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**BIBLIOGRAPHY**

# Abbreviations

OAPI:	Organisation Africaine de la Propriété Intellectuelle (African Intellectual Property Organization)
LDC:	Least-developed countries
R&D:	Research and Development
TB:	Tuberculosis
TRIPS:	Agreement on Trade-Related Aspects of Intellectual
UNAIDS:	Joint United Nations Programme on HIV/AIDS
WHO:	World Health Organization
WTO:	World Trade Organization
WIPO:	World Intellectual Property Organization
AID:	Acquired Immunity Defects Syndrome
ARV	Antiretroviral (drugs)
HIV:	Human Immune deficiency Virus
MSF:	Medecines Sans frontieres
NGO:	No-Governmental Organization
TRIPS:	Agreement on trade Related aspect of Intellectual property Rights
UNAIDS:	Joint United Nations Programme on HIV/AIDS
USTR:	United Nations Trade Council
CESCR:	Committee on Economic Social and Cultural Rights
PHARMA:	Pharmaceutical Research and Manufacturing of America
IFPMA:	International Federation of Manufacturing Association
UNAIDS:	United Nations AIDS Programme

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# 1 INTRODUCTION

## 1.1 Overview

The World Trade Organisation (WTO) Agreement on Trade Related Aspects of Intellectual Property (TRIPS) sets out the minimum standards for protection with which all the (WTO) members must abide. Unlike in the days before the TRIPS Agreement, WTO members can no longer rule out granting patents in particular fields of technology such as the pharmaceutical sectors. Now all inventions in the pharmaceutical sector fall within the scope of patentability requirements of the TRIPS Agreement and national authorities must provide patent protection for a minimum term of 20 years provided that the invention is new, inventive and capable of industrial application.

The importance of effective patent protection is crucial for the pharmaceutical industry which is most directly involved in discovering and developing new pharmaceuticals. Indeed, without the incentive provided by the patent system it is doubtful that private sector would have invested so much in the discovery or development of medicines, many of which are currently in use both in developed and developing countries. The pharmaceutical industry is more strongly dependent on the patent system than most other industrial sectors to recoup its past research and development (R&D) costs, to generate profits, and to fund R&D for future products. The industry understandably takes a close interest in the global application of intellectual property rights protection, and generally resists the



contention that they constitute a major barrier to access or a deterrent to development in developing countries.

Having said that, it is important to raise the concerns expressed by, and on behalf of, developing and least developed countries about the impact that such rights may have in those countries, particularly access to pharmaceutical patented drugs. The author is of the view that, if strong patent protection is enforced, it will fall especially hard upon poor people, particularly in the absence of widespread provision for public health as exists in most developed countries.<sup>1</sup>

The critics of strong pharmaceutical patents claim that patents are a major factor in the lack of access to essential drugs<sup>2</sup>. A point hotly disputed by the pharmaceutical industry and its proponents. The pharmaceutical industry denies that patents are responsible for the lack of affordable drugs. Instead, the industry blames other barriers for the lack of access to essential drugs.

Thus, the central focus of this paper is to examine the issues surrounding access to essential drugs in Sub-Saharan Africa. It starts with the assumption that pharmaceutical patent is one of the barriers for access to essential drugs. It tries to put the debate on access to essential drugs in

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<sup>1</sup> **Commission on Intellectual Property Rights, *Integrating Intellectual Property Rights and Development Policy***. Report of the Commission on Intellectual Property Rights, London, 2002, p.4

<sup>2</sup> Essential drugs are those drugs that satisfy the health care needs of the majority of the population, at a price they and the community can afford; they should therefore be available at all times and in adequate amounts, and in appropriate dosage forms. (WHO, '12<sup>th</sup> Model List of Essential Medicines' available at: <http://www.who.int/medicines>)

perspective by taking into account the human rights aspect of the matter.

## **1.2 Purpose of the thesis**

The purpose of this of paper is to analyze the nexus between diminished access to essential drugs and pharmaceutical patents. In the process, the arguments often made about the need for strong intellectual property rights, which are based on a number of assumptions, will be objectively reviewed. Justification for patent law will be examined, particularly it's utility in promoting R&D and innovation with salient counter-arguments. This paper will limit itself on the pharmaceutical patents and access to essential drugs in the Sub-Saharan countries and related issues in general.

## **1.3 Methodology**

It is library-based research, involving review of literature from range of sources. The Westlaw online database has been extensively used. In order to achieve the purpose of this thesis, both comparative and analytical methods are utilized.

## 1.4 The Scope and Nature of the Health Crisis in Africa

Infectious diseases kill over 10 million people each year, more than 90 percent of which are in the developing world. The leading causes of illness and death in Africa are HIV/AIDS, Malaria and Tuberculosis. The magnitude of this health crisis in Africa has drawn attention to the fact that millions of people in the developing world do not have access to the medicines that are needed to treat diseases or alleviate suffering.

Sub-Saharan Africa accounts for more than 1.5 million new cases of TB every year and 27% of the global burden. Nine of the world's 22 high-burden countries are in Africa, and twelve of the world's fifteen countries with a TB incidence rate of over 400 cases per 100 000 of the population are in Africa. Most of these are countries with the highest HIV prevalence on the continent.<sup>3</sup>

Up to 90% of all malaria deaths occur in tropical Africa, south of the Sahara. It is generally agreed that malaria causes around 20<sup>4</sup>% of all deaths of African children under the age of five years, and that it is now the most important cause of death in this age group in the Continent

The statistics on Acquired immunodeficiency syndrome (HIV/AIDS) prevalence remain no less dire than they have been in recent years. The sub-Saharan African (SSA) region

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<sup>3</sup> **The Global Fund**, *HIV/AIDS, Tuberculosis and Malaria: The Status and Impact of the Three Diseases*, p.30. Available at: [http://www.theglobalfund.org/en/files/about/replenishment/disease\\_report\\_en.pdf](http://www.theglobalfund.org/en/files/about/replenishment/disease_report_en.pdf)

is by far the most affected by the global epidemic of HIV/AIDS with approximately 26.6 million people in the region estimated to be living with HIV/AIDS. There were 3.2 million new infections in 2003 and approximately 2.3 million people died of AIDS in the same year.<sup>5</sup>

South Africa has the highest HIV/AIDS population in the world with 5.1 million infected adults and a prevalence rate amongst adults of 21.5 per cent.<sup>6</sup>

Despite the rapid spread of the virus, it has been estimated that only 2% of those needing antiretroviral treatment in Africa are actually receiving the life-saving drugs that can slow the effects of the virus on the body's immune system and significantly extend the lives of those infected. The World Health Organization's ("WHO") new "3 by 5 initiative" (designed to provide HIV/AIDS treatment to three million people by the end of 2005) is of course directed at alleviating this lack of access.<sup>7</sup>

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<sup>4</sup> Malaria in Africa. Available at:  
[http://www.rbm.who.int/cmc\\_upload/0/000/015/370/RBMInfosheet\\_3.htm](http://www.rbm.who.int/cmc_upload/0/000/015/370/RBMInfosheet_3.htm)

<sup>5</sup> See the UNAIDS annual report of 2003. available at:  
[http://www.unaids.org/html/pub/publications/irc- pub06/jc943-epiupdate2003\\_en\\_pdf.htm](http://www.unaids.org/html/pub/publications/irc- pub06/jc943-epiupdate2003_en_pdf.htm)

<sup>6</sup> According to the UNAIDS 'Report on the Global HIV/AIDS Epidemic, July 2004' available at:  
[http://www.unaids.org/bangkok2004/GAR2004\\_html/GAR2004\\_00\\_en.htm](http://www.unaids.org/bangkok2004/GAR2004_html/GAR2004_00_en.htm)

<sup>7</sup> Treat 3 Million by 2005 Initiatives,  
<http://www.unaids.org/en/treat3millionby2005initiative.asp>

# 2 International Patent Protection Regime

## 2.1 TRIPS Agreement

### 2.1.1 Overview

A new international system for securing intellectual property protection for pharmaceutical and other technologies was consolidated in 1994 when the World Trade Organization was founded and when its Member States adopted the Agreement on the Trade Related Aspects of Intellectual Property Rights (TRIPS Agreement)<sup>8</sup>. Under key provisions relating to medicines, Member States must provide patent protection from the filing date of a patent application for any invention, including a pharmaceutical product or process.<sup>9</sup>

Via TRIPS Agreement, major pharmaceutical producers secured exclusive rights to exclude others from making, using, offering for sale, selling or importing patented pharmaceutical products or products made with a patented process<sup>10</sup>.

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<sup>8</sup> Art. 8(1), Marrakech Agreement Establishing the World Trade Organization,

<sup>9</sup> Brook K. Baker, ***The Process and Issues for Improving Access to Medicine: willingness and Ability to Utilize the TRIPS Flexibilities in Non Producing Countries***, DEIED Health System Resource Centre, 2004 p 6. Available at: [http://www.dfidhealthrc.org/Shared/publications/Issues\\_papers/ATM/Baker.pdf](http://www.dfidhealthrc.org/Shared/publications/Issues_papers/ATM/Baker.pdf)

<sup>10</sup> Lissett Ferreira, ***Access to Affordable HIV/AIDS Drugs: The Human Rights Obligations of Multinational Pharmaceutical Corporations***, Fordham Law Review, and Fordham University, 2002

## 2.1.2 Rights Conferred and Exceptions

Patents<sup>11</sup> are granted in relation to products<sup>12</sup> and processes<sup>13</sup>, dealt with in paragraphs 1&2 of article 28<sup>14</sup> of the TRIPS Agreement. This article sets the exclusive rights that are conferred on patent holders. Reading this article together with article 33 providing a minimum of twenty years protection for such rights from the date of patent filing. In the absence of any good reason, a member is bound by the Agreement to confer such rights on all inventions whether product or processes, in all field of technology, provided they are new, involve an inventive step and are capable of industrial application.

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<sup>11</sup> Under the Paris Convention for the Protection of Industrial Property, states were free to exclude certain areas from patentability, as well as to provide special rules for certain types of inventions. In addition, they had freedom to define the requirements for patentability. The TRIPS Agreement has changed this situation. Article 27(1) includes a general obligation of patentability addressing one of the major concerns raised by the pharmaceutical industry with respect to prevailing regimes prior to TRIPS.

Any application for a patent must satisfy the basic criteria of novelty, inventive step and industrial applicability. Accordingly, Article 27.1 makes it clear that patents are to be granted for *inventions*. The TRIPS Agreement, however, does not define what an "invention" is; it only specifies the requirements that an invention should meet in order to be patentable (Article 27.1). This leaves Members considerable freedom to determine what should be deemed an invention and, if they so desire, to exclude from patentability any substance which exists in nature as being a mere "discovery" and not an "invention".

<sup>12</sup> Product is a thing or substance produced by natural process or manufacture

<sup>13</sup> Process is a series of operations in manufacture, printing, photography, etc.

<sup>14</sup> Article 28 reads:

1. A patent shall confer on its owner the following exclusive rights (a) where the subject matter of a patent is a product, to prevent third parties not having the owner's consent from the acts of: making, using, offering for sale, selling, or importing for these purposes that product; (b) where the subject matter of a patent is a process, to prevent third parties not having the owner's consent from the act of using the process, and from the acts of: using, offering for sale, selling, or importing for these purposes at least the product obtained directly by that process.

2. Patent owners shall also have the right to assign, or transfer by succession, the patent and to conclude licensing contracts.

It permits the title-holder, if successful in the exploitation of the invention, to obtain significant rents during the lifetime of the patent, thus fulfilling one of the basic purposes of patent grants.

Rigid application of these rights for such a period of time will, in many cases, frustrate the objectives and principles of TRIPS Agreement<sup>15</sup>. The conferred rights are not absolute. Under most patent laws, such rights may not be exercised with regard to certain acts by third parties. This means that under certain specified circumstances, there may be exceptions to the exclusive rights.<sup>16</sup>

### 2.1.3 Transition Period

In partial recognition of the social and economic adjustments that developing Members would face as they provide patent protection for pharmaceutical products, the TRIPS Agreement allows those Members that have not provide such protection until January 1, 2005 to implement it. In the interim, under the so-called "mailbox"<sup>17</sup> rule, developing countries are required to establish mechanisms

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<sup>15</sup> The general paragraphs in the TRIPS Agreement (preamble and general provisions) stress the need to promote adequate and effective protection of intellectual property rights, but to do so as part of a series of broader economic objectives. The protection of intellectual property rights is not an absolute and exclusive obligation Articles 1, 7 and 8 were included in the Agreement to make for a balance between the rights of patent holders and their obligations *vis-à-vis* society. Member States may therefore base certain particular provisions of their national regulations on these principles. **(World Health Organization, Globalisation, TRIPS and Access to Pharmaceuticals, World Health Organisation policy perspective on Medicines: WHO Medicines Strategy: 2000-2003,pp.19-20**

<sup>16</sup> Please refer to pp.61-73 of this work

<sup>17</sup> The mail box system is a TRIPS- Imposed obligation on the developing countries that wished to benefit from TRIPS transitional period by delaying granting of patents for pharmaceutical products until 2005 or 2016. In exchange for not

for receiving and preserving priority in regard to pharmaceutical patent applications, and to allowing for the grant of exclusive distribution rights when prescribed conditions are satisfied.

