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The right to health, the TRIPS Agreement and the public health safeguards to encourage the universal access to essential medicines

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Résumé et mots clé en français

Les droits issus des brevets d'invention sur les produits pharmaceutiques empêchent souvent la réalisation pleine et entière du droit à la santé, plus spécialement dans les pays en voie de développement ayant des ressources plus limitées. Ce mémoire de recherche retrace d'abord les accords internationaux ayant établi le droit à la santé en droit international, les obligations et les violations qui en découlent, la problématique quant à la mise en œuvre des droits de l'homme sur le terrain, en comparaison avec la mise en œuvre et les sanctions pour le non-respect de droits économiques dans le cadre réglementaire de l'Organisation Mondiale du Commerce (OMC). Ensuite, une étude comparative des cadres législatifs de pays développés et de pays en développement révèlera dans quelle mesure le Canada, les États-Unis, l'Union Européenne, le Brésil, l'Inde, et l'Afrique du Sud se sont conformés aux exceptions aux règles de protection issues du droit international des brevets pour cause de santé publique. L'auteur identifie finalement les points de première importance qu'il considère primordial de considérer afin d'évaluer si une approche conforme au droit à la santé à été respectée dans le commerce de médicaments essentiels, avant de souligner l'aspect temporaire des mesures courantes prévues dans l'OMC et des futurs enjeux quant à l'accroissement de l'accès aux médicaments essentiels.

Mots clés : accord de libre-échange, brevets, commerce international, droits humains, droit international, licence obligatoire, médicaments génériques, OMC, propriété intellectuelle, VIH/SIDA.

Résumé et mots clé en anglais

The privileges arising from patent protection on pharmaceutical products often prevent the full realization of the right to health, especially in developing countries with scarce resources. This thesis first identifies the international agreements that have established the right to health in international law, obligations and violations associated with it, the problems encountered in the implementation of human rights on the field, compared with the implementation and sanctions associated with economic rights from the World Trade Organization regulatory framework. A comparative study of the legislative frameworks of both developed and developing countries will reveal to what extent Canada, the United States, the European Union, Brazil, India, and South Africa conformed with patent protection exceptions arising from international patent law to protect public health. Finally, the author identifies the crucial indicators that need to be considered in order to assess the conformity of a given approach with the right to health, before he underscores the temporary character of the relevant WTO measures, and the future stakes concerning an increased access to essential medicines.

Key words: compulsory license, free-trade agreement, generic drug, HIV/AIDS, human rights, intellectual property, international law, international trade, patent, WTO.

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Liste des abréviations

ALP: Aids Law Project (South Africa)

ARV: Antiretroviral drug

BI: Boehringer Ingelheim

CAFTA: Central America Free-Trade Agreement

CRO: Contract research organization

DDA: Doha Development Agenda

DSU: Dispute settlement understanding

EMEA: European Agency for the Evaluation of Medicinal Products (Europe)

EMR: Exclusive marketing right

EU: European Union

FDA: Food and Drug Administration (United States)

FDC: Fixed-dose combination

FTAA: Free-Trade Area of the Americas

GATT: General Agreement on Tariffs and Trade

GSK: GlaxoSmithKline

ICESCR: International Covenant on Economic, Social, and Cultural Rights

IPR: Intellectual property right

LDC: Least developed country

NAFTA: North American Free-Trade Agreement

NGO: Non governmental organization

OECD: Organization for Economic Cooperation and Development

PhRMA: Pharmaceutical Research and Manufacturers of America

PMPRB: Patented Medicine Prices Review Board (Canada)

PREPFAR: President's Emergency Plan for AIDS Relief

SACU: South African Customs Union

TAC: Treatment Action Campaign (South Africa)

TRIPS: Trade Related Aspects of Intellectual Property Rights

UNDP: United Nations Development Programme

UN: United Nations

USC: United States Code

USTR : United States Trade Representative

WIPO: World Intellectual Property Organization

WTO: World Trade Organization

PART I- INTRODUCTION

The human right to health, being fundamental for the exercise of other human rights, is universally recognized in numerous international legal instruments, such as the *Universal Declaration on Human Rights*[1], the *International Covenant on Economic, Social and Cultural Rights*[2], many international conventions on specific rights[3] and several human rights instruments[4]. Moreover, the right to health has also been proclaimed by the *Commission on Human Rights of the United Nations* in 1989[5] and in the *Vienna Declaration and Program of Action*[6], which is meant to foster the implementation of diverse human rights around the world. A large range of international texts recognizes the right to health, but very few of them are legally binding. The 'right to health' is intimately related to numerous fields of other human rights, and is usually described as «the right to the highest attainable standard of health»[7]. In fact, according to this latter definition, equal access to health care, access to safe drinking water, equal distribution of food, an adequate standard of living and an adequate housing, a safe and healthy workplace and living environment, as well as the right to education regarding sanitary measures may all be regrouped under its scope. The dimension of the right to health that will be at stake in this mémoire is the right to access to medicines in developing countries.

In spite of this large international recognition of the right to health, many problems have been raised regarding access to health care issues. On the one hand, in developing countries, national governments, non-governmental organizations (NGOs) and United Nations (UN) institutions claim that several drug companies, by abusing their dominant position conferred by their intellectual property rights (IPRs), prevent millions of ill people from getting treated as a result of high prices. On the other hand,

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[1] Resolution of the United Nations General Assembly 217 A (III), 10 December 1948, section 25(1) (Hereafter quoted as "Declaration on human rights").
[2] Resolution of the United Nations General Assembly 2200 A (XXI), 16 December 1966, section 12. It entered into force on 3 January 1976, in accordance with article 27 (Hereafter quoted as "ICESCR").
[3] *International Convention on the Elimination of All Forms of Racial Discrimination*, 1965, section 5, 11 and 12; and the *Convention on the Rights of the Child*, 1989, section 24.
[4] *European Social Charter of 1961*, as revised, section 11; the *African Charter on Human and Peoples' Rights*, 1981, section 16; and the *Additional Protocol to the American Convention on Human Rights in the Area of Economic, Social and Cultural Rights*, 1988, section 10.
[5] *Resolution 89/11 of the Commission on Human Rights of the United Nations*, 1989.
[6] A/CONF.157/23, 12 July 1993.
[7] ICESCR, op. cit., note 2, section 12.

the drug companies are within their economic rights considering international law when they prevent generic companies anywhere in the world to produce, use, offer for sale, sell or import generic drugs in a market where it is patented in accordance with the *TRIPS agreement*[8]. The 20-year monopoly conferred when a patent application is granted in a national jurisdiction is meant to cover research and development (R&D) costs and to encourage private investment in innovation. The best example showing the clash between the individual right to receive treatment and the global need to maintain private investment in innovation are the difficulties incurred in containing the AIDS pandemic in Africa (an example which will be referred to throughout the text).

Obviously, IPRs also increase the cost of medicines in developed countries. The effect on the treatment of the population in these countries is less however, since they often have a strong public health care system. Yet, there are growing concerns that the patent system fails to achieve, even in developed countries, the two main goals that justified initially its entry into force: provide an incentive for R&D in all sector of technology and disseminate the resulting information in the public domain. Indeed, recent concerns over the patentability of human genes are an example of potential flaws in a strong patent system regarding R&D in the health systems of developed countries[9]. However, the scope of this analysis will be limited to issues arising from the application of international patent law in developing countries.

Are human rights and economic interests irreconcilable? The right to access to health care for those suffering from HIV/AIDS in Africa and other developing countries may, at first glance, seem to enter into direct conflict with patent rights, which have been set up to encourage investment in R&D to find better treatments for the global public good. If so, does this mean that we should let millions of people in poor countries die every year from lack of treatment and let life expectancy in some developing countries plunge to around 30 years old by the end of the decade[10], in order that pharmaceutical

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[8] *Agreement on Trade-Related Aspects of Intellectual Property Rights*, Marrakech Agreement Establishing the World Trade Organization, signed in Marrakech, Morocco on 15 April 1994, article 28 (hereafter quoted "TRIPS").

[9] Michael A. HELLER and Rebecca S. EISENBERG, "Can Patents Deter Innovation? The Anticommons in Biomedical Research", (1998), *Science*, 280, 698-701.

[10] KAISERNETWORK.ORG, "Life Expectancy in 51 Nations to Decline Due to AIDS, U.S. Census Bureau Report States", (2002), Daily HIV/AIDS Report, July 8th, available at: http://www.kaisernetwork.org/daily_reports/rep_index.cfm?DR_ID=12166.

manufacturers make billions of dollars of profits and find R&D in health care appealing? Clearly, if one considers this question taking the interests of the majority of the world's population and not only the richest segment of it, this makes no sense at all. Thus, we strongly believe that both human and intellectual property rights are essential features of the globalization process.

Traditionally, human rights law and trade law have been regrouped into different kind of agreements, with very few links between each other[11]. Even trade and intellectual property rights (IPRs) used to be governed by separate agreements prior to the advent of the *World Trade Organization (WTO)*, i.e. the 1947 *General Agreement on Tariffs and Trade (GATT)* and the *World Intellectual Property Organization (WIPO)*. Thus, by integrating trade and IPRs in the same legal framework, the WTO introduced a new mechanism for regulating public health, i.e. the market forces[12].

This is in line with the central assumption of this analysis. In the current globalization context where more and more variables are interdependent, it is shortsighted to consider only one field at a time when it comes to policy and law making. Nowadays, international legal frameworks should formulate the right balance between numerous interests from different fields; in our case, trade law and human rights law. One of the main goals of this analysis is to show that human right concepts have an increasing influence in the formulation of international trade law; this through the example of the interrelations between the right to access to health care and the international trade of pharmaceutical products and restrictions to traditional patent rules. Although very few other interests than economic ones have been taken into account in the early nineties when globalization had its biggest impulse, we think that the tide might be turning slowly. On the one hand, we believe that the inclusion of human right concepts in the international trade framework will strongly contribute to the recognition and the implementation of human rights since 'one of the distinguishing features of the WTO is its dispute resolution mechanism, as established in the *Dispute Settlement Understanding (DSU)*[13]. Human/social right international tools do not provide any sanctions or dispute resolution mechanism other than political sanctions through public

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[11] Infra, Part II, chapter c).
[12] Andrea M. CURTI, "The WTO Dispute Settlement Understanding: An Unlikely Weapon in the Fight Against AIDS", (2001), *American Journal of Law & Medicine*, 27, 471.
[13] Id., 473.

opinion, which make them hard to monitor and to enforce. On the other hand, the WTO will see its image, credibility and legitimacy greatly improved by advocating the interests of the majority of human beings instead of favoring the interests of powerful worldwide economic entities controlled by very few individuals.

Thus, although IPRs and especially patents are a crucial element in the right to access to health care formula, this analysis is not intended to cover all aspects of patent law. In fact, what will be further analyzed here regarding patent law will be the means of exception in the implementation of patent rules to support a broader access to treatment for HIV/AIDS and other diseases in developing countries. Currently, compulsory licenses, coupled with parallel imports in some cases, seem to be the favorite means of expanding access to treatment for HIV/AIDS in developing countries at both national and international levels. However, further patent amendments have been proposed in international or national bodies to expand access to essential drugs. They will be exposed at the end of this analysis.

Compulsory licensing is key to the safeguard of public health interests. This important tool, whereby a government temporarily overrides a patent in the public interest and authorizes the production of cheap generic versions of patented products, is a feature of most intellectual property systems[14]. It is an essential way of helping balance the rights of inventors and the broader public interests. However, since a compulsory license can be authorized only for the territory within the jurisdiction where it has been issued, a country that would not have the required technical or financial resources to build its own pharmaceutical manufacture would not find much help in compulsory licensing provisions. This is where compulsory licensing shall be discussed along with parallel imports.

Parallel importation refers to the importation of a patented product that has been placed on markets both abroad and domestically but is sold more cheaply elsewhere. It can be an important tool for developing countries to save money by importing patented drugs

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[14] Canada: *Patent Act,* R.S., c.P-4, sections 65 to 71, and 19 to 19.3; United States: *Drug Price Competition and Patent Term Restoration Act of 1984* (Hatch-Waxman Act), *Bayh-Dole Act* – 35 USC 201, sect. 28 USC 1498; Brazil: *Law 9279/86 on Intellectual Property Law*, effective as of May 15th, 1997; India: *Patent Act no. 39 of 1970*, section 84; South Africa: *Medicines and Related Substances Act No. 90 of 1997*, section 15C; and North America: *North American Free Trade Agreement*: section 31 b).

approved for domestic sale from other countries where they may be sold at a lower price. Generally, parallel importation is possible when patents have been 'exhausted', meaning that once a patented product is placed on a market in the world, the patent holders' control over what can be done with that product in the jurisdictions where it is not patented has ended. Parallel importation may also be possible for some countries, in exceptional circumstances provided by the WTO where the patent is not 'exhausted', as it will be examined further on.

Although compulsory licensing regimes may have resemblances, the conditions on which they may be granted, the scope of these conditions and the extent of their interpretation by national courts will vary significantly from one jurisdiction to another.

The way patentability criteria are applied in each jurisdiction is also an important variable to the access to essential medicines issue. In order to be granted a patent, an inventor must show that his or her invention is novel, involves an "inventive step" (or non-obviousness), and that his of her invention is industrially applicable. Whether the interpretation of these criteria is strict or flexible will be a crucial determinant of the pool of knowledge that is taken out of the public domain, especially concerning pharmaceuticals[15]. The application of these criteria will determine the extent to which free competition prevails. On the one hand, technologically developed countries investing substantial amounts in R&D will often favor permissive patentability standards, although these policies are increasingly controversial "given the importance of incremental innovation in some sectors and the growing number of patents that protect trivial developments"[16]. On the other hand, countries that are less developed technologically will prefer to set higher patentability standards in order to preserve and enhance competition without violating minimum international standards. This comparison expresses well the need for flexibility in the implementation of the *TRIPS Agreement*:

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[15] Carlos M. CORREA, "Integrating Public Health Concerns into Patent Legislation in Developing Countries", (2000), South Centre, Geneva, p.37.
[16] Id., p.39.

> "The way in which such options are implemented should be consistent with the level of development of each country and, in particular, with its research and manufacturing capabilities in the pharmaceutical sector[17]".

The next chapter following this introduction will seek to demonstrate that the right to health is a well-established principle of international law. It will demonstrate the constant evolution of the right to health since the advent of the contemporary international legal framework linked to the United Nations system from a simple intention to a legal/policy principle that has become increasingly present in the formulation of international agreements on all topics, in our case free-trade agreements.

Then, we will next examine two different national legislations, as well as the European Union's legislation, to find out to what extent sovereign governments of developed countries recognize the existence of the right to health and what measures they have taken to ensure its implementation within their jurisdiction. The legislation of these countries or entities have been chosen because of their involvement in new legal developments regarding the right to access to health care and the international trade of pharmaceuticals. Canada and the European Union were among the first to formulate legal regimes allowing the issuance of a compulsory license for the export of generic pharmaceuticals to developing countries at cheaper prices, following the *WTO Decision WT/L/540 on the implementation of paragraph 6 of the Doha Declaration on TRIPS Agreement and public health*[18] (along with Norway)[19]. The United States, the country with the most influence on the international scene, happens also to have the most developed and powerful brand-name pharmaceutical industry around the world. Therefore, the analysis of its legislation seems rather relevant, although it does not seem to favor a broad access to essential medicines for the majority of the population not only around the globe, but also within its own borders.

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[17] Id., 9.
[18] WTO GENERAL COUNCIL, WT/L/540, 1 September 2003 (Hereafter quoted as "August 30th Decision").
[19] Richard ELIOTT, "Generics for the developing world : a comparison of three approaches to implementing the WTO Decision", *World Pharmaceutical News*, 24 November 2004, accessible at: www.scrippharma.com.

Then follows an examination of the laws of three developing countries that were determined to take appropriate measures to favor access to essential medicines to their large poor population basin. Brazil and South Africa, when they attempted to adopt measures of health safeguards which they claim to be consistent with the *TRIPS Agreement*[20] to increase the access to treatment for HIV/AIDS, were sued by many brand-name pharmaceutical companies as well as the government of the United States in front of the WTO, stating that they were in breach of their obligations related to patent protection arising also from the TRIPS Agreement. And India, which was until recently a major provider of cheap generic pharmaceuticals to the developing world as a result of its policies of non-patentability of pharmaceutical products, had to update its patent system to WTO standards, since it had to comply with the *TRIPS Agreement* from the year 2005[21].

This comparative study will allow us to distinguish trends in these six jurisdictions enumerated above, and help us to circumscribe the implementation of the right to health at the national level. Such a comparison will help us to overview how countries have reacted to recent WTO developments regarding the access to essential medicines.

> "Countries will be most successful in meeting their own needs if they are able to draw on the varied experience of national systems worldwide, which means that a good knowledge of comparative law is valuable"[22].

The strengths and weaknesses of these different approaches will be underscored in order to propose blueprints for the formulation of a legal framework taking its roots in both human rights and trade law traditions. Before concluding, we will stress the importance of striking the right balance between trade rights and human rights in international relations, considering the growing interdependence between most different sociologic, cultural, intellectual and political backgrounds in the globalization process.

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[20] TRIPS, article 31 b).
[21] Donald G. MCNEIL Jr., "Selling Cheap Generic Drugs, India's Copycats Irk Industry", (2000), *New York Times*, December 1st.
[22] Carlos M. CORREA, loc. cit., note 15, p.5.

PART II- THE RIGHT TO HEALTH AS A PRINCIPLE OF INTERNATIONAL LAW

Chapter a) First benchmarks of the right to health

Although largely recognized, one should be aware that for millions of people throughout the world, the full enjoyment of the right to health is an objective that is far from being achieved. For most populations, this goal is becoming increasingly remote. Many of the obstacles standing in the way of the achievement of this objective are in fact beyond the reach of many national governments. The right to health has evolved through several international tools. It was first recognized in 1946, in the *World Health Organization's Constitution:*

> «The enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, religion, political belief, economic or social conditions»[23].

And then in 1948, in the *Universal Declaration of Human Rights*, which also states that:

> **Article 25.**
>
> Everyone has the right to a standard of living adequate for the health of himself and of his family, including food, clothing, housing and medical care and necessary social services.

However, the right to health took a more definite and tangible form, one that was more likely to lead to international obligations for UN Member States regarding their own population in 1976, with the entry into force of the article 12 of the *International Covenant on Economic, Social and Cultural Rights* which was formulated as follows:

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[23] *Preamble to the Constitution of the World Health Organization* as adopted by the International Health Conference, New York, 19-22 June, 1946; signed on 22 July 1946 by the representatives of 61 States (Official Records of the World Health Organization, no. 2, p. 100) and entered into force on 7 April 1948.

Article 12.

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

2. The steps to be taken by the States Parties to the present Covenant to achieve the full realization of this right shall include those necessary for:

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

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

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

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

It must be underlined that the right to health does not mean that there is a right to be healthy. The right to health should be read as containing both rights and entitlements. One should have the right to control one's health and body, to be free from interference, such as the right to be free from torture and from non-consensual medical treatment and research[24]. In contrast, entitlements include the right to a health care system that provides equality of opportunities for people to enjoy the highest attainable standard of health[25].

This "highest attainable standard of health" will be expressed through an individual's biological and socio-economic characteristics as well as the available resources of a country. A country cannot ensure that its population is healthy as many factors weigh in the balance, such as lifestyle, the environment and genetics. Thus the right to health must be understood as a right to the enjoyment of a variety of facilities, goods, services and conditions necessary for the realization of the highest attainable standard of health.[26]

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[24] ECONOMIC AND SOCIAL COUNCIL OF THE UNITED NATIONS, *The right to the highest attainable standard of health,* substantive issues arising from the implementation of the international covenant on economic, social and cultural rights, E/C 12/2000/4, 11 August 2000, paragraph 8.
[25] Id., paragraph 8.
[26] Id., paragraph 9.

It is important to mention that the right to health not only creates obligations on a state towards its population but also towards other states. It can be inferred from the article 12 of the *Covenant* that all States must take steps, whether individually or through international cooperation, towards the full realization of the right to health. This level of accountability will be particularly relevant in this report in further sections. The State parties to the *Covenant* should refer to the *Alma-Ata Declaration* which states that the enormous gap between the health status of different people and within countries is politically, socially and economically unacceptable and of common concern to all countries[27]. The State parties to that conference held in Alma-Ata, U.S.S.R. in 1978, meant to express the need for urgent action by states, health workers and the international community to protect and promote the health of all people of the world. It had asserted the necessity for the State to provide accessible, affordable, and comprehensive health care services to all their citizens.

In order for the State parties to comply with their obligations arising from article 12, they have to respect the enjoyment of the right to health in other countries. They can also prevent third parties from violating this right if they can influence them by way of legal or political means, in accordance with the *Charter of the United Nations* and applicable international law[28]. State parties should also ensure that the right to health receives due consideration in the formulation and the implementation of other international agreements in other fields, such as the *World Trade Organization (WTO)* Treaty, the *TRIPS* agreement[29], and especially in bilateral or regional trade agreements.

There may be violations of the right to health through direct actions or through omissions. Direct actions may emanate from the State itself or through entities not properly regulated by it. The adoption of retrogressive measures incompatible with the core obligations under the right to health constitutes a violation of the right to health. Violations through acts of commission include the formal repeal or suspension of legislation necessary for the continued enjoyment of the right to health or the adoption

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[27] *Alma-Ata Declaration*, Report of the International Conference on Primary Health Care, Alma-Ata, 6-12 September 1978, artivle II.

[28] ECONOMIC AND SOCIAL COUNCIL OF THE UNITED NATIONS, op cit., note 24, paragraph 39.

[29] Infra, Part III.

of legislation or policies that are manifestly incompatible with pre-existing domestic or international legal obligations in relation to the right to health[30]. The other types of violations occur through the omission or the failure to adopt measures compatible with the legal obligations of the State to provide for the enjoyment of the highest attainable standard of physical and mental health. The failure to have a national policy on occupational safety and health as well as occupational health services, and the failure to enforce relevant laws also fall in this category[31].

A State will have three different types of legal obligations emanating from the right to health: the obligation to respect, the obligation to protect, and the obligation to fulfill. Under the obligation to respect, the State must adopt laws and policies compatible with the article 12 of the *Covenant.* These should decrease unnecessary morbidity and preventable mortality. According to this obligation, when a State enters a bilateral or a multilateral agreement with another State, international organization or another entity such as a multinational corporation, it will have to respect the different components of the right to health[32].

The obligation to protect implies that a State shall take all necessary measures to safeguard persons within their jurisdiction from infringements of the right to health by third parties. The protection of the population shall be carried on by the adoption of adequate rules regarding the health of the population within the State's jurisdiction, including those that apply to drug manufacturers[33].

The obligation to fulfill signifies that the State parties shall ensure that the necessary steps are taken towards the realization of the right to health. This foresees the field of practice, such as the equitable distribution of medicines or facilities among the population, the adoption of health policies and the effective monitoring of the realization of the right to health at the national level. Examples of failures to the obligation to fulfill

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[30] ECONOMIC AND SOCIAL COUNCIL OF THE UNITED NATIONS, op. cit., note 24, paragraph 48.
[31] Id., paragraph 49.
[32] Id., paragraph 50.
[33] Id., paragraph 51.

> "include the failure to adopt or implement a national health policy designed to ensure the right to health for everyone; insufficient expenditure or misallocation of public resources which results in the non-enjoyment of the right to health by individuals or groups, particularly the vulnerable or marginalized; the failure to monitor the realization of the right to health at the national level, for example by identifying right to health indicators and benchmarks; the failure to take measures to reduce the inequitable distribution of health facilities, goods and services; the failure to adopt a gender-sensitive approach to health; and the failure to reduce infant and maternal mortality rates"[34].

Chapter b) Issues involving the right to health and its enforceability in developing countries

At the international level, even though States have agreed to be bound by the international texts mentioned, sanctions for non-compliance are hard to impose. This is because there are no established central legislatures comparable to those existing in national systems, no compulsory or even widely used judicial system, and no effective machinery to enforce international law either[35]. Neither of these texts provides a procedure to follow in case of non-compliance. However, this does not mean that the state parties are not liable to their commitment to human rights legal texts. The absence of a control mechanism do not affect the liability of the state-parties, it only affects the efficiency of their implementation on the field. Most importantly, it is not because these instruments are harder to enforce that they are irrelevant in international law, and this for different reasons.

