices"



One weak point in the implementation of the generics law attributes to poor monitoring and weak penalties. The perception is that nobody really gets penalized because the government has the hard time to track of what the concerned bodies are doing.<sup>86</sup>

Another reason of the unsuccessful implementation of the generics law is that instead of generic drugs, many doctors prescribe branded medicines and they do not encourage patients to consider the generic equivalents of the branded medicines they recommend.<sup>87</sup> On the part of the doctors, they argued that they prescribe branded medicines because of quality of which generic medicines lack.

But according to Bureau of Food and Drugs, the perception in the difference in quality between branded and generic medicines lies more in the marketing strategy to condition the consumers' mind that generic drugs are cheaper because they are inferior of quality.<sup>88</sup>

Amid different views about the fate of the generics law, the proposed Cheaper Medicines Law is hoped to carry the purpose under the Generics Act 1988.

#### ***5.4 The Pfizer case***

On March 01, 2006, Pfizer, an American-based pharmaceutical company filed a complaint<sup>89</sup> against the government of the Philippines for importing and subsequently selling Pfizer's antihypertensive amlodipine besylate or commonly called Norvasc in the Philippines.<sup>90</sup> The patent of the said drug has yet to expire. The equivalent product of Norvasc in India is Amlogard which is available at much cheaper price.

The purpose of the importation before the expiration of the patent was to expedite regulatory approval from Bureau of Food and Drugs (BFAD). BFAD registration was a requirement even in the absence of intention to sell until the expiry of the Pfizer patent. The BFAD issued an approval of the drug through parallel import drug registration.

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<sup>86</sup> see [www.pcij.org/i-report/2006/generics.html](http://www.pcij.org/i-report/2006/generics.html)

<sup>87</sup> The WB Report (2002)

<sup>88</sup> See [www.pcij.org/i-report/2006/generics2.html](http://www.pcij.org/i-report/2006/generics2.html)

<sup>89</sup> Pfizer vs. PITC, Civil Case No. 06-172 under Br. 149, Makati City, Philippines

<sup>90</sup> See <http://www.cptech.org/ip/health/c/phil/pfizer-v-pitc.pdf>

According to PITC, Pfizer was informed that they do not have the intention to manufacture the drug but only to begin the process of registering the equivalent product so it can immediately enter the market upon the expiration of the patent

The PITC was the only body which has the authorization from the Department of Health (DOH) of the Philippines to conduct parallel importation on drugs. As part of its defence, the PITC filed a counter suit against Pfizer because of its attempt to restrain the government from importing generic drugs.

The legal issue in this case was whether or not the importation of the Amlogard was violating the patency right of Pfizer. The case resulted to a settlement. Further review of this case is discussed below.

#### **5.4.1 Drugs pricing in the Philippines**

The Philippines suffers from some of the highest drug prices in Asia or even in the world. The product in question in the Pfizer case was still under patent. The drug is called Norvasc (amlodipine besylate). Its purpose is to treat blood pressure and does not have any cheaper versions available in the Philippines.

The drug is sold in two dosage format: 5mg and 10 mg. Tablet. Pfizer charges half the prices in Indonesia and Thailand. The Philippine price for the equivalent product in India is 650% higher. Pfizer was a holder of Philippine patent on Norvasc until June 2007. The reason of high drug prices is the dependence of the local industry on pharmaceutical multinational corporations for raw materials, technology and finished products.

A comprehensive drug industry includes all the basic processes in manufacturing medicines, from the manufacture of raw materials and production of basic chemical to the manufacture of finished products. The process of extracting and producing raw materials from local sources in the Philippines is generally absent. Multinational pharmaceutical companies are involved only in the importation of raw materials and finished goods, formulating, processing, packaging and distribution. Production is not available because the country lacks an organic chemical industry that will produce the inputs though many of the imported raw materials can be produced locally.