Whereas, least developed countries (LDCs) had until January 1, 2006 to provide patent protection. As a consequence of the Doha Declaration paragraph7, the transition period will be extended regarding pharmaceutical products until January 1, 2016.

The value of this added flexibility is highly dependent on the capacity of the LDCs to increase manufacturing capacity, and this will depend on factors such as the availability of World Bank grants or loans to provide working capital, and the availability of technical assistance.

## **2.2 African Intellectual Property Organisation (OAPI)**

Until 1962, patent rights in the majority of francophone member states of OAPI, were governed by French laws. The French National Patent Rights Institute was the National Authority for each of these states, and then grouped within the French Union (Union Française). The majority of the French Union member countries having become independent in 1960s, found it necessary to create a body of their

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granting patents, these countries had to establish a mail box system for receiving and filling patent applications from the beginning of the transitional period in 1995



common territory, in respect of conventions on patent rights<sup>18</sup>.

The creation found its legal justification in article 19 of the Paris Convention for the Protection of Patent Rights, which states that countries, which are signatories to this convention, serve the right to undertake separately among themselves, specific agreements for the protection of patent rights, so long as these arrangements are not in contradiction with the provisions of the said convention. It is on the basis of this provision that 12 African countries together decided to create a single body to act as the national patent rights authority for each of them.<sup>19</sup>

The African and Malagasy Patent Rights Authority (OAMPI) was thus born on 13<sup>th</sup> September 1962 by the agreement known as the 'Libreville Agreement'. But the withdrawal of the Malagasy Republic coupled with the need to expand coverage to other categories of IP led the Member States to revise the Libreville Agreement and to create the African Intellectual Property Organisation (OAPI) by the adoption of a new convention signed in Bangui on 2<sup>nd</sup> March 1977.<sup>20</sup>

### **2.2.1 The Bangui Agreement as amended in**

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<sup>18</sup> See History of African intellectual Property Organization available at: <http://www.oapi.wipo.net/en/index.html>

<sup>19</sup> History of OAPI available at: <http://www.oapi.wipo.net/en/index.html>

## 1999

The Bangui Agreement was amended in 1999 to give clear effect to the provisions of the TRIPS Agreement<sup>21</sup>. The issuing of patents in OAPI member states is regulated by the Bangui Agreement, which has the status of national patent law for all member states. OAPI receives all patent applications and registers regional patents, which have a binding effect in all member states<sup>22</sup>. Once the patents have been issued by OAPI, they are then regulated at the national level by each respective state.<sup>23</sup>

In accordance with TRIPS Agreement, the revised Bangui Agreement automatically extends the duration of a patent to 20 years, starting from the date the application is filed.<sup>24</sup> However, the revised version of the Agreement introduced limitation on the rights of patent holder<sup>25</sup>. The Bangui Agreement permits parallel imports between OAPI member countries. This means that from now on it will be possible to import a patented drug sold at a lower price in one OAPI member country to another member country.

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<sup>20</sup> **Phil Thorpe**, *Study on the Implementation of the TRIPS Agreement by Developing Countries*, unpublished, Commission on Intellectual Property Rights, 2002 p.5. Available at [http://www.iprcommission.org/papers/pdfs/study\\_papers/sp7\\_thorpe\\_study.pdf](http://www.iprcommission.org/papers/pdfs/study_papers/sp7_thorpe_study.pdf)

<sup>21</sup> The Revised Agreement entered into force for all OAPI members in early 2002 following ratification by at least 10 OAPI states.

<sup>22</sup> The current member states of OAPI are: Benin, Burkina Faso, Cameroon, Central Africa, Congo, Cote d'Ivoire, Equatorial Guinea, Gabon, Guinea, Guinea Bissau, Mali, Mauritania, Niger, Senegal, Chad, and Togo.

<sup>23</sup> **Boulet, P.**, *Drug Patent in French –speaking Africa*, Report of an MSF-OMS-ONUSIDA joint mission, Cameroon, 2000,p.4

<sup>24</sup> Article 9 of The revised Bangui Agreement

<sup>25</sup> Ibid, Article 8

## 2.3 African Regional Industrial Property Organisation (ARIPO)

ARIPO was established to promote, among other objectives, the harmonization and development of the Industrial Property Laws, and related matters appropriate to the needs of its members and the region at large. Subsequent to the Lusaka Agreement, ARIPO adopted the Harare Protocol on Patents and Industrial Designs, which empowers ARIPO to grant and administer patents on behalf of member states. Applications for patents can either be lodged with the ARIPO secretariat or, where the law of the contracting state permits, with the Industrial Property Office of the Contracting State.

The Harare Protocol empowers the ARIPO office to receive and examine patent applications, and to grant regional patents on behalf of the 15 ARIPO member states<sup>26</sup>. Patents granted by the ARIPO office have the same effect as national patents in each ARIPO country that has been designated in the patent application. The ARIPO office undertakes only the formal and substantive examination of the application and formally notifies designated member states.<sup>27</sup>

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<sup>26</sup> The following member states are contracting parties to ARIPO: Botswana, The Gambia, Ghana, Kenya, Lesotho, Malawi, Mozambique, Namibia, Sierra Leone, Sudan, Swaziland, Tanzania, Uganda, Zambia and Zimbabwe. See the web site of ARIPO: <http://www.aripo.org/Protocols.html>

<sup>27</sup> **Robert Lewis-Lettington, et al, *A Survey of Policy and Practice on the Use of Access to Medicines-Related TRIPS Flexibilities in Malawi***, DFID Health System Resource Center, UK, 2004,p.34

The decision whether to accept the patent or not ultimately rests with the designated Member State. Silence is understood as acceptance, with each designated state having six months to inform ARIPO that the patent shall have no effect on its territory, according to its own law. Until recently, ARIPO patents, once granted, were subject to the national patent law of each designated state with regard to the patent term, compulsory licenses, or the use of the patent in the public interest<sup>28</sup>.

Following the entry into force of the TRIPS Agreement, the Harare Protocol was revised on 16 November 1999 and the duration of all ARIPO patents was extended to 20 years starting from the date when the application was filed. Since the entry into force of the Harare Protocol, foreign pharmaceutical companies seem to prefer the regional procedure, which is cheaper and easier than applying for patents in each respective country of the region.

From the foregoing discussion it is established that 15 member countries of OAPI have offered a system of pharmaceutical product and process patents since the Bangui Agreement was signed in 1977. Similarly, pharmaceutical patent protection has been available in most of the ARIPO member parties since at least 1984.

It is therefore undoubted that, these three instruments i.e. TRIPS Agreement, OAPI, and ARIPO provide for patent

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<sup>28</sup> Pascale Boulet, *Patent Protection of Medicines in Kenya and Uganda (Report for discussion at the MSF Conference on Improving Access to Essential Drugs)*, 2000,p.1

protection. The question we have to ask ourselves here is whether this international legal regime constitutes a barrier for the access to essential drugs or not? And how to strike a balance between the right to health and patent protection if the two clash?

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An attempt to answer these questions and other issues is the subject of our next topic.

# 3 Right to Health

## 3.1 General

In the context of international human rights, economic, social, and cultural rights are generally distinguished from civil and political rights. However, there is an international consensus that all human rights, civil and political rights on the one hand and economic, social and cultural rights on the other, are of equal status and interdependent.

All human rights are in fact derived from the inherent "dignity and worth" of the individual person. With such recognition as a core value, the international community has long taken the position that, 'All Human rights are Universal, indivisible, and interdependent'<sup>29</sup>. This statement refers to intrinsic linkage among the rights. It recognizes that it is not possible to realize any one right without also promoting and protecting the other rights as well<sup>30</sup>

When it comes to health as a human right, there is an initial problem with regard to its definition<sup>31</sup>. Specifically, there is confusion and disagreement over what is the most appropriate term to use to address health as a human right. Due to this disagreement, various authors use different

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<sup>29</sup> World Conference on human Rights, Vienna Declaration and Programme of Action, Vienna, 1993, para.5

<sup>30</sup> **Audrey R. Chapman**, *The Human Rights Implications of Intellectual property Protection*, Journal of International Economic Law, 2002 p.862

<sup>31</sup> It has been argued that the term "right to health" is awkward because it suggests that people have a right to something that cannot be guaranteed, namely perfect health or to be healthy. It has also been noted that health is a highly subjective matter, varying from person to person and from country to country. It is argued, therefore, that the terms "right to healthcare" or "right to health protection" are more realistic. (**Audrey R. Chapman**)

terms. The terms that most commonly appear in human rights and health law literature are: the "right to health," the "right to healthcare" or to "medical care," and to a lesser extent, the "right to health protection"<sup>32</sup>.

### **3.2 Human Right To Health In International Law**

The right to health as laid down in the preamble to the Constitution of the World Health Organization (WHO) constitutes the point of departure on which most of the provisions of other instruments are based. The international community has recognized the enjoyment of the highest attainable standard of health as a fundamental right since the adoption of the constitution of the World Health Organization<sup>33</sup>

The preamble of the WHO Constitution states that the enjoyment of the "highest attainable standard of health" is one of the fundamental rights of everyone and defines health as a "state of complete physical, mental and social well-being and not merely the absence of disease or infirmity."

The Charter of the United Nations<sup>34</sup> makes no specific reference to a right to health; nonetheless, it does impose by treaty a legal obligation on member states to take action

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<sup>32</sup> **Toebes. B.** *Towards an Improved understanding of the International human Rights to Health*, Human Rights Quarterly 1999, pp661-671

<sup>33</sup> Constitution of the World Health Organization, 14 U.N.T.S. 186, 22 July 1946 (entered into force 7 April 1948), reprinted in Basic Documents of the WHO (32d ed. Geneva, 1981).

<sup>34</sup> United Nations Charter 1945

to achieve universal respect for, and observance, of human right. While UN Charter does not specify the content of human rights norm, it leaves no doubt as to the legally binding nature of member states' obligations to realize human right. by way of the Charter, UN member states have agreed to support and fulfil the purposes of the UN. Reference to human rights in both article 1 and 55 of the Charter establish as legally binding states obligations to fulfil those rights.<sup>35</sup>

Universal Declaration on Human Rights (UDHR) guarantees that all persons should have "the right to a standard of living adequate for the health and well-being of himself and of his family, including . . . medical care"<sup>36</sup> UDHR as a Declaration of the UN General Assembly is not legally binding on states as a treaty.

However, it is now accepted that the UDHR forms part of customary international law-namely those general practices recognized, with substantial uniformity, by states as being required by prevailing international law (*opinion juris*) traditionally, rules of customary international law evolve over substantial periods of time as nations engage in more or less consistent patterns of conduct which reflect their shared perception of the required behaviour in particular circumstances. As a part of customary international law, the UDHR is legally binding upon all states<sup>37</sup>.

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<sup>35</sup> **Canadian HIV/ AIDS Legal Network** ,TRIPS and Right: International Human Rights Law, Access to Medicine and the Interpretation of the WTO Agreement on Trade Related Aspects of Intellectual Property Rights, 2001, p.7

<sup>36</sup> **Article 25(1) of UDHR**

<sup>37</sup> *Ibid*



### 3.3 The Right to Health and Access to Medicines under ICESCR

Article 12 of the ICESCR is an improved version of article 25 of the UHDR, which provides:

*Every one 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*

This article treats health and medical care as a component of the right to an adequate standard of living. Unlike the UHDR, the ICESCR is more specific and recognises health as a separate right to an adequate standard of living.

Reference to the highest attainable standard in article 12 of ICESCR is a positive departure from WHO's definition of health as a state of complete health. The ICESCR conceptualisation of health recognises that a state can at most ensure what is achievable taking into account the state's resources, and the individual's natural and socio-economic conditions.

Under the ICESCR, the definition of the right to health is not confined to health care alone. Rather, it extends to the underlying conditions for health such as food, nutrition, housing, access to safe and potable water and adequate nutrition.<sup>38</sup>

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<sup>38</sup> UN Committee on Economic, Social and Cultural Rights, General Comment 14: the right to the highest attainable standard of health(article12), July 2000, UN Doc.E//C.12/2000/ 4, CESCR at para4

In addition to generally guaranteeing the right to the highest attainable standard of health, article 12(2) of the ICESCR specifically enjoins states to take steps to achieve this right progressively by taking measures that suggest that states have an obligation to provide essential medicines.

### **3.4 The duty to provide Essential Medicine as a core Obligation**

As with all socio- economic rights, the right to health under the ICESCR is subject to progressive realisation and resources availability. This qualification might give rise to an inference that access to medicine is a right that is incapable of immediate claim.