In order to assess the enforceability of an international rule, it must be given a status to find out to what extent the parties to an international agreement are legally or politically bound. This status will often depend of the formulation of the rule and the extent of its recognition. As mentioned above, the right to health was included half a century ago in the *WHO Constitution* and in the *Universal Declaration of Human Rights*, and then in the *International Covenant on Economic, Social and Cultural Rights* in the late sixties. According to Alexandre Kiss, the constant reaffirmation of an international legal principle tends to confirm it as an international legal rule that is

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[34] Id., paragraph 52.
[35] David FREESTONE, "The road from Rio: International environmental law after the earth summit", (1994) 6 *Journal of Environmental Law*, No.2, p.195.

more and more generally accepted as customary law[36]. And even if a legal principle is too novel to qualify as a customary law rule, its recognition in one or several major international instruments will contribute to give it the status of an emerging international rule. The right to health has been reaffirmed or at least has had influence in all kinds of contemporary texts, which will be enumerated below. This ongoing international recognition since the creation of the UN system works significantly towards the improvement of its credibility. However, since the right to health has been reaffirmed in important human rights conventions, thus constituting a well established conventional right, the recognition of the right to health as a customary law rule will not be at stake in this analysis.

The objective of reaching better access to health care for all, although not mentioned in the *Rio Declaration on Environment and Development*[37], was however part of the *United Nations Conference on Environment and Development* (UNCED) negotiations. *Agenda 21*, the plan of implementation of the principles and guidelines agreed by the State parties in Rio, in 1992, stresses the importance of access to health care in reaching sound and sustainable development. Its chapter 6 is wholly devoted to the protection and promotion of human health. Particular attention should be given, among other things, to the provision of immunization and essential drugs to all[38], including rural populations. An objective specifically concerning access to health care and AIDS in this chapter of *Agenda 21* is to mobilize and unify national and international efforts against AIDS to prevent infection and to reduce the personal and social impact of HIV infection[39].

UNCED took place on the 20th anniversary of the 1972 *United Nations Conference on the Human Environment*. That meeting in Stockholm, Sweden, was the first contemporary, global diplomatic gathering to address human activities in relation to the environment. Then, it will be eventually followed 10 years later by the *World Summit on Sustainable Development* (WSSD), held in Johannesburg, South Africa, in August and September 2002. UNCED and WSSD were separated by a number of

[36] Alexandre KISS, *The Rio Declaration on Environment and Development*, International Environmental Law and Policy Series, London, Kluwer Academic Publishers, 1994, p.56.
[37] United Nations Conference on Environment and Development (UNCED), Rio de Janeiro, June 1992.
[38] *Agenda 21*, United Nations Conference on Environment and Development (UNCED), Rio de Janeiro, June 1992, paragraph 6.3.
[39] Id., paragraph 6.12 j).

conferences to ensure the follow-up of the commitments taken in Rio, including the *International Conference on Financing for Development*, which will be discussed further on in this chapter.

The negotiations that led to the establishment of WTO and TRIPS Agreements in 1994 brought provisions that are reconcilable with these ideals. Under TRIPS, it is allowed to use a patented subject matter without the authorization of the right holder when the law of that country allows it. In this case, article 31 provides some conditions that must be respected by national lawmakers:

> **Article 31. Other Use Without Authorization of the Right Holder**
>
> ...
>
> (b) Such use may only be permitted if, prior to such use, the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time. This requirement may be waived by a Member in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use. In situations of national emergency or other circumstances of extreme urgency, the right holder shall, nevertheless, be notified as soon as reasonably practicable. In the case of public non-commercial use, where the government or contractor, without making a patent search, knows or has demonstrable grounds to know that a valid patent is or will be used by or for the government, the right holder shall be informed promptly[40].
>
> ...

This provision, depending on how it is interpreted and who interprets it, may be key to universal access to essential medicines. The acknowledgement that intellectual property may negatively affect public health in the *TRIPS Agreement* is crucial since it provides official sanctions, as opposed to human/social right agreements that usually do not provide sanctions in case of infringement. This issue will be examined in further detail in the next chapter. Moreover, the *TRIPS Agreement* also provides more general provisions that will guide its interpretation; specifically article 7, which contains some general objectives, and article 8, which contains general principles for the implementation of the agreement. Both of these provisions also implicitly support the recognition of the right to access to essential medicines:

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[40] TRIPS, article 31 (b).

Article 7. Objectives

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

Article 8. Principles

1. Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement.

2. Appropriate measures, provided that they are consistent with the provisions of this Agreement, may be needed to prevent the abuse of intellectual property rights by right holders or the resort to practices that unreasonably restrain trade or adversely affect the international transfer of technology.

Following the *Uruguay Round* negotiations, developing countries did not immediately take advantage of the flexibilities provided by the *TRIPS Agreement*, often because of the pressure exercised by developed countries with a strong brand-name pharmaceutical industry through legal proceedings, alleging that such measures were in breach of their intellectual property rights[41]. UN member States then reaffirmed the objectives and principles included in the *TRIPS Agreement*, by supporting many initiatives that aimed to provide a response to the global HIV/AIDS crisis. In June 2001, UN member States unanimously adopted a *Declaration of Commitment on HIV/AIDS*, which stated:

> "By 2003... in an urgent manner make every effort to provide progressively and in a sustainable manner, the highest attainable standard of treatment for HIV/AIDS, including the prevention and treatment of opportunistic infections and effective use of quality-controlled anti-retroviral therapy in a careful and monitored manner to improve adherence and effectiveness and reduce the risk of developing resistance..."[42]

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[41] Infra, Part V, chapters a) and c).

[42] *Declaration of Commitment on HIV/AIDS*, United nations General Assembly, UN General Assembly's special session on HIV/AIDS, June 2001, article 55.

There also have been many several unanimous resolutions from the UN Commission on Human Rights, in which the Commission recognized that, in the context of pandemics such as HIV/AIDS,

> "access to medication... is one fundamental element for achieving progressively the full realization of the right to everyone to the highest attainable standard of physical and mental health"[43].

The *Doha Ministerial Declaration*[44], issued from the WTO negotiations held in Doha in November 2001, reinforces this commitment of the international community towards an increased access to essential drugs:

> 17. We stress the importance we attach to implementation and interpretation of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) in a manner supportive of public health, by promoting both access to existing medicines and research and development into new medicines and, in this connection, are adopting a separate declaration.

This separate Declaration adopted by the WTO Members is the *Declaration on the TRIPS agreement and public health*[45]. It recognizes that the TRIPS Agreement should not prevent States from taking measures to protect public health, and that the members should fully use the tools contained in the TRIPS agreement as they provide enough flexibility to cope with emergency situations. More specifically, this Declaration states that «each member has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted»[46]. It also maintains that

> «...each member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency»[47].

Such guidance in the interpretation of article 31 b) of the *TRIPS Agreement* clearly establishes that universal access to essential drugs has prevalence over intellectual

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[43] CANADIAN HIV/AIDS LEGAL NETWORK, *Global Access to Medicines: Will Canada Meet the Challenge?*, February 26th, 2004, p.10, available at: http://www.aidslaw.ca.
[44] WT/MIN (01)/DEC/1, Doha, 14 November 2001.
[45] WT/MIN(01)/DEC/2, Doha, 14 November 2001 (Hereafter quoted "Doha Declaration").
[46] Id., article 5 b).
[47] Id., article 5 c).

property rights in the WTO. However, these provisions are not going to be of any help if the country subjected to the emergency situation does not have the proper manufacturing capacities in the pharmaceutical sector.

The Council of TRIPS was mandated to find further solutions to that matter and report it to the *WTO General Council* before the end of 2002[48]. The *WTO General Council* released an official decision on 30 August 2003 about compulsory licenses for the export of patented drugs to an eligible importing Member, as we will see below. Developed countries are also encouraged to provide incentives to their pharmaceutical industry to promote technology transfers to least-developed country members[49], pursuant to article 66(2) of the *TRIPS Agreement:*

> «Developed country Members shall provide incentives to enterprises and institutions in their territories for the purpose of promoting and encouraging technology transfer to least-developed country Members in order to enable them to create a sound and viable technological base».

During the negotiations of the *International Conference on Financing for Development*, the State members also acknowledge some issues are of particular concern to developing countries and countries with economies in transition, including the implementation and the interpretation of the TRIPS Agreement in a manner supportive of public health[50].

The *Decision of the WTO General Council on the Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and public health*[51] was adopted to allow especially the least developed countries but also the developing countries facing a national or an extreme emergency situation, to import generic drugs when they do not have the manufacturing capacities to produce these drugs, or when these current capacities are insufficient to meet their needs[52]. The countries with proper manufacturing capacities can be granted a compulsory license for the provision of

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[48] Id., article 6.
[49] Id., article 7.
[50] *International Conference on Financing for Development,* Secretariat of the United Nations, Monterrey, March 2002, article 28.
[51] *WTO Decision WT/L/540 on the implementation of paragraph 6 of the Doha Declaration on TRIPS Agreement and public health,* op. cit., note 18.
[52] Id., annex, Assessment of Manufacturing Capacities in the Pharmaceutical Sector.

generic drugs to an eligible Member, but only for non-commercial purposes and to the extent needed for public health purposes.

The month of September 2002 saw many new initiatives intended to improve the full realization of the right to health. The plan of action of the *World Summit on Sustainable Development* devoted its whole Chapter VI on health and sustainable development issues. It supports the strengthening of health care systems to deliver basic health services to all in an efficient, accessible, and affordable manner aimed at preventing diseases and other health threats, in conformity with human rights and fundamental freedoms[53]. Paragraph 54 (b), stresses that an equitable and improved access to affordable and efficient health care services be promoted, as well as safe drugs at affordable prices, immunization services and safe vaccines and medical technology. Paragraph 100 reaffirms the importance of the *Doha Declaration on the TRIPS agreement and public health* and its provisions mentioned above, and of the right to promote access to medicines for all.

Moreover, the *guideline 6 of the HIV/AIDS and Human Rights: International Guidelines*, was amended to take account of these developments. Following the recent developments in international law regarding better access to health care for the population, it provides that:

> "States should enact legislation to provide for the regulation of the HIV-related goods, services and information, so as to ensure widespread availability of quality prevention measures and services, adequate HIV-prevention and care-information, and safe and effective medication at an affordable price.
>
> States should also take measures necessary to ensure for all persons, on a sustainable and equal basis, the availability and accessibility of quality goods, services and in formations for HIV/AIDS prevention, treatment, care and support, including antiretroviral and other safe and effective medicines, diagnostics and related technologies for preventive, curative and palliative care of HIV/AIDS and related opportunistic infections and conditions.

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[53] *Report of the World Summit for Sustainable Development*, United Nations Secretariat, A/CONF.199/20, Johannesburg, August-September 2002, paragraph 54.

> States should take such measures at both the domestic and international levels, with particular attention to vulnerable individuals and populations[54]".

Finally, the first Special Rapporteur of the Commission on Human Rights on the right the health, Professor Paul Hunt, was nominated also in September 2002[55]. In an addendum to a report on his mission to the World Trade Organization, he affirms that:

> "Intellectual property protection can affect the enjoyment of the right to health, and related human rights, in a number of ways custom"[56].

He further establishes a link between the right to health and the right to essential medicines by stating that:

> "Given that the right to health includes an obligations on States to provide affordable medicines according to the WHO essential drugs list, intellectual property protection can lead to negative effects on the enjoyment of the right to health[57]".

And then, he extends this State obligation to other states when he reaffirms that:

> "...protracted negotiations that led to [the Decision on Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health] should have been informed by the human rights responsibility of rich States to engage in international assistance and cooperation in relation to the right to health. The Special Rapporteur underlines the effectiveness of the Decision will depend on the extent to which it actually does lead to increased access to medicines for the poor"[58].

Considering its increased recent recognition in all kinds of international forums, it seems that the right to health reached the threshold of a well-established international legal rule. From now on, it is more accurate to use 'the right to access to essential drugs', instead of 'the right to health', the first being an aspect of the other more likely to qualify as a formal legal obligation.

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[54] UNAIDS and UNOHCR, *HIV/AIDS and Human Rights: International Guidelines – Revised guideline 6: Access to prevention, treatment, care and support*, New York and Geneva, September 2002.
[55] OFFICE OF THE HIGH COMMISSIONNER FOR HUMAN RIGHTS, *Special Procedures of the Commission on Human Rights – Thematic Mandates*, CHR res. 2002/31.
[56] ECONOMIC AND SOCIAL COUNCIL OF THE UNITED NATIONS, *Addendum to the Report of the Special Rapporteur, Paul Hunt – Mission to the World Trade Organization*, Commission on Human Rights, Sixtieth session, item 10 of the provisional agenda, E/CN.4/2003/58, 13 February 2003, par.42.
[57] Id., par. 43.
[58] Id., par. 43.

Chapter c) Integrating human right concepts in the WTO

As discussed earlier, when the right to health was first mentioned in the instruments of international law, it was closer to a policy than a legal principle. Such statements as "enjoying the highest attainable standard of health is a fundamental right of every human being"[59], or that "everyone has the right to a standard of living adequate for the health of himself and of his family"[60], can hardly create legal obligations enforceable in court. However, such recognition had opened up a large debate on who should benefit from the right to health? What is its content? And who should ensure its implementation? These questions had to be raised when the right to health became a fundamental right for every human being. The right to health provided benchmarks for member States to adopt national policies and legislations concerning health care among other things[61], and debates and discussions did eventually lead to further international legal principles.

We wish to distinguish two general categories of contemporary international legal agreements. In the first category, *Agenda 21,* the *WSSD Plan of Action,* the *Declaration of Commitment on HIV/AIDS* and the *International Guidelines for HIV/AIDS* mentioned previously reinforce the establishment of the right to access to health care, as these give a further indication of its contents by providing actions that need to be undertaken, by both developed and developing countries. They do not provide traditional legal obligations though, and that for two reasons. First, they are meant to be plans of action, formulated to respect the sustainable development objectives established in various international declarations under the *United Nations* umbrella, and not traditional legal texts *per se*. Secondly, it seems that many member States did not wish to be bound legally by such texts in case of non-compliance, because of a lack of resources. This is why such plans of action do not provide any sanctions or legal authority to ensure compliance. Usually, it is international legal instruments on environmental and social rights that do not provide provisions for sanctions in case of non-compliance, opposed to international agreements of an

[59] ICESCR, op. cit, note 2, section 12.
[60] Declaration on Human rights, op. cit., note 1, article 25.
[61] See South Africa, Part V, chapter c), which included a right to health in its Constitution very similar to the one described in the ICESCR.

economic nature, such as WTO agreements for example. However, a breach in the obligations arising from UN conventions and resolutions can involve economic sanctions by the General Assembly or military actions by the Security Council[62].

The second general category includes the *TRIPS Agreement,* the *Doha Ministerial Declaration,* the *Declaration on the TRIPS agreement and public health,* and the *Decision of the WTO General Council on the implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and public health.* If these are fully used, they will be key to the enforceability of the right to access to essential medicines at the international level, because the WTO provides a *Dispute Settlement Understanding* (DSU) along with applicable sanctions. Detailed measures arising from the right to health are strongly supporting an increased access to health care for the population; these are now included in the WTO legal agreements, and this even though these measures go against the economic interests of the pharmaceutical transnational corporations. For those who believe that international trade is a means to achieve something rather than an end itself, and that globalization be grounded on human rights, as well as social and cultural values, this is an important achievement. Developing countries that declare themselves under a national or extreme emergency situation will be able to either produce generic drugs while paying reasonable royalties to the right holder, or import them from another jurisdiction if they lack the sufficient manufacturing capacity to produce enough of these drugs to deal with their emergency situation. If the right holder alleges infringement of intellectual property rights, the developing countries will have solid legal grounds to defend themselves from infringement procedures. Similarly, the developed countries will have more latitude to authorize the issuance of a compulsory license if the right holder of a research tool does not agree to grant a license for the use of this tool upon reasonable terms. However, it should be mentioned that only national governments are allowed to use the legal provisions of the WTO agreements, contrary to individuals and corporations.

It is interesting to note that the legal provisions supporting the right to access to essential medicines, one of the fundamental components of the human right to health[63],

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[62] Stephen P. MARKS, "Economic Sanctions as Human Rights Violations: Reconciling Political and Public Health Imperatives", in Sofia GRUSHIN, Michael A. GRODIN, Georges J. ANNAS, and Stephen P. MARKS, *Perspectives on Health and Human Rights*, Taylor and Francis Group, New York, 2005, p.367.

have been included in a trade agreement which was first intended to cover economic interests. The mention of the right to access to essential medicines in the international trade framework happened not even 10 years after intellectual property rights themselves were included in the WTO.

> "Before the WTO, the World Intellectual Property Organization (WIPO) governed IP rights. The 1947 GATT mentioned intellectual property rights only in passing. However, as the WTO Agreement was being negotiated, the U.S. and other developed nations insisted that the new trade institution link IP rights to the terms of trade for goods and services. As a result, the WTO Final Act included the new TRIPS Agreement as part of a newly conceptualized trade regime[64]".

Thus, instead of establishing a central authority involving sanctions for the non-compliance of human/social rights, not an easy task to carry out, social considerations were included into the international trade framework. Therefore, as mentioned under the article 23 of the *Dispute Settlement Understanding* (DSU), countries will need to submit trade disputes to the DSU before imposing sanctions[65]. Since the DSU provides a comprehensive mechanism for resolving complex trade disputes, it will take specific notice of the particular trading context of the least-developed countries[66]. This seems more realistic than eventually creating parallel international panels on human and environmental rights, as the UN Members can agree step by step to which social consideration should be included in international trade agreements, as these social rights will become at the same time legally-binding for all parties. It also avoids the multiplication of international courts.

In fact, it seems that the human right to health has become a subject that raises much debate at the international level, as shown at the Doha ministerial conference of the WTO in 2001. Although the problem of access to drugs regarding HIV/AIDS needs to be urgently resolved considering the amplitude of the disease, it is a general concern in almost all of the developing countries. According to Mr. Philippe Cullet, there are two

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[63] Philippe CULLET, "Patents and Medicines: The Relationship between TRIPS and the Human Right to Health", in Sofia GRUSHIN, Michael A. GRODIN, Georges J. ANNAS, and Stephen P. MARKS, *Perspectives on Health and Human Rights*, Taylor and Francis Group, New York, 2005, p.182.
[64] A.M. CURTI, loc. cit., note 12, pp. 469-485.
[65] Id., p.475.
[66] Id., p.475.

main areas of law that are specifically relevant to the debate on access to drugs; human rights law and the patentability of medicines:

> "Intellectual property law and human rights law have largely evolved independently. However, with the broadening scope of patents in areas related to basic needs such as health, and recent development in the health sector itself, the links between the two fields are becoming increasingly obvious and direct, necessitating further consideration of the relationship between the right to health and patents on medicines, in particular in the case of developing countries. While human rights documents have given some consideration to the position of intellectual property in relation to human rights, there has been no similar efforts in the field of intellectual property[67]".

Since the main goals of patent law are to encourage innovation and to spread new technologies, it has not traditionally been linked with socioeconomic concerns. However, with the improvement of new technologies, the scope of patentability of new inventions was extended to sectors directly linked to the fulfillment of basic needs, such as health[68]. Therefore, we submit that the scope of application of human rights, and especially the right to access to health care, should also be extended to other sectors such as trade in case of essential medicines, as it was the case for intellectual property with the fulfillment of essential needs.

The right to access to health care is increasingly recognized around the world, as seen in the numerous documents reaffirming it, and is considered as a crucial issue for sustainable development. Moreover, one author affirmed that "public health advocates welcomed the Doha declaration as an important achievement because it gave primacy to public health over intellectual property, and clarified WTO Members' rights to use TRIPS safeguards"[69]. However, access to health care in developing countries and access to knowledge that could arguably be within the public domain are two objectives that are far from achievement. The next section will further analyze the international law provisions on the protection intellectual property and its effect on the realization of the right to access to essential medicines.

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[67] P. CULLET, loc. cit., note 63, pp.179-180.
[68] Id., p.186.
[69] Ellen 't HOEN, "TRIPS, Pharmaceutical Patents, and Access to Essential Medicines: A Long Way From Seattle to Doha", in Sofia GRUSHIN, Michael A. GRODIN, Georges J. ANNAS, and Stephen P. MARKS, *Perspectives on Health and Human Rights*, Taylor and Francis Group, New York, 2005, p.203.

PART III- WHERE INTELLECTUAL PROPERTY NEGATIVELY AFFECTS THE ACCESS TO ESSENTIAL MEDICINES IN DEVELOPING COUNTRIES

The global community is at crossroads in expanding access to HIV treatment and care. In fact, the conditions for spreading treatment have hardly been as good as now: unprecedented political will in many countries; unprecedented resources to fund treatment, care and support; and unprecedented affordability of medicines and diagnostics.

Important commitments have been taken by the international community, especially developed countries, towards combating the spreading of the HIV/AIDS pandemic, certainly in international texts of a social nature, but also in free trade agreements: the best example being the *Doha Declaration on the TRIPS Agreement and Public Health*[70] and its further amendments[71]. Three recently created multi-billion-dollar programs to supply life saving antiretroviral drugs to poor countries are also expected to get going very soon: the multilateral global fund; President Georges W. Bush PREPFAR (President's Emergency Plan for AIDS Relief) for 15 selected countries; and the World Health Organization "3 by 5 Initiative" (3 million people on antiretroviral therapy by 2005)[72]. And moreover, due to the generic production of antiretroviral and the increase of their overall production, the cost of treatment per patient per year decreased from about 10 000 US$ to about 265 US$, if the medicines are bought from generic producers such as India's Ranbaxy Laboratories Ltd[73]. Still, more people than ever are dying of AIDS. In 2003, three million people died and five million became infected[74]. There are a number of reasons for this, and this chapter will focus on how some national governments from developed countries have acted to comply with international law provisions supporting wider access to treatment for HIV/AIDS victims. Some of the provisions seen in the previous section will be

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[70] Doha Declaration, op. cit., note 45.
[71] August 30th Decision, op. cit., note 18.
[72] Anne V. REELER and Joseph SABA, "Needless Battle of Brands vs. Generics", *International Herald Tribune*, July 9th, 2004.
[73] Mark SCHOOFS, "*At Zimbabwe Clinic, Wait Is Long And U.S. Drug Cupboard Is Bare*", Wall Street Journal, 1 July 2004, p.A8.
[74] WORLD HEALTH ORGANIZATION, "Unprecedented opportunity to fight HIV/AIDS and change the course of history", *WHO Press release*, May 11th, 2004, accessible at: www.who.org.

analyzed in relation with patent protection provisions and from a more balanced perspective taking account of economic interests protected by intellectual property.

States Members who ratified the *Agreement Establishing the WTO* in Marrakech in 1994, must reform their legislation to comply with their new legal obligations. Regarding the patentability of the subject matters, member States must adopt national legislation in line with the article 27 of the *TRIPS Agreement*:

> **Article 27**
>
> ***Patentable Subject Matter***
>
> 1. Subject to the provisions of paragraphs 2 and 3, patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application. Subject to paragraph 4 of Article 65, paragraph 8 of Article 70 and paragraph 3 of this Article, patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.
>
> 2. Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect *ordre public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law.
>
> 3. Members may also exclude from patentability:
>
> (a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals;
>
> (b) plants and animals other than microorganisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof. The provisions of this subparagraph shall be reviewed four years after the date of entry into force of the WTO Agreement.

The rights conferred by patents are stated in the article 28 of the *TRIPS Agreement:*

> 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.

The patent system is a distortion of the free market rules established to encourage innovation. It makes R&D investments more appealing by conferring a 20-year monopoly[75] as a reward for creating a subject matter that is new, involves an inventive step and is capable of industrial application.

> "Patents constitute a derogation from the principle of free trade by offering exclusive rights to an inventor to exploit the invention and stop others from using it without his consent. The rationale for granting patents is the need to reward an inventor[76]".

This system has been in general very efficient to stimulate R&D, as the expectation of profits for a marketable invention is high. However, there are limits to patentability. WTO Member States are allowed to exclude from patentability inventions that would go against morality or the *ordre public* in a particular jurisdiction[77]. Moreover, there are some patentable subject matters that can hardly be associated with common commodities, as it is the case for essential drugs and other health care devices. The international community realized this and formulated exceptions to monopolies in case of national or extreme emergencies, including taking measures to protect public health, in case of a potential abuse of a dominant position by a right holder[78], as mentioned in the previous chapter on the right to health[79].