Another reason than dependence on inputs is that, the local industry is under multinational control, through licensing agreements which involved technological or marketing tie-ups. Multinational pharmaceutical companies are able to impose whatever price they want for their raw materials, chemicals and pharmaceuticals, because of this dependence and the monopoly power conferred by patents, leaving Filipino consumers no alternative but to meet high drug prices as best they can.

The goal of the Philippine government-owned trading company was to begin the process of registering the imported version, so it can promptly enter the market upon the expiration of the Pfizer controlled patent. The Philippines has implemented the Agreement on TRIPS which allows countries flexibilities from the agreement such as parallel importation.

But the Philippines does not have a clear policy agreement and there is no general law that governs parallel imports. But there are a number of bills pending on the issue, and parallel import of pharmaceuticals from countries like India is allowed in the Philippines based on Administrative Order 85 which was issued by the Department of Health in year 2000.

#### **5.4.2 Reactions from the multinational pharmaceutical industry**

In the case filed by Pfizer, it alleged that the Philippines was trying to import Norvasc from India. It said that the Indian company that manufactures the cheaper drugs was not licensed by Pfizer to produce the drug.

Pfizer argued that the suit it filed concerned a health issue. It said that the products that enter the Philippines through parallel importation may carry health risks associated with counterfeits. Pfizer also claimed that by respecting patent rights ensures that Pfizer will be able to sustain its mission to innovate and bring new and better life saving medicines to more patients.

Based on the price differences of drugs between the Philippines and other countries like India, the multinationals contended, however, that there are cheaper generic drugs available in the Philippines which are priced the same as Indian prices. It is also argued by the multinationals that recovery of research and development costs justifies the differences in pricing strategy in the Philippines and in India.

Further, the PHAP expressed their concern that parallel import is not the proper way to lower medicines prices in the Philippines. They were claiming that through parallel importation, the drug counterfeiters are taking advantage by labelling fake drugs as branded drugs imported from India and passing them off as part of the parallel importation by the government.

#### **5.4.3 Counter reactions from the Philippine government**

On the alleged attempt of importation of Norvasc from India by the PITC, it counter argued that it would import the versions of Norvasc only when the patent expires and that the products would come from patented producers. It was said further that PITC is the implementing body in the government's importation program for pharmaceuticals, which aims to improve public access to high-quality branded medicines for common and life threatening ailments by cutting retail prices by at least half. The purpose of the PITC's program, it was argued, was to import drugs that are priced cheaper than they are in the Philippines and to legally put them on the market in other countries. In countering the argument of Pfizer that the importation may yield risk to public health, the PITC argued that it was attempting to certify the safety of all the products it hoped to import in the future.

Notwithstanding with the arguments given, it still does not answer the situation that the high Philippine prices have deprived at least half of the Filipinos access to affordable medicines and further limited access for those Filipinos who have some money to purchase the same.

#### **5.4.4 Criticisms on the outcome of the case**

The government of the Philippines entered into a settlement with Pfizer.<sup>91</sup> The BFAD in an agreement undertaking not to import Norvasc before its patent expires. In the same vein it also agreed not to grant marketing approval with regard to pharmaceuticals until the end of the validity of the applicable patent. This grant of marketing approval is commonly known as "linkage".<sup>92</sup> There are criticisms on this linkage for the reason that it transforms drug

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<sup>91</sup> See <http://www.cptech.org/ip/health/c/phil/order.jpg> and <http://www.cptech.org/ip/health/c/phil/order2.jpg>

<sup>92</sup> Patent-Registration Linkage ("linkage") is the practice of linking drug marketing approval to the patent status of the originator's product and delaying the grant of marketing approval to any third party until expiration of the patent term unless by consent of the patent owner. Under this kind of regulation, national

regulatory agencies into patent enforcers even though they typically do not examine the validity of the patent they are enforcing nor do they have the expertise to carry out concerted examination. But what was left unclear in the settlement agreement was whether or not the Philippines will be able to make use of the early working provisions in the future. Critics also said that the settlement entered into would undermine the effectiveness of the Philippines' parallel imports.<sup>93</sup>

### ***5.5 Non applicability of Compulsory Licensing***

Compulsory licensing entails authorizing the government to allow someone else to produce the patented product or process without the consent of the patent owner. It is not applicable in the Philippines because drug manufacturers have no technical capacity to make drugs in the true sense of the term. What the Philippines has is secondary manufacturing which is compounding, tableting and capsuling.