However, the committee on Economic, Social and Cultural Rights (CESCR) has warned against such an interpretation. While acknowledging that the qualifications ' progressive realisation' and ' to the maximum of the available resources 'are necessary flexibility devices given the practical difficulties surrounding the full realisation of economic, social and cultural rights, the CESCR has stated that article 2 (1) establishes clear obligations for states parties to move as expeditiously and effectively as possible towards full realisation of these rights.<sup>39</sup>

States have an obligation to refrain from taking and implementing 'deliberately retrogressive measures' resulting

in the denial of existing rights. Otherwise, such measures would have to be justified fully by reference to all rights recognised in the Covenant in the context of the full use of the maximum available resources.<sup>40</sup>

Significantly, the CESCR has developed the concept of minimum core obligations in order that economic, social and cultural rights are not interpreted as being entirely programmatic or ideals to be attained. The minimum core concept holds that each state party is obliged to satisfy, at the very least, minimum essential levels of each of the rights recognised under the Covenant.

The concept is not intended to cripple under-resourced states. While recognising that resource constraints are legitimate limitations on the realisation of these rights, it requires that priority be given to the satisfaction of basic needs of people.<sup>41</sup>

This balance is struck by requiring states pleading resources constraints as a defence to failure to meet at least the minimum core obligations engendered by economic, social and cultural rights to demonstrate that every effort was made to use all resources that are at their disposal in an effort to satisfy, as a matter of priority, those obligations.

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<sup>39</sup> UN Committee on Economic, Social and Cultural Rights, General Comment 3: the Nature of State Party Obligation,(2 para.1), December 1990, UN Doc.E/1991/23

<sup>40</sup> *ibid*

<sup>41</sup> **Danwood Chirwa**, *The Right to Health in International Law: Its Implications for the Obligations of States and non-state actions in ensuring access to Essential Medicines*, South African Journal of Human Rights vol.19, 2003 p.549

It is notable that the provisions of essential medicines and equitable and non-discriminatory access to medical facilities constitute part of the minimum core obligations engendered by the right to health. According to the CESCR, the following are some of the core obligations on states in respect of the right to health:

- To ensure that right of access to health facilities, goods and services on a non discriminatory basis,
- To provide essential drugs, as defined from time to time under WHO action plan Programme on Essential Drugs; and
- To ensure equitable distribution of all health facilities, goods and services.<sup>42</sup>

In addition, the Maastricht Guidelines on violations of economic, social and Cultural Rights stipulates that a state party violates the minimum essential level of the right to health if a significant number of its people are deprived of essential primary health care<sup>43</sup> as defined by the Alma- Alta Declaration, primary health care includes...prevention and control of locally endemic diseases; appropriate treatment of common disease and provision of essential drugs<sup>44</sup>.

As is the case with minimum core obligations, the state has the onus of justifying that every effort has been made to use all available resources at its disposal to satisfy those obligations as a matter of priority.

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<sup>42</sup> supra note 38 at paras. 43(a),(d)-(d) 44( c)

<sup>43</sup> Maastricht Guideline para 9

<sup>44</sup> Declaration of Alma- Ata on Primary Health Care, International Conference on Primary Health Care,1978

It must be noted, however that the minimum core obligations listed above are non-derogable. The implication of this is that, although states have a margin of discretion with regard to satisfaction of minimum essential level of other aspects of the right to health on the ground of resource constraints, such justification would be unacceptable under any circumstances with regard to non-derogable obligations.<sup>45</sup>

### **3.5 Obligation of states Inherent in the Right to health in relation to Essential drugs**

An analytical framework has been developed by scholars that are used to discern the specific state obligations with respect to economic, social and cultural rights. This so-called tripartite typology of state obligations makes a distinction between obligations to respect, protect, and fulfil each separate human right. Its basic assumption is that all human rights imply state obligations to respect, protect and fulfil. Whereas obligations to respect are in essence negative obligations to refrain from action. Obligation to protect and fulfil are positive obligations to protect individuals against certain acts by third party, or to facilitate a certain services.<sup>46</sup>

#### **3.5.1 Duty to respect**

The duty to respect compels the state to refrain from interfering in the enjoyment of fundamental rights. It also obligates the state to abstain from preventing and impairing

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<sup>45</sup> Supra note 38 at para 47

access to human rights. In the context of health, the duty to respect means that the state should desist from limiting equal access to preventive, curative and palliative health care. Thus, denying access to drugs or other medical products would constitute a violation of this duty.<sup>47</sup> The state will be in violation of the duty to respect if it adopts legislation or policies so that the right to access essential drugs is interfered with.<sup>48</sup> Failure to take into account its legal obligations regarding this right when entering into bilateral or multilateral agreements with other states, international organizations and other entities such as multinational corporations would also amount to a violation of this duty.<sup>49</sup>

### 3.5.2 Duty to protect

The duty to protect summons the state to take positive action to protect citizens from damaging acts that may be perpetrated by private actors. Accordingly, the state has the duty to ensure equal access to health care (including access to essential drugs) provided by third parties. It also has an obligation to ensure that third parties do not limit people's access to information relating to essential drugs. Where the service is privatised the state must ensure that the privatisation does not constitute a threat to the availability, accessibility and quality of health facilities.<sup>50</sup>

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<sup>46</sup>The Right to Health by **Brigit Toebes** in **Asbjorn Eide**, *Economic Social and Cultural Rights*, Martinus Nijhoff Publishers London, 2001 p.179

<sup>47</sup> supra note 41

<sup>48</sup> ibid

<sup>49</sup> ibid

<sup>50</sup> supra note 38 at para 35

The state discharges the duty to protect through the creation and maintenance of an atmosphere or framework by an effective interplay of laws and regulations to enable individuals to freely realise their rights and freedoms.

### **3.5.3 Duty to fulfil**

The duty to fulfil encompasses the duty to facilitate, promote and provide<sup>51</sup>. The duty to fulfil entails an obligation to facilitate the actual realisation of the rights. As part of discharging this duty, the state must give sufficient recognition to the right to health in its domestic legal system. The obligation to fulfil the right to health may be violated if a state does not make sufficient efforts to supply everyone with health services required. For example, a state may be violating the right to health if it structurally fails to offer adequate health services to certain segments of society.<sup>52</sup>

## **3.6 Obligation Under Article 2 of ICESCR**

Article 2 of the ICESCR indicates further that state parties are required to take steps, "individually and through international assistance and co-operation, . . . to the maximum of their available resources, with a view to achieving progressively the full realization of the rights recognized in the present Covenant by all appropriate means, including the adoption of legislative measures." This article articulates two obligations in regard to the rights

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<sup>51</sup> Supra note 38 at para 25

<sup>52</sup> **Supra note 46 at p.181**

included in the ICESCR--the duty to provide (and accept) international assistance and the duty to take steps, including legislative measures, toward the achievement of these rights.<sup>53</sup>

The CESCR has interpreted the "international assistance and co-operation" requirement as imposing an obligation for all states, especially those in the situation to assist others, to the joint realization of economic, social and cultural rights. Under Article 56 of the Charter of the United Nations, Members pledge "to take joint and separate action in co-operation with the [UN]" to find solutions to international economic, social, health and related problems<sup>54</sup>.

Although the exact definition of international obligations is not clear, some commentators have interpreted this as imposing obligations to respect, protect, and fulfil at the international as well as the domestic level. A group of delegates of state parties unanimously adopted a set of principles in Maastricht in 1986 (the Limburg principles). They interpreted the obligation of international co-operation and assistance to include the "establishment of a social and international order in which the rights and freedoms set forth in the Covenant can be fully realized."

Many international law experts have interpreted the obligation to take all appropriate measures to achieve economic, social, and cultural rights broadly. The Maastricht

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<sup>53</sup> Patrick Wojahn, ***A conflict of Rights: Intellectual Property Under TRIPS, the Rights to Health and AIDS Drugs***, UCLA Journal of International Law and Foreign Affairs, 2002.469



delegates determined that this requires state parties to use "legislative, administrative, judicial, economic, social and educational" measures consistent with the nature of the rights in the ICESCR in order to fulfil their obligations. The CESCR has also interpreted this obligation to require steps that are "deliberate, concrete and targeted as clearly as possible towards meeting the obligations recognized in the Covenant."<sup>55</sup>

### **3.7 Justiciability of the Right to Health**

The right to health is a typical economic, social and cultural right. It may therefore be claimed that it is not capable of judicial enforcement. At the United Nations, as well as the regional levels, very few examples exist where courts have reviewed the right to health; however there are some sources of inspiration for judicial review of the right to health.

At the UN level there are no specific complaint procedures in force to make health rights and other economic, social and cultural rights justiciable.<sup>56</sup>

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<sup>54</sup> UN Charter article 55-56

<sup>55</sup> supra note 39

<sup>56</sup> Given this fact, significant steps have been taken to subject the rights recognized in the ICESCR to a complaint procedure. To this effect, the Commission on Human Rights adopted a resolution on 22 April 2003 inviting Special Reporters whose

mandates deal with the realization of socio-economic rights to share views on an optional protocol to the said protocol at its sessions.

At regional level the situation is somewhat more encouraging. For example, the development of complaint procedure for economic, social, and Cultural rights has proceeded somewhat further at the regional levels than at the UN. In principle, the right to health as contained in the African Charter in its article 16 is susceptible to invocation before and review by the African Commission. For example the African Commission found in the case of SERAC<sup>57</sup> a violation of a range of socio-economic rights.

### **3.8 The Human Right to Intellectual Property Law**

Key international human rights instruments have acknowledge that intellectual products have an intrinsic value as an expression of human creativity and dignity, which should be protected as other rights.

Article 27 of the UDHR states that 'everyone has the rights to the protection of moral and material interests resulting from any scientific, literary or artistic production of which he is the author.

Building on article 27 of the UDHR, Article 15(1)(c) of the ICECR requires states parties to recognize the right of the author to benefit from the protection of moral and material interests resulting from any scientific, literary or artistic production of which he is the author. To achieve this goals, the Covenant mandates that states parties to undertake a series of steps. These include those necessary for the

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<sup>57</sup> The Social Economic Rights Actions Center and the Center for Economic and Economic and Social Rights. V. Nigeria Commission 55 of 1996

conservation, development, and diffusion of science and culture<sup>58</sup>.

Nevertheless, intellectual property conceptualized as a universal human right differs in fundamental ways from its treatment as an economic interest under intellectual property law. A human rights approach takes what is often an implicit balance between the rights of inventors and the interest of the wider society within intellectual property paradigms. A human rights approach is predicated on the centrality of protecting and nurturing human dignity and common good. The goal is to improve human welfare and not to maximize economic benefits.<sup>59</sup>

While the language of the Covenant stipulates a right to benefit from the protection of the moral and material interests of authors, artists, investors, or creators, from a human rights perspective the rights of the creator are not absolute. In order for intellectual property to fulfil the conditions necessary to be recognized as a universal human rights, intellectual property regimes and the manner in which they are implemented first and foremost must be consistent with the realization of all other internationally recognised human rights.<sup>60</sup>

Given their linkage in article 15 of the Covenant, a human rights approach must be particularly sensitive to interconnections between intellectual property and the

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<sup>58</sup> Human Rights and Intellectual Property: Statement by the Committee on Economic, Social and Cultural Rights ( general discussion on article 15(1)(c ) 2001

<sup>59</sup> **Supra note 30 at p.60**

<sup>60</sup> Ibid

rights to take part in cultural life and to enjoy the benefits of scientific progress and its applications. To be consistent with the full provisions of article 15, the type and level of protection afforded under any intellectual property regime must therefore facilitate and promote cultural participation and scientific progress and do so in a manner that will broadly benefit members of society both on an individual and collective level.

Noting that actual or potential conflicts exists between the implementation of TRIPS Agreement and the realization of Economic, social and cultural right, the Sub-Commission on the Promotion and Protection of Human Rights adopted a resolution in its August 200 session<sup>61</sup>. The resolution affirms that the right to protection of the moral and materiel interests resulting from any scientific, literary or artistic production of which one is the author is a human right, subject to limitations in the public interest. <sup>62</sup>

### **3.9 The obligation of private actors**

The state centric application of human rights is increasingly being challenged. It has been argued, among other things, that public/private divide constitutes a smokescreen for concealing violations of human rights by non-state actors.

It is common knowledge that, private actors have increasingly claimed part of the role of the state in the

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<sup>61</sup> Intellectual Property Rights and Human Rights, Sub-Commission on the Promotion and Protection of Human Rights, Fity- Second session, agenda item 4, E/CN.12 2000/12

provision of goods and services. Privatisation of health services is an example through which the state has ceded part of its sovereignty. Some private actors such as multinational corporations and international financial institutions also exercise considerable control on state and their policies relating to health. In particular decisions and policies of pharmaceutical corporations, private employers, insurance companies, medical aid societies and other actors have significant bearing on accessibility of drugs.

It must be said in conclusion that there are exceptions to this state- based paradigm. For example, the new International Criminal Court will have jurisdiction to hold individuals criminally responsible for grave human rights crimes, such as genocide and crimes against humanity. The preambles of the two Covenants as well as UDHR explicitly refer to non- state human rights duties. Furthermore, momentum is building up within the international legal community towards the imposition of human rights duties directly upon multinational corporations, given their uniquely powerful, international nature<sup>63</sup>.

It is also possible to imply direct obligation in the preamble to the UDHR, which provides that every individual and every organ of state... Shall strive.... To secure the universal and effective recognition and observance of all human rights.