According to these provisions, a country that qualifies under a national emergency or an extreme urgency situation (which explicitly include public health crisis, such as HIV/AIDS, malaria, tuberculosis and other epidemics[80]) will be able to allow the

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[75] TRIPS, op. cit., note 8, article 30.
[76] P. CULLET, loc. cit., note 63, p.180.
[77] TRIPS, op. cit., note 8, article 27 (2).
[78] Id., article 31(b).
[79] Supra, Part II.
[80] Alma-Ata Declaration, article 5 c).

production of generic drugs in its jurisdiction[81]. These measures will help the developing countries with the required pharmaceutical manufacturing capabilities to produce pharmaceutical products, but the problem remained for the countries without such infrastructures, until the General Council of the TRIPS Agreement will issue a decision to solve this problem. Now, a state Member will be allowed to export generic drugs to an eligible importing member under specific conditions, which will be analysed further on. The eligible importing member must be a state that does not have sufficient or no capacity at all in the pharmaceutical sector to cope with an epidemic within its borders[82].

However, the application of these international provisions, even if agreed in theory by all state Members of WTO, is often delayed due to complex, wide-ranging trade talks between nations. Despite the gravity of the HIV/AIDS situation, the affected countries continue to face considerable pressure not to use the flexibilities provided by the *TRIPS Agreement* that allow WTO members to set their own balance between protecting private patent rights and pursuing important public policy objectives such as protecting public health. Even very powerful or rich countries, such as the United States and Canada, face considerable pressure from the brand-name industry when they are considering limiting patent rights for the health of their own people. This was the case when large quantities of Cipro, a powerful antibiotic against anthrax, needed to be bought resulting from serious threats of large-scale bioterrorism in United States and Canada[83].

Moreover, bilateral or regional free-trade agreements can also be used to significantly tighten patent rules, although this is not exactly in line with the interpretation of TRIPS made in Doha. Countries with a strong brand-name pharmaceutical industry defend their national companies from foreign copycats; and according to public-interest groups, when it comes to essential drugs, these efforts are keeping the prices too high for poor countries[84]. These countries, especially the United States, will not indefinitely

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[81] Id., article 4; ECONOMIC AND SOCIAL COUNCIL OF THE UNITED NATIONS, op. cit., note 24, article 17; and TRIPS, section 31 b).
[82] August 30th Decision, article 2 a).
[83] Infra, Part IV, chapter b).
[84] Marilyn CHASE and Sarah LUECK, "In New Trade Pacts, U.S. Seeks To Limit Reach of Generic Drugs", *Wall Street Journal*, July 6th, 2004, p. A1.

seek to deny the availability of generic drugs. But they do seek to delay their introduction. These delays are often imposed by bilateral trade agreements containing provisions restricting trading partners from approving for five years a generic drug application if it relies on test data compiled by the original drug manufacturer[85]. This seems to be intended to protect brand-name products from the new WTO health safeguards enumerated above, and also to seek protection in developing countries who were given until 2016 to implement a patent system which would efficiently protect intellectual property rights, as laid down in the *TRIPS Agreement*[86].

So far, the United States have reached agreements including 'TRIPS-plus' protections with Jordan, Chile, Singapore, Australia, Bahrain, Morocco, as well as the six Central American countries part of the Central American Free Trade Agreement: Costa Rica, El Salvador, Guatemala, Honduras, Nicaragua, and the Dominican Republic. Other 'TRIPS-plus' provisions may be included in current FTA negotiations with Oman and Panama, as well as the five countries part of the South African Customs Union: South Africa, Namibia, Botswana, Lesotho and Swaziland, and the four Andean countries: Peru, Bolivia, Columbia and Ecuador[87]. Intentionally or not, such agreements are, in some cases, either pushing up prices or preventing them from falling[88]. In Jordan for example, AIDS drugs purchased with the Global Fund for Aids monies cost an average of 7 000$ per patient per year, compared to an average of 250$ to 400$ in other countries supported with Global Fund grants[89]. In return, Jordan is now cited as a solid example of free trade benefits, as its exports went up 30%, it had thirty new drug introductions in the market, and its trade relationship increased significantly[90].

But many countries may be caught between opposing needs. On the one hand one needs to respect U.S. patent law or risk jeopardizing the U.S. market for its main products. On the other hand, if it is hard-hit by HIV/AIDS, it needs to produce or import generic drugs for patients who cannot pay U.S. drug prices. The newer brand-name treatments would likely be off-limits to generic copies under such free trade

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[85] Id., p. A1.
[86] TRIPS, op. cit., note 8, article 66.
[87] UNITED STATES TRADE REPRESENTATIVE (USTR), section on trade agreements, available at: http://www.ustr.gov/.
[88] M. CHASE and S. LUECK, loc. cit., note 84.
[89] Id.
[90] Id.

pacts. This makes it quite difficult for a developing country affected by an epidemic to ensure its access to the American markets and to provide accessible treatments to most of its population. Some countries, such as Bahrain and Morocco, have signed side letters in which it is claimed that both parties will be entitled to take appropriate measures in case of a public health emergency[91], but these documents are not part of the agreement, they only help in its interpretation.

When developed and developing countries are facing such a difficult dilemma, they will have to make 'choices of society' that will be expressed through their national legislation. The next chapter will provide a comparative study of Canadian, United States and European Union' legislations to see how human rights and WTO mechanisms supporting a better access to essential medicines for the poor are implemented at the national level in developed countries, and how they assume their responsibility towards other states regarding the full realization of the right to health, which is now well-established in human rights law.

PART IV – COMPARATIVE STUDY OF CANADIAN, UNITED STATES AND EUROPEAN UNION LEGISLATIONS SUPPORTING AN INCREASED ACCESS TO ESSENTIAL MEDICINES IN POOR COUNTRIES

Chapter a) Canada

1) Canada's background in trying to prevent abusive pricing of medicines

The *Doha ministerial declaration*[92] and the *Doha Declaration on TRIPS and Public Health*[93] have binding effects on WTO Members, and therefore must guide the interpretation and implementation of the *TRIPS Agreement*[94]. Subsequent texts adopted by WTO members that are modifying the agreement, such as the *WTO General Council Decision of 30 August 2003*[95], will also bind WTO Members, and in fact are the basis for Canada's *Act to amend the Patent Act and the Food and Drugs*

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[91] USTR, loc. cit., note 87.
[92] Doha Ministerial Declaration, op. cit., note 44.
[93] Doha Declaration, op. cit., note 45.
[94] *Vienna Convention on the Law of Treaties*, section 31(3), and TRIPS, op. cit., note 8.
[95] August 30th Decision, op. cit., note 18.

Act[96], also called 'The Jean Chrétien Pledge to Africa'. The main purpose of this Act is to 'give effect to Canada's pledge to Africa by facilitating access to pharmaceutical products to address public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics' as stated in article 21.01. The Act should provide amendments to the *Patent Act*[97] that fully reflects the obligation to take steps leading toward the full realization of the human right to health, including the promotion of the access to affordable medicines for all. In fact, the *Canadian HIV/AIDS Legal Network* is of the opinion that:

> "Bill C-9 is Canada's legislation to implement the WTO General Council Decision of 30 August 2003. The Bill should, therefore, fully reflect the flexibility that the WTO Decision creates for countries to use compulsory licensing to import cheaper, generic pharmaceutical products."[98]

Canada is one of the developed countries with the most extensive experience in using compulsory licensing for balancing patent protection and universal access to medicines.

> "From 1969 to 1992, Canada issued more than 600 compulsory licenses on medicines. In nearly every case, the compensation to the patent owner was a standard 4% royalty applied to the generic competitor's sale price."[99]

In fact, it was Canada's policy until 1993 not only to grant patents to encourage inventive efforts and investments, but also to ensure that new inventions should, as far as possible, be worked on a commercial scale in Canada with undue delay[100]. The

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[96] *An Act to Amend the Patent Act and the Food and Drugs Act*, Bill C-9, sanctioned on May 14th, 2004, Third Session, Thirty-seventh Parliament, 52-53 Elizabeth II, 2004, section 21.04, (Hereafter quoted as "Bill C-9").
[97] *Patent* Act, R.S., c. P-4.
[98] CANADIAN HIV/AIDS LEGAL NETWORK, loc. cit., note 43, p.6.
[99] Id., p.11, with further references to: F.M. SHERER (2003) "The Economic of Compulsory Drug Patent Licensing"; Jerome H. REICHMAN and Catherine HASENZAHL, (2002) "Non-voluntary licensing of patented inventions: The Canadian experience", UNCTAD/ICTSD Capacity-building Project on Intellectual Property Rights and Sustainable Development; Joel LEXCHIN (1993) "Pharmaceuticals, patents and politics: Canada and bill C-22", 23 *International Journal of Health Services*, 47-60; Joel LEXCHIN, (1997) "After compulsory licensing: coming issues in Canadian pharmaceutical policy and politics", 40 *Health Policy*, 69-80.
[100] Id., REICHMAN & HASENZAHL, p.8.

relevant provisions of the *Patent Act* prior 1993 allowing the issuance of a compulsory license 'as of right' were formulated as follows:

> "...if the patented invention (being one capable of being worked in Canada) is not being worked within Canada on a commercial scale, and no satisfactory reason can be given," and the non-working is not excusable and for good cause[101];
>
> "if the working of the invention within Canada on a commercial scale is being prevented or hindered by the importation from abroad of the patented article" by the patentee or other related parties including unprosecuted infringers[102].

At that time, in some cases, the courts have agreed on lower royalties in the case of compulsory licenses for medicines. In Beecham Group Ltd. v. Franck W. Horner Ltd.[103], the Federal Court of Appeal unanimously upheld the Commissioner's decision to award a 1% royalty on the selling price of a pharmaceutical product. Of course, Canadian consumers have largely benefited from compulsory license practices. In fact, the Eastman Commission, a Royal Commission of Inquiry on the Pharmaceutical Industry, came to the conclusion that compulsory licensing practices have saved the consumers $200 million in the year of 1983 alone, this without negatively affecting the research-based Canadian pharmaceutical industry[104]. More recently, it was estimated by the *United Nations Development Program* that Canadian consumers saved $US 171 million because of compulsory licenses[105].

The national courts taking account that the Canadian market is relatively a rich one, have established this standard practice of the 4% royalty being paid by the generic company to the brand-name company[106]. When the production of generic drugs would be intended to supply developing countries and especially least developing countries with essential drugs, it would be appropriate that a rate certainly lower than the one being used in Canada be established.

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[101] See *Patent Act*, R.S.C. 1985, c.P-4, section 65(2)(a); *Patent Act*, R.S.C. 1970, c.P-4, sections 67(1)(d), 67(2)(a).
[102] See *Patent Act*, R.S.C. 1985, c. P-4, section 65(2)(b); *Patent Act*, R.S.C. 1970, c.P-4, section 67(2)(b).
[103] [1974] 1 F.C. 9.
[104] Harry C. EASTMAN, *Report of the Commission of Inquiry on the Pharmaceutical Industry*, Ottawa, Supply and Services Canada, 1985.
[105] UNITED NATIONS DEVELOPMENT PROGRAMME, *Human Development Report 2001: Making New Technologies Work for Human Development*, p.107, available at: http://www.undp.org.
[106] CANADIAN HIV/AIDS LEGAL NETWORK, loc. cit., note 43, p.12.

While the 'duty to work' provisions mentioned above[107] were repealed in 1993, Canada has kept other means to prevent excessive pricing of medicines within its jurisdiction. These mechanisms may be regrouped within four categories, which recognize that patent rights may sometimes be limited in light of other public policy concerns:

- "Canada's *Patent Act* continues to provide the opportunity of compulsory licensing, for the purposes of supplying the domestic market, in cases where the patentee abuses his exclusive rights under a patent (sections 65 to 71);
- Canada's *Patent Act* continues to include provisions authorizing government use of patented inventions (sections 19 to 19.3). All that is required in such cases is notification to the patentee by the Commissioner and the payment of such amount as the Commissioner considers to be adequate consideration in the circumstances, taking into account the economic value of the authorization;
- Under Canada's *Competition Act*, if a patent holder uses his patents rights in a manner that unduly prevents or lessens competition, the Federal Court may grant a compulsory license to use a patented invention on terms that it deems appropriate. Alternatively, it may revoke the patent entirely (section 32);
- Under the *Patent Act*, Canada aims to contain the prices of patented medicines through the Patented Medicine Prices Review Board (PMPRB), and in recognition of the significant cost savings for public health insurance programs, Canadian jurisdictions have long pursued politics that promote generic substitution where this is feasible"[108].

Although the Canadian courts did not take the opportunity to link BRCA-1 and BRCA-2 cases with abusive pricing, the fact that the Canadian government has a strong tradition of adopting means and mechanisms to prevent abusive pricing of medicines in its own territory might have led to its predominant role following the Doha negotiations in providing developing countries with much needed medicines when

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[107] Patent Act, op. cit., note 101 and note 102.
[108] CANADIAN HIV/AIDS LEGAL NETWORK, loc. cit., note 43, p.13.

these countries do not have the capacity to manufacture these drugs themselves. Canada is the first G8 country to formulate rules and regulations to comply with its new international obligations arising from Doha, setting a global precedent with its Bill C-9 amending the *Patent Act*[109] and the *Food and Drugs Act*[110], which was generally welcomed by most of the international community. This initiative was said as being "the right way to address the global crisis posed by HIV/AIDS, and particularly that the same World Health Organization has recently declared as a public health emergency"[111].

2) Main characteristics of bill C-9

On 14 May 2005, Bill C-9, *An Act to Amend the Patent Act and the Food and Drugs Act* (the Jean Chrétien Pledge to Africa), along with its accompanying regulations, have entered into force[112]. Bill C-9 received royal assent on 14 May 2004 but its entry into force was delayed for one year in order to finalize its regulations. Bill C-9 modified two important legislations in Canada to allow the furniture of cheaper drugs to developing countries; namely the *Patent Act*[113] and the *Food and Drugs Act*[114].

The changes brought to the *Patent Act* will make it possible for third parties to use patented inventions to address public health problems afflicting developing countries, especially those arising from epidemics such as HIV/AIDS, malaria, and tuberculosis. Canadian generic pharmaceutical companies, through compulsory licenses issued by the Canadian Government, are now able to manufacture patented pharmaceuticals, for the purpose of exporting them to developing countries that do not have the required infrastructures and technical knowledge to produce themselves the pharmaceuticals needed to respond to their public health problems[115]. The Honorable David L. Emerson, Minister of Industry declared that the ball is now in the hands of the private sector and NGOs:

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[109] Patent Act, op. cit., note 97.
[110] *Food and Drugs* Act, S.R., ch. F-27 (Hereafter quoted as "FDA").
[111] EUROPEAN AIDS TREATMENT GROUP, *Letter sent to Paul Martin, Prime Minister of Canada*, 10 March 2004, available at: http://www.cptech.org/ip/health.
[112] INDUSTRY CANADA, "Coming into Force of the Jean Chrétien Pledge to Africa", Ottawa, 13 May 2005, available at: www.innovationstrategy.gc.ca.
[113] Patent Act, op. cit., note 97.
[114] FDA, op. cit., note 110.
[115] Bill C-9, op. cit., note 96.

> "With the coming into force of the 'Jean Chrétien Pledge to Africa', the government of Canada has established a legal framework allowing lower-cost versions of patented pharmaceutical products to be exported to less fortunate countries unable to manufacture their own such products. It now falls to the private sector and non-governmental organizations to identify opportunities to assist these countries. This groundbreaking initiative is the end result of extensive consultation with pharmaceutical industry stakeholders, NGOs and Parliamentarians[116]".

These amendments were elaborated after the Doha negotiations, arising from some concerns of the Canadian authorities to simultaneously deal with the protection of the intellectual property rights of patent holders and their new responsibility towards developing countries regarding access to essential medicines.

The new version of the *Patent Act* will specify the pharmaceutical products (Schedule 1) and the eligible countries (Schedules 2 to 4) that will be targeted by this new compulsory license regime. The countries automatically covered by Bill C-9 are the countries that were identified as least-developed countries by the United Nations[117] (Schedule 2), whether they belong to WTO or not, and the developing countries members of WTO[118] (Schedule 3). As for the less vulnerable non-WTO Members, they will have to state that they are facing urgent circumstances and that they do not have a sufficient manufacturing capacity to face these circumstances; these conditions are substantially the same than those that apply to mid-income WTO Members[119] which do not qualify as developing countries (Schedule 4). To benefit from Bill C-9, they need to notify the WTO with the name and the quantity of the required product, and indicate the Member's intention to grant authorization to use the invention pertaining to the product if that product is protected by a patent, as well as a declaration stating that they have insufficient manufacturing capacity for the required product[120].

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[116] INDUSTRY CANADA, loc. cit., note 112.
[117] Bill C-9, 21.03(1)b).
[118] CANADIAN INTELLECTUAL PROPERTY OFFICE, "Use of Patents for International Humanitarian Purposes to Address Public Health Problems", available at: http://strategis.ic.gc.ca/sc_mrksv/cipo/jcpa/p1-e.html#elig.
[119] Id.
[120] Id.

When Canada adhered to the *Doha agreements,* it acknowledged that its new compulsory license regime will not be covering all pharmaceutical products, but only those characterized as medicines needed to treat public health problems[121]. This list of eligible medicines has been inspired by the *Model List of Essential Medicines,* which provides the most efficacious, safe, and cost-effective medicines for priority conditions in a basic health-care system[122]. This list was used as a main guide to establish the initial 46 eligible products that are currently subjected to a patent in the Canadian jurisdiction.

To remain flexible and face the evolution of global epidemics, the amendments provide a regulatory mechanism to add to or delete from the schedules as the needs arise or as international consensus emerges[123]. Moreover, an expert advisory committee may be created by the Ministers of Health and Industry, composed of experts in different relevant fields, which "may be asked to provide advice on amending the schedule of pharmaceutical products"[124].

A dubious rule brought at first with the amendments was the right to a "first refusal" from the brand-name companies, which basically give them the opportunity to be the first supplier of a requested pharmaceutical product, following a notice of intent by a generic pharmaceutical company seeking a compulsory license under the regime of Bill C-9. The patent holder would have 30 days to decide whether he intends to fulfill the demand or not at a price adapted to the local market where the request is coming from[125]. In case the patent holder decides not to fulfill the market opportunity, the compulsory license would be subjected to the following conditions:

- "Use of the pharmaceutical must be limited to a specific quantity and for use in a specific country (article 21.05(2));
- A website must be established disclosing the information relating to the license (article 21.06);

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[121] See Bill C-9, article 21.03(1)a).
[122] INDUSTRY CANADA, "Government of Canada reinstates legislative proposals to enable exports of low-cost pharmaceutical products to least-developed and developing countries", News Releases, Ottawa, 12 February 2004.
[123] Bill C-9, sections 21.03(1) to 21.03(4).
[124] INDUSTRY CANADA, loc. cit., note 122, and Bill C-9, section 21.18.
[125] Bill C-9, section 21.04(3)c).

- The licensee must pay a royalty of 2% of the value to the importing country of the exported pharmaceutical product (article 21.08);
- The license shall have an effective period of two years from date of grant (article 21.09); and
- Health Canada must notify the Commissioner of Patents that the pharmaceutical product meets the requirement of the Food and Drug Regulations, including that it be distinguishable from the domestic brand product (e.g., by labelling, packaging, marking, embossing, etc.) in order to discourage re-importation and diversion[126]".

Bill C-9 also modified the *Food and Drugs Act*[127] and the *Food and Drugs Regulations*[128]. Since the countries that will usually benefit from the new regime of the Bill C-9 will rarely have the institutional capacity to carry out scientific assessments of the generic drugs imported from Canada, Health Canada will make sure that these medical devices are manufactured as if they were intended for the Canadian market, including the same scientific assessment.

The subsequent changes brought to the *Food and Drugs Regulations* deal with the requirements for Health Canada to notify the Commissioner of patents on products that meet the Canadian standards and "that they carry distinguishing markings as compared to those available on the Canadian Market"[129].

c) Identified issues and flaws in Bill C-9

Although *Bill C-9* was most welcomed as the first initiative from a G8 country following the Doha negotiations, WHO, UNAIDS as well as many NGOs have identified five important flaws that needed to be addressed prior to its adoption.

i) Requirement to first seek a voluntary license from patent-holder

In previous drafts of Bill C-9, a 'right of refusal' for a brand-name manufacturer was contained in section 21.04(3)c). By the said right of refusal, the patent holder was

[126] INDUSTRY CANADA, loc. cit., note 122.
[127] FDA, op. cit., note 110.
[128] C.R.C., ch. 870.
[129] INDUSTRY CANADA, loc. cit, note 122, and FDA, section 37(2).

entitled to replace the generic company in the drug-supplying contract, even if this generic manufacturer conducted all the negotiations with the supplier in a developing country. In order for the brand-name company to replace the generic manufacturer, it had to be done within 30 days after the patent holder has received a notice about the intention to provide the patented drug at lower cost in such a market. The brand-name company will have to notify the Commissioner of Patents that it will prevail itself of the terms of the contract negotiated with the generic company.

Mr. Stephen Lewis, UN Secretary-General's special envoy for HIV/AIDS in Africa, has expressed serious doubts over the opportunity of the inclusion of the right of refusal in Bill C-9:

> "That is a very serious flaw in the bill, and it has to come out; it is important that it comes out, because it does compromise the integrity of the legislation"[130].

Of course, in a case where a generic company seeks a compulsory license to deal with a medicine supplier in a developing country, the consumer would receive the product at a lower cost even if the innovative company moves in and uses its right of refusal, since the terms of the contract would be those negotiated with the generic company. However, by allowing brand-name companies to substitute themselves to the generic companies that conducted the negotiations with a potential buyer from the developing world, few incentives would be left to negotiate these contracts in first place, since they would face the certainty or the very real possibility of being blocked from obtaining the Canadian licenses they need to follow through and, indeed, could lose the contract to the originator company[131]. It follows that the Canadian generic pharmaceutical industry would have been significantly blocked from making business with developing countries. Incentives for prices to go down would have been strongly diminished in countries in which Canada should favor access to essential medicines considering its international obligations regarding the right to health, and also regarding public health safeguards allowed in WTO rules. Moreover, the section 21.09 of bill C-9 would have reinforced the advantage that brand-name companies have over

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[130] *Globe & Mail*, February 14th, 2004.
[131] CANADIAN HIV/AIDS LEGAL NETWORK, loc. cit., note 43, p.15.

generic ones, since the compulsory license has to be renewed every two years, giving an opportunity for the right of refusal to be exercised at the same time.

> "In very short order, therefore, bill C-9 will amount to very little, if the 'right of refusal' remain in the bill, frustrating the very objective of improving access to very affordable medicines. These provisions must be deleted in their entirety or the system will become a globally embarrassing example of how not to implement the WTO Decision of 30 August 2003 to assist countries in making effective use of compulsory licensing to obtain more affordable medicines[132]".

Fortunately, important amendments have been brought to modify the article 21.03(3)c), which abandoned the 'right of refusal' and requires the generic manufacturer to negotiate at least for 30 days in order to get a license from the brand-name manufacturer:

> "The Commissioner shall authorize the use of the patented invention only if
>
> ...
>
> (c) The applicant provides the Commissioner with a solemn or statutory declaration in the prescribed form stating that the applicant had, at least thirty days before filing the application,
>
> (i) Sought from the patentee or, if there is more than one, from each of the patentees, by certified or registered mail, a licence to manufacture and sell the pharmaceutical product for export to the country or WTO Member named in the application on reasonable terms and conditions and that such efforts have not been successful, and
>
> (ii) Provided the patentee, or each of the patentees, as the case may be, by certified or registered mail, in the written request for a licence, with the information that is in all material respects identical to the information referred to in paragraphs (2)(*a*) to (*g*)".

Under WTO rules, the generic producer must seek to negotiate a voluntary licence 'within a reasonable period of time'[133] before a compulsory licence may be issued. The newest version of article 21.03(3)c) is in line with the TRIPS obligations and is no longer stricter than what is required by the TRIPS Agreement.

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[132] Id., p.15.
[133] TRIPS, article 31 (b).

ii) Limited list of pharmaceutical products in schedule 1

Another important criticism of Bill C-9 is the inclusion of a limited list of pharmaceutical products covered by Bill C-9, included in the schedule 1 of the Bill. This position is partially grounded in the *Statement of the World Health Organization on WTO Access to Medicines Decision, 1 September 2003* where it is stated that:

> "The agreement covers all medicines."

And;

> "For the agreement to have the intended impact on public health, countries will need to review the full range of medicines required from multiple suppliers, including generic producers when making purchasing decisions".