Given its dependence on imported raw materials and chemicals, the Philippine pharmaceutical industry cannot be considered a true drug industry. Although 90 percent of the drugs sold are locally produced, Philippine drug companies are mainly compounders, formulators and packagers. The big pharmaceutical firms either import their products or have them totally manufactured at the foreign owned Inter-Phil. Laboratories though there are a few local companies like United Laboratories, Elin Pharmaceuticals and Pascual Laboratories that are engaged in the manufacture of active substances.

### ***5.6 The Cheaper Medicines Law of 2008***

In 1988, the Philippines passed the Generics Act of 1988. But despite the fact that it has been on the statute books for 20 years of existence, it is by fact a law which lacks enforcement. The unsuccessful enforcement was one of the reasons why the drugs sold in the Philippines are quite expensive compared to other countries like India. Due to the high prices of drugs, a lot of Filipino people have no access to medicines. Hence a substantial number died as a result of ailments that would have been easily treated had there been accessible drugs. This threat to the obligation of the Philippine government to protect the

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regulatory authorities have the obligation to prevent the registration and marketing of second applicants when a patent covers the product.

<sup>93</sup> See <http://www.cptech.org/ip/health/c/phil/Settlement.pdf>

right to health of its people prompted the legislators to pass a bill which will mitigate the high prices of drugs and for the people to have access to affordable medicines. The case filed by Pfizer against the Philippine government became an eye opener to the legislators about the existence of an ominous threat to the progressive realisation of the right to health through access to affordable medicines by the Filipino people.

According to WHO-commissioned book “Drugs and Money: Prices, Affordability and Cost Containment,” the main reasons for high drug prices are costs invested in research and development, factors that tend to create monopolies like patent protection, and third party players that make consumers attitudes’ tendency to use price to judge the quality or efficacy of drugs.

Though the citation of the main reasons for high drug prices by the WHO, the intellectual Property Office (IPO) of the Philippines weighed in by stating that patents are still the primary reason for the high cost of medicines in the country. The monopoly of patent gives the owner some leeway in controlling the price of patented drugs.<sup>94</sup> Hence, a bill which amends the existing patent law is to be effected.

The bills are called House Bill (HB) 2844 and Senate Bill (SB) 1658 and were passed by Congress and Senate of the Philippines respectively. The House and Senate bills have a handful of twin provisions which propose for the amendment of the Republic Act 8293, the IP Code of the Philippines. But under HB 2844, there was a provision that only generic names of medicines must appear on medical, dental and veterinary prescriptions.<sup>95</sup> This generics-only provision created a battle of disagreements between the legislative bodies and criticisms from observers and other political parties. It was argued that without scrapping the generics-only provision will have a big impact to the ethical obligation of the doctors in prescribing which drugs that they think is best for the patient.

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<sup>94</sup> see [www.pcij.org/stories/2008/cheaper-medicines.html](http://www.pcij.org/stories/2008/cheaper-medicines.html)

<sup>95</sup> The HB 2844 Pertinent Amendments to Generics Act of 1988 or RA 6675; Subject: Generic Terminology provides “House bill mandates all medical, dental and veterinary practitioners, including private practitioners, to write their prescriptions using only the generic name of the drugs or medicines. It also orders that the following statement appears prominently on the label of the generic drug: “the product has the same therapeutic efficacy as any other generic product of the same name”. Signed: BFAD (Section 6))

But despite the criticisms and disagreements, the Senate and House of Representatives came to a compromise agreement that they will postpone the effectivity of the generics-only medicine labelling requirement for 3-5 years after the passage of the Cheaper Medicines Law. Observers and legislators believe that the passing of the two bills was well overdue. They said that the Senate and House bills trace the situation of the overpriced medicines to the country's legal structure of intellectual property and trademarks. After all, six years after the Doha Declaration, intellectual Property law of the Philippines has yet to incorporate many of the flexibilities provided in the TRIPS Agreement.