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<sup>62</sup> Ibid

<sup>63</sup> The draft UN Code of Conduct for translational corporations is an ongoing effort to define the human rights obligations of translational corporations. The UN Draft Code calls on translational corporations to respect and contribute to the realization of human rights including the right to health. For more discussion on the human rights obligation of translational corporations. Available at: [http://www.cetim.ch/en/interventions\\_details\\_print.php?iid=184](http://www.cetim.ch/en/interventions_details_print.php?iid=184)

This statement suggests that private actors have not only the obligation to respect human rights but also the duty to take positive steps to ensure their realisation.<sup>64</sup>

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<sup>64</sup> *Ibid*

# 4 Battle for Access to Essential Drugs

## 4.1 The South African Experience

### 4.1.1 The South African Medicine Act Case

In 1997, the South African government introduced the Medicines and Related Substances Control Amendment Act (the Act). The Act was designed to bring in important measures designed to facilitate access to cheaper drugs.<sup>65</sup> The Act of 1997 was designed to correct some of the distortions of the apartheid years, where private sector health care was very expensive, and the public sector health system charged prices in excess of those in neighbouring countries<sup>66</sup>.

Along with other provisions, there were two measures introduced to encourage reductions in prices. The first - generic substitution - entails prescribing a generic drug once the patent has expired on the brand name drug as long as the generic is cheaper. The second is parallel importation<sup>67</sup>.

The large pharmaceutical companies vigorously opposed these provisions, arguing that parallel importation was a violation of the Patents Act of South Africa, which does not

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<sup>65</sup> Sarah Joseph, *Pharmaceutical Corporations and Access to Drugs: the fourth wave of Corporate Human Rights Scrutiny*, Human Rights Quarterly, 2003 p.442 available at: [http://muse.jhu.edu/journals/human\\_rights\\_quarterly/v025/25.2joseph.pdf](http://muse.jhu.edu/journals/human_rights_quarterly/v025/25.2joseph.pdf)

<sup>66</sup> Don Ross, the 1998-2001 Legal Interaction Between the South African Government and the International Pharmaceutical Industry: a Game- Theoretic Analysis 2002,p.1

<sup>67</sup> for more detail on this topic please refer to pp 63-79

allow for exhaustion of rights once a product is sold for the first time.

Instead of amending the Patents Act, the government responded by introducing Section 15C to the Medicines Act. This section was designed to override the exhaustion of rights problem by giving the Minister of Health new over-riding administrative discretion. The text of 15C reads as follows:

*The Minister may prescribe conditions for the supply of more affordable medicines in certain circumstances so as to protect the health of the public, and in particular may-*

*(c ) Prescribe the registration procedure for, as well as the use of, the medicine referred to in paragraph (b)*

In other words, section 15 (c ) of The Act purports to confer on the Minister the powers to prescribe conditions which would render lawful the supply, import and the registration and use of certain medicine, even contrary to the Patent Act, 1978.

Section 15(c ) covers parallel of importation of genuine patented goods. In essence section 15 (c ) is a measure intended, inter alia, to allow the Minister of Health to regulate patented medicines in the public and private sectors, and allow any purchaser to buy the patented medicines where they are sold at prices lower than those offered by the manufacturer



or its licensee in South Africa, under certain circumstances and only to protect public health<sup>68</sup>.

At the time of passing the Act in South Africa, more than 4 million adults and children were living with HIV/AIDS. This was the largest population of people living with HIV/AIDS in any country in the world, with a countrywide adult infection rate of 19.4 percent. South Africans die from HIV/AIDS at a rate of approximately 250,000 per year.<sup>69</sup>

The known effective versions of HIV/AIDS drugs were protected at that time by patent and were far more expensive than the South African health system could afford.

At this same time, generic equivalents of patented drugs were being manufactured in countries such as Thailand, India, and Brazil, and could have been available in South Africa at markedly reduced prices, except for the pressures applied by the pharmaceutical manufacturers to defend their patents and by many governments, including the United States at that time, who were determined to protect intellectual property rights in international trade.<sup>70</sup>

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<sup>68</sup> **Buchaner Sarah**, The South African Government/ Pharmaceutical Companies Case: Background and Issues, Tralac, 2002, p.7. Available at: [www.tralac.org/scripts/content.php](http://www.tralac.org/scripts/content.php)

<sup>69</sup> **David Barnard**, ***In the High Court of South Africa, Case No. 4138/98: The Global Politics of Access to Low-Cost AIDS Drugs in Poor Countries***, Kennedy Institute of Ethics Journal, 2002, p.160

<sup>70</sup> Ibid

## 4.1.2 Reactions

### 4.1.2.1 Pharmaceutical Industry

Not surprisingly, it is the clause "The Minister may prescribe..." as well as section 15C (a) that particularly upset the major pharmaceutical industries. It argued that this section could be used to justify and sanction both parallel importation and compulsory licensing of certain medicines.

1. On February 18, 1998, the pharmaceutical company lawsuit by forty-two applicants against the Government of South Africa was filed. (The number of applicants would decrease to thirty-nine by the time the case reached court, Pfizer being the most notable of the companies to withdraw.) According to the Pharmaceutical Industry Notice of Motion, Section 10 of the Amendment Act<sup>71</sup>, introducing Section 15C of the Medicines Act, was unconstitutional.<sup>72</sup>

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<sup>71</sup> **Supra note 66 at p.6**

<sup>72</sup> the pharmaceutical industry challenged the constitutionality of the Act on one or more of the following grounds:

(1)It allows the Minister of Health to prescribe the conditions for the supply of more affordable medicines. It does not set out any guidelines, which would limit the power of the Minister in this regard.(2)It allows the Minister to decide on the extent to which rights under a patent shall apply, irrespective of the provisions in the Patents Act.(3)It allows the minister to deprive patent owners of their property without any provisions for compensation.

It only discriminates against patent owners in the pharmaceutical field. This is in conflict with TRIPS, which has been given effect in South Africa by the passing of the Intellectual Property Laws Amendment Act of 1997.

#### 4.1.2.2 USA

The United States Government put public lobbying pressure on the South African Government. Highlights of this pressure include the placing of South Africa on the United States Trade Representative's Special 301<sup>73</sup> Watch List (mainly because of the Medicines Act) in May 1998 (Department of Health, 2001a). An example of the level of feeling against Section 15C is evident in a US Department of State report<sup>74</sup>

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<sup>73</sup> Special 301 provisions of the Trade Act 1974 require the USTR to identify foreign countries that deny adequate and effective protection of intellectual property rights or fair and equitable market access for US. Special 301 was amended in the Uruguay Round Agreement to clarify that a country can be found to deny adequate and effective intellectual property protection even if it is in compliance with its obligations under the TRIPS Agreement.

<sup>74</sup> According to the report "All relevant agencies of the U.S. Government, the Department of State together with the Department of Commerce, its U.S. Patent and Trademark Office (USPTO), the Office of the United States Trade Representative (USTR), the National Security Council (NSC) and the Office of the Vice President (OVP) – have been engaged in an assiduous, concerted campaign to persuade the Government of South Africa (SAG) to withdraw or modify the provisions of Article 15 (c) that we believe are inconsistent with South Africa's obligations and commitments under the WTO Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS)

Since the passage of the offending amendments in December 1997, U.S. Government agencies have been engaged in a full court press with South African officials from the Departments of Trade and Industry, Foreign Affairs, and Health, to convince the South African Government to withdraw or amend the offending provisions of the law, or at the very least, to ensure that the law is implemented in a manner fully consistent with South Africa's TRIPS obligations"

### 4.1.3 Dropping the Case

In any event, the legal issues underlying the lawsuit were never tested. From the time the PMA lawsuit was filed a global coalition was formed in support of the South African government's position and buried the pharmaceutical industry under a relentless avalanche of negative publicity. It is important to emphasize here that the Pharmaceutical Industry unconditionally dropped the lawsuit not because of a sudden change of heart or altruistic feelings towards the poor South Africans suffering from AIDS. Rather, it was the result of a sustained campaign by a number of health activists and groups.<sup>75</sup>

### 4.1.4 Assessment of the Case

The action of the pharmaceutical Industry were motivated by altogether different intention, the stakes were much higher for them than the market for AIDS drugs in South Africa, which is just 1% of the global drug sale. They were apprehensive that if the South African Law was allowed to stand, other countries may be encouraged to enact similar legislation.

In particular, the Pharmaceutical Industry was worried about the adverse impact in the US markets where they earn the bulk of their profit. They feared that if the poor and developing countries were allowed to buy low- priced drugs, American consumers might similarly demand lower prices.<sup>76</sup>

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<sup>75</sup> Kavaljit Singh, *Patents vs. patients: AIDS, TNCs and drug price wars.* available at: [www.twinside.org.sg/twr131c.htm](http://www.twinside.org.sg/twr131c.htm).

<sup>76</sup> *Ibid*

The pharmaceutical industry opposed the Act tooth and nail on the ground that it violets the TRIPS Agreement. But this position is erroneous because there are provisions within the TRIPS Agreement, which allow governments to take special measures to protect the health of their citizens.

The TRIPS Agreement makes it clear that invocations of this doctrine of first sale was legal and cannot be challenged under the TWO dispute settlement mechanism as long as there is no discrimination on the grounds of nationality of the patent holder<sup>77</sup>.

Once a patent is granted, article 30 of the TRIPS Agreement states that member states may make limited exceptions to the exclusive rights conferred by a patent. Furthermore, article 31 of TRIPS Agreement deals directly with the issue of using patents without the authorization of the rights holder and such usage includes compulsory licensing. Compulsory licensing is part of the TRIPS Agreement's overall attempt to strike a balance between promoting access to existing drugs and promoting research and development into new drugs<sup>78</sup>.

Moreover, article 31 specifies procedures by which a WTO member country may seek permission from a patent holder for permission to manufacture generic versions of a

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<sup>77</sup> Article 6 of the TRIPS Agreement explicitly states that nothing in the agreement should be taken to apply to the issue

<sup>78</sup> WTO's TRIPS and Pharmaceutical Patents: Fact Sheet, 2001

protected product, a procedure that may be waived "in the case of a national emergency or other circumstances of extreme urgency." TRIPS Agreement is thus relatively permissive about unauthorized use of patents, especially in the case of HIV/AIDS, which is widely recognized as constituting a national emergency in South Africa.

Article 15(c) of The Act besides being in accordance with TRIPS Agreement, is justified in relation to the fundamental human rights of people with HIV/AIDS that are protected and are required to be promoted by the Bills of Rights, namely the rights to dignity, equality, life, the right of access to health care services and the duty on the government to comply with international obligations. The priori justification for the measures in the Act is that it is an attempt to respect, promote and fulfill these rights.

As a result of public pressure in South Africa and elsewhere<sup>79</sup>, pharmaceutical industry took initiatives aimed at providing greater access to the medicine by reducing the prices, this offer while welcome and consonant with what is ethically and morally required to relieve suffering, can be withdrawn as easily as they are made.

It is important to note here that, the offers do not do away with the need for national legislation that aims to ensure citizens sustainable access to essential drugs, regardless of

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<sup>79</sup> The public relations efforts of NGOs such as Medecins sans frontiers (MSF), Consumer Protect on Technology, Oxfam, Third World Network, and Treatment Action Campaign have been a decisive factor campaign against pharmaceutical industry and in moving forward the interests of the developing countries in for a such as the TWO and WHO.

their income. This is particularly important with anti retroviral medicines for HIV/AIDS.

# 5 Patent Law and Access to Drugs

## 5.1 The need for Strong Patent Protection

The purpose of patents, as we have noted, is to provide a temporary monopoly<sup>80</sup> to rights holders as a means of encouraging inventors to put their inventions into practice<sup>81</sup>. A patentee receives exclusive rights over his or her creation for a limited period of time in exchange for a complete, public disclosure of the knowledge upon which the invention is based<sup>82</sup>.

Not only may the public use this knowledge upon the patent term's expiration, but also the knowledge may serve (even during the patent term itself) as the foundation for further advancement of science and technology in a variety of fields. In addition to this general dissemination, the monopoly that is granted serves to encourage the patentee to license the discovery so that the invention can be commercialized, technology can be transferred, and other products can be developed for the benefit of society.

Each of these dimensions are reflected in Article 7 of the TRIPS Agreement, which notes that the protection of

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<sup>80</sup> While almost every one refers to a patent as a monopoly, some commentators question why patents are not understood in the same way as any other exclusive rights in property. As all private property rights give rise to exclusion, it is there believed that monopoly rights is common to all such rights( **Roger E. Meiners et al.**, *Patents, copyrights, and Trademarks: Property or Monopoly?* Harvard Journal Law and Public Policy,1990,p.915

<sup>81</sup> **Berger JM**, Tripping Over Patents: AIDS, Access to Treatment and the Manufacturing of Scarcity, Conn. J. INT.Law,2002pp157-248

<sup>82</sup> This is based on essential quid pro quo theory that is the grant of the patent rights exclusivity must be to the benefit of the society.



intellectual property rights will promote both technological innovation and the transfer and dissemination of technology "to the mutual advantage of producers and users in a manner conducive to social and economic welfare"<sup>83</sup>.