As seen in the Doha agreements, each country should determine the grounds on which the decision of whether a compulsory license should be granted or not is to be based. This legal principle provides some benchmarks defining the extent of importing countries' national sovereignty in the delicate situation where the economic interests of the countries hosting the medicine providers are affected. However, Bill C-9 reflects that some economic control concerns of the medicine exporting countries should have prevalence over the urgent needs for affordable medicines of the importing countries. This will obviously raise criticisms. Moreover, the definition of 'pharmaceutical product'[134] does not limit the scope of these products that could be covered by the Doha Declaration or any other eventual legislation adopted by a WTO-Member.

> "Paragraph 1 of the Doha Declaration does not in any manner qualify 'public health' in paragraph 4; neither does it limit the scope of diseases that may be addressed when finding an expeditious solution to the problem referred to in paragraph 6. There must therefore be no *a priori* exclusions regarding diseases that may be addressed by importing and exporting Members or the products in the pharmaceutical sectors used to address public health. It is neither practicable nor desirable to predict the pharmaceutical products needs of members desiring to protect the public health by promoting access to medicines for all"[135].

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[134] Doha Declaration, article 1a).
[135] CANADIAN HIV/AIDS LEGAL NETWORK, loc. cit., note 43, p.19.

The Canadian authorities claim that schedule 1 has been formulated taking account of the WHO Model List of Essential Medicines, which should include the most efficacious, safe, and cost-effective medicines for priority conditions in a basic health care system. All of the 46 products chosen to be included in schedule 1 were taken from this list[136]. But still, there are numerous anti-retroviral drugs available on the Canadian market missing from schedule 1. The *Canadian HIV/AIDS Legal Network* thinks that the approach of formulating a list of pharmaceutical products which may be manufactured under this regime would be a mistake, since this list was drafted considering specific needs of developing countries and may not have considered all the interests at stake of all the countries susceptible of taking advantage of the regime for the health of their populations. Moreover, the words 'essential medicines' clearly point out the products that are medically necessary, therefore not comprehensive of all health needs[137]. The WHO Model List was not created to work as the 'gatekeeper' of the innovative pharmaceutical industry in Canada or anywhere else; limiting the manufacture of generic drugs under the compulsory license scheme to the WHO Model List would be a misinterpretation of WHO's intentions, especially if the list has been formulated considering cost-effectiveness factors. The more a drug will be costly, the less chances it has to be placed on the WHO list. However, some other factors might outweigh the higher price of a drug, especially if the regime's very aim is to decrease the price of HIV/AIDS treatments for those who cannot afford it.

Clearly, the limitations included in schedule 1 were formulated to prevent any abuse of the new regime by potential importing countries that would be tempted to import pharmaceutical products for other ends than treating health problems within their jurisdiction. Although we think that a restrictive definition of 'pharmaceutical product' is not appropriate considering the main objectives of Bill C-9's regime, we trust that the article 21.03(1)a)i) will be used as often as possible to expand the scope of schedule 1. So far, it has been used once already on 14 May 2005 to include for the first time a 'fixed-dose combination' (FDC) of three antiretroviral drugs marketed under the name "lamivudine + nevirapine + zidovudine"[138]. Antiretroviral (ARVs) FDCs are a major breakthrough for HIV/AIDS treatment in developing and least-

[136] INDUSTRY CANADA, loc. cit., note 122.
[137] CANADIAN HIV/AIDS LEGAL NETWORK, loc. cit., note 43, p.20.
[138] *Order amending schedule 1 to the Patent Act*, Canada Gazette Part I, 14 May 2005, p. 1752, (Hereafter quoted as "Order on schedule 1").

developed countries as they promote greater patient adherence and require less medical supervision[139], which are often crucial advantages especially in least-developed countries. Hopefully the Canadian authorities will continue to expand the scope of schedule 1 towards FDCs, an essential device in the fight against AIDS.

iii) Exclusion of non-WTO countries from bill C-9

Since the forum where the Doha negotiations were conducted was the WTO, one would say that their legal consequences would only apply to WTO Members. However, the right to health for all as included in the *Covenant for Economic, Cultural and Socioeconomic Rights* and other legal documents has nothing to do with the WTO.

Considering the fundamental idea behind the Doha declaration, Members agreed that its effects would apply to every country categorized as a 'Least Developed Country' (LDC) based on UN criteria, countries that are all regrouped in schedule 2 of Bill C-9. But among the rest of the developing countries, only the WTO Members could at first benefit from Bill C-9, i.e. the countries mentioned in schedule 3. The developing countries not part of the WTO were prevented from contracting with Canadian generic drug manufacturers to obtain lower-cost medicines.

The first part of the issue at stake here is that among these developing countries, many would not have been able to fight HIV/AIDS effectively partly due to the costs of reliable medicines, such as Viet Nam, East Timor, Lebanon, Uzbekistan and many others[140]. Everyone should be entitled to the benefits of this important legislation, and furthermore Canada should respect all its international obligations:

> "...Canada's human rights obligations are not limited to realizing the right to the highest standard of health only in countries that join the WTO. An international decision has been taken, by all WTO Members, to relax the restrictions in TRIPS on using compulsory licensing to export lower cost generic pharmaceuticals. There is nothing in WTO that prevents Canada from sharing the benefit of this development with non-WTO countries, and Canada's human rights obligations do mandate such assistance[141]".

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[139] Id.
[140] CANADIAN HIV/AIDS LEGAL NETWORK, loc. cit., note 43, p.22.
[141] Id., p.22.

The second part of the issue is that political matters, such as choosing for a state whether to belong or not to the WTO, should not prevent the fulfillment of the right to health for the population of that state. Since the legal effects of Doha already did apply to the LDCs not members of the WTO, the moral responsibility of Canada towards developing countries outside the scope of Doha could become very large. Accordingly, under the pressure of Canadian civil societies, a developing country non-WTO Member, that is eligible for official development assistance according to a list maintained by the Organization for Economic Cooperation and Development (OECD), and which declares it is facing an emergency or other circumstances of extreme urgency will be able to benefit from the regime of Bill C-9[142]. These requirements are substantially the same as for those mid-income countries WTO Members that do not qualify as a developing country but that could possibly lack manufacturing capacity to face a grave health crisis. These countries are included in schedule 4 of Bill C-9.

iv) Restrictions in the acquisition of generic pharmaceuticals

Before the bill was amended, only national governments could enter a contract with a Canadian generic manufacturer under the Bill C-9 regime. This was probably due to concerns from the brand-name manufacturers and their governments over the effective control on who will be able to acquire the generics, and in which market they will sell these products. Most of the criticism over this comes from the fact that some governments have never shown interest in effectively fighting HIV/AIDS, nor have they required the knowledge to do so. This leaves the entire responsibility to abate the HIV/AIDS pandemic to these same governments, which seems irresponsible and negligent.

But most importantly, political interests or decisions do not bind NGOs. For example Myanmar, which is a member of WTO and has been declared a LDC by the United Nations, but is not mentioned in Schedule 2, and therefore is not eligible under the Bill C-9 regime, because of a Canadian policy toward illegitimate military governments[143]. Bill C-9 could provide an alternative way for the Canadian government to ensure the

[142] Bill C-9, section 21.03(1)d)ii).
[143] CANADIAN HIV/AIDS LEGAL NETWORK, loc. cit., note 43, p.23.

distribution of cheaper drugs in developing countries where political matters stand in the way. This could also be seen as a breach of Canada's international obligations arising from the right to health:

> "To comply with their international obligations in relation to article 12, States parties have to respect the enjoyment of the right to health in other countries, and to prevent third parties from violating the right in other countries, if they are able to influence these third parties by way of legal or political means, in accordance with the Charter of the United Nations and applicable international law. Depending on the availability of resources, States should facilitate access to essential health facilities, goods and services in other countries, wherever possible and provide the necessary when required"[144].

However, the Canadian government eventually accepted that NGOs could contract directly with Canadian generic manufacturers, as long as they get the permission from the government of the importing country. Unfortunately, this requirement considerably weakens that amendment, as non-transparent bureaucracy, rampant corruption and bad faith from the state authorities are often significant characteristics of regimes under sanctions from the international community.

v) Concerns over the emergency and the safety criteria in Canada

The pharmaceuticals manufactured to be distributed or sold in Canada must comply with strict safety requirements in order to avoid defective drugs entering the market[145]. The products exported under Bill C-9's regime will also be subject to the same requirements to ensure that these products are of good quality, safe, and effective for the intended recipients.

However, the extent of the pandemic requires that the drugs manufactured under Bill C-9 be distributed with no delay while ensuring similar safety standards as if they were distributed in Canada. Therefore, NGOs and United Nations organs claim that essential safety requirements should be applied to these drugs and that the Canadian authorities should stay flexible in the implementation of further regulatory

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[144] ECONOMIC AND SOCIAL COUNCIL OF THE UNITED NATIONS, op. cit., note 24, paragraph 39.
[145] FDA, section 37.

requirements. Following usual drug assessment trends prior to marketing, the *Canadian HIV/AIDS Legal Network* is of the opinion that:

> "...every national drug regulatory authority must weigh, on the basis of the best available evidence, the risks and benefits associated with the product, in light of its intended and foreseeable use in that country's particular context. Thus, giving different contexts, the national regulator in one country may make a different assessment than the regulator in another country, where the context may be quite different"[146].

The main issue regarding drug safety is that generic medicines manufactured only for use in poor settings, such as FDCs, are rarely marketed in developed countries such as Canada[147]. As such, there is no single Canadian Reference Product against which this particular FDC could be compared for the purposes of establishing bioequivalency, a condition precedent to obtaining Health Canada approval of a generic drug[148]. However, Health Canada has explored the feasibility of a preliminary assessment of the process for reviewing an FDC and is satisfied that an approval would be possible in circumstances where sufficient clinical data respecting the composite ARV agents is supplemented by bioequivalency comparisons between the products and the agents in question, the latter having already been individually approved and marketed in Canada[149]. Finally, it seems that Health Canada is determined to go on with this procedure, which would significantly reinforce Bill C-9's regime by improving the number of medicines that would be allowed to be exported (schedule 1) and the quality of these drugs, taking into account that these measures favor FDCs:

> "It should be noted that while section 21.18 provides for the establishment of an expert committee to advise the Ministers of Industry and of Health on their recommendations to the Governor in Council respecting the amendment of schedule 1, that committee is not yet in place. The government has nonetheless elected to proceed with pre-publication of the proposed amendment immediately on the understanding that discussions are already underway between Health Canada and parties intent on securing approval to export the FDC in question. Furthermore, the ARV agents which make up the FDC already appear individually on schedule 1 and the Canadian manufacturers of those agents have been advised of the government's

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[146] CANADIAN HIV/AIDS LEGAL NETWORK, op cit., note 43, p.24.
[147] Order on Schedule 1, op. cit., note 138.
[148] Id.
[149] Id.

proposed amendment and will have an opportunity to submit their views during the 30-day comment period"[150].

4) A Memorandum of Understanding between Canada and the United States

In addition to adopting Bill C-9 on May 12th, 2005, Canada entered into a Memorandum of Understanding (MoU) with the United States to regularize the *North American Free Trade Agreement* (NAFTA) with Doha in July 2004. This is required since the article 1709(10)f) prevents a compulsory license granted in one jurisdiction to be used to supply foreign markets. The parties, as provided in the *Memorandum of Understanding,* agreed to suspend the section 1709(10)f) of NAFTA as between themselves, consistent with the *Vienna Convention on the Law of Treaties*, with respect with compulsory licenses issued in accordance with the terms of the WTO Decision[151].

Article 1709(10)h) of NAFTA states that adequate remuneration must be given to the right holder considering the economic value of the authorization. This will be interpreted as 'the economic value to the importing country of the use that has been authorized in the exporting country'[152]. Moreover, any cross-reference with article 1709(10) will be interpreted in light of this MoU.

The adoption of this MoU is important for the cohesion of international trade rules between such close trade partners. If Canada has placed a milestone on universal access to medicines and decent health care with Bill C-9, the United States has no easy choices between respecting their international obligations arising from Doha, and protecting as much as possible the interests of its national brand-name pharmaceutical industry, by far the biggest around the world. The case of United States shows how and where the patent debate can become highly political.

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[150] Id.
[151] USTR, *Memorandum of Understanding on the access to medicines for poor countries*, San Antonio, Texas, July 16th, 2004, available at: http://www.ustr.gov/assets/Trade_Sectors/Intellectual_Property/asset_upload_file426_6319.pdf.
[152] Id.

Chapter b) United States

1) A different perspective on compulsory licensing of pharmaceuticals in the United States

The United States has quite a different tradition regarding the issuance of compulsory licenses. Even if subject to the same international obligations as Canada by virtue of being a member of the WTO and subject to the UN international instruments mentioned in previous sections, the international behavior of USA on access to cheap and essential drugs to poor countries remain contradictory. The U.S. legislation has been included in this analysis not because it brings anything innovative in terms of flexibility for intellectual property rights and public health considerations but because of its dominant position on the pharmaceutical markets worldwide and the way it favors some international obligations to the expense of others.

There is a very recent example showing the reserve of the American authorities when it is time to grant compulsory licenses for national public health issues, even when the potential health threats concern their own population: the Cipro-anthrax case.

After the September 11th terrorist attacks and the threats of bio-terrorism with anthrax that followed shortly afterwards, the American authorities were facing a potentially very serious public health emergency on its own territory, as the national health experts evaluated that medication for 10 million people were needed. For the 120 pill recommended course of treatment for ciprofloxacin, this comes to 1.2 billion pills[153]. The main problem with ciprofloxacin is that it was subject to patent protection until December 2003, so the only authorized manufacturer was the German company Bayer, which could only produce 2 million pills a day. At this rate, it would take about 600 days to produce and stockpile the 1.2 billion pills requirement established by the health authorities. These facts raised a number of concerns among the American population but especially among one part of the scientific community, as some of it evaluated the need for generic ciprofloxacin based on three questions:

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[153] Ralph NADER and James LOVE, *Letter from Ralph Nader and James Love to DHHS Secretary Tommy Thompson*, October 18th, 2001, available at: http://www.cptech.org/ip/health.

- Can anthrax be delivered to a large number of people through a terrorist attack?
- Are strains of anthrax resistant to other (cheaper and widely available) antibiotics available to terrorist groups?
- Could such an attack take place before Bayer could deliver large quantities of cipro?[154]

The *Consumer Project on Technology* further provided itself the answer that the risk was existent even if the probabilities of its occurrence were not high:

> "Based upon what we know, there is a non-zero chance that all of these things could happen. In fact, no one knows what the probability is, but it is clearly not a trivial risk, given the consequences"[155].

But still, the government would not grant a compulsory licence even if generic firms like Ranbaxy, Mylan, Geneva Pharmaceuticals and Novopharm have had received US FDA clearance for the quality of their version of ciprofloxacin; and would not exercise its power of government use of patented inventions, which if used would avoid the need for the government to negotiate a license and allow any federal employee to use or to authorize the use of a patent[156]. Mr. Ralph Nader and Mr. James Love expressed their concerns to the Secretary of the *Direction of Health and Human Services*, Tommy G. Thompson, to deny the right to authorize generic production of ciprofloxacin arising from this statute:

> "We were shocked by your comments in the October 17, 2001 Washington Post, indicating that you do not have the legal authority to authorize generic production of ciprofloxacin . . . This, of course, is not true. As your own staff is well aware, you may use 28 USC 1498 to issue compulsory licenses for patents, and you could immediately authorize the five companies who have already satisfied US FDA requirements for the quality of their products to speed the manufacturer of ciprofloxacin, and indeed this could and should be done for any other medicine needed to confront the current crisis. By failing to act, you are putting Americans at risk. By

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[154] CONSUMER PROJECT ON TECHNOLOGY, *Talking points on Cipro patent dispute*, Health Care and Intellectual Property Branch, Washington D.C. 24 October 2001, version 1.0, available at: www.cptech.org/ip/health.
[155] Id.
[156] See 28 USC 1498.

> acting to authorize generic competitors to manufacture ciprofloxacin, you would reduce public anxiety over the supply of the drug, and take steps to introduce competition which would ensure redundant capacity and a more favourable procurement environment"[157].

So the main question according to the *Consumer Project on Technology* is "why not let the generic firms do it?" - especially when it is believed that the generic producing ciprofloxacin along with Bayer, which is operating its factories at high capacity, are only running theirs slowly waiting for Bayer's patent to expire[158]. Asking this question brings the unavoidable comparison between the issues at stake in the Cipro case in United States and those regarding the treatment of HIV/AIDS in Africa. Nancy Bradish Myers, senior political analyst at *Lehman Brothers,* acknowledged the common issues at stake in both situations:

> "It's a very interesting parallel to the position taken by the U.S. in urging South Africa not to override patents of U.S. drug companies and make generic versions of AIDS drugs available to patients in that country"[159].

From there assumptions that the US government was acting as such to protect its negotiating position in the upcoming WTO negotiations in Doha, from November 9th to November 13th 2001 started to flow in. It was said that the US government was cutting corners on public health of Americans to avoid being forced to make high compromises with other nations in the Doha talks, where the issue of compulsory licensing of drugs, and imports under a compulsory license where a country does not have domestic capacity for production is a central issue, and where the US, Canada and the EU were opposing the Africa group[160].

In Canada, where the background regarding compulsory licensing is quite different as analyzed in the previous section, the authorities were more inclined to consider granting a compulsory license to stockpile a generic version of Cipro to treat the population in case of a bio-terrorist attack with anthrax. Claiming 'extraordinary and unusual times', *Health Canada* had first agreed to override Bayer's patent for Cipro,

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[157] R. NADER and J. LOVE, op cit., note 153.
[158] Matthew HARPER, "Should Bayer Cut Prices To Protect A Patent?", *Forbes.com magazine*, 24 October 2001.
[159] Jill CARROLL and Ron WINSLOW, "Bayer to Slash by Nearly half Price U.S. Pays for Anthrax Drug", *Wall Street Journal*, 25 October 2005.
[160] R. NADER and J. LOVE, op. cit., note 153.

stating that it had to answer the population's demand that necessary steps be taken to protect their health and safety[161].

However, the Canadian government backed up under the pressure exercised by displeased reactions of the US authorities and the head of the *International Federation of Pharmaceutical Manufacturers Association*, which said that the move was unwarranted and threatened to undermine research on new drugs[162]. Bayer further stated that any Cipro units ordered before October 22nd, date the agreement was signed between Bayer and the Canadian government, would become the property of Bayer; although they did not state who would have to pay Apotex, the generic manufacturer of these units.

In an attempt to avoid any further temptations for any national government to contract with a generic manufacturer for the supplying of Cipro, Bayer accepted to cut its prices in half, as it is often the case when a threat to contract with a generic manufacturer occurs due to too high pricing of a drug.

This section on the Cipro and anthrax case was included in this paper to show the different backgrounds in compulsory licensing between Canada and the United States, to describe the interests which may be advantaged in slowing down as much as possible the implementation of obligations arising from Doha, and also to disclose the political side of this patent versus the access to medicines in situation of crisis debate. The legal instruments within American legislation to avoid abusive pricing of drugs will be analysed in next section.

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[161] Amy HAMON and Robert PEAR, "Canada overrides patent for Cipro to treat anthrax", *New-York Times*, 19 October 2001.

[162] CNN Money, "Canada makes Cipro deal: Government says Bayer to stay sole supplier of anti-anthrax drug Cipro", available at: http://money.cnn.com/2001/10/23/companies/bayer/.

2) Tools to avoid abusive pricing of drugs in the American legislation

i) Hatch-Waxman Act

1- Description of the Hatch-Waxman Act

The official name of the statute that is most commonly referred to as the 'Hatch-Waxman Act' is the *Drug Price Competition and Patent Term Restoration Act of 1984.* This statute was intended to amend the *Federal Food, Drug, and Cosmetic Act* in order to accelerate the applications for new drugs by allowing an abbreviated procedure for generic manufacturers. Instead of requiring the generic manufacturer to provide clinical data to get marketing approval of its product from the FDA, it will only have to submit bioequivalence studies. This abbreviated application will need to include:

- Information to show that the conditions of use prescribed in the labelling proposed for a new drug have been previously approved for a drug that appears on a list prepared by the Secretary of Health and Human Services (listed drug);
- A certification relating to patents covering such listed drug[163].

The applicant will also need to certify in the application that a specified notice has been sent to each owner of the patent or their representative, and also to the holder, or his representative, of the approved application for the drug or drug use claimed by the patent.

This statute also provides an extension of maximum 5 years of marketing exclusivity additional to the 20-year period already given by the issuance of a patent to cope with the time a patented drugs remains in the development pipeline. Moreover, the statute grants a 30-month stay to brand name companies that file suit against a generic manufacturer that challenges their patents[164]. However this last provision became controversial as brand-name companies made an abusive use of it keeping generics off

[163] *Bill Summary and Status for the 98th Congress*, available at http://thomas.loc.gov/.
[164] CONSUMER PROJECT ON TECHNOLOGY, *The Hatch-Waxman Act and the Legislation to Close its Loopholes*, available at: http://www.cptech.org/ip/health/generic/hw.html

the market by adding other patents of poor quality on their products. In this case it does not matter if the lawsuit will be lost since brand name companies get extra marketing exclusivity anyway.

2- Actions to close the loopholes of the Hatch-Waxman Act

To avoid the occurrence of abuses of the *Hatch-Waxman Act* by the brand-name companies, George W. Bush, the President of the United States launched a new initiative on October 21st, 2002, to lower prescription drug costs by improving access to generic drugs. It was intended to close the loopholes in the implementation of the *Hatch-Waxman Act.* According to White House website, the new proposed FDA rule on generic drugs will:

- "Allow one 30-month automatic stay at most in patent infringement litigation involving a generic drug application: Drug manufacturers would be limited to only one 30-month stay per generic application, to resolve allegations that a generic drug maker is infringing a drug patent. According to the FTC, this is an appropriate time period for courts to resolve cases of patent infringement. Multiple 30-month stays, which have led to delays in generic entry of an additional 4 to 40 months, would not be permitted.
- Tighten requirements and increase disclosures for drug patent listings: Drug manufacturers would no longer be allowed to list patents in the FDA Orange Book for drug packaging, drug metabolites, and intermediate forms of a drug. Permitted listings include patents on active ingredients, drug formulations, and uses of a drug. In addition, a more detailed signed attestation accompanying a patent submission will be required, and false statements in the attestation can lead to criminal charges. This will significantly reduce opportunities to list inappropriate patents just to prevent fair competition from generic drugs.
- Provide billions of dollars in savings for public and private health insurance programs: The rule will not only provide savings for patients by giving them more safe and effective, low-cost prescription drug alternatives; it will reduce budgetary pressures on state Medicaid programs, and reduce the cost burdens facing employer-provided coverage.
- Lower the cost of improving Medicare with prescription drug coverage: The rule provides important relief for seniors, but it is only a first step. Seniors really need an improved and strengthened Medicare program like the President has proposed, with better and more secure coverage options. While the House of Representatives took an important first step this year by passing legislation to provide drug coverage, the Senate failed to act. The President is calling on the leadership of the Senate to put politics aside and pass a prescription drug benefit for

> Medicare. The proposed rule makes this job easier by reducing the cost of a Medicare prescription drug benefit"[165].

To limit the brand name industry to only one 30-month automatic stay undoubtedly would help generic copies of the 200 drugs that the patent expired, from 2002 to 2005, to reach the market much faster. This is said to bring cost savings to employer health plans, to state Medicaid programs and to seniors of more than $3 billion a year only in the United States.

The announcement of the beginning of the implementation of this initiative was made almost a year later, on June 12th, 2003. It was described as mean to "streamline the process of making safe, effective generic drugs", and "to help improve the speed and reduce the cost of determining that a new generic drug is safe and effective" in implementing changes in its review procedure[166]; thus, respecting the engagements he made mentioned above.

However Sherrod Brown, the lead Democrat and the House companion to the McCain/Schumer bill (similar to Gregg/Schumer proposal, which will be explained below), stated these measures were insufficient to actually bring significant savings to American consumers on prescription drugs, and that the grounds to take action were more about politics than pricing[167].

The Gregg/Schumer bill, even if similar to the President Bush and McCain/Schumer initiatives, use a different approach to modify patent laws answering some criticism made on previous initiatives. First, the 30-month stay remains but would run concurrently to the FDA's consideration of the generic company's application. This

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[165] U.S. WHITE HOUSE, "President Takes Action to Lower Prescription Drug Prices By Improving Access to Generic Drugs", available at: http://www.whitehouse.gov/news/releases/2002/10/20021021-4.html.