On 29 April 2008, the Senate and House bill versions of the Cheaper Medicines Law were finally consolidated and created a new law called "Universally Accessible Cheaper and Quality Medicines Act of 2008" and on 6 June 2008, the president of the Philippines, Gloria Macapagal Arroyo appended her signature that made the bill an enforceable law. The new law amends certain provisions of the three laws- the Intellectual Property Code, the Generics Act of 1988 and the Pharmacy Law. It aims to cut the cost of medicines in the country which has among the priciest pharmaceuticals in Asia.

The new cheaper medicines law also prohibits new patents based only on newly discovered uses of known drugs and allows local companies to test, produce and register generic versions of patented drugs so they can be sold immediately after patent expiry. It also gives the President the power to put price ceilings on various drugs and strengthens the government drug regulatory bureau.<sup>96</sup> The full implementation of the new law will start upon the adoption of its Implementing Rules and Regulations.

### **5.6.1 Outlook and Implications**

The new law will represent a heavy pressure to research-based multinational drug companies, with US companies in particular to reduce their prices in order to increase competition that will lead towards a lowering of prices as well as assuring quality medicines.

The new Law constitutes just one of series of measures currently being undertaken to combat rising prices especially food and fuel, for the Philippine government.

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<sup>96</sup> See <http://newsinfo.inquirer.net/inquirerheadlines/nation/view/20080607-141254/cheaper.....>)

### **5.6.2 Reactions from the multinational pharmaceutical industry**

Multinational drug companies were against with the proposed amendments to the intellectual property law. They said that the amendments are discriminatory and violate the Constitution's due process and equal-protection clauses. They said that the proposed changes are inconsistent with the international treaty obligations of the Philippines.

One of the amendments they objected to which follows the lead of other countries like United States, Canada, Australia, Israel, Argentina and Thailand is the provision allowing a generic manufacturer to start preparing a generic version about two years before a drug's patent expires. Thus, as soon as the patent expires, the generic equivalent is ready for selling in the market. This is commonly called the early working or "Bolar provisions," after a 1984 US case law decision.

Another objection from the pharmaceutical industry is based on Section 22 in the House Bill 2844 and Section 26 in the Senate Bill 1658 which they said are discriminatory against the three basic requirements of patentability: novelty, inventive step and industrial application.

They said that the Intellectual Property Code has sufficient safeguards against double patenting and "ever-greening"<sup>97</sup>, which do not have a significant impact on access to medicines. They argued that after all, only 1 percent of the drugs on WHO's List of Essential Medicines are patented, with the rest already outside the patent system.

### **5.6.3 Counter argument against multinationals' view point**

The BFAD reacted on the arguments of the Pharmaceutical industry by asserting that the Philippine Intellectual Property Code has sufficient safeguards against double patenting and in the first place, only 1 percent of the drugs listed by WTO are under patent hence, 99 percent are outside the patent system. It asked what would happen if the 1 percent under patent is the most essential drugs needed by the people and the 99 percent are molecules that may again be patented for new use without the provision preventing patentability based on "new use".

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<sup>97</sup> Ever greening, in one common form, occurs when the brand-name manufacturer obtains separate 20-year patents on multiple attributes of a single product. These patents can cover everything from aspects of the manufacturing process to tablet colour, or even a chemical produced by the body when the drug is ingested and metabolised by the patient. Downloaded from <http://www.engagenerics.com/gen-evergrn.htm>



#### **5.6.4 Application of Parallel Imports without barriers**

After the signing of The Cheaper Medicines Law, any person or entity in the Philippines can now legally import cheaper branded medicines and sell them locally. The new law only requires the prospective importers to register with the BFAD beforehand. The legislation removes all barriers to parallel imports of drugs and provides safeguards against the counterfeiting of medicines.