However, a number of new medicines that are vital for the survival of millions are already not accessible to the vast majority of people in poor countries. In addition, investment in research and development ("R&D") towards the health needs of people in developing countries is not encouraging.

Given that in developing countries most people are poor and that patent protection may hypothetically, be a barrier to get access to essential drugs, it is necessary to examine the nexus between diminished access to essential drugs and patent protection.

## **5.2 Pharmaceutical patents as an incentive for Research and Development**

### **5.2.1 The Pharmaceutical Industry's Arguments**

The pharmaceutical industry, relative to other industrial sectors, is very heavily dependent on intellectual property protection<sup>84</sup> – especially patent protection – in order to

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<sup>83</sup> Wesley A. Cann, JR, *On the Relationship Between Intellectual Property Rights and the Need of Less Developed Countries for Access to Pharmaceuticals: Creating a Legal Duty to Supply Under a Theory of Progressive Constitutionalism*, University of Pennsylvania Journal of International Economic Law, 2004, p. 761

<sup>84</sup> International Federation of Pharmaceutical Manufactures Association, *TRIPS, Pharmaceuticals and Developing Countries: Implications for Health Care Access, Drug Quality and Drug Development*, IFPMA Geneva, 2000 p.2

develop and introduce new pharmaceutical products. Drugs and vaccines are expensive to develop; but they are often very cheap to copy, intellectual property protection is a necessary incentive for the discovery and development of new medicines. <sup>85</sup>.

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<sup>85</sup> **Harvey E. Bale**, *Access to Essential Drugs in Poor Countries -- Key Issues The Industry Perspective* Workshop on Differential Pricing and Financing of Essential Drugs, World Health Organization and World Trade Organization 11 April 2001 available at [http://www.who.int/medicines/library/edm\\_general/who-wto-hosbjor/02Bale\\_e.doc](http://www.who.int/medicines/library/edm_general/who-wto-hosbjor/02Bale_e.doc)

A number of studies have shown that patents are significantly more important to pharmaceutical firms in appropriating the benefits from innovation compared with other high tech industries. The reasons for this is because the costs of drug innovation are very high while the cost of imitation are relatively low. Hence the industry is subject to significant free-rider problems.

Based on surveys made by the British economists, Taylor and Silberston, they estimate that pharmaceutical R&D expenditures would be reduced by 64% in the absence of patent protection. By contrast, the corresponding reduction was only 8% across all other industries<sup>86</sup>.

The explanation for why patents are more important to Pharmaceutical firms in appropriating the benefit from innovation follows directly from the characteristics of the pharmaceutical R&D process. In essence, it takes several hundred million dollars to discover, develop and gain regulatory approval for a new medicine

Accordingly, the pharmaceutical industry concludes that intellectual property protection must be granted for those research efforts that ultimately prove successful. Such protection diminishes some of the risks associated with R&D and thereby encourages private investment in innovative activities. Without potential reward, incentives for investing private capital would be substantially lacking.

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<sup>86</sup> C.T. Taylor and Z. A. Silberstein, *The Economy Impact of the Patent System*, Cambridge University Press, UK 1997 . See also Henry Grabowski, *Patent, Innovation and Access to New Pharmaceutical*, Journal of Economic Law, Oxford University Press,2002, p.850

Pharmaceutical Research and Manufacturing of America (PhRMA) maintains that without intellectual property protection, there would be no research-based pharmaceutical industry, no generic pharmaceutical industry (since there would be no new drugs to copy), and a greatly diminished flow of life-saving medicines.

Additionally, any reduction in protection would first be felt by those with diseases that affects smaller numbers of individuals or those with diseases that primarily affects the poor.<sup>87</sup>

## **5.2.2 Arguments against pharmaceutical stance**

### **5.2.2.1 Exaggeration in the cost and role of pharmaceutical Industry in Research and development of Drugs**

It is conceded that most essential drugs, to some extent owe their existence to exclusive rights in patents. Notwithstanding the potential abuse, without strong patent protection in certain key industrialised nations and in the absence of any other system of rewards or incentives, these medicines may very well never have been developed or marketed.<sup>88</sup> So patents have an indispensable role in the development and commercialisation of essential drugs.

However, it is argue that, the development of new drugs is often claimed as a distinct contribution by the private pharmaceutical industry, in many cases the discovery of

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<sup>87</sup> *supra* note 81 at p.95

<sup>88</sup> Edwin Cameron, *Patents and Public Health: Principle, Politics and Paradox*, Inaugural British Academy Law Lecture, London, 2004  
Unpublished, at p.5 available at: <http://www.law.ed.ac.uk/ahrb/script-ed/docs/cameron.asp>

important new drugs is made by public institutions<sup>89</sup>, which later licence their development and exploitation to private firms. Some 70% of drugs with therapeutic gain were produced with government involvement<sup>90</sup>.

In addition to direct involvement in the R&D many developed countries grant tax and other incentives for R&D, including or particularly in pharmaceuticals. Subsidies for R&D are available in many OECD countries, and are permissible, under certain conditions, under the WTO agreements.

According to one study, pharmaceutical companies received \$106.9 million between 1989-1993 in tax credit<sup>91</sup> and it seems possible, concluded one scholar *-pending a more systematic work on this subject-* that the public sector makes a significant contribution to pharmaceutical research, including the discovery and/or development of many important drugs.

The public sector's role is not substantially dependent on the availability of intellectual property protection<sup>92</sup>. In sum, a significant part of pharmaceutical R&D is not directly dependent on the availability of intellectual property law protection, since invention undertaken by public laboratories would take place in any case.

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<sup>89</sup> Marcia Angell, *The Pharmaceutical Industry to whom its Accountable?* New England Journal of Medicine, 2000. Available at:

<http://www.conent.nejm.org/cgi/content/short/342/25/> . See also supra note 65 p.4

<sup>90</sup> UNDP, Human Development Report, Oxford University Press, 1999,p69

<sup>91</sup> Callos M.Correa, *Some Assumptions on Patent Law and Pharmaceutical R&D*, Quaker United Nations Office, Geneva 2001 p. 2

<sup>92</sup> Ibid

### **5.2.2.2 strong Patent Protection and research incentive for Neglected Diseases(Tropical Diseases)**

The Pharmaceutical industry and many proponents of the TRIPS Agreement argue that a key benefit for developing countries in Intellectual Property Protection is that, it will improve the conditions necessary to attract Foreign Direct Investment (FDI) and technology transfer, inputs necessary to help develop local R&D capacity.

It is however, contended that, relatively little public or privately supported R&D investment is currently directed to diseases specific to developing countries such as malaria and tuberculosis. This lack of strong interest is illustrated by the fact that only 13 of the 12,000 new drugs introduced globally between 1975 and 1997 were specifically directed to tropical disease.<sup>93</sup> The basic problem, from a return on the investment perspective, is the low income and low expected potential sales in developing countries markets.

In other words, Pharmaceutical research by the private sector is driven by commercial considerations and if the effective demand in terms of market size is small, even for the most common diseases such as TB and malaria, it is often not commercially worthwhile to devote significant resources to addressing the needs.

So what role does intellectual property protection play in stimulating R&D on diseases prevalent in developing countries? All the evidences-argue human rights activists-suggest that it hardly plays any role at all, except for those

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<sup>93</sup> Bernard Pecoul, et al., *Access to Essential Drugs in Developing Countries: A lost Battle*, Journal of the American Medical Association 1999 pp 361-367

diseases where there is a large market in the developed world (for example, diabetes or heart disease).

Therefore, it is concluded that presence or absence of IP protection in developing countries is of, at best, secondary importance in generating incentives for research directed to diseases prevalent in developing countries<sup>94</sup>.

The pharmaceutical industry may not be expected, in reality, to allocate substantial resources in areas where the profitability that may be obtained is low, even if strong patents are granted. There is no visible increase in R&D for diseases such as malaria, chagas, and leprosy, despite the fact that most developing countries already grant product patents for pharmaceutical, or such countries will be bound to do so in 2005 and 2016.

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<sup>94</sup> supra note 1

## 5.3 Drug prices and Patent Protection

The price of medicines is a critical issue in rich countries as well as in poor countries. In Britain and the United States, the budget implications of escalating drug prices are a matter of mounting political concern. But it is the poorest countries, where budget resources are more limited, and where household poverty is most widespread, that face the gravest threat from rising drug prices<sup>95</sup>.

### 5.3.1 Pharmaceutical Industry's stance

Pharmaceutical industry is of the view that, the linkage between price of drugs and patents protection is rather weak." Improving intellectual property protection does not cause prices of existing branded or licensed pharmaceutical product to increase".<sup>96</sup> The International Federation of Pharmaceutical Industry (IFPMA) argues that, patent protection and the high price of patented pharmaceuticals do not determine the extent of access to medicines in developing countries, and in particular in relationship to the HIV/AIDS pandemic.

The logic of this argument is that lowering the price of pharmaceuticals by decreasing the level of patent protection or encouraging the use of safeguard measures would not standing alone establish improved healthcare treatment, or even materially improve the level of treatment.

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<sup>95</sup> Oxfam, *Patent Injustice how world Trade Rules threatens the Health of the Poor*, Oxfam, London, 2001, p4

<sup>96</sup> Rozek and Berkowitz, *The Effect of Patent protection on the Prices of Pharmaceutical Products*, The Journal of World Intellectual Property, March, 1998, pp.179-243



There are import taxes, tariffs, customs and value added taxes (vat) that vary from country to country, and are applied to both patented and copy drugs. For instance, in Malawi there is a 15% duty plus 20 % surtax on the drugs. In the Congo, there is a 30 percent duty plus 15 % turnover tax. In South Africa pharmacists apply a vat of 15 % before releasing a prescription to a customer. It is concluded that all of these duties, tariffs, and customs charges distributors mark up, and vat increase drug prices well beyond their advertised prices<sup>97</sup>.

### **5.3.2 Counter Argument Against the Pharmaceutical View Point**

It is argued that pharmaceutical patents by design and function increase the price of medicine to consumers<sup>98</sup>. To begin with, if we are considering a life saving or essential pharmaceutical, it is logical to assume that any person who could afford to pay the price for the drug, and who needed it, would buy it.

The desirability of the product is so great to the consumer who needs it that consumers with unlimited resources are likely to be very insensitive to price. There is no price above which someone with unlimited resources, who would otherwise die, will refuse to buy the drug. However, for those with limited resources, the ability to enter the market is strictly determined by price. As the price of the life-saving

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<sup>97</sup> **Corol C. Adelman, *Myths and Realities on Prices of AIDS Drugs, IFPMA*, 2004,p.3.** Available at:

[http://www.ifpma.org/documents/NR2216/Hudson\\_WhitePaper.pdf](http://www.ifpma.org/documents/NR2216/Hudson_WhitePaper.pdf)

<sup>98</sup> **Patrick L. Wojahn, *A Conflict of Rights: Intellectual Property Under TRIPS, The Right to Health, and Aids Drugs*, Journal of International Law and Foreign Affairs, 2002,pp.476**

pharmaceutical decreases, all potential consumers with adequate resources will purchase it, or otherwise die.

Moreover, Patents enable pharmaceutical manufactures to sustain prices higher than their marginal costs of production by discouraging the emergence of competitors. In other words, a patent on a pharmaceutical product prevents a competing producer from entering the market with an identical product. The price, which the producer is able to charge for the drug, does not depend on its marginal cost of production because the producer does not face potential competitors for the same product.

The holder of a patent on a unique life-saving drug is in a position to charge a high price without fear that competitive products will enter the market, although it still must account for the ability of consumers to pay, and for potential government intervention. These factors explain why, until quite recently at least, pharmaceutical companies charged very high prices in poor developing country markets for patented life-saving drugs that could be afforded only by a small segment of the population<sup>99</sup>

There are few products on the world market that are useful without some form of infrastructure, but that does not mean that lowering the price of those products does not make them more accessible to a greater number of consumers.

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<sup>99</sup> Fredrick M. Abbott, *The TRIPS Agreement, Access to Medicines and the WTO Doha ministerial Conference*, QuakeUnitedNationsOffice (QUNO)Genevaat40.availableat:<http://www.geneva.quno.info/waysOfWorking.php?pageid=lin1>

There are, in fact, very few products for which price matters more than life-saving drugs, because price is the major obstacle to most potential consumers who otherwise have an intense demand for the product.<sup>100</sup>

In fact, the presence or absence of generic substitutes can also have a profound impact on the cost of drugs. In a study of drug prices for ten essential AIDS drugs in eight countries, Perez-Casas of Medecins Sans Frontieres (MSF)<sup>101</sup> found that the price of AIDS drugs was 82% less than the US price in the developing countries with access to generic copies of on-patent drugs.

According to Perez-Casas, "The presence or absence of generic competition in the market is a key determinant of pricing levels." Another study prepared by MSF in Fall 2001 provides an example of steep price reductions on the combination AIDS therapy d4T+3TC+nevirapine following introduction of low priced generic versions on the world market.<sup>102</sup> Health groups have argued that it is generic competition, not voluntary drug company price reductions, that have lead to steep and sustained price reductions on AIDS therapies in Africa<sup>103</sup>.