[166] US DEPARTMENT OF HEALTH & HUMAN SERVICES, "HHS Revises Regulations And Procedures To Speed Access To Generic Drugs: Changes To Save Consumers Billions Of Dollars Each Year", News Release, 12 June 2003, available at : http://www.hhs.gov/news/press/2003pres/20030612.html.

[167] Sherrod BROWN, "White House Prescription Drug Proposal Is About Politics, Not Price", available at: http://www.house.gov/sherrodbrown/oldsite/generics1021.html.

will not delay the introduction of a generic product on the market significantly since it takes from 18 to 25 months to approve a generic drug[168].

Secondly, to ensure that brand-name companies do not make frivolous uses of patents to delay the introduction of generics on the market (such as patents on the colour of a pill for example), the Gregg/Schumer initiative allows a generic company to initiate a counter-claim against a brand-name company if the latter sues the generic for patent infringement, claiming that the patent at stake should have been included in the Orange Book in the first place[169].

Thirdly, the initiative also prevents a generic company from making an abusive use of the legislation. As it stood previously, a generic company has an incentive to be the first one to be able to market a product because it obtains a 180-day exclusivity. Under the bill, a generic company is not entitled to this exclusivity if it was found to have made an anti-competitive deal with a brand-name company, or if it fails to market the product within the timeframe it said it would[170].

And fourth, the bill clarifies that the FDA does have the required authority to establish test of bioequivalence for drugs that are not absorbed in the bloodstream, if these tests are based on solid scientific evidence.

This bill was enacted by the House of Representatives and the Senate under the title "Greater Access to Pharmaceuticals Act" on 10 June 2003.

3- Relevance of the Hatch-Waxman Act to poor and developing nations

When compared to other IP regimes active around the world, the *Hatch-Waxman Act* may not do much to facilitate the access of cheaper medicines for those in need within the United States. Neither does it provide exceptions for the use of generics outside the country for those who cannot afford to buy brand-name products. But preventing brand-name companies from using the American patent legislation by extending the

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[168] Rep. SCHUMER, "Schumer Generic Drug Legislation passes Full Senate", 19 June 2003, available at : http://schumer.senate.gov/SchumerWebsite/pressroom/press_releases/PR01804.html.
[169] Id.
[170] Id.

length of their patents by abusing the 30-month stay is at least a good start. Moreover, "the *Hatch-Waxman* model has been used to develop regulatory systems in developing and poor nations"[171], after the much admired Canadian compulsory license regime had to be abandoned with the advent of NAFTA in 1993. It required the right holder to license his invention for a fee in certain cases, bringing much lower prescription medicine costs[172]. The *Hatch-Waxman Act* became an important model world-wide as it allowed the entry of generic drugs on the "world's largest and most profitable pharmaceutical market", as these products were "virtually excluded from the marketplace" because of the extremely heavy regulatory burden that had to be supported by the industry prior to the advent of the act[173]. But more importantly, the *Hatch-Waxman Act* acknowledges that a generic is interchangeable with a brand-name product when it is properly tested, bringing an end to the argument that a brand-name product is chemically superior to its generic version.

ii) The Bayh-Dole Act

The *Bayh-Dole Act* deals with the commercialization of products issued from R&D financed by public funds. It will allow "the transfer of exclusive control over many government funded inventions to universities and businesses operating with federal contracts for the purpose of further development and commercialization"[174]. These universities and businesses will then be allowed to exclusively license the invention to other parties, while the Government will retain 'march-in' rights to allow the licensing of the invention to third parties if it decides the invention is not being made available to the public on a reasonable basis[175]. In that case, the Government will not need the agreement nor to preliminary negotiate with the patent holder or the original licensee for the use of this provision[176].

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[171] William HADDAD, "Generic Medicines: The Solution or the Problem?", 21 October 2004, p.8, accessible at : http://www.cptech.org/ip/health/generic/haddad10212004.doc.
[172] Id., p.8.
[173] Id., p.9.
[174] CONSUMER PROJECT ON TECHNOLOGY, Bayh-Dole Act web page, available at : http://www.cptech.org/ip/health/bd/.
[175] Id.
[176] 35 USC 203.

The most recent famous case involving the use of the *Bayh-Dole Act* is the CellPro case, where CellPro asked the Clinton administration for a compulsory license for 4 patents held by John Hopkins University. This was a very important dispute, which concerned the use of patents based upon government-funded research. To determine if 'march in' rights shall be exercised, the *National Institute of Health* (NIH) needed to examine whether:

- "Baxter has failed to take, or is not expected to take in a reasonable time, effective steps to achieve practical application of the subject inventions;
- It exists a health or safety need which is not reasonably satisfied by Hopkins or Baxter"[177].

The NIH has decided not to initiate proceedings to pursue 'march-in' rights on the basis of the available information. It stated that Hopkins and Baxter have taken the required steps to achieve practical application of the applicable patents, and that the evidence did not show an unmet health need that is not reasonably satisfied by Hopkins and Baxter. This case has come under important criticism at that time, some authors affirming that this case 'exemplifies the problems arising from academic secrecy, broadly defined patents, and the lack of government oversight of commercialization of university discoveries made using federal funds"[178].

Moreover, Mr. Ralph Nader, Mr. James Love and Mr. Robert Weissman have tried to use the *Bayh-Dole Act* to enter into an agreement that would enable the *World Health Organization* as well as other public health organizations to use US government rights in patents on medicines and other health care inventions. In fact, under the *Bayh-Dole Act* and its regulations[179], 'the government can enter into an agreement with the *World Health Organization* or other international public health and development groups, such as UNICEF or UNAIDS, giving the organizations the right to use foreign rights in

[177] NATIONAL INSTITUTE OF HEALTH, *Determination in the case of Petition of CellPro*, Office of the Director, August 1997.
[178] Avital BAR-SHALOM and Robert COOK-DEGAN, "Patents and Innovation in Cancer Therapies: Lessons from CellPro", *Milbank Quarterly*, December 2002.
[179] 18 USC 200 and seq.

patents that benefited from federal funding"[180]. The same request was made under the Clinton's administration with no results. The absence of will to act from the last two American administrations has left a lot of bitterness:

> "The fact that this has not happened [the use of the Bayh-Dole to enter licensing agreements with public health organizations regarding government-funded patents], after years of requests, shows a disregard for public health in poor countries. It is also shortsighted, because with increasing globalization, diseases in other countries intensify dangers for our citizens. This is not a proud chapter in our government's history, and we ask that the Bush Administration correct this longstanding failure, and do what is best for the public health"[181].

iii) 28 USC 1498

Section 28 USC 1498 renders it possible for the government of the United States to use a patented invention or a copyright without being obliged to seek a license and negotiate this use with the right holder. Through this section any government employee may authorize or use a patented invention while it is impossible for the right holder to prevent this use, although he is entitled to compensation. This immunity of the government of the United States extends to any contractor, sub-contractor, firm or corporation exercising activities on the behalf of the government.

This provision was referred to in this chapter where the Cipro/Anthrax case was studied. The NIH also recommended that the researchers of publicly funded R&D projects use section 28 USC 1498 to accelerate the negotiations over the use of patented research tools, such as cell lines and human genes, as a result of growing difficulties and longer delays in negotiating a license for the use of such inventions in biomedical research[182]. So far this provision is what comes the closest, considering liberal standards, in the US federal jurisdiction, to a compulsory license regime that we find in many legislations of western countries. However, it is doubtful that this provision can be used, at least under its current form, to allow a generic manufacturer to enter into an agreement with a developing country for the provision of essential

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[180] Ralph NADER and al., *Letter from Ralph Nader, James Love, and Robert Weissman to US Secretary of Health and Human Services Tommy Thompson*, 28 March 2001, available at: http://www.cptech.org/ip/health.

[181] Id.

[182] WORKING GROUP ON RESEARCH TOOLS, *Report of the National Institute of Health*, June 4th, 1998.

medicines. Section *28 USC 1498(c)* prevents the use of this provision for a claim arising in a foreign country. Moreover, the work of the generic manufacturer in question would need to qualify as 'under a government project' according to the United States case law[183].

iv) Prescription Drug Compulsory Manufacture License Act of 2005 (Washington D.C. Compulsory Licensing Bill)

Since the last two federal governments have shown no interest in anything but strengthening rather than lessening patent enforcement, state administrations, which must bear the resulting sharp increase of the costs of Medicaid programs, are exploring new avenues to force some kind of control over drug pricing into their jurisdiction.

One recent initiative that may lead to further actions by other states comes from Washington D.C. On 1 February 2005, Councilman David Catania introduced a bill[184] that would allow the D.C. government to issue compulsory licenses to FDA-approved firms for the production of certain pharmaceuticals at rates far below those currently offered. The bill would authorize Washington, D.C.'s mayor to declare a health emergency and, under 'eminent domain' authority, issue a compulsory license to a generic firm to produce selected patent drugs. The authority that leads to such action takes its roots in a 1999 U.S. Supreme Court decision granting states immunity from patent infringement in cases of legitimate public need [527 U.S. 627 (1999)][185]. The 'eminent domain' authority is the one used by governments to:

> "...appropriate private property for its own use without the owner's consent. Governments must commonly use the power of eminent domain when the acquisition of real property is necessary for the completion of a public project such as a road, and the owner of the required property is unwilling to negotiate a price for its sale"[186].

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[183] Crater Corporation V. Lucent Technologies. Docket No. 00-1125.
[184] B16-0114: *Prescription Drug Compulsory Manufacture License Act of 2005.*
[185] COUNCIL OF THE DISTRICT OF COLUMBIA, "Catania Continues Crusade to Expand Prescription Drug Access", 1 February 2005, accessible at: http://www.dccouncil.us/CATANIA/news/20050201drugaccess.asp.
[186] Wikipedia Encyclopedia, Definition of 'Eminent domain', available at: http://en.wikipedia.org/wiki/Eminent_domain.

The 'eminent domain' authority remains untested regarding the appropriation of a patent, i.e. it has never been used to appropriate intellectual (and immaterial) property rights.

This initiative follows another measure from Mr. Catania last year which led to a Access Rx bill, which requires in part that the District negotiate with drug companies for discounted prices[187].

However, this initiative did not receive a warm welcome among Washington D.C.'s newspapers, nor from the brand-name manufacturers. In a Washington Post editorial on 17 March 2005, the proposed *Prescription Drug Compulsory Manufacture License Act* was stated as being 'an act of criminal socialism'[188]. The act of using the eminent domain authority to give the right compensation to patent owners for public use is qualified as no less than 'stealing' in that same article. Another editorial from the same newspaper warns that if a government in the United States seizes control of drug patents resulting from high prices of medicines, it might also nationalize energy companies, seize control of the private housing market, and also own supermarkets[189]. The brand-name manufacturers also wanted to warn lawmakers that such legislation would 'kill companies' financial incentives to research and develop new drugs', through their patent law expert David Remes, representing the Pharmaceutical Research and Manufacturers of America[190].

In fact, in addition to the allegations mentioned in the previous paragraph, the *Prescription Drug Compulsory License Act* faces serious challenges before becoming law. First, courts will have to determine whether the *Florida Prepaid Postsecondary Education Expense Board* V. *College Service Bank*[191] is applicable to Washington D.C., which is not a state but a federal territory. Secondly, the eminent domain authority has never been used for the appropriation of intellectual property contrary to land or real property. This would also have to be determined by the courts. Thirdly, this bill may be unconstitutional as Congress alone has the power to regulate patents

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[187] Susan LEVINE, "Eminent Domain Urged as Tool to Cut Drug Costs", *Washington Post*, 17 March 2005.
[188] *"No Rx for Rising D.C. Costs"*, *Washington Times*, 17 march 2005.
[189] Doug BANDOW, "D.C.'s Drug Problem", *Washington Times*, 23 March 2005.
[190] Id.
[191] 527 U.S. 627 (1999).

and licenses[192]. This is the bottom line argument against its validity. Even if the bill succeeds through these three previous tests, it is far from sure that this bill will bring any savings at all to the D.C. administration. In fact, under the eminent domain authority, the D.C administration would have to compensate the right holder for the loss of purchases at the rate this right holder would have sold his medicines in first place. And moreover, there is still the 4% royalty of the generic price to be paid to the right holder under the compulsory license regime. Perhaps a more profitable state approach for public health authorities would be issuing the license as a remedy to anticompetitive practices, under a state anti-trust regime, where the license is not just a simple taking, but a remedy[193].

Even considering all this uncertainty around the validity of the bill, Mr. Catania's initiative is certainly a fresh approach that might put more attention on the patent debate and the unwillingness to act from the President and the Congress. As eminent domain requires just compensation for the patent, this may lead to a long, drawn-out due process review and hearings to determine just compensation[194]. Increased transparency in drug pricing may not be very profitable to brand-name manufacturers. The bill may also serve as a model for other states that would be interested in this kind of action.

3) Free-Trade Agreements with other countries

i) A new trend in adopting numerous Free-Trade Agreements

Over the last few years, the trends underlying world trade liberalization have reached an interesting and somehow controversial juncture. While being in an ambitious round of multilateral trade negotiations, the world, but especially the United States, have increased their will and efforts to also conclude bilateral or regional trade agreements, commonly referred to as *Free Trade Agreements* or *FTAs*.

> "Recent FTAs negotiated by the US include US-Chile (2003), US-Jordan (2000), US-Morocco (2004), US-Singapore (2003), and the US-Central America Free Trade Agreement (CAFTA

[192] *Constitution of the United States of America*, Article 1, section 8, clause 8.
[193] Information gathered from a partially open forum on intellectual property, hosted by the Consumer Project on Technology, section on health and intellectual property, archives, 13 February 2005, accessible at: http://lists.essential.org/pipermail/ip-health/2005-February/007469.html.
[194] Barbara T. DREYFUSS, "Patents Pending", *The American Prospect*, 23 February 2005.

> 2004) that includes the Dominican Republic. The US is also negotiating numerous new FTAs with other developing countries including the Free Trade Area of the Americas (FTAA deadline 2005), Andean Countries, Thailand, Panama, Bahrain, and Southern African countries, with others under consideration"[195].

Since the momentum in forging bilateral or regional trade agreements is so well advanced, there is very little debate as to whether the policy itself should be pursued[196]; the United States may, except for specific sectors, support this policy so as to increase its geopolitical influence and facilitate the fight against terrorism rather than increasing the trade in goods *per se*. As a shown by an *International Monetary Fund* Study:

> "...apart from NAFTA members, US export of goods to other potential partners are not significant as a share of total exports – less than 3% for Australia, Bahrain, Chile, Egypt, Israel, Jordan, Morocco, Singapore, SACU and CAFTA individually. On the other hand, the partners rely much more on their trading relationship with the United States and their shares of exports to the US market have generally increased over time..."[197]

Much of the economic incentive for the U.S. to pursue their policy toward increasing the number of FTAs with diverse partners lies outside of merchandise trade. FTAs not only regulate merchandise trade but also the trade in services, where the U.S. have a very strong interest in opening the market as the world's principal exporter of services:

> "Rules on liberalizing services as well as on such matters as intellectual property rights, the environment, labor standards and provisions for uninhibited capital transfers are now standards components of the new genre of FTAs"[198].

The increased attention on bilateralism or regionalism will likely have consequences for other countries that are not party to the agreement. As concentration on building bilateral and regional trade alliances increases, there is momentum towards multilateral trade liberalization, where a larger scope of issues is covered and where developing countries have more bargaining power and visibility as they often can team up together under the same interests. As the number of FTAs increases, confusion may arise from

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[195] OXFAM INTERNATIONAL, *Undermining Access to Medicines: Comparison of five US FTAs*, June 2004, p.1.
[196] Alvin HILAIRE and Yongzhen YANG, *The United States and the New Regionalism/Bilateralism*, IMF Working Paper, WP 03/206, October 2003, p.3.
[197] Id., p.5.
[198] Id., p.5.

sometimes overlapping trade agreements and the increased administrative burden of managing numerous trade agreements.

Developing countries may also become more vulnerable in the exercise of their national sovereignty once an agreement is concluded, since trade preferences may be modified or withdrawn, for political or other reasons[199].

ii) Entering FTAs to extend pharmaceutical patent protection at the expense of poor populations

One of the sectors where merchandise trade is rather important for the United States is the pharmaceutical manufacturing industry. According to Oxfam International:

> "The U.S. is using bilateral and regional free-trade agreements to impose unnecessarily stringent intellectual property standards on developing countries that go beyond even the damaging requirements of the World Trade Organization (WTO) rules. These new higher standards favor the short term commercial interests of U.S. pharmaceutical companies, at the expense of public health in developing countries"[200].

Such agreements including more restrictions on trade than required by TRIPS to protect patents are called TRIPS-plus agreements. TRIPS-plus agreements, while not contravening the TRIPS agreement itself, are often entering in conflict with human rights obligations such as the right to health and more particularly the access to essential medicines. The provisions of five TRIPS-plus agreements, gathered by an Oxfam study[201], will be analyzed below.

The power to negotiate bilateral or regional FTAs is currently delegated to the President of the United States by the Congress through the *Trade Promotion Authority Act of 2002*[202]. When the Trade Act came to the floor of the Senate, the Senators Feinstein and Kennedy brought an amendment to the section on the negotiating objectives of the United States in trade negotiations[203] that required the respect of the *Declaration on the TRIPS Agreement and Public Health* adopted by the WTO in Doha

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[199] Id., p.8.
[200] OXFAM INTERNATIONAL, op. cit., note 195, p.1.
[201] Id.
[202] Public Law 107-210, 107th Congress, August 6, 2002.
[203] *Trade Promotion Authority Act of 2002*, section 2102b)(4)(c).

on 14 November 2001. Even if it is stated in this declaration that the *TRIPS Agreement* does not and should not prevent any member from taking measures to protect public health, thus confirming the primacy of public health over patents in international law, the U.S. administration has clearly ignored its international obligations arising not only from the *Declaration on the TRIPS Agreement and Public Health* and the WTO Decision of August 2003 on parallel imports, but also from its own legislation[204]. In his speech of February 16th, 2005, the Senator Kennedy regretted that instead of using the American legislation to allow urgently needed access to medicines, the administration has used trade agreements to promote the interests of the pharmaceutical industry at the expense of the access to drugs in developing nations[205].

The report of Oxfam International[206] has compared five FTAs with the *TRIPS Agreement* and the *Doha Declaration* to examine if these FTAs comply with the obligations the United States contracted in Marrakech and Doha; and this in different fields related to patents and access to healthcare: patent term and regulatory approval, compulsory licensing and data exclusivity, parallel importations, and the inclusion of a bolar provision. The five agreements that will be examined are the *North American Free Trade Agreement* (NAFTA), US-Chile, US-Singapore, the *Central America Free Trade Agreement* (CAFTA), and the *Free Trade Area of the Americas* (FTAA).

1- Patent term and regulatory approval

The period of monopoly granted for a patent is intended as a reward for investing in R&D that will improve the life of others and as a means to recover the related costs and make profits to make investment in R&D appealing.

> "The harmonization of the patent term among WTO members under TRIPS at 20 years reflected a significant extension of the patent term in international law. This period was agreed by WTO members as adequate for recuperation of the inventor's R&D and other investment costs. TRIPS does not require extension of the patent term beyond 20 years for any reason"[207].

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[204] Id.
[205] *Senate Records*, 15 February 2005, p. S1498-99.
[206] OXFAM INTERNATIONAL, op. cit., note 195, p.4.
[207] Id., p.6.

However, all of the five FTAs open the door for a patent extension beyond 20 years as a compensation for delays in issuing the patent or for delays in granting regulatory approval[208].

2- Compulsory licensing and data exclusivity

Compulsory licensing, as mentioned previously in this report, serves as a means to override patents, while providing compensation to the patent owner, for public health purposes. The provisions on compulsory licensing included in *TRIPS* and *Doha Declaration* are the best examples of the consensus of WTO members on the fact that public health interests should be given priority over patent rights in cases of national emergency or other circumstances of extreme urgency. The *Doha Declaration* affirmed the right of WTO members to use compulsory licensing, and to determine for themselves the grounds for its use.

However, all of the five FTAs provide language restricting grounds on which compulsory licensing can be used. Four out of five agreements provide a data protection period (NAFTA, US-Chile, US-Singapore, CAFTA) that would prevent generic manufacturers from using clinical data gathered by the brand-name company. Usually generic companies may use this data and need only to demonstrate bioequivalence between the products. This period corresponds to the whole patent protection period for US-Chile, US-Singapore and CAFTA; while for five years in NAFTA.

Moreover, in the US-Singapore and FTAA agreements, compulsory licensing may only be used in certain circumstances, when TRIPS and the Doha Declaration leave it to WTO members to determine when its use is appropriate or necessary:

- For anti-competitive behavior;
- For public non-commercial use;

[208] See NAFTA, Section 1709, article 12 – US-Chile, section 17.9(6), 17.10(2) and 17.9(5) – US-Singapore, article 16.7(7), 16.8(4a) and 16.7(8) – CAFTA, article 15.9(6), 15.10(2) and 15.9(8) – FTAA, section B.2.e, article 9 and section B.2.j, article 1.

- For national emergencies.

When it comes to compensation for the right holder from the generic manufacturer benefiting from the compulsory license, the US-Singapore agreement also brings a higher standard of evaluation by using 'reasonable and entire' instead of 'adequate' compensation[209].

3- Parallel importation

According to *TRIPS* and the *Doha Declaration*, each member of WTO can determine their own rules on parallel importations[210]. The term 'parallel importation' refers to the importation of a patented product that has been commercialized both abroad and domestically but sold for a cheaper price abroad.

There is no mention of 'parallel importation' in NAFTA, US-Chile or CAFTA, which implies that the standards laid down in TRIPS should prevail. However, US-Singapore and FTAA may be considered as 'TRIPS-plus' agreements. Article 16.7(2) of US-Singapore limits parallel importation by requiring that the US and Singapore provide patent holders with the means to block the importation of patented drugs into the US or Singapore when same is done in violation of a distribution agreement anywhere in the world. In FTAA, each country is allowed to determine its own rules regarding parallel importation and exhaustion of right matters, as expressed in TRIPS. However, the agreement becomes TRIPS-plus when the article 4 of section B.2.e obliges the parties to review their exhaustion rules, at least at the regional level, within five years from the entry into force of the agreement. This leaves the door open for the application of political pressure from the U.S. to adopt national exhaustion rules according to Oxfam International[211].

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[209] For relevant provisions on compulsory licensing, see: NAFTA, section 1709, article 10 – US-Chile, article 17.9(4) and 17.10 – US-Singapore, article 16.7(6) – CAFTA, article 15.10(3) and 15.10(1) – FTAA, section B.2.e, article 6.

[210] See TRIPS, op. cit., note 8, article 6, and the Doha Declaration, op. cit., note 45, paragraphs 4 and 5c.

[211] OXFAM INTERNATIONAL, op. cit., note 195, p.12.

4- Bolar provision

A 'bolar provision' is an exception to patent rights that allows generic manufacturers to produce a patented product in order to get marketing approval, so as to enter the market upon patent expiry. Without such a provision, the patent term would be substantially extended and generic firms would not be able to enter the market soon after a patent expires. *TRIPS* provides flexibility for governments to set up bolar provisions or other limited exceptions to patent rights[212].

All of the five agreements reflect *TRIPS* language on bolar provisions[213]. However, the FTAA agreement is more restrictive than TRIPS on two points. The article 5 of section B.2.e requires an extension of the patent where granting of the patent is made prior to marketing approval. Moreover, governments would have to notify the patent owners who is seeking marketing approval and who would rely on originator test data during the patent term. According to Oxfam International, "this type of provision has been abused in the U.S. context by pharmaceutical companies and is under investigation"[214].

Chapter c) European Union

1) Position of the European Union in increasing the access to essential medicines for developing countries

The European Union (EU) is one of the most important entities in the international community, which confers it a predominant role in the formulation of human right treaties, WTO obligations or other bilateral or regional trade agreements. This is because the European Union has a common foreign policy, where the European Commission negotiates on behalf of the Union's 25 Member States. As such, the EU is one of the driving forces in the new round of multilateral trade negotiations in the

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[212] See TRIPS, article 30.
[213] NAFTA, section 1790, article 6 – US-Chile, section 17.9(3), section 17.9(4) – US-Singapore, section 16.7(3) and section 16.7(5) – CAFTA, section 15.9(3) and section 15.10(5) – FTAA, section B.2.e, article 5.
[214] OXFAM INTERNATIONAL, op. cit., note 195, p.19.