## **6 CONCLUSION**

The TRIPS Agreement provides for a number of minimum standards for global intellectual property protection. But it also leaves considerable room for national legislation to recognize a number of important areas of intellectual property law. The development and enhancement of intellectual property laws domestically can be used for the achievement of the purpose and objectives of the TRIPS Agreement and its flexibilities.

This writing explores the legal issues on the effects of the implementation of the TRIPS Agreement and its flexibilities, specifically parallel importation on pharmaceutical products on the one hand and the realisation of the right to health in the Philippines. Every concluded covenant has its own purposes and objectives. Treaties tend to protect and enhance the rights of their members only or the global community as a whole. The TRIPS Agreement was concluded for the protection of the intellectual property rights of the WTO members. But the Agreement on TRIPS also recognized and guaranteed fundamental human rights of the people.

Innovations through patents are recognized rights hence they deserve to be protected. A patent is a public policy tool that can benefit the society as a whole. But as other laws, the implementation of a patent must be in accordance with the public and private welfare. The implementation of patent rights must not expose to risk the public health otherwise the governments may exercise their legal and moral duty to limit patent monopolies.

The Doha Declaration on TRIPS Agreement, while acknowledging the importance of intellectual property protection, specifically recognized the substantial concerns on the inaccessibility of affordable essential drugs due to monopolized high prices by the patent holders. The right on access to affordable medicines is embedded in the fundamental right to health. The right to health is one of the core obligations of the states to respect, protect and fulfil. As a core obligation, the governments are under duty to fulfil by taking health

measures...e.g. The Cheaper Medicines Law of the Philippines, and to ensure the accessibility of essential medicines to the people.

Denial of access to affordable medicines is denial of the enjoyment of the right to life,<sup>98</sup> and the rights of the highest attainable standard of physical and mental health.<sup>99</sup> Although the inventors' rights to exploit their scientific inventions commercially are also guaranteed<sup>100</sup>, this right cannot outweigh the right to life and health. Based on the principles set out in various human rights instruments and various treaties, in setting priorities, the governments will have to give attention to their international human rights obligations enjoining the progressive realisation of the human rights of their people as enshrined in international human rights instruments. It is my argument that an international recognised fundamental right as the right to health cannot be derogated by the right to scientific invention; if more resources have been allocated to certain rights, care must be taken to ensure that other rights maintain at least their initial level of realization – patency rights are legally recognized but not without limitations.

Despite the presence of criticisms from different legal and independent bodies, especially the patent holders, the pharmaceutical industry in the Philippines is trying its best to commit itself towards the fulfilment of the right to access to essential medicines. Like in the case of the Pharmaceutical and Healthcare Association of the Philippines (PHAP), with regard to the newly legislated Cheaper Medicines Law 2008, it has committed itself towards the objective of the law in aiming not only to improve access to medicines but also to the healthcare services of the Philippines.<sup>101</sup>

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<sup>98</sup> Article 6 of the ICCPR

<sup>99</sup> Article 12 of the ICESCR

<sup>100</sup> Article 15(1)(c) of the ICESCR

<sup>101</sup> PHAP Press Statement on New Legislation on Universally Accessible Cheaper and Quality Medicines Act 2008 <http://www.phap.org.ph/about.aspx>

Based on the arguments presented by different bodies, one can say that patent is not an isolated factor to pin point as the cause in the denial on access to affordable medicines. The economic constraints, the inequality of social rights, and the divided political opinions are only some of the main factors for the failure of the states to fulfil their obligation on the right to health of their people.

It is noteworthy that despite the apparent clash of two rights, the right to intellectual property protection on the one hand and the right to health on the other, the concerned bodies must have realized that there are few legal remedies to choose from. Although in order to minimize conflict and to meet resolution at the end, one or some must sacrifice their purely commercial private interests for the benefit of all. The adoption of the above named legislation was undoubtedly a step in the right direction by the Philippines in its endeavour to ensure the progressive realisation of the right to health, an obligation which it undertook by being party to multilateral human rights instruments such as the ICESCR which enjoins state parties to do so.

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