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<sup>100</sup> Ibid

<sup>101</sup> Perez-Casas, C., et al, *HIV/AIDS Medicines Pricing Report. Setting Objectives: is there a Political Will?*, Medecins Sans Frontieres, 2000

<sup>102</sup> Perez-Casas, C, et al, "*Accessing ARVs: Untangling the Web of Price Reductions for Developing Countries.*" Campaign for Access to Essential Medicines, Medecins Sans Frontieres, October 5, 2001

<sup>103</sup> Nearly all of the patented, brand-name essential medicines (except Cipro and Lariam) are deeply discounted in developing countries, so that the original products and their generic counterparts are often priced similarly-there is no rule that one be cheaper than the other. Price data gathered by MSF in late 2003 show that some brand-name products can cost more than generics (for example, nevirapine made by Boehringer Ingelheim and by Hetero), while others can cost less (for example, ritonavir made by Abbott and by Cipla). 25 These discounts

## 5.4 Prevalence of Patenting Essential Drugs in Sub Saharan Africa

### 5.4.1 Pharmaceutical Industry View Point

Pharmaceutical industry argues that, although patent protection for pharmaceutical products is available in most developing and least developed countries, multinational companies have not patented their products in all of them. This is normally the case for countries with small markets and limited technological capacity<sup>104</sup>.

A study made by Amir Attaran in 2001 in 53 African countries found that the extent of patenting of 15 important antiretroviral drugs was 21.6% of the possible total.<sup>105</sup> In 13 countries there were no patents on these medicines at all. The conclusion was drawn that, because the patenting rate was so small, patents “generally do not appear to be a substantial barrier to treatment in Africa today<sup>106</sup>”.According

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have ended the order-of-magnitude price differences that formerly made generic treatment imperative, but, unfortunately, they have not cooled overwrought debate (Amir Attaran, infra note....)

<sup>104</sup>The vast majority of sub-Saharan African Countries belong to one of the two regional patent systems that are serviced by the two regional offices for Africa: ARIPO for English speaking countries and OAPI for French speaking countries. All OAPI states are members of the two as well are all ARIPO states

<sup>105</sup> Attaran Amir, & Gillespie-White, L. “*Do Patents for Antiretroviral Drugs Constrain Access to AIDS Treatment In Africa*”, *JAMA*, vol. 286:15., 2001 available at: <http://jama.ama-assn.org/issues/v286n15/full/jsc10222.html>

<sup>106</sup>Five health advocacy groups, including the Consumer Project on Technology, Essential Action, Oxfam, Treatment Access Campaign, and Health Gap, responded to the Attaran article with a statement claiming that several combinations of AIDS treatments were not adequately included in the published survey. The joint health group statement also emphasizes the special circumstance of patents in South Africa, and the role of that country in the region. The joint statement of this group was that “In South Africa every three drug ARV cocktail is blocked by patents...The South Africa market is important for several reasons. First, there are 4 to 5 million HIV+ persons in South Africa. Second, the

to UNAIDS' analysis, most proprietary drugs used in the treatment of HIV/AIDS are not protected by patents in the majority of developing countries.<sup>107</sup>

Dr Amir Attaran in his latest study published in 2004<sup>108</sup> is of the view that, the 319 products on the WHO's list of essential drugs are rarely under patent in low- and middle income developing countries, according to the study regarding the actual level of patenting of essential medicine in 65 countries in Asia, Africa, and Latin America, covering a population of over 4 billion people.

According to his analysis the overall patent incidence for essential drugs in his sample of countries is only 1.4% and patents are especially infrequent in the poorest or smallest countries. Thus, as he notes "patents cannot cause essential medicines to be inaccessible in many developing countries because they do not exist 98.6 percent of the time".<sup>109</sup>

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South Africa economy has more than 40 percent of the GDP for sub-Saharan Africa, a per capita income of more than \$3 thousand and a relatively good health care infrastructure, making ARV treatment feasible, if drug prices are low enough. Third, entry into the South Africa market is necessary for generic suppliers to reach the economies of scale (volume) needed for the most efficient production, particularly for those products with post 1996 patents that are patented in Brazil, such as efavirenz or nelfinavir, and currently lack a significant generic market outside of Africa". (MSF, ***Patent Do Matter in Africa According to NGOs***, Joint Statement by Oxfam, Treatment Action campaign, Consumer Project on Technology, Medicins Sans Frontieres and Health Gap, 2001. available at: [www.accessmed.msf.org/campaign/faq.shtml](http://www.accessmed.msf.org/campaign/faq.shtml)).

<sup>107</sup> UNAIDS, Patent situation of HIV/AIDS- related Drugs in 80 countries, UNAIDS; Geveva, 2000. available at:

<http://www.who.int/medicines/library/par/hivrelateddocs/patentsshivdrugs.pdf#search=patent%20situation%20of%20essential%20drugs>

<sup>108</sup> Attaran Amir, ***How Do Patents And Economic Policies Affect Access To Essential Medicines In Developing***, Health Affairs. 2004, issue No 23 pp, 155-

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<sup>109</sup> Ibid

The pharmaceutical industry concurred the finding of Dr Attaran and further argues that, even where there is no patent protection, the drugs are still not available.<sup>110</sup> For instance, India is given as good example where an absence of product patents and a flourishing generics industry has failed to secure broad based access to many drugs by the Indian population.<sup>111</sup>

#### **5.4.2 A Challenge to the Pharmaceutical Industry's Stance**

The critics counter argue that, although multinational companies have not patented their products in most African countries, it does not follow that the patent system has no adverse effects. Even if patents do not exist for particular products and in particular countries, the patent system may still have an effect on access to essential medicines. Most low-income developing countries have to rely on imports for their supplies. The existence of patents in potential supplier countries may allow the patentee to prevent supplies being exported to another country, particularly through controls on distribution channels.<sup>112</sup>

More over, the argument forwarded by the pharmaceutical industry suggests that because potentially patentable medicines have not always been patented in certain African countries, demonstrates that patenting is not a significant

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<sup>110</sup> **Pharmaceutical Research and Manufacturers of America** *Health Care in the Developing World*, PhRMA, Washington DC. Source: <http://world.phrma.org/ip.access.aids.drugs.html>

<sup>111</sup> **International Pharmaceutical Federation Manufacture associations**, TRIPS; Pharmaceuticals and Developing Countries.....p15

<sup>112</sup> supra note 1

obstacle to access.<sup>113</sup> Yet inventing enterprises have always patented selectively, strategically targeting those countries with the greatest sales potential, and those countries where they are most likely to confront competitive production capacity and other commercial threats.

The patenting pattern in Africa represents strategic planning that was deemed appropriate by Pharmaceutical industry in its specific time-frame, emphasizing South Africa as the principal potential source of competitive production, and countries such as Kenya, Nigeria and Zimbabwe as markets with comparatively high income.<sup>114</sup>

Furthermore, Following the full implementation of the TRIPS Agreement as of January 1<sup>st</sup> 2005 in developing countries not yet granting pharmaceutical patents, access to affordable new drugs is expected to become more difficult. For example, most of the essential drugs currently available

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<sup>113</sup> International Intellectual Property Institute (IPI) argues that Infrastructure and financial resources are the most pressing issues with regard to AIDS drugs in Africa. The IPI paper suggest that patents need not be a major problem in drug access in Africa because TRIPS Agreement permits flexibility to expand access using such as compulsory licensing and parallel importing. (**International Intellectual Property Institute, *Patent Protection and Access to HIV/AIDS Pharmaceuticals in Sub-Saharan Africa***, International Intellectual Property Institute, 2000.)

Treatment Action Campaign in South Africa (TAC) has responded to the IPI paper by arguing that some of the essential drugs are not available in the public sector medical system largely because of cost, which is closely related to strong. Responding to IPI's claim that TRIPS allows countries flexibility to maximize drug access, TAC has argued that, the scope of TRIPS is sufficiently complex to allow pharmaceutical companies to pursue time-consuming costly legal action with the goal of delaying implementation of alternatives.

<sup>114</sup> **Frederick M. Abbott, *WTO TRIPS Agreement and Its Implications for Access to Medicines in Developing Countries***, Unpublished, Commission on Intellectual Property Rights, 2002,p.8. Available: [http://www.iprcommission.org/papers/word/study\\_papers/sp2a\\_abbott\\_study.doc](http://www.iprcommission.org/papers/word/study_papers/sp2a_abbott_study.doc).

at affordable prices come from India<sup>115</sup>. Successful health programmes such as those of Brazil and Thailand were possible because key pharmaceuticals were not patent-protected and could be produced locally at much lower costs<sup>116</sup>.

In major supplying countries the status of drugs discovered between 1995 and 2000, which are being held in India's mail box pending review of their patentability after 1 January 2005. drugs potentially affected by this retroactive review include newer ARVs for HIV drugs. Similarly, as of 1 January 2005, India will be required to grant patent protections for the newest pharmaceutical innovations. The patent status of active pharmaceutical ingredients (API) and their legitimate export, is also of concern currently, other producing countries such as Brazil, Thailand and South Africa rely on (API) import from India and china<sup>117</sup>.

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<sup>115</sup> As the Indian Parliament granted final approval Wednesday, March 25, 2005 to drug patent protections, supporters hailed them as a step toward greater innovation, while critics warned it would end cheap medicine for the poor. The law amended the Patent Act of 1970, which allowed Indian companies to make cheap copies of other companies' drugs by using a different process. Under the new law, local manufacturers would be required to pay a "reasonable royalty" to the patent holder. S. Ramkrishna, chief lobbyist for Pfizer India, a subsidiary of the world's largest drug maker, which fought vigorously for patent legislation, said the bill's passage abandoned "the utopian concept that every invention should be as free as air or water." "That assumes every invention is as easy to make as air or water," he said. (**Anand Giridharadas**, *End of Era for Indian Generics*, International Herald Tribune, Thursday, March 24, 2005)

<sup>116</sup> **Ellen Hoen**, *TRIPS, R&D and Access to Medicines: a Guide to Post 2005 world*, a presentation to the members of the European Parliament in January 18<sup>th</sup> 2005. Available at: <http://www.accessmedmsf.org/documents/guide/20to/20TRIPS./20R&D/20and/20Access/20to/20Medicines/20Feb/2024/202005/20FINAL.doc>. see also Medecins sans frontieres, The Effect of the 2005 TRIPS implementation deadline on access to medicine, MSF, 2005. Available at: <http://www.accessmedmsf.org/documents/technical/202005/20briefing/20Feb/2024/20FINAL.doc>

<sup>117</sup> It is however, argue that, although access to essential medicines will worsen after 2005, theoretically correct, in reality this hypothesis is undermined by a key



It is clear from the above discussions that a pharmaceutical patent has raised some fundamental questions with regards to access to essential drugs in Sub-Saharan Africa. These fundamental question need to be addressed.

But before addressing that, it is pertinent to pay a visit to Doha Declaration and the flexibilities provided under TRIPS Agreement. As I have said earlier that rigid application of the rights conferred on the patent holder for a period of 20 years will, in many cases, frustrate the objectives and principles of TRIPS Agreement.

Our next topic is dedicated to these mechanisms.

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observation: Many countries, including twenty-eight of the thirty least-developed African countries, adopted pharmaceutical patent laws years or decades ahead of being required to by TRIPS Agreement meaning that the feared watersheds at 2005 and 2016 have already occurred to a large extent. Despite this, patents for essential medicines remain infrequent, both because pharmaceutical companies chose to patent their inventions in few developing countries.

# 6 TRIPS Agreement and Public Health

## 6.1 Doha Declaration

The WTO Council for TRIPS held sessions in June and September 2001 specifically devoted to issues concerning access to medicines. Recognizing the gravity of the public health problems afflicting many developing countries, WTO members at the Doha Ministerial Conference attempted to integrate the TRIPS Agreement into part of the international action to address public health problems.

Following extensive negotiations based on a compromise text prepared by the WTO Secretariat, Ministers in Doha Conference adopted a Declaration on the TRIPS Agreement and Public Health.<sup>118</sup> Although there were some conflicting views regarding the conditions under which the flexibility of the TRIPS Agreement could be used, the Doha Declaration helped to prevent situations where developing country Members could not avail themselves fully to the flexibility provided in the TRIPS Agreement due to pressure from interested groups.<sup>119</sup>

### 6.1.1 The Implication of the Doha Declaration

The Doha Declaration marked a turning point for political and legal relations at the WTO. As the Doha Declaration

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<sup>118</sup> WT/MIN(01)/DEC/2.

<sup>119</sup> Haochen Sun, *A wider Access To Patented Drugs Under The TRIPS agreement*, Boston University International Law Journal, Boston University Press, 2003,p102

states, “protection of intellectual property is important for the development of new medicines, however, the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health”. Accordingly, the Agreement can and should be interpreted and implemented in a manner supportive of a WTO Member's right to protect public health and, in particular, to promote access to medicines for everyone<sup>120</sup>.