WTO, the Doha Development Agenda (DDA), among other things. The EU trade policy is based on article 133 of the *European Community Treaty*. Under this article 133, a special committee shall be formed with one representative from each of the 25 Member States and the European Commission. This special committee has the power to determine future policies of the EU regarding trade and trade-related aspects.

The Trade Commissioner of the EU has ambitious objectives when it comes to international trade in relation to developing countries:

> "The main objective of the new round is to put development at the heart of the world trade system in a way that will help them combat poverty"[215].

However, it has not always been this way. When South Africa adopted a legislative framework to increase the availability of affordable medicines for HIV/AIDS by way of generic substitution[216], the European Commission joined the U.S. in pressuring the South African authorities to repeal the legislation[217]. Since the European Union adopted a Program for Action to Accelerate Actions on HIV/AIDS in February 2001, malaria and tuberculosis, it recognized the need to rebalance its priorities, reflecting a shift in support of a pro-public health approach to TRIPS:

> "DG Trade dropped its objections to the use of compulsory licensing to overcome patent barriers to medicine access and became an advocate for a global tiered pricing system for pharmaceuticals. These policy changes are in stark contrast to previous European Commission policies, which closely track the pharmaceutical industry's agenda"[218].

As a major innovative force in the pharmaceutical sector the EU recognized that intellectual property rights are an essential stimulus for creativity. It believes that adequate protection should be enacted through WTO in order to encourage investment in research and development of new medicines, and particularly those targeted at the

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[215] European Union's website accessible at: http://europa.eu.int/comm/trade/issues/newround/index_en.htm.
[216] Infra, Part V, chapter c).
[217] E. HOEN, loc. cit., note 69, p.206.
[218] Id., p.211.

major communicable diseases[219]. However, the EU also recognizes that essential medicines should not be diverted away from the patients who need them the most. It took an important step towards this recognition on 26 May 2003 when it adopted a regulation allowing exporters of life saving pharmaceuticals to deliver their products at a sharply reduced price to developing nations. This new regulation[220] was brought to the discussion agenda at the Evian G8 Summit on 3 June 2003 (a noticeable effort to press other G8 Members to address this issue) while the focus of the debates of the other G8 Members was mainly on international terrorism and the ailing international economy. In a joint answer to written questions on Doha trade talks and anti-retroviral drugs, the Trade Commissioner Mr. Pascal Lamy reiterated on behalf of the Commission its will to integrate public health concerns in intellectual property policies:

> "...the Commission is fully committed to incorporating the Doha Declaration on Public Health and TRIPS into its trade policies, and with particular regard to trade assistance for the implementation of the TRIPS Agreement. It is the view of the Commission that proper implementation will improve access to medicines including antiretroviral (ARVs) to treat HIV/AIDS"[221].

In fact, the European Community describes itself, within its Program of Action to Fight HIV/AIDS and other grave diseases, as being "at the forefront of international efforts to establish a global tiered pricing system for key pharmaceuticals for the poorest developing countries"[222]. It further states in that program of action that:

> "[The European Community] remains convinced that a firm, long-term commitment from manufacturers to supply these products at the lowest possible prices would be a major contribution to the problem of access to affordable medicines. Further discussions will therefore be pursued with the pharmaceutical industry, and with the public authorities in the poorest developing countries, with a view to setting up such a system at the earliest

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[219] EUROPEAN UNION, *TRIPS: Council Discussion on Access to Medicines*, paper submitted by the EU to the TRIPS Council, for the special discussion on intellectual property and access to medicines, IP/C/W280, 12 June 2001, (01-2903).

[220] *Council Regulation (EC) No 953/2003 of 26 May 2003 to avoid trade diversion into the European Union of certain key medicines*, Official Journal L 135, 03/06/2003, p. 0005-0011.

[221] *Written question E-1779/03 by Claude Moraes (PSE) to the Commission*, Doha trade talks and antiretroviral drugs, Official Journal 011E, 15/01/2004, p.0225-0226.

[222] *Programme for action: Accelerated action on HIV/AIDS, malaria and tuberculosis in the context of poverty reduction*, Communication from the Commission to the Council and the European Parliament, COM(2001) 96 final, p.10.

> opportunity. In the future, tiered pricing for the poorest developing countries should no longer be the exception, but the rule"[223].

The European Community, through the Program of Action and the regulation cited above, has placed much emphasis on preventing product diversion, i.e. the reintroduction of the 'tiered priced' products in exporting markets, as it would both harm the interests of the brand-name manufacturers and the much-needed medicines would still be diverted from the population who needs them the most.

Following this, since the *WTO General Council Decision of 30 August 2003 on the implementation of Paragraph 6 of the Declaration on the TRIPS Agreement and Public Health* was finally adopted, the European Parliament and the Council formulated a proposal for a regulation allowing compulsory licensing of patents for developing countries with public health problems[224]. The European Union, while it held the *Joint Parliamentary Assembly of the Partnership Agreement between the members of the African, Caribbean and Pacific Group of States and the European Community and its Member States*, also adopted the *Resolution on the importation and local production of generic drugs*[225], which will be described below.

2) European Union legal documents supporting an increased access to essential medicines for developing countries

i) Resolution on the importation and local production of generic drugs

From 19 to 22 March 2001, in Libreville, Gabon, members of the African, Caribbean and Pacific Group of States and the European Community and its member states met to discuss and negotiate initiatives for the importation and the local production of generic drugs in developing countries. At that time, the efforts by South Africa to import and locally produce affordable generic drugs were being hampered by a court action brought by multinational pharmaceutical companies against their 1997 Act concerning

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[223] Id., p.10.
[224] COMMISSION OF THE EUROPEAN COMMUNITIES, *Proposal for a Regulation of the European Parliament and of the Council on compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems*, Brussels, November 2004, accessible at: http://europa.eu.int/comm/internal_market/en/indprop/patent/draft_medicines_en.pdf.
[225] Official Journal (European Union) 265, 20/09/2001, p. 0024-0025.

the control of medicines and related substances. In the meantime, the prices of essential medicines were decreasing very slowly if decreasing at all, even though the WHO was supporting South Africa in its efforts to obtain cheaper medicines by importing and producing locally generic drugs for HIV/AIDS.

Thus, the developed and developing countries present in Libreville adopted this Resolution probably to increase political pressure on the pharmaceutical manufacturers and the governments involved to withdraw the court action with South Africa. Specifically, the Resolution calls for:

- The multinational pharmaceutical companies to reduce the costs of patented HIV/AIDS drugs to honor the commitments made in Seattle (paragraphs 1 and 2);
- The TRIPS Agreement to be revised in order to render developing countries able to adopt legislation favoring fair access to cheapest medicines as possible for the population and obtain partial or full waivers on patents in favor of public health interests (paragraphs 3 and 4);
- The pharmaceutical industry to make available affordable HIV/AIDS medicines to developing countries, to withdraw the court action against South Africa, and to participate to the establishment of a global funding mechanism to promote development of vaccines as well as the purchase, in large quantities and for distribution amongst the poor, of a full range of drugs to combat HIV/AIDS and other diseases (paragraphs 5, 7 and 8);
- The development of safeguards within the WTO, including compulsory licensing, and the commitment by the Commission to launch a debate in the WTO on reconciling the TRIPS Agreement with the objectives of health protection in developing countries (paragraph 6)[226].

[226] Id.

ii) Council Regulation (EC) No 953/2003 of 26 May 2003 to avoid trade diversion into the European Union of certain key medicines[227]

This EU Council Regulation on trade diversion is formulated to encourage pharmaceutical companies to reduce the price of certain medicines in a number of poor countries by preventing their re-importation in the markets of rich countries, as this measure facilitates the policing of existing laws regarding the illegal import of patented products. This regulation will apply to all products that are offered at tiered prices, whether patented or generic, since the article 1(2)(a) defines 'tiered priced product' as "any pharmaceutical product used in the prevention, diagnosis and treatment of a disease referred to in Annex IV which is priced in accordance with one of the optional price calculations set out in article 3, verified by the Commission or an independent auditor as provided for in article 4 and entered in the list of tiered priced products set out in Annex 1"[228]. The diseases targeted by the Council's regulation, as set out in Annex IV, are HIV/AIDS, malaria, tuberculosis, and related opportunistic diseases.

Territorially, the scope of the regulation is relatively broad, although some countries where the damage caused by HIV/AIDS are significant were omitted in Annex II. For example, for no apparent reason, Papua New Guinea, with a gross national income of per capita of only $700US, cannot benefit from this important and symbolic European development initiative[229]. This Annex still provides a list of the 72 countries where the exportation of 'tiered priced' pharmaceuticals is allowed.

The core mechanism of this regulation is included in article 2:

> **Article 2**
>
> 1. It shall be prohibited to import into the Community tiered priced products for the purposes of release for free circulation, re-export, placing under suspensive procedures or placing in a free zone or free warehouse.

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[227] Official Journal L 135, 03/06/2003, p. 0005-0011.
[228] Id., article 2 (a).
[229] OXFAM INTERNATIONAL, "Oxfam response to EU trade diversion regulation", accessible at : http://lists.essential.org/pipermail/ip-health/2002-December/003898.html.

> 2. The following shall be exempted from the prohibition regarding tiered priced products as set out in paragraph 1:
>
> **(a)** re-export to countries of destination;
> **(b)** placing under a transit or customs warehouse procedure or in a free zone or free warehouse for the purposes of re-export to a country of destination.

Although the NGO Oxfam 'welcomes the Commission's efforts to boost access to medicines for developing countries and believes that the Commission has a critical role to play in the immediate development of an international system to promote offers of cheaper prices in developing countries'[230], it still states that this regulation on trade diversion is insufficient to significantly reduce the pricing of essential medicines in the developing world. It further states that:

> "...comprehensive reductions in the cost of medicines will only be achieved through reform of the TRIPS Agreement to allow flexible patenting, combined with improved drug procurement measures"[231].

These views were expressed prior to the adoption of the *Decision of the WTO General Council on the Implementation of the paragraph 6 of the Doha Declaration*[232], which gives more flexibility on patenting rules and allows parallel imports in developing countries under specific conditions as we have seen previously in this analysis. In fact, the adoption of this new device in international law was essential to give full effects to this regulation, allowing a government of a developing country where a drug is patented to import the 'tiered priced' drug, therefore not limiting the effects of the European regulation only to developing countries where such drug would not be patented.

Moreover, Oxfam suggests three other amendments to this regulation that would make it more adequate to efficiently combat poverty and recurring diseases in the developing world:

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[230] Id.
[231] Id.
[232] Doha Declaration, op. cit., note 18.

- The disease scope of this regulation should be broadened beyond HIV/AIDS, malaria and tuberculosis. Diabetes and asthma are also problems in developing countries;
- The country scope of the regulation should be extended, as currently it does not protect pharmaceutical manufacturers offering 'tiered priced' medicines in other poor countries. This appears to be an arbitrary cut-off point, all developing countries should benefit from a system that reduces the price of vital, lifesaving medicines;
- As products exported under this regime will be deemed to be 'fairly priced', incentives for maximum discounts should be given. As set out in article 3, 20% of the average OECD price will not provide sufficient incentive for companies to offer maximum discounts, i.e. as close as possible to the costs of production[233].

iii) Proposal for a Regulation of the European Parliament and of the Council on compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems

The European Commission issued this proposal for a regulation on 29 October 2004 to implement at Community level the *WTO General Council Decision of August 30th, 2003 on the Implementation of Paragraph 6 of the Declaration on the TRIPS Agreement and Public Health*[234]. The main goal of this proposed regulation is to allow generic manufacturers to produce patented medicines that will be exported to developing countries with insufficient or no capacity in the pharmaceutical sector. This would be done by way of compulsory licenses, as provided in the General Council's Decision. Under the current system in force in the European Community, the national governments can only grant compulsory licenses for use within their own jurisdiction and cannot export compulsory licensed products to the majority of countries that have no domestic pharmaceutical industry for essential medicines.

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[233] OXFAM INTERNATIONAL, loc. cit., note 229.
[234] COMMISSION OF THE EUROPEAN COMMUNITIES, op. cit., note 224, preamble.

There are no limitations on the scope of medicines or diseases that are targeted by the proposed regulation. In fact, the definition of 'pharmaceutical product' in article 2 refers to 'any product of the pharmaceutical sector, including medicinal products as defined in article 1(2) of *Directive 2001/83/EC of the European Parliament and the Council*'[235]. However, only WTO Members will be able to seek cheap medicines manufactured under a compulsory license under this regulation[236]. According to the article 4 of the proposed regulation, the WTO members that do not qualify as a 'least developed country' will need to notify the World Trade Organization 'of its intention to use the system as an importer, including whether it will use the system in whole or in a limited way'. Restricting the potential benefits to the populations of the members of the WTO seems to be in total contradiction with the right to health. We think that all least-developed countries and developing countries should be entitled to contract with European generic manufacturers, whether they belong to the WTO or not. Moreover, the WTO members that declared previously to the WTO that they will not use the system as an importing member are not eligible for the current regime[237].

Similarly to what we have in the *Council Regulation (EC) No 953/2003 of 26 May 2003 to avoid trade diversion into the European Union of certain key medicines*[238], some emphasis has been put on preventing the re-importation in the European Community of the products exported under a compulsory license, except if those products are re-imported to be further exported to the same WTO member cited in the application and identified in the packaging and documentation associated with those products[239]. In that case, the right holder over a patented product will be entitled to use existing national laws to enforce its rights if the product is smuggled back in[240].

Additional restrictions regarding who can contract with European generic manufacturers are also included in the proposed regulation. According to article 5(3)g), the generic producer applying for a compulsory license has to submit evidence of a specific request for the pharmaceutical product in question 'from authorized representatives' of the importing country, 'indicating quantity of product required'.

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[235] Official Journal, L 311, 28/11/2001, p.67.
[236] EUROPEAN COMMUNITIES, op. cit., note 224, section 4.
[237] Id.
[238] Id., section 10.
[239] Id., section 11.
[240] Id., article 12.

According to the Canadian HIV/AIDS Legal Network, "this likely means that only governments of importing developing countries can purchase products from generic manufacturers"[241]. Since NGOs are already purchasing medicines from brand name and generic manufacturers for use in their programs, it is quite unfortunate to cut off this avenue to obtaining cheaper medicines for their patients. Moreover, to efficiently carry out their task in some cases, NGOs need to be independent from the local government. The way article 5(3)g) of the proposed regulation is currently drafted, NGOs would need to become the agents of a government to have access to these cheaper drugs.

As required by the *TRIPS Agreement*[242], article 7 of the proposed regulation states that:

> "The applicant shall provide evidence to satisfy the competent authority that he has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time.
>
> The determination of a reasonable period of time shall take into account whether the importing WTO member has declared a situation of national emergency or other circumstances of extreme urgency".

Médecins Sans Frontières declared on 29 October 2004 that they regret that the proposal requires prior negotiations with the patent holder, which will inevitably delay the swift use of the mechanism[243]. The *Canadian HIV/AIDS Legal Network*, added that:

> "...the EU [proposed] regulation is dangerously vague on these points. It does not provide any guidance as to what is a 'reasonable term and condition' of a license, nor as to what constitutes a 'reasonable period of time' for trying to negotiate a voluntary license before the way is clear to apply for a compulsory license. It simply repeats the undefined terms from the original WTO agreement"[244].

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[241] Richard ELIOTT, "Doha para 6 implementation: EU proposal vs. Canadian legislation" opinion given on the Consumer Project for Technnology Forum, available at : http://lists.essential.org/pipermail/ip-health/2004-November/007091.html.
[242] TRIPS, section 31(b).
[243] MÉDECINS SANS FRONTIÈRES, *MSF Statement on EC proposal for export of generics to developing countries*, accessible at : www.accessmed-msf.org/prod/publications.
[244] Richard ELIOTT, loc. cit., note 241.

Oxfam also expressed their concerns about costly delays in ordering generic essential pharmaceutical products:

> "...in the event of a public health emergency in a developing country, European governments should not require potentially time-consuming negotiations with the patent holder before issuing a compulsory license for export"[245].

Even if developing countries manage to negotiate reasonable terms with European generic manufacturers, the legal mechanism agreed within the WTO is complex, their markets may not be large enough to allow generic companies to offer cheaper prices. The European governments will need to monitor how this new legal framework will work in practice, in order to reach the point where generic production is no longer the exception but the norm in developing countries[246].

There is an interesting provision in the proposed regulation that we think should be underlined concerning the regulatory approval for the safety of a particular drug. According to the article 16 of the proposed regulation, a generic manufacturer may avail itself of the scientific opinion procedure provided in the *Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use*[247] but it is in no way mandatory. As a result, some requirements regarding the length of the marketing authorization and the communication of pharmacovigilance information to the general public are not applicable to the regime provided in the proposed regulation[248]. This exception to the usual regulatory review of generic products only applies to the products that will be exported under the regime of the proposed regulation. Generic producers selling versions of existing products that have already been approved for sale in the European Community usually need only to go through an abbreviated review process demonstrating the bioequivalence of both products. Bioequivalence will still be the requirement regarding drug safety for exported generic drugs, since an exception has been included in the proposed regulation if there is no 'reference product' approved in

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[245] OXFAM INTERNATIONAL, *EC gives positive signal on access to cheap medicines*, Oxfam press release, available at: http://lists.essential.org/pipermail/ip-health/2004-November/007090.html.
[246] Id.
[247] *Official Journal* L 311, 28/11/2001, p.0067-0128.
[248] See sections 24(4) and (5) and 14(4) and (5) of *Regulation (EC) No. 726/2004* of the European Parliament and the Council and section 6 of *Directive 2001/83/EC* of the European Commission.

the European Community. In that case, if it was not under the exception, a generic product for export would need to comply with the full regulatory process that brand name drugs usually need to go through, which is time-consuming and very costly[249]. This would be the case, for example, with numerous 'fixed dose combinations' of anti-retroviral drugs that combine several drugs in only one pill, described as a 'first-line therapy by the WHO[250]. Very few 'fixed dose combinations' have been approved for sale in western jurisdictions since they combine drugs which are patented by different competitor brand-name companies. The study for the safety of a generic drug could be based on data information that may be obtained from other jurisdictions, or from scientific studies carried out in universities or by NGOs for, and not necessarily from the formal regulatory review body of the European Community.

After reviewing laws and policies from developed countries mentioned above regarding an increased access to essential medicines for developing countries, we will now turn to the analysis of public health safeguards in intellectual property legislation at the national level favouring an increased access to essential medicines in developing countries.

PART V – MEASURES TAKEN IN INTELLECTUAL PROPERTY LAW BY BRAZIL, INDIA, AND SOUTH AFRICA IN ORDER TO INCREASE ACCESS TO ESSENTIAL MEDICINES FOR THEIR POPULATIONS

Chapter a) Brazil

1) U.S. vs. Brazil: The Brazilian AIDS Program

From the mid-1990's, the Brazilian government has implemented a state program on AIDS care, through which universal access to ARV treatment was promoted. The capacity to control the HIV/AIDS epidemic in Brazil and the number of sick people under ARV treatment makes the Brazilian state program one of the best example to follow for other states to fight HIV/AIDS. That program also proved to have positive effects on public spending as a consequence of significant cuts in hospital costs at the

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[249] Richard ELIOTT, loc. cit., note 241.
[250] Id.

charge of the state. In fact, Brazil achieved very sound results through its health policy based on universal access to ARVs:

> "An estimated 536,000 people are infected with HIV in Brazil, with 203,353 cases of AIDS reported to the Ministry of Health from 1980 through December 2000. In 2001, 105,000 people with HIV/AIDS received ARV treatment. The Brazilian AIDS program has reduced AIDS-related mortality by more than 50 percent between 1996 and 1999. In two years, Brazil saved $472 million in hospital costs and treatment costs for AIDS-related infections"[251].

Brazil could afford to take the means to achieve universal access to ARVs as a result of its ability to produce medicines locally. In Brazil, the price of AIDS drugs fell by 82 percent over five years because of generic competition. In the meantime, the price of the drugs that had no generic competitors within this market only fell 9 percent over the same period[252].

In fact, the implementation of the Brazilian program shows the benefits that increased competition may bring to pricing of essential drugs. When Brazil began to purchase antiretroviral drugs in large quantities in 1996, it purchased the active ingredients for two of these products from Asian generic suppliers for prices in excess of US $20,000 per kilo[253]. By 1999, the prices for these two ingredients have fallen respectively to US $8,000 and US $5,000. Since the Brazilian purchases constituted a significant market for generic products, the prices for these products have recently fallen to approximately US $500 per kilo[254].

However, although the Brazilian program constituted one of the best examples to follow for high-income developing countries regarding the achievement of significant progress through universal access to ARVs for its population, the United States and the Pharmaceutical Manufacturers Association (PhRMA) have done everything to discredit that program, claiming that it was not meeting the international standards on patent protection.

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[251] Ellen 't HOEN, loc. cit., note 69, p.206-207.
[252] Id., p.207.
[253] *Affidavit of James Love*, South Africa - Competition Commission Complaint Against GlaxoSmithKline and Boehringer Ingelheim, 3 February 2003, paragraph 19.
[254] Id.

The conflict between the U.S. and Brazil can be traced back to June 11th, 1987, when the Pharmaceutical Manufacturers Association filed a petition to USTR complaining of Brazil's lack of process and patent protection for pharmaceutical products as an unreasonable practice that burdens or restricts US commerce[255]. Accordingly, on July 23rd, 1987, the USTR initiated an investigation and requested consultation with Brazil, which were held on February 29, 1988, but did not lead to any results. On July 21st, 1988, the President of the U.S. determined that the Brazilian policies regarding patent protection were unreasonable regarding U.S commerce, and this lead to public hearings that were held on September 8th and 9th. This eventually lead to tariff increases of 100% *ad valorem* on certain Brazilian products, such as some paper products, non-benzenoid drugs, and consumer electronics items, which were proclaimed on October 20th, 1988, and became effective on October 30th, 1988[256].

As a result of these trade sanctions, the Government of Brazil announced on June 26th, 1990, that it would follow-up with the presentation of a bill ensuring the provision of patent protection for pharmaceutical products and the process of their production. Therefore, the USTR announced on June 27th, 1990, that it was in the interest of the United States to terminate trade sanctions against Brazil since it was determined that 'Brazil has taken satisfactory measures to eliminate the practices that were determined by the President to be unreasonable and a burden or restriction to U.S. commerce[257].

Since patent rules would now find a stricter application in Brazil, the authorities formulated provisions and mechanisms that would allow the local industry to survive, and the interests of the population in general to be respected, such as public health. An example of these provisions that brought much controversy is the article 68 of the 1996 industrial property law (Law no. 9.279/96):

> "Under that provision, Brazil requires holders of Brazilian patents to manufacture the product in question within Brazil – a so-called 'local working' requirement. If the company does not fulfill this requirement, the patent shall be subject to compulsory licensing after three years, unless the patent holder can show that it is not economically feasible to produce in Brazil or

[255] PhRMA, *PhRMA's 1987 petition to USTR*, from which passages are available at: http://www.cptech.org/ip/health/c/brazil/.
[256] Id.
[257] Id.

> can otherwise show that the requirement to produce locally is not reasonable. If the company is allowed to work its patent by importation instead of manufacturing in Brazil, parallel import by others will be permitted"[258].

In February 2001, the U.S. took action against Brazil through the WTO procedure over this article 68 of the Brazilian patent law. The U.S. argued that the Brazilian law was discriminating U.S. patent holders registered in Brazil and that their rights were curtailed by this provision[259]. Moreover, the U.S. stated that the article 68 of the Brazilian patent law was violating article 27 (1) and article 28 (1) of *TRIPS*[260], which lay down the basic rights and obligations conferred by patents at the international level. Brazil answered by stating that article 68 was in line with the spirit of TRIPS, including article 5 (4) of the Paris Convention, which allows compulsory licensing if there is a failure to work a patent[261]. Brazil also issued a counter-complaint, which focused on articles 204 and 205 of Title 35 of the US patent code, stating that it was discriminating against foreign producers[262]. The outcome of this action would have been rather interesting for Canada since it had a 'local working' requirement until it became a member of NAFTA in the early nineties, when this provision needed to be repealed to comply with new international obligations[263]. Section 68 of the Brazilian patent law translated in English may be read as follows:

> "**Section 68**: A patentee will be subject to having its patent compulsorily licensed if he exercises rights resulting therefore in an abusive manner or by means of abuse of economic power proven under the terms of the law by an administrative or court decision.
>
> §1 The following may also result in a compulsory license:
>
> - Non-exploitation of the subject matter or the patent in the territory of Brazil, by lack of manufacture or incomplete manufacture of the product or, furthermore, by lack of complete use of a patented process, except in the case of non-exploitation due to economic unfeasibility, when importation will be permitted; or
>
> - Commercialization that does not meet the market needs.