The Declaration clearly outlines all the key flexibilities available in the TRIPS Agreement, including: the right of Members to use compulsory licensing and to determine the grounds upon which such licenses are granted; the right of Members to determine what constitutes a national emergency<sup>121</sup> or other circumstances of extreme urgency, which can ease the granting of compulsory licenses; the right of Members to determine their own parallel import regimes, and the right of least developed country Members to postpone providing pharmaceutical patents until at least 2016, and possibly longer.<sup>122</sup>

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<sup>120</sup> Paragraph 4 of the Doha Declaration on TRIPS Agreement and Public Health

<sup>121</sup> In an effort to produce cheaper anti-retroviral drugs, Zambia has declared that the HIV/AIDS situation in the country is a national emergency. In terms of World Trade Organisation (WTO) rules a developing country that declares an emergency is able to produce the cheaper generic drugs. About one in five Zambians are infected with the HIV virus, with more than 800 000 children being orphaned due to the virus and nearly 700 000 Zambians being killed since the first reported instance of HIV/AIDS in 1984. The national emergency has been declared by the government from August 2004 to July 2009, according to the Zambian Permanent Secretary of Commerce, Trade and Industry, Davidson Chilipamushi. “The Minister of Commerce, Trade and Industry has signed a statutory instrument to declare an (HIV/AIDS) emergency. available at: <http://www.tralac.org/scripts/content.php?id=2888>

<sup>122</sup> Doha Declaration para. 7 provides that “Pursuant to Decision on Implementation-Related Issues and Concerns, the provisions of Article 66.2 of the TRIPS Agreement are mandatory. The TRIPS Council shall put in place a

## **6.2 The Flexibilities Under the TRIPS Agreement**

### **6.2.1 Overview**

Subject to a variety of transition periods, members of the World Trade Organization ("WTO") have the duty to implement the TRIPS Agreement and adhere to its mandates. Such a duty is in no way synonymous with a guarantee to protect all intellectual property or to honour all notions of patent-holder rights. Because the Agreement contains a number of both limited and broad-based exceptions, as well as a variety of subjective provisions that are open to differing interpretations. The TRIPS Agreement specifically recognizes the "special needs" of less developed countries in regard to maximum flexibility in the domestic implementation of laws and regulations.

## **6.3 Compulsory Licensing**

Compulsory license is a license for a patented product issued by the government to a third party to manufacture generic<sup>123</sup> versions of medicine under patent without the

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mechanism for ensuring the monitoring and full implementation of the obligations in question. To this end, developed-country Members shall submit prior to the end of 2002 detailed reports on the functioning in practice of the incentives provided to their enterprises for the transfer of technology in pursuance of their commitments under Article 66.2. These submissions shall be subject to a review in the TRIPS Council and Members shall update information annually.

<sup>123</sup>One of the strongest generic-drugs industries is in India. Before 1970, the country was almost entirely dependent on imported drugs. Today, over 70 percent of pharmaceuticals consumed in the country are locally produced. India has some 250 large pharmaceutical firms and 16,000 small producers. Local market prices are far lower than international prices for equivalent products. Moreover, India has one of the lowest inflation rates for drugs prices. Leading Indian companies such

patent holder's permission. In return, the government grants the patent holder what it believes to be reasonable compensation.

Compulsory license can be used either by way of (a) actually granting it and exploiting the license or (b) threatening its use and forcing the patent holder to revise its own pricing and supply strategy<sup>124</sup>. Developing countries, in particular have a compelling need to use compulsory licensing to improve access to medicines, vaccines, and other public health related inventions<sup>125</sup> the main justification for its use is that, it results in increased access to critical lifesaving medicines.<sup>126</sup>

Developed countries have been the most active users of compulsory licensing for a number of purposes including importantly in anti-trust cases in the USA. Canada used compulsory licensing extensively in the pharmaceutical field from 1969 until late 1980s. This resulted in prices of licensed drugs being 47% lower than in the USA in 1982<sup>127</sup>. whereas, developing and least developed countries have made limited use of compulsory licensing as a tool to

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as Cipla and Ranbaxy are also important exporters. This transition has been achieved partly as a result of a 1970 patent law, under which local companies were allowed to copy patented drugs, provided that they found a new process. However, WTO rules commit India to full implementation of the new IP regime by 2005, and its patent law has already been reformed to give interim exclusive marketing rights for patents.

<sup>124</sup> The use of compulsory licensing has been used by Brazil in pursuit of its national health care programmes. As a result of its research capability, and the development of public sector manufacturing capacity, Brazil has been able to use the threat of compulsory licensing in negotiations with pharmaceutical companies.

<sup>125</sup> **Amit Gulpa, *Patent Rights on Pharmaceutical Products and Affordable Drugs: can TRIPS Provide a Solution?*** Buffalo Intellectual Property Law Journal, p.137

<sup>126</sup> **Divya Murthy, *The Future of the Compulsory Licensing: Deciphering the Doha Declaration on the TRIPS Agreement and Health***, American University International Law Review, 2002, p.1307

address public health issues<sup>128</sup>.

### **6.3.1 Anthrax and Cipro intervene**

Following the terrorist attacks on the World Trade Centre and Pentagon, the United States experienced a bio-terror threat apparently via mailings of highly refined powder containing the anthrax virus.

The government of Canada announced that it had overridden Bayer's patent on Ciprofloxacin, the antibiotic thought to be most effective against anthrax, and granted a compulsory license to a Canadian generic producer so that the government might obtain low cost and prompt access to supplies.

Shortly after that, US announced that it had threatened Bayer executives with the grant of a compulsory license on the Bayer Ciprofloxacin patent if the company did not meet its demands for price reductions.<sup>129</sup> Bayer subsequently reduced by half the price at which it had initially offered to supply the drug.

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<sup>127</sup> supra note 1

1.1.1 <sup>128</sup> This stems from a number of causes:(1) the TRIPS Agreement has only recently begun to increase the incidence of patent protection:(2) use has been opposed by developed country WTO members and interested industry groups within them, and a strong political commitment to act in the face of this opposition is required; (3) some developing countries have expressed concern regarding a potential backlash from foreign direct investors (4) developing country enterprises may find it easier to reach accommodation with foreign patent holders than to challenge them through the compulsory licensing process for various economic and administrative reasons and,(5) effectively implementing compulsory licensing require that certain preconditions relating to administrative, financial capacity be met.

<sup>129</sup> Fredrick M. Abbott, The Doha Declaration on the TRIPS Agreement and Public Health: Lighting a Dark Corner at the TWO, Journal of International Economic Law,2002,p.487

Both the United States and Canada negotiated very substantial discounts off the patent holder's normal price for a patented essential medicine under an explicit threat of granting compulsory license in the event that satisfactory arrangements were not achieved. In both cases, the government acted promptly following the emergence of a medical threat.

The news that the US government had within weeks of onset of a disease outbreak threatened to grant compulsory licences was startling. The US had persistently threatened to impose trade sanctions and withdraw economic benefits from countries that granted compulsory licenses <sup>130</sup>

Why was the us government willing to threaten to grant a compulsory licence for Bayer's Ciprofloxacin patent when it has so steadfastly opposed similar measures by developing countries?

### **6.3.2 Advantages and Legality of Using Compulsory Licensing under TRIPS Agreement**

In practice, the introduction of several manufacturers of drugs, promotes market competition and reduces the drug's price; ultimately, compulsory licensing can cut the prices of some drugs up to ninety percent. For example, if South Africa were to issue a compulsory licence to generic manufacturer to produce drugs, the government could then purchase the cheaper generic version of that drug from the generic manufacturer. This enables the compulsory licensee

to use, manufacture, import, sell and export (with some limitation) the product under patent.

Article 31 of the TRIPS Agreement does not mention the term 'compulsory license' in the text, but when read along with article 2(1) of the TRIPS and 5(a)(2) of the Paris Convention; the allowance of compulsory licensing is implied. Article 2(1) of the TRIPS Agreement states that WTO members must comply with specific articles of the Paris Convention, including article 5, which permits the use of compulsory licensing<sup>131</sup>.

Article 31 of the TRIPS Agreement permits all WTO members to grant compulsory licenses regarding inter alia, pharmaceutical products and processes. The term of article 31 are in general permissive and flexible. As confirmed by paragraphs 5(b) and (c) of Doha Declaration, this article does not limit the grounds upon which license may be granted, and it permits each member to determine in its own discretion what constitute national emergency or circumstance of extreme urgency.

### **6.3.3 Analysis of article 31(1)(f) and latest development on it**

The main limitation of a compulsory license, in practice, is that a country needs to have a reasonably sophisticated pharmaceutical industry in order to produce the medicine concerned, and must be able to achieve economies of scale

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<sup>130</sup> Ibid

<sup>131</sup> **Anthony P. Valach, Jr. *TRIPS: Protecting the Rights of Patent Holders and addressing Public Health Issues in Developing Countries*, Chicago Kent Journal of Intellectual Property Law, 2005, p.161**



to bring the price down to affordable levels. This limitation is due to article 31(f) of The TRIPS Agreement which provides:

*"Any such use shall be authorized predominantly for the supply of the domestic market of the member authorizing such use"*

Article 31(f) establishes that, the terms of the compulsory license should include the condition that the licensee uses the patented invention "*predominantly*" to supply the domestic market of the member granting the license. The word predominant would appear to refer to the major part or majority. And would generally suggest that more than 50 percent of the production by a compulsory licensee should be intended for supply of the domestic market of the member granting the license<sup>132</sup>.

The limitation imposed by Article 31(f) creates two inter-linked problems (1) by restricting the availability of export drugs made under compulsory license, it limits countries that are not in a position to support manufacturing under compulsory license in the availability of supply of generic import drugs, and (2) by requiring compulsory licensees to supply a predominant part of their product to the domestic market, it limits the flexibility of countries to authorize the export economies of scales.

Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, adopted at the fourth WTO ministerial Conference, instructed the WTO council for TRIPS

to address how WTO members lacking or with insufficient manufacturing capacities in pharmaceuticals can make effective use of the compulsory licensing. Many developing and least developed countries cannot produce either active ingredient or formulations, due to a lack of technology, equipment, human resources or economic viability of domestic production.<sup>133</sup>

In response to paragraph 6 of the Doha Declaration, the General Council approved a decision that was designed to make easier for poor countries that lack domestic capacity to import cheaper generics produced under compulsory licensing. The decision takes an interim waiver of article 31(f), to be applicable until the TRIPS Agreement is formally amended, that allows any member country that produces generic copies of patented pharmaceuticals under a compulsory license to export these products to eligible importing countries<sup>134</sup>. Such a waiver system should be used in good faith to protect public health and not as an instrument to pursue industrial or commercial policy objectives.<sup>135</sup>

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<sup>132</sup> Fredrick M. Abbott, *The Doha Declaration on the TRIPS Agreement and Public Health: Lighting A Dark Corner at the WTO*, Journal of International Economic Law, 2002, p.499

<sup>133</sup> Carlos M. Correa, *Implementation of the WTO General Council Decision on paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health*, World Health Organisation, Geneva, 2004 p.2

<sup>134</sup> In characterizing the decision to waive Article 31(f) and to allow compulsory licenses to be issued for the purpose of exporting pharmaceuticals, Director-General Supachai Panitchpakdi indicated that "this is a historic agreement for the WTO" that allows poorer nations "to make full use of the flexibilities in the WTO's intellectual property rules in order to deal with the diseases that ravage their people." (Press Release, WTO, Decision Removes Final Patent Obstacle to Cheap Drugs, Press/350/Rev.1 (Sept. 4, 2003). available at <http://www.wto.org>)

<sup>135</sup> The Decision of the WTO General Council on paragraph 6 of the Doha Declaration on 30 August of 2003 available on line: [www.wto.org/wt/l/540](http://www.wto.org/wt/l/540)

On the face of the Decision, it seems as if the humanitarian objectives that were defined in the Doha Declaration are being achieved. Upon further analysis, however, it becomes apparent that the developing countries have to go through a lot of red tape to purchase drugs from the developed countries, which goes against the main goal of the Doha Declaration: to provide easy access to pharmaceuticals for developed and developing countries. In looking at the Decision, there are 10 possible steps that least developed and developing countries must go through before the drugs would be available to them.<sup>136</sup>

A country where the drug has been patented that is seeking to import a drug through a compulsory license would first have to seek a voluntary license on commercially reasonable terms for a reasonable period of time. Second, if the importing country was unsuccessful in obtaining a voluntary license, they would have to apply to the WTO for a compulsory license. Third, if the compulsory license is for import, the importing country must assess its generic industry's capacity to produce the medicine locally. Fourth, if the capacity is insufficient, it must notify and explain to the WTO the reason for its decision. Fifth, the importing country must notify a potential exporter.

Sixth, that exporter must in turn seek a voluntary license on commercially reasonable terms for a reasonable period of time. Seventh, that exporter must seek a compulsory license from its own government on a single-country basis.

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<sup>136</sup> Supra note 131 at p.168

Eighth, compensation by royalty must be set based on standards of reasonableness in the importing country. Ninth, if a license is granted to a generic producer, the exporter must investigate pill size, shape, colour, labelling, and packaging of the patent-holder's product in the importing country and differentiate its new product in all respects, regardless of cost. And finally, the generic producer would need to seek product registration and prove bio-equivalence based on a pill of different size and shape.

This added procedural nightmare is not in the spirit of the Doha Declaration for it will further complicate matters for countries trying to provide relief for their citizens. Citizens that are in desperate need of life-saving pharmaceuticals.<sup>137</sup>

## 6.4 Parallel Import

Parallel importing allows importation of a product from a country where a patent holder sells it at a lower price, essentially taking advantage of differential pricing. The underlying concept for allowing parallel imports is that since the inventor has been rewarded through the first sale or distribution of the product, they now have no right to control the use or resale of goods put on the market with their consent.

In other words, the inventor's rights have been "exhausted" Parallel imports allow consumers to shop on the world

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<sup>137</sup> Ibid. See also **supra note** 81 at p.891

market for the lowest price for a patented product. They are particularly important in the health sector, where the pharmaceutical industry sets prices differently throughout the world for the same medicine<sup>138</sup>. The Price for the same product can vary widely among countries because of many factors, such as differences in intellectual property rules, differences in local incomes, and the degree of competition among producers.

Importation of a patented medicine from a country where it is sold at a lower price enables more patients in the importing country to gain access to the product, without preventing the patent owner from receiving the remuneration for the patented invention in the country where the product was first sold.

The availability of parallel importing depends on how the doctrine of exhaustion of rights is interpreted. A country that allows parallel importation from any other country has an "international exhaustion regime". A country adopting "regional exhaustion" would only allow parallel importation from other countries that are members of the same regional trade agreement. An international exhaustion regime will be more helpful than a regional exhaustion regime in this respect as prices within a region will probably be similar.

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<sup>138</sup> **Lissett Ferreira, *Access to affordable HIV/AIDS Drugs: The Human Rights Obligations of Multinational Pharmaceutical Corporations***, Fordham Law Review, US, 2002, p

The language of article 6<sup>139</sup> of the TRIPS Agreement excludes the patent rights exhaustion question from WTO's dispute resolution jurisdiction, unless there is discrimination based on the nationality of the rights holder.<sup>140</sup> General GATT principles seem to support the permissibility of parallel imports and WHO also explicitly supported the use of parallel imports in order to advance the principle of preferential pricing in the poor countries.<sup>141</sup> Paragraph 5(d) of the Doha Declaration clarified the fact that countries are free to determine their exhaustion regimes it reads:

*"The effect of the provisions in the TRIPS Agreement that are relevant to the Exhaustion of Intellectual property rights is to leave each member free to establish its own regime for such exhaustion without challenges"*

#### **6.4.1 Debate on Parallel Import**

Understandably, the developing and developed nations of the world each took a different perspective on the issue of parallel importation<sup>142</sup>. The developing countries argue that

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<sup>139</sup> article 6 of the TRIPS Agreement has variously described as agreement to disagree or proof that the TRIPS Agreement says nothing about exhaustion. as a result of article 6, WTO dispute settlement panels will not have subject matter jurisdiction over measures that address the exhaustion of intellectual property rights. It must be said that article 6 does not suspend the substantive obligations in article 28.1 of the TRIPS Agreement.

<sup>140</sup> supra note 125 at p.140

<sup>141</sup> WHO has stated that in cases where drug prices are higher in poor countries than in the richer countries, recourse to parallel imports in low-income countries in order to reduce prices might be appropriate, while preventing parallel exports to industrialized countries.( ibid)

<sup>142</sup> **Harvey E : Bale, Jr**, The Conflicts Between Parallel Trade and Product Access and Innovation: the Case of Pharmaceuticals, Journal of International Economic Law, 1998

parallel importation is essential to ensuring the lowest possible for drugs of compatible quality and effectiveness; the developed nations and their pharmaceutical industry argue that parallel importation, and their accompanying danger of cheaper products flowing back into developed countries markets, has the potential of undermining efforts aimed at establishing an effective system for differential pricing<sup>143</sup>.

In other words, it may be difficult to maintain higher prices in industrialized countries that are necessary for companies to recoup investment and seek profit if parallel trade makes a significantly lower price available internationally<sup>144</sup>. Ultimately, the pharmaceutical industry's fundamental concern is that lower prices in the markets of developing countries will have a negative effect on the much more significant European and American Markets. Either way, the industry argue, this scenario would decrease worldwide profits and substantially reduce the incentives for companies to invest in researching new drugs<sup>145</sup>.

It must be said here that, Parallel importation does not deprive the patent owner of contributions to future R&D, though the level of such contributions may be lower than what it would have obtained if the segmentation of markets prevail. There is no evidence that the parallel importation of

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<sup>143</sup> **Arnoldo Laayo**, *Seeking A Balance: International Pharmaceutical Patent Protection, Public Health Crises, and the Emerging threat of Bio-Terrorism*, University of Miami International American Law Review, 2002,p.308

<sup>144</sup> **Hannah E. Ketteler**, supra note , p.51

<sup>145</sup> **Barton Gellam**, *An Unequal Calculus of Life and Death: As Millions Perished in Pandemic, Firms Debated Access to Drugs*, Washington Post, 2000,p.287. Available at: [http://www.lobby.la.psu.edu/020\\_Compulsory\\_Licensing/News\\_Stories/Washington\\_Post\\_122700.htm](http://www.lobby.la.psu.edu/020_Compulsory_Licensing/News_Stories/Washington_Post_122700.htm)

medicines is taking place on a broad scale in developing countries (Sub-Saharan Africa). In many developing countries, such imports are not permitted or are restricted.

In the case of South Africa, the scope for parallel imports is also quite limited, since it is subject to a Ministerial order (by the Minister of Health) and only applies for medicines put on the market by the owner or with his consent (article 15C, Medicines Act). Despite this narrow scope, the provision of the South African law was strongly questioned by large Pharmaceutical companies.<sup>146</sup>

If parallel import becomes a serious problem, an international agreement barring parallel export from developing countries to high-income countries may be necessary to avoid this adverse consequence. Such an international agreement will serve the interest of patients in developing countries.

## **6.5 Exception under article 30 of the TRIPS Agreement**

Article 30 of the TRIPS Agreement expressly authorizes members to provide "limited exceptions" to patent rights under certain conditions. The term "limited exceptions" in the article allows for deviations from general rules within established boundaries. The exception should not unreasonably conflict with the normal exploitation of patents and should not unreasonably prejudice the legitimate interests of patent holders by taking into account legitimate

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<sup>146</sup> C. Correa, Patent Law, TRIPS, and R&D Incentives: A Southern Perspective, WHO, Commission on Macroeconomic and Health, working group 2 papers.



interests of third parties<sup>147</sup>. There can be no doubt that one such legitimate interest of third parties is the interest – recognised in the international law as human right- in enjoying the highest attainable standard of health<sup>148</sup>.

Article 30 of the TRIPS Agreement was adopted as a compromise solution following the inability of negotiators during the Uruguay Round to agree on a list of exceptions to patent holder rights that might be recognized by members.<sup>149</sup>The article represents a balancing process between the rights of patent holders and third parties, including those citizens of the Third World, that specifically allows for prejudicing, although not the unreasonable prejudicing, of patent holder rights. Such a balancing process, of course, is inherently subjective and incapable of precise boundary.

Whether based upon its subjectivity or mere confusion to which it gives rise, if article 30 is read with article 7 and 8 of the TRIPS Agreement, limited exceptions can be justified for public health crisis and may provide a substantial means for delivering low-cost generic pharmaceuticals.

Medicines Sans Frontieres (along with a variety of other organizations) have suggested, for example, that Article 30 be interpreted to allow Members to provide an exception to the exclusive rights conferred by a patent that would permit a nation to produce and export patented products to another nation when the product is either not patented, or a

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<sup>147</sup> supra note 125 at p.140

<sup>148</sup> Robert Hawse, *The Canadian Generic Medicines Panel: A Dangerous Precedent in Dangerous Time*, Journal of World Intellectual Property, 2000,p.503

compulsory license has been granted in the importing nation. If such an activity were deemed to be protected by the Article 30 exception, there would be no patent infringement by the exporting country and thus no need for that country to acquire patent-holder permission or render compensation<sup>150</sup>.

It is therefore worthy of noting here that, TRIPS Agreement provides substantial flexibility and it is within these flexibilities that developing countries have the right to formulate and implement their own public health policies and to implement the TRIPS Agreement in ways that best accommodate those policies. The Agreement should not be used to undermine this discretion and patent protection should not be viewed as paramount to fundamental public health needs. After all, the incorporation of this "room to manoeuvre" served to accommodate the different positions of the WTO Membership at the time of the original negotiations<sup>151</sup>.

The Declaration on TRIPS also recognized that each provision of the TRIPS Agreement must be interpreted in light of the Agreement's objectives and principles as is mandated by Article 31 of the Vienna Convention on the

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<sup>149</sup> Supra note 129 at p.31

<sup>150</sup> Joint Letter From Consumer Project on Technology, Essential Action, Medicines Sans Frontieres, Oxfam International, Health GAP Coalition, and the Third World Network to the World Trade Organization's TRIPS Council 2002. Available at: <http://www.cptech.org/ip/health/art30exports.html>

<sup>151</sup> supra note 81 at p.805

Law of Treaties<sup>152</sup>. The objectives of the TRIPS Agreement, as outlined in Article 7, reflect far more than merely the protection of intellectual property rights. Instead, Article 7 speaks in terms of protecting intellectual property in a way that creates a "mutual advantage" for producers and consumers, that establishes a "balance of rights and obligations" and that is applied "in a manner conducive to social and economic welfare."

Intellectual property rights do not exist in a vacuum, and when pharmaceutical patents are not exercised in a way that meets the objectives of Art TRIPS Agreement, nations may take measures (such as the granting of compulsory licenses and Parallel Import ) to ensure that those objectives are achieved.

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<sup>152</sup> Article 31 of the Vienna Convention on Law of Treaties provides that "A treaty shall be interpreted in good faith in accordance with the ordinary meaning to be given to the terms of the treaty in their context and in the light of its object and purpose....."

## 7 Concluding Remarks

Real innovation deserves to be recognized, protected and encouraged. Patents are public policy tools, means to the end of benefiting society as a whole. The very purpose of patent protection is defeated if the system prevents those benefits from reaching the vast majority of the world's people who need them. Patent policy must acceptably balance public and private interests: when the strict enforcement of patent rights endangers the public health, governments are not only entitled to limit patent monopolies, but have legal and moral duty to do so.

Issues will persist regarding the effect of intellectual property protection on access to pharmaceutical patents in general, whether those pharmaceutical patents are directed at HIV/AIDS or other diseases that will infect the poor in years to come. While acknowledging the importance of intellectual property protection, the Doha Declaration on TRIPS specifically recognized substantial concerns regarding its effects on access, and simple logic supports the proposition that, patents facilitates artificially high prices due to their conferral of long term monopoly rights.

The consequent denial of access to essential drugs threatens the enjoyment of the right to life, protected in article 6 of the ICCPR and the rights to the highest attainable standard of physical and mental health in article 12 of the ICESCR.

On the other hand, article 15(1)(c) of the ICESCR guarantees authors rights to commercially exploit, among

other things, their scientific inventions. If one accepts that the right to property is a human right, it is surely doubtful that the right to property can routinely outweigh the right to life and health.<sup>153</sup>

Nevertheless, it must be recognized that the pharmaceutical industry has in fact taken steps to make their medicines more available in poor countries. Whether based on altruism or substantial public pressure, companies have provided drugs to these nations at severely discounted prices and, at least in a number of instances, at prices that are at or below their costs.

*Merck, Bristol-Myers Squibb, and Abbot, for example, have lowered their prices for antiretroviral to levels that are at their stated costs of production and distribution, and Videx and Zerit have been offered to African countries at 93% below their North American price. Glaxo SmithKline and Boeringer Ingelheim have agreed to allow more generic versions of their patented drugs to be produced in South Africa and other Sub-Saharan nations, and Glaxo has agreed not only to cap its royalty fees, but to allow generic licensees to export these drugs to forty-seven other poor nations.*<sup>154</sup>

Despite these efforts, and irrespective of the motives upon which they may be based, Patents clearly affect the price of newer therapeutic drugs, and in a resource-constrained world these prices have a direct impact on drugs access.

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<sup>153</sup> **supra note 65 at p..3**

It must be said lastly that intellectual property is far from being the only factor involved in access to medications. The economic, social, political, and infrastructural problems surrounding the health crisis in the Sub Saharan Africa such as Tuberculosis, Malaria and AIDS will remain.<sup>155</sup>

Having said this, there are many mechanisms provided under TRIPS Agreement that may be used by the developing and least developed countries (such as Compulsory licensing, parallel importing) for the purpose of facilitating access to essential drugs.

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<sup>154</sup> *supra* note 81 at p.803

<sup>155</sup> Hannah E. Kettler, et al, *Using Innovation Action to Meet Global Health Needs through Existing Intellectual Property Regimes*, unpublished, Commission on Intellectual Property Rights,2001,p.40

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