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[258] Ellen 't HOEN, loc. cit., note 69, p.207.
[259] Id.
[260] Supra, Part III.
[261] Ellen 't HOEN, loc. cit., note 69, p.207.
[262] BUREAU OF U.S. NATIONAL AFFAIRS, *United States Drops WTO Case Against Brazil Over HIV/AIDS Patent Law*, June 26th, 2001, (800-372-1033).
[263] Patent Act, op. cit., notes 101 and 102.

...

> §5 A compulsory license, to which §1 refers, may only be requested after 3 (three) years form grant date"[264].

While this was a trade dispute, Brazil was also active on the human rights scene to condemn U.S. behavior regarding the application of patent law. On April 23, 2001, the UN Commission on Human Rights passed a resolution promoting access to pharmaceuticals proposed by Brazil and titled *Access to Medication in the Context of Pandemics Such As HIV/AIDS.* The resolution was adopted 52 votes against none with only the U.S. abstaining. Among other things, the resolution calls for:

> "- The availability in sufficient quantities of pharmaceuticals and medical technologies used to treat pandemics such as HIV/AIDS or the most common opportunistic infections that accompany them;
> - The accessibility to all without discrimination, including the most vulnerable sectors of the population, of such pharmaceuticals or medical technologies and their affordability for all, including socially disadvantaged groups;
> - The accessibility to all without discrimination, including the most vulnerable sectors of the population, of such pharmaceuticals or medical technologies and their affordability for all, including socially disadvantaged groups.

About two months later, the U.S Trade Representative announced on June 25th, 2001, that the United States and Brazil 'have agreed to transfer their disagreement over a provision of Brazil's patent law from formal WTO litigation to a newly created bilateral consultative mechanism'[265].

> "The Bush administration wants to resolve trade disputes by seeking constructive solutions to problems that arise. I stand four-square behind strong enforcement of the WTO rules on intellectual property. However, litigating this dispute before a WTO panel has not been the

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[264] *Law 9279/86 on Intellectual Property Law*, effective as of May 15th, 1997.
[265] USTR, *United States and Brazil agree to use newly created Consultative Mechanism to promote cooperation on HIV/AIDS and address WTO patent dispute*, The Office of the United States Trade Representative, June 25th, 2001, accessible at: http://www.ustr.gov/document_library/press_releases/2001/June/United_States_Brazil.

> most constructive way to address our differences, especially since Brazil has never actually used the provision at issue"[266].

Still, the U.S. continues to view local manufacturing requirements as being contrary and inconsistent to various WTO rules and general principles. As a counterpart, Brazil has agreed to provide advance notice to the U.S. if it plans to use article 68 of its intellectual property law[267]. The Government of Brazil issued a press communiqué on June 25th, 2001, to announce the withdrawal of the case, stating that it was still holding its grounds regarding the litigation:

> "The Government of Brazil receives with great satisfaction the decision by Government of the United States to withdraw the panel against Brazil at the WTO concerning the compatibility of article 68 of the Brazilian Industrial Property Law (Law 9279/96) with the TRIPS Agreement. In the event it deems necessary to apply article 68 to grant compulsory licenses on patents held by U.S. companies, the Brazilian Government agrees to hold prior talks with U.S Government. These talks would be held within the scope of the U.S.-Brazil Consultative Mechanism, in a special session scheduled to discuss the subject.
>
> Brazil maintains its conviction that Article 68 is fully consistent with the TRIPS Agreement and an important instrument available to the Government, in particular in its efforts to increase access of the population to medicines and to combat diseases such as AIDS"[268].

In fact, it was widely viewed that the request seeking an appointment with a WTO panel was dropped by the U.S. as a result of fierce criticisms from NGOs and the general public[269], as they feared that it would have a detrimental effect on the Brazil's successful AIDS program[270].

On August 22, 2001, Brazil threatened to issue a compulsory license for the production of the antiretroviral drug nelfinavir as a result of unsuccessful negotiations between the Brazilian Government and Roche. On August 31st, the parties reached an agreement

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[266] Id..
[267] Id.
[268] Government of BRAZIL, *Press Communiqué by the Government of Brazil*, June 25th, 2001, accessible at: http://www.cptech.org/ip/health/c/brazil/brazilstatement05252001.html.
[269] Id.
[270] Ellen 't HOEN, loc. cit., note 69, p.207.

through which Roche will continue to sell nelfinavir in Brazil at an additional 40 percent discount while Brazil will not issue the compulsory license[271].

Although Brazil has certainly benefited from the withdrawal of the U.S. complaint to the WTO, giving away a 'right of supervision' on day-to-day administration of patent law to another nation, especially one as powerful as the U.S. should be the object of cautious reflections. Even if the objection of the U.S. aimed solely at the 'local working' requirement, the joint U.S.-Brazil statement seems to cover the entire article when it states that:

> "The Brazilian Government will agree, in the event it deems necessary to apply Article 68 to grant compulsory license on patents held by U.S. companies, to hold prior talks on the matter with the U.S.. These talks would be held within the scope of the U.S-Brazil Consultative Mechanism, in a special session scheduled to discuss the subject." [272]

2) Compulsory licensing used as a threat in order to get price reductions

So far, Brazil never needed to make use of its compulsory license regime to produce cheap drugs. In fact, after long negotiations with the Swiss drug giant Roche, the Brazilian Government came to an agreement to cut the price of the AIDS drug Viracept by a further 40 percent, which ended the threats by the government to break the patent and produce the drug locally[273]. After that discount, the price for Viracept in Brazil will amount to about 30 percent of its price in the United States; it was about 50 percent of that price prior to the negotiations. It was reported that no country has ever issued a compulsory license as a result of high prices on essential drugs and health crisis, and it was widely viewed that if Brazil would have gone ahead with the idea, other developing countries with high numbers of people suffering from AIDS might have followed[274]. This agreement happened, as it must be underscored, a few weeks prior to the WTO negotiations held in Doha on patents and access to health care.

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[271] See the Consumer Project on Technology web page on Brazil at: http://www.cptech.org/ip/health/c/brazil/.

[272] Governments of BRAZIL and the U.S., *Joint Communication Brazil-United States*, Statements concerning the U.S./Brazil trade dispute over the local production on drugs, June 25th, 2001, available at: http://www.cptech.org/ip/health/c/brazil/statement06252001.html.

[273] Jennifer L. RICH, "Roche Releases Accord on Drug with Brazil", *New York Times*, September 1, 2001.

[274] Id.

Similarly, the same story repeated itself in 2003 when Brazil announced on November 18th that it had reached an agreement with Merck for the provision of Efavirenz at 25 percent off, and with Bristol-Myers Squibb for Atazanavir at a 76 percent reduction one week before that[275]. Again, Brazil has put pressure on pharmaceutical companies to reduce their drug prices by threatening to make generic copies locally if they did not oblige. Moreover, the Brazilian Health Ministry said it was continuing talks with two other drug companies in an effort to negotiate further price reductions, namely Roche, which produces Nelfinavir, and Abbott, which manufactures Lopinavir[276].

These two deals occurred about two months after the *Decision of the WTO Council on the implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and public health,* allowing the issuance of a compulsory license for the provision of pharmaceuticals for foreign markets lacking the manufacturing capacity to produce essential drugs and the subsequent announcement made by Brazil that it intended to import generic medications from China and India[277].

On June 24th, 2005, since the negotiations with Abbott did not come to a conclusion, Brazil announced that a compulsory license would be issued in 10 days for lopinavir + ritonavir (kaletra). The Ministry of Health of Brazil has declared the antiretroviral drug kaletra of public interest, which enables the Brazilian Government to adopt a compulsory license regarding this medication in case the manufacturer does not provide guarantees for the sustainability of the national AIDS Program[278]. This time, the authorities decided not to use the 'local working' requirement at article 68 but the article 71 of the Brazilian patent law on national emergencies and public interest:

> "**Article 71:** In cases of national emergency or public interest, declared in an act of the Federal Executive Authorities, insofar as the patentee or his licensee does not meet such demand, a

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[275] BBC News, *New anti-HIV drug deal for Brazil*, November 18, 2003, available at: http://news.bbc.co.uk/go/pr/fr/-/1/hi/world/americas/3281683.stm.
[276] Id.
[277] Mario OSAVA, "IPS: Brazil Imports Generic AIDS Drugs from India and China", September 6th, 2003, available at: http://www.ipsnews.net/interna.asp?idnews=3D19997.
[278] NATIONAL STD/AIDS PROGRAM, "The Government declares anti-retroviral Kaletra to be of public interest and will produce it in Brazil", June 24th, 2005, available at: http://www.prnewswire.com/cgi-bin/stories.

> temporary *ex-officio* non-exclusive compulsory license for the exploitation of the patent may be granted, without prejudice to the rights of the respective patentee"[279].

The notice to the manufacturer was intended as an ultimatum; the laboratory had ten days from receipt of the notice to inform the Brazilian Ministry of Health that it was prepared to reduce the sales price of Kaletra to national production levels[280]. In case Abbott would not agree to reduce its sales price, the Ministry of Health would go ahead in issuing the compulsory license to a national laboratory. There are 16 types of antiretroviral drugs that are distributed free of charge through the national program in Brazil. Kaletra is from a new generation of antiretroviral drugs and is administered to those that have already developed resistance to other medication[281]. But the share of expense for the newest generation of ARVs in the total budget devoted to the acquisition of drugs in the Brazilian program is enormous:

> "Today close to 80 percent of the budget of the AIDS National Program for ARVs is spent on imported patented drugs. 70 percent is spent on the purchase of four patented drugs, Lopinavir/Ritonavir, Tenofovir, Efavirenz and Nelfinavir. Brazilian public and private companies are only producing 7 out of 16 drugs that are used in the tri-therapy while there is capacity to produce all of the needed medicines"[282].

The announcement of the ultimatum provoked significant reactions from different stakeholders. Obviously, civil society organizations were very enthusiastic regarding the procedure that the Brazilian Government had taken, and some asked for a wider non-application in developing countries affected by HIV/AIDS. That was the case for *Health GAP (Global Access Project)*, which issued this statement when the decree authorizing a compulsory license was proclaimed:

> "The medicines are critical for HIV treatment when initial combinations of medicines have failed. The high cost of second generation patented HIV/AIDS drugs threatens the sustainability of treatment program not only in Brazil, but troughout the developing world... Now other countries, particularly countries with the capacity to produce and export medicines

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[279] Law 9279/86, note 264.
[280] Id.
[281] Id.
[282] GRUPO DE TRABALHOSOBRE PROPRIEDADE INTELECTUAL, *Declaration of Civil Society regarding the Brazilian Negotiations for Voluntary License for AIDS drugs*, GTPI – da Rede Brasilaira pela Integraçao dos Povos – Rebrip, Rio de Janeiro, May 5th, 2005.

> to other countries must follow suit and break the patent monopolies of overpriced AIDS drugs in order to ensure access to affordable life-long treatment"[283].

Even within the United States, the announcement of the possibility of the issuance of a compulsory license in Brazil raised positive reactions among U.S. Congressmen. U.S. Representative Tom Allen expressed publicly his agreement with the measure taken by the Brazilian Government:

> "Brazil's issuance of a compulsory license for HIV/AIDS drugs is an appropriate and legal tool to use when the high prices charged by brand-name manufacturer limit the number of HIV/AIDS patients that can be treated"[284].

He further reaffirms that the use of a compulsory license in the public interest is unconditionally legal under the light of the *TRIPS Agreement* and the *Doha Declaration on Public Health*, and made direct reference to the latter, its paragraph 4 stating that 'each WTO Member has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted'.

Moreover, U.S. Representative Henry A. Waxman, the father of the so-called *Hatch-Waxman Act* that has been discussed previously[285], has also showed support for the Brazilian initiative.

> "Some who oppose Brazil's action have claimed that it violates trade rules. In fact, the World Trade Organization's 1994 Agreement on Trade Related Aspects of Intellectual Property specifically permits compulsory licensing"[286].

But PhRMA and many pro-industry groups also expressed hostile reactions towards the Brazilian action. PhRMA expressed its polite disagreement in a press statement on July 1st, 2005, stating that the solution for HIV/AIDS does not lie in breaking patents,

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[283] HEALTH GAP (Global Access Project), *Brazil Breaks Patent on Monopoly on Costly HIV Medicine to Increase Access to Treatment*, press statement – June 24th, 2005, available at: http://www.cptech.org/ip/health/c/brazil/hgap06242005.html.

[284] Tom ALLEN, "Statement on Brazil's Issuance of a Compulsory License for HIV/AIDS", June 29, 2005, available at: http://tomallen.house.gov.

[285] Supra, Part IV, chapter b).

[286] Henry A. WAXMAN, *Rep. Waxman Statement on Brazilian Compulsory License Dispute*, Congressional Record: June 28th, 2005, p.E1389-E1390, or from the Congressional Record Online via GPO Access: wais.access.gpo.gov, DOCID: cr28jn05-51.

since the members of PhRMA are 'devoted to inventing medicines that allow patients to live longer, healthier, and more productive lives'[287]. Therefore, PhRMA is of the opinion that:

> "As a matter of policy, the solution to helping Brazilian HIV/AIDS patients lies in furthering the constructive relationships between our companies and the government of Brazil – not breaking patents"[288].

The U.S. Chamber of Commerce warned 'all investors around the world' about the dangerous precedent the Brazilian initiative sets for the treatment of intellectual property[289]. Abbott, the patent holder of Kaletra, affirms that Brazil, as the world's 9th largest economy, should not benefit from the same relief as developing countries and that this would be contrary to the spirit of the TRIPS Agreement[290].

> "Compulsory licensing would have significant negative consequences for the global discovery and development of future treatments for all disease areas, not just HIV/AIDS. In the end, without innovation and new therapies, it is the people fighting HIV/AIDS and many other devastating diseases who will lose"[291].

Opposite to some reports, other countries have previously used a compulsory license to attempt to slow down the spread of HIV/AIDS within their borders: Mozambique, Malaysia, Indonesia, and South Africa[292]. But most certainly, perhaps along with South Africa, but probably for different reasons that will be discussed in next section, this was the most meditated case of this sort.

As brand-name manufacturers did previously when their interests were threatened by the issuance of a compulsory license, Abbott announced that a deal has been reached with Brazil on July 8th, 2005. Abbott was pleased to affirm that 'the agreement accomplished Abbott's objectives of helping Brazil to expand patients access to

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[287] PhRMA, *PhRMA Statement on Protecting Patent Rights in Brazil*, July 1st, 2005, available at: http://biz.yahoo.com/prnews/050701/dcf032.html.
[288] Id.
[289] U.S. CHAMBER OF COMMERCE, *Chamber Urges Brazil to Abandon its Drug Ultimatum – Warns Weakening Intellectual Property Protections Will Hurt Investors*, July 1st, 2005, available at: http://www.uschamber.com/press/releases/2005/july/05-116.htm.
[290] ABBOTT, *A Statement from Abbott*, June 29th, 2005, available at: http://biz.yahoo.com/prnews/05629/cgw056.html.
[291] Id.
[292] GRUPO DE TRABALHOSOBRE PROPRIEDADE INTELECTUAL, op. cit, note 282.

Kaletra while preserving the company's intellectual property rights, which Abbott was not willing to negotiate'[293]. It further underscores that strong intellectual property is the reason why many HIV treatments are available today, and will make it possible to find new cures in the future as the HIV virus continues to evolve. Abbott reiterates its "commitment to the protection of intellectual property in order that innovation keep on flourishing for the benefit of the patients all over the world[294]".

However, this agreement with Abbott frustrated many Brazilians. The terms of the agreement were said to be ambiguous and impossible to evaluate because of the lack of transparency of the information given by the government[295]. In fact, 'Abbott presented a gradual price reduction proposal up to 2010, foreseeing an increase on the number of patients from around 23 to 60 thousand in this period. Additionally, the company would offer technology transfer from 2009 onwards, only 6 years before the patent expires in Brazil'[296]. The *Associaçao Brasileira Interdisciplinar de AIDS* has identified three serious flaws into the agreement:

- Pricing will only drop from 2006 at a very gradual pace, and in order to reach the lowest price provided by the agreement by 2010, it would be necessary to prescribe Kaletra to patients that do not need it. Such an increase of users of Kaletra is not expected, and this requirement is not necessary.
- The fact that Brazil, the largest market amongst the middle-income countries, will not have a dramatic cut in price before 4 or 5 years, will dramatically restrict the room of maneuver of other developing countries in the price reduction negotiations.

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[293] ABBOTT, *Abbott Statement on Agreement with Brazilian Government for Kaletra ® (Lopinavir/Ritonavir)*, Canada Newswire, July 9th, 2005, available at: http://press.arrivenet.com/bus/article.php/665926.html.

[294] Id.

[295] INTELLECTUAL PROPERTY WORKING GROUP of Rede Brasileira pela Integração dos Povos, "Agreement of the Brazilian Government with Abbott frustrates Brazilians", July 14th, 2005, available at: http://www.rebrip.org.br/publique/cgi/public/cgilua.exe/web/templates/htm/_template01/frameset.htm?user=reader.

[296] ASSOCIAÇAO BRASILEIRA INTERDISCIPLINAR DE AIDS, *Overview of the Compulsory Licensing Process in Brazil*, July 2005, English version available at: http://www.cptech.org/ip/health/c/brazil/abia07152005.html.

- The technology transfer will start too late, only 6 years before patent expiration, even if a Brazilian laboratory has the means to start production as early as 2006[297].

For these reasons, the *Associaçao Brasileira Interdisciplinar de AIDS* believes that compulsory licensing is the only valid alternative to secure short and long term cuts in pricing and to provide alternatives for developing countries to ensure newest line treatment for patients in need. Surprisingly, 6 days after the agreement was announced and through a new Minister of Health, reports that an agreement was reached with a U.S. drug manufacturer were denied despite earlier statements that such a deal was finalized[298]. To this day, no confirmation has been given whether a compulsory license will be issued or not. More developments are expected regarding these negotiations.

3) Exemption of patentability for pharmaceutical products

On June 1st, 2005, the Brazilian Chamber of Deputies approved Bill No. 22/03, which would amend the Law No. 9.279 of May 14th, 1994, which lists exemptions to patentability, thus making HIV/AIDS drugs unpatentable in Brazil. The new article 18 goes as follow:

> "**Article 18**: The following shall not be patentable:
>
> ...
>
> **IV** – the medication, together with its respective procurement procedure, specifically for the prevention and treatment of the Acquired Immunodeficiency Syndrome SIDA/AIDS.
>
> ...

Mr. Roberto Gouveia justified this amendment by maintaining that patent protection in Brazil "is so broad that in many cases this results in economic or commercial abuse under the aegis of the law (9.279/96) itself", and by the powerful influence of the pharmaceutical lobby very present in Legislative and Executive circles, delaying as

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[297] Id.

[298] ASSOCIATED PRESS, "Brazil Minister Says no AIDS Drug Deal", July 14th, 2005, available at: http://www.forbes.com/business/feeds/ap/2005/07/14/ap2139640.html.

much as possible the application of Law No. 9787/99 on generics, among others[299]. This is an interesting initiative, as it may comply with Brazil's international obligations concerning patents, since article 27(2) of TRIPS provides that:

> "Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect *ordre public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law".

It remains to be seen if this Bill was part of the negotiation strategy of the Brazilian Government to get price cuts on HIV/AIDS drugs from foreign brand-name pharmaceutical firms. To come into force, the Bill still needs to get the approval of the Federal Senate and the President's sanction[300]. Unfortunately, most likely because of the political crisis affecting the current government in Brazil, there have not been any developments concerning *Bill No. 22/03* since June 1st, 2005.

Chapter b) India

1) Trends in Indian patent law regarding the patentability of medicines

What distinguishes India from other developing countries wishing to produce generic drugs is that it had already a strong generic industry prior to the implementation of WTO and TRIPS within its jurisdiction. In fact, this section devoted to India is a good opportunity to have a closer look at the interests at stake when the TRIPS Agreement was negotiated as a component of the WTO Uruguay Round of negotiations in the early nineties. Because of the difference of their interests at stake, TRIPS gave rise to extensive debates between developed and developing countries. On one side, strong business interests in the developed world claimed that illegitimate use of their innovation was being made in the developing world, and that this was leading not only to important financial losses for the industry in the developed countries, but also a

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[299] Mr. Roberto GOUVEIA, "Justification and the original text of Bill Number 22/03 – PARLIAMENTARY BILL", available at: http://www.cptech.org/ip/health/c/brazil/gouveia06082005.html.

[300] INTERFARMA, "Brazilian Research-Based Pharmaceutical Manufacturers Association - on Bill 22/03", available at: http://www.cptech.org/ip/health/c/brazil/interfarma06022005.html.

disincentive for foreign investment, technology transfer and greater domestic research and development[301]. On the other side, developing countries governments were strongly opposed to this view, and were worried that the higher prices brought by a stronger and compulsory IP international regime would prevent the blossoming of a new high-tech industry in their jurisdiction.

India was considered as one of the most vehement opponents of TRIPS, and no part of TRIPS was, and continues to be, more sensitive than the proposal to require product patents on pharmaceutical innovations[302]. This is indeed a strong national sentiment, as well expressed in a statement by Indira Gandhi at the World Health Assembly in 1982:

> "The idea of a better-ordered world is one in which medical discoveries will be free of patents and there will be no profiteering from life and death"[303].

According to Mr. Philippe Cullet, India is particularly noteworthy in respect of taking into consideration the price of medicines and the access to drugs in the development of their legal and policy framework in the health sector[304]. In 1970, India adopted patent legislation that prohibited product patents for medicines, restricting the scope of patentability of medicines only for the production processes and not for the end product itself. This constituted a major incentive for the development of a relatively strong pharmaceutical industry[305].

> **"5. Inventions where only methods or processes of manufacture patentable.**
>
> In the case of inventions-
>
> (a) claiming substances intended for use, or capable foe being used as food or as medicine or drug, or
>
> (b) relating to substances prepared or produced by chemical processes (including alloys, optical glass, semi-conductors or inter-metallic compounds),

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[301] J.O. LANJOUW. "The Introduction of Pharmaceutical Product Patents in India: Heartless Exploitation of the Poor and Suffering", WP 07/99, OIPRC Electronic Journal of Intellectual Property Rights, available at: http://www.oiprc.ox.ac.uk/EJWP0799.html.
[302] Id.
[303] Id.
[304] P. CULLET, loc. cit., note 63, p.182.
[305] Id., p.182.

> no patent shall be granted in respect of claims for the substances themselves, but claims for the methods or processes of manufacture shall be patentable"[306].

One of the most important impacts of the Indian Patents Act under its 1970 version and the development of a strong generic industry is the advent of significantly lower prices for drugs compared to other countries[307]. Moreover, because India did not have to comply fully with WTO standards until 2005, it became the home of a number of independent drug manufacturers that make generic copies of drugs that were originally developed and patented in the west[308]. Through these trends, India became one of the main suppliers of cheap drugs to developing countries. Among others, Indian drug manufacturers have contracted with Cameroon[309], Nigeria and South Africa[310] for the provisioning of cheap generic AIDS drugs. Thus, India clearly became one of the most important actors in the provisioning of essential drugs to poor populations. Médecins Sans Frontières even assessed that as much as 50 percent of the 700,000 people estimated to be on ARV treatment in developing countries rely on Indian generic production[311].

Moreover, the general provisions for compulsory licensing will become much more relevant since *TRIPS* has started to be implemented in India from March 2005, therefore modifying significantly India's patent legislation. Section 83 of the *Patent Act no. 39 of 1970* first provides general principles about the working of a patent in India. It states that without prejudice to other provisions of that Act, "that patents are granted to encourage inventions and to secure that the inventions are worked in India on a commercial scale and to the fullest extent that is reasonably practicable without undue delay"; and "that they are not granted merely to enable patentees to enjoy a monopoly for the importation of the patented article". Section 84 allows the issuance of a compulsory license if an invention is not made available to the public in India at a reasonable price after three years since the invention has started to be commercialized.

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[306] *The Patent Act – Act no.39 of 1970*, article 5.
[307] P. CULLET,loc. cit., note 63, p.183.
[308] A.M. CURTI, loc cit., note 12, p.478.
[309] INDIA PRESS, "Cipla to provide AIDS drugs to Cameroon", Dow Jones Asian Equities Report, July 27th, 2001.
[310] AGENCE FRANCE-PRESSE, "Nigeria Buying Generic drugs for an AIDS Treatment Trial", *New York Times*, November 30th, 2001.
[311] MÉDECINS SANS FRONTIÈRES, "MSF statement about new Indian Patent Bill", March 23rd, 2005, available at: http://www.accessmed-msf.org/prod/publications.asp?scntid=2432005941218&contenttype=PARA&.

2) Amendments to Indian Patent Law as a result of the implementation of WTO in 2005

As stated earlier, the main vehicle for the introduction of medical patents in developing countries is the TRIPS Agreement. All WTO member states have to comply with the minimum IP standards included in TRIPS, which are equivalent to a consensus position among developed countries, through their national legislation[312]. Even though TRIPS was never considered as a good bargain by developing countries, they nonetheless agreed to be part of it since it was itself part of the broader package deal of the GATT agreements of Marrakech in 1994 and because it includes broad safeguards provisions for public interests. Moreover, to facilitate the implementation of these new rules in countries lacking the required technical and financial resources, many developing countries had delays to comply with WTO rules. India had until 2005 to fully comply with WTO standards, although it had interim obligations to meet during its transitional period, which were in fact a matter of dispute in itself as the United States brought an action against India before a WTO panel. The U.S. claimed that India was not meeting its transitional obligations according to article 70(8) and 70(9) of TRIPS[313]. Furthermore, the new amendments to the *Indian Patents Act* that were adopted in March 2005 led to much debate recently since their effect goes well beyond the fields of trade and intellectual property, and the standards of protection of patents went way beyond what is required by TRIPS.

i) New use of known medicines

Initially it was proposed to provide a patent for new uses and dosages of known medicines, which would considerably extend the traditional scope of patentability, opposed to patents given only to new chemical entities, which require a much higher degree of inventive step and novelty from the manufacturer[314]. The mere discovery of a new use for a known chemical entity did not qualify under the threshold of inventive

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[312] P. CULLET, loc. cit., note 63, p.183.
[313] A.M. CURTI, loc. cit., note 12, p.478.
[314] AFFORDABLE MEDICINES AND TREATMENT CAMPAIGN, "Alert: Send protests to the PM of India on Patent Amendment", a statement by Affordable Medicines and Treatment Campaign (AMTC), available at: http://lists.essential.org/pipermail/ip-health/2004-October/007057.html.

step in the former *Indian Patents Act,* as in most other countries[315]. This proposition would also involve a lax interpretation of the novelty standard of patentability, thus extending the scope of patentability of the *Indian Patents Act* beyond the requirements of TRIPS Agreement[316].

Moreover, such broad standards of patentability may delay significantly the introduction of generic medicines in the Indian market by allowing frivolous patent applications on the colour/shape of a pill, its composites or its dosage, as seen in the U.S[317]. Effective provisions defining 'product', 'novelty' and 'inventive step' should be provided in the legislation, in order to avoid patent grants for insignificant innovation or improvement, thus unjustifiably prolonging the life of a patent at the cost of access to drugs for poor populations.

Not surprisingly, after considerable pressure from civil society associations, the final version of the Indian *Patents Act* provided some safeguards regarding the 'evergreening' of patents. The amendments to the Ordinance tabled by the government have now restricted the scope for the granting of patents on frivolous claims[318]. They clarify the definition of 'inventive step' as an invention that:

> "...involves technical advances as compared to the existing knowledge or having economic significance or both."[319]

Furthermore, the Bill clarifies the concept of 'new invention' in Indian law, which is:

> "...any invention or technology which has not been anticipated by publication in any document or used in the country or elsewhere in the world before the date of filling of patent application

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[315] N.V. ZAVERI, "Some critique on patent amendment bill (India)", a statement by Affordable Medicines and Treatment Campaign (AMTC), available at: http://lists.essential.org/pipermail/ip-health/2004-October/007039.html.
[316] Id.
[317] Supra, Part IV, chapter b)2)i).
[318] Amir Sen GUPTA, *Changes in the New Patents Bill*, National Working Group on Patent Laws, New Delhi, India, March 22nd, 2005, available at: http://www.cptech.org/ip/health/c/india/gupta03222005.html.
[319] INDIAN MINISTRY OF COMMERCE AND INDUSTRY, "Important Changes Incorporated in the Patents (Amendment) Bill, 2005, as Compared to the Patents Amendment Bill, 2003", press releases, March 23rd, 2003, available at: http://pib.nic.in/release/release.asp?relid=8096.

> with complete specification, i.e. the subject matter has not fallen in public domain or that it does not form part of the state of art."[320]

The amendments also bring a definition for 'pharmaceutical substance'. In order to get a patent on such a subject matter, the compound will need to be:

> "...a new entity involving one or more inventive step."[321]

This will clarify the above-mentioned ambiguities regarding the scope of patentability of pharmaceuticals under the new Patents Law in India and will bring it back to usual international standards predominant in most countries around the world, such as those studied in this document. Patent claims evaluation should be restricted to the significance of the improvement of a drug opposed to the expectation of profits of its new use. Extending the scope of patentability of pharmaceuticals, especially in a country like India with a strong tradition of providing developing countries with very low cost pharmaceuticals, and with such a large and increasing population infected with HIV/AIDS, would have been a very strong blow and a dangerous precedent against human rights law and especially the right to access to health care for all populations.

ii) Incorporation of August 30th Decision of the TRIPS General Council in the Indian legislation

As seen in previous chapters, the *August 30th Decision of the TRIPS General Council* exceptionally authorizes the grant of a compulsory license for export purposes, to countries with no or insufficient manufacturing capacity in the pharmaceutical sector. Initially, the draft bill for the amendment of the Patents Act did not fully comply with this decision. The Bill was proposing to allow compulsory licensing to a country with no or insufficient manufacturing capacity in the pharmaceutical sector if there was a corresponding patent in the importing country[322]. This is clearly more restrictive than what has been laid out in the *TRIPS Agreement*, the *Doha Declaration on TRIPS and Public Health*, and the *August 30th Decision of the TRIPS General Council*, since no

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[320] Id.
[321] Id.
[322] AMTC, loc. cit., note 314.

such requirement as the issuance of a compulsory license in the importing country is included in these legal agreements. Moreover, this provision completely ignored the transition period granted to least developed countries by the WTO to comply with the TRIPS requirements, which will be over only in 2016[323]. Because of this transition period, many LDCs have not yet implemented IPR schemes in their jurisdiction. In that case, Indian drug manufacturers could not export cheap medicines to LDCs, which would be totally against the spirit of *TRIPS*, the *Doha Declaration on TRIPS and Public Health*, and the *August 30th Decision of the TRIPS General Council.*

Other critiques reported that the new Indian compulsory licensing scheme was not respectful of the spirit of the Doha Declaration since it was burdened with conditions and time-consuming requirements, allowing anyone to oppose the grant of a compulsory license[324]. The *Doha Declaration* does not contemplate any right to oppose or hold elaborate inquiries for the grant of compulsory licenses[325]. Such a mechanism is pretty much an open invitation for brand-name pharmaceutical manufacturers having a valid patent in India to initiate costly and endless court proceedings to protect these patents. In the meantime, very serious illness may continue to spread as a result of the lack of affordable medicines in India and in many other developing countries. Although the scope of the opposition proceedings was later restricted, the grant of a compulsory license remains burdensome compared to the previous Indian *Patents Act*[326]:

> "A key safeguard to assure availability of affordable medicines is the procedure of compulsory licenses - government grants patents but allows generic companies to make their versions of the patented medicines against a payment of a royalty to the patent holder. However, in the Bill that passed the Lower House (Lok Sabha) today procedures are still extremely complex and there is no control on levels of royalties to be paid, which will lead to endless litigation and delays" [327].

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[323] Id.
[324] Charubala ANNUNCIO, "A bitter Concoction: The Patents Bill disappoints the industry, which calls it pro-MNC", *Outlook India Magazine*, May 20th, 2002, available at: http://www.outlookindia.com/full.asp?fodname=20020520&fname=Drugs+%28F%29&sid=1.
[325] Id.
[326] Indian Patent Act, op. cit., note 306.
[327] AMTC and al, "The Beginning of the End of Affordable Generics", a statement by Affordable Medicines and Treatment Campaign (AMTC), Médecins Sans Frontières, Lawyers Collective, HIV/AIDS Unit and the Alternative Law Forum, March 22nd, 2005, Delhi, India, available at: http://www.cptech.org/ip/health/c/india/ngos03222005.html.

In short, whether or not the new compulsory licensing scheme will be efficiently used to promote public health in India and other developing countries will depend on the strength of the will of the health authorities, which at this point remains uncertain since India has never used a compulsory licensing scheme, at least since 1970:

> "India previously has not used compulsory licensing to produce drugs because it has not provided patent protections under TRIPS. Compulsory licenses allow the production of patented material without authorization from the patent holder, but TRIPS places certain conditions on the use of compulsory licensing."[328]

What remains certain for Indians though is the fact that most of them will have to wait at least three years until they will be able financially to afford the last generation of HIV/AIDS medicines, since this is the delay a generic company will have to wait before it is entitled to issue an application to produce the drug[329]. The government of India may avoid this delay by declaring a health emergency as provided by the *TRIPS Agreement,* the *Doha Declaration on TRIPS and Public Health*, and the *August 30th Decision of the TRIPS General Council*, which will put again under the spotlight the will of the Indian health authorities to efficiently use their compulsory licensing scheme to protect public health.

Another important late addition to the compulsory licensing scheme is the provision of a time-line that will give better indications on what constitutes 'a reasonable period of time' to carry out the negotiations between the right holder and the generic company regarding the terms of the compulsory license[330]. This period shall not exceed six months, which however seems disproportionately long compared to the 30-day period provided by the Canadian legislation in similar situations[331].

iii) Pre-grant opposition procedure

The pre-grant opposition procedure constitutes 'an important mechanism for civil society to oppose frivolous patents,' by allowing public scrutiny over patent

[328] Id.
[329] Id.
[330] Amit Sen GUPTA, loc. cit., note 318.
[331] Supra, Part IV, chapter a)2) and 3).

applications pending in the 'mailbox' of the Indian Patent Office[332]. Pre-grant opposition may be particularly important to redress a lax application of patentability requirements on new uses of already known molecules[333]. It is also said to be more effective, faster and less expensive than claims in post grant reexamination procedures or legal proceedings after grant of the patent.[334] However, it seems that the intention expressed in the Bill was to abandon the pre-grant opposition procedure, to the great discontent of the Indian civil society.[335] It was claimed that if the pre-grant opposition procedure would have been abandoned, 6000 patent applications might have been granted with no delay. This is about 12 times the number of patent application that received marketing approval from 1995 to 2004.[336]

More precisely, the number of grounds under which the grant of a patent could be opposed was reduced from 9 to 2, and the clause that provided for the hearing of a person to the person making the opposition was deleted.[337] However, under pressure again from the civil society organizations, the Ordinance from which these changes arose was repealed:

> "The new amendments have now restored all the original grounds in the previous Act for opposing grant of a Patent and has also provided that: "the Controller shall if requested by such person for being heard, hear him ..." The time for filing such opposition has also been extended from 3 months to 6 months."[338]

iv) Availability of generics marketed prior to the grant of a patent in India after that patent has been granted

This issue was said to be one of the biggest concerns expressed by many about the new patent Bill[339]. Without a clear exception, drugs that were being produced by Indian companies and for which patent applications are pending in the mailbox, would go off

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[332] AMTC, loc. cit., note 314.
[333] Supra, Part V, chapter b)2)i).
[334] N.V. ZAVERI, loc. cit., note 315.
[335] Id., and AMTC, loc. cit., note 314.
[336] AMTC, loc. cit., note 314.
[337] Amir Sen GUPTA, loc. cit., note 318.
[338] Id., and see also *The Patents Amendment Act no.15 of 2005*, Gazette of India Extraordinary, April 5th, 2005.
[339] Id.

the market once the patents are granted[340]. This of course would have probably involved a sharp raise in the pricing of these drugs since free competition would have been replaced by a monopoly. In a similar case, an anti-cancer drug named Glivec was granted an Exclusive Marketing Right (EMR) by the NDA Government in 2003 to Novartis. This led to a tenfold hike in prices and misery to ten of thousands of patients.[341]

Fortunately, the new amendments to patent law provide patent protections prospectively, which means pharmaceutical patent applications registered under a so-called mailbox arrangement allowed under WTO rules will not get the protections promised to them under the TRIPS Agreement. Under the new amendments, the local manufacturers that were already producing these drugs will be able to continue to produce them after payment of a royalty even if the drug is placed under a patent[342]. The right holder will be entitled to receive 'a reasonable royalty from such enterprises which have made significant investment and were producing and marketing the concerned product prior to the first day of January, 2005 and which continue to manufacture the product covered by the patent on the date of grant of a patent and no infringement proceedings shall be instituted against such enterprises'[343]. No time-line has been provided in the law to circumvent what constitutes 'a reasonable royalty'. Around 9000 patent applications have been registered in the mailbox since it was set up in 1995[344].

The mailbox is a device provided by the WTO that developing countries had to set up in case they chose not to implement the patent protections under TRIPS. In the meantime, companies could register patent applications for their drugs in that mailbox and eventually get patent protection after January 1st, 2005[345]. However, India's new law might be in clear violation of articles 70(8) and 70(9) of TRIPS since a five-year exclusivity for patent applications registered in the mailbox is not provided. No

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[340] Id.
[341] Id.
[342] Id.
[343] *The Patents Amendment Act no. 15 of 2005*, Gazette of India Extraordinary, April 5th, 2005.
[344] "Industry says Indian drug law violates WTO, but no WTO case seen", *Inside U.S. Trade*, April 15th, 2005, available at: http://www.cptech.org/ip/health/c/india/insideustrade04152005.html.
[345] Id.

recourses are provided for right holders to seek the removal from the market of products that violate their patent[346].

3) The Indian pharmaceutical industry and the recognition of the safety of generic medicines

i) A few words about the WHO pre-qualification project

The pre-qualification project, a service provided by the WHO, was set up in 2001 in order to unify the standards of quality, safety and efficacy of drugs, thus facilitating access to HIV/AIDS, malaria and tuberculosis drugs. It was first intended for UN procurement agencies, but with time it became a useful tool used by anyone wishing to bulk purchase medicines, including countries and NGOs[347]. This list of drugs is little known outside the world of essential drugs but is also a vital part of drug delivery in the developing world[348].

To see their products included on the pre-qualified products list, manufacturers need to provide extensive information in order to carry out a proper examination of the products submitted to be on the list, and open their manufacturing sites for stringent inspections by the WHO or another reliable regulatory body[349]. Principles and practices of the world's leading regulatory agencies, such as the European Agency for the Evaluation of Medicinal Products (EMEA) and the U.S. Food and Drug Administration (FDA), forged the standards of assessment of the pre-qualification project, through which:

- "The manufacturer provides a comprehensive set of data about the quality, safety and efficacy of its product, including details about the purity of all ingredients used in manufacture, data about finished products, such as information about stability, and the results of in vivo bioequivalence tests (clinical trials conducted in healthy volunteers);

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[346] Id.
[347] WORLD HEALTH ORGANIZATION, "Key Facts about the WHO Pre-Qualification Project", available at: http://mednet3.who.int/prequal/Prequal_keyfacts.htm.
[348] "The Important World of Drug Pre-Qualification" (2004), 364 *The Lancet*, Issue 9448, Editorial, November 20th, 2004, p.1830.
[349] WORLD HEALTH ORGANIZATION, loc. cit., note 347.

- The team of assessors evaluates all the data presented and if satisfied with the evidence sends the product to professional control testing laboratories contracted by WHO in France, South Africa or Switzerland for analytical verification of quality;
- If the product is found to meet the specified requirements, and the manufacturing site complies with GMP, both the product linked to this manufacturing site and company are added to a list hosted by WHO on a public web site"[350].

The evaluation process takes a minimum of three months if the product satisfies to all required standards. Moreover, all medicines need to be re-qualified after three years or earlier. So far, 42 brand names and 61 generic medicines have been registered on the list, including pills with more than one active ingredient or fixed-dose combinations (FDCs):

> "In soliciting applications from companies, WHO does not question whether the products presented are patented or generic, since patent laws vary according to different national legal systems. It suffices that a company is duly authorized for pharmaceutical manufacture in its own country and that the final product meets stringent standards of quality, efficacy and safety"[351].

ii) Concerns over the safety of generic drugs

Some concerns have been raised in at least three articles in three different newspapers in the U.S., about the safety and the efficacy of generic drugs, as well as the development of a resistant strain of HIV/AIDS because of the use of these drugs in developing countries[352]. These concerns were expressed after a series of withdrawal of generic drugs from the WHO list of pre-approved essential drugs. On November 9th, 2004, after having found discrepancies in the documentation relating to the bioequivalence study of the generic drugs with originator medicines, the company Ranbaxy Laboratories Limited India informed the WHO that it would withdraw

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[350] Id.
[351] Id.
[352] Collin LEVEY, "Cheap drugs help no one if they are not effective", *Seattle Times*, guest column, November 12th, 2004; Carol ADELMAN, "Deadly medicine", *Wall Street Journal*, December 9th, 2004; and Abner MASON, "Slouching towards drug resistance", *San Francisco Chronicle*, December 1st, 2004.

voluntarily all its antiretrovirals temporarily from WHO pre-qualification[353]. At that time, Ranbaxy provided the WHO with a plan indicating proposed dates for the submission of new study reports for these products[354].

And then, ten days later, another Indian generic manufacturer withdrew six antiretroviral medicines from the WHO pre-qualification list in order to further review data on their bioequivalence. The company recognized that the centers it had used to carry out the bioequivalence studies were not compatible with the current standards used by the WHO[355]. Again, Hetero Drugs Ltd. has committed to submit new test results for the bioequivalence of the six medicines as soon as possible, after it would contract with different contract research organizations (CROs).

These two withdrawals have joined another one made by an Indian generic manufacturer, Cipla, in May 2004 due to non-compliance with international standards at the CRO hired by Cipla to conduct bioequivalence tests on the products[356].

The withdrawals brought a lot of bad press for generic pharmaceutical, the WHO and the pre-qualification project, which was anything but justified. An author from San Francisco Chronicle accused the United Nations of carrying out inefficient tests, or even not carrying out tests at all, on drugs that were intended for poor populations in Africa, which will lead to the development of strains of HIV/AIDS resistant to drugs:

> "The hasty approval of cheap, untested AIDS drugs by one of its agencies has likely caused new strains of HIV to emerge in the developing world, according to the American Foundation for AIDS Research. American taxpayers give nearly $1 billion per year to the United Nations and its agencies, comprising roughly 25 percent of its budget. Congress is now sure to take a hard look at how tax dollars have been mismanaged in the U.N. fight against AIDS"[357].

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[353] WORLD HEALTH ORGANIZATION, "Ranbaxy withdraws all its antiretroviral medicines from WHO pre-qualification", *WHO press release*, November 9th, 2004, available at: http://www.who.int/mediacentre/news/releases/2004/pr79/en/print.html.
[354] Id.
[355] Lembit RAGO, "Hetero Drugs Ltd withdraws antiretrovirals from WHO prequalification list for further review", *Statement by WHO*, November 19th, 2004, available at: http://www.essentialdrugs.org/edrug/archive/200411/msg00071.php.
[356] WORLD HEALTH ORGANIZATION, "Two Cipla AIDS medicines back on WHO pre-qualification list", *Statement by the WHO*, November 30th, 2004, available at: http://www.who.int/mediacentre/news/releases/2004/pr87/en/.
[357] Abner MASON, "Slouching towards drug resistance", *San Francisco Chronicle*, Open forum, December 1st, 2004.

Another author from the Seattle Times, stated that Africans should not be given untested and inferior drugs, and that they deserve better than being 'caught in a Western spitball contest over drugs, pricing and intellectual property rights':

> "A principle no one would question for Western citizens — that no group of people should systematically be given an inferior and untested class of drugs simply because they are unable to pay — has become a source of fury against the United States' contributions to the global AIDS crisis"[358].

These statements have been judged 'deliberately misleading'[359], being 'irresponsible and inaccurate claims about generic AIDS medicines'[360] by two Médecins Sans Frontières heads of missions in Malawi and South Africa. In the cases of withdrawal that the above-mentioned citations refer to, the generic products were withdraw from the WHO list of medicines not because they potentially involved deadly side effects, but 'to resolve important questions about the paperwork demonstrating the drugs bioequivalence'[361]. In fact, Cipla's products that were withdrawn from the WHO list were reinstated after the bioequivalence study was repeated, and data clarifications sent to the WHO. Ranbaxy, after submitting filing data for its range of ARVs with the U.S. FDA in January 2005, under its expedited review process for the U.S. President Emergency Program For AIDS Relief, has also made three fresh filings for its ARV agents to the WHO for its approvals[362]. The recent saga about Vioxx, an original anti-inflammatory commercialised by Merck, shows that drug safety should never been taken lightly, whether the drug is original or generic.

However, in a statement issued on January 7th, 2005, MSF expressed its concerns about the lack of support from the World Health Organization leadership for the WHO

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[358] Collin LEVEY, "Cheap Drugs Help No One if They are not Effective", *Seattle Times*, editorial column, November 12th, 2004.
[359] Eric GOAMERE, "Doctors Without Regrets", *Seattle Times*, The Reader's View, November 20th, 2004.
[360] Roger TECK, "Generic AIDS Drugs Work", *San Francisco Chronicle*, letter to the editor, December 4th, 2004.
[361] Rowan GILLIES and Bernard HIRSCHEL, "In War on AIDS, Generics give Poor a Fighting Chance", statements by Dr. Rowan Gillies, President of *Médecins Sans Frontières International Council*, and by Bernard Hirschel, *Head of HIV/AIDS division, Geneva University Hospital*, available at: http://lists.essential.org/pipermail/ip-health/2004-December/007257.html.
[362] RANBAXY, "Ranbaxy Makes Three Fresh Filings of Antiretrovirals to WHO", Ranbaxy press release, January 24th, 2005, available at: http://www.ranbaxy.com/newsroom/pressrelease_det.asp?sno=197.

pre-qualification project[363]. The WHO pre-qualification project is a key instrument in improving the access to quality and affordable medicines, through ensuring that generic and originator products are of quality[364].

> "Before the pre-qualification project, information on the quality of generic drugs used in developing countries was limited. Regulatory agencies in developing countries often lack the capacity to conduct quality assessments. In the case of HIV/AIDS, for instance, many countries would have chosen to use medicines of unknown quality or more expensive originator drugs due to this lack of information on quality of generics. Considering the difference on prices between originator and generic products, there was and continues to be a real need to make quality assessments of generics available"[365].

MSF further states that the several products that have been delisted from the pre-qualification list show the rigour of the assessment process.

> "The delisted products are subject to reassessment. Some products have been put back on the list again after new data was submitted. WHO needs to take a proactive approach with companies to ensure that drugs are rapidly reassessed"[366].

With new TRIPS/Doha flexibilities, an efficient pre-qualification process becomes even more important in order to dispatch safe, efficient and affordable medicines worldwide. Unfortunately, the program has not received the required resources and internal support it should have had in order to carry out its important task.

> "The project remains severely understaffed and under funded and therefore risks not being able to face the growing challenges of AIDS, TB and malaria"[367].

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[363] MÉDECINS SANS FRONTIÈRES, "MSF briefing note regarding WHO pre-qualification for the 115th Session of the WHO Executive Board", *Campaign for access to essential medicines*, available at: http://www.cptech.org/ip/health/who/index.html#pre.
[364] Id.
[365] Id.
[366] Id.
[367] Id.

Chapter c) South Africa

1) Human rights and the spread of HIV/AIDS in South Africa

Considering the particular history of South Africa, one would not be surprised at the tendency of the constitution of the newborn country to defend a global approach for the respect of human rights. But that's not the only positive feature in the new South African Constitution regarding the definition of the right to health.

> "Even more significantly, it has conspicuously recognized socioeconomic rights closely modeled on those found in the ICESCR as justiciable rights in its Constitution"[368].

The right to health is found in numerous provisions of South African legislation, but is more clearly expressed in Section 27 of the Constitution:

> **27.** (1) Everyone has the right to have access to:
>
> (a) health care services, including reproductive health care;
>
> (b) sufficient food and water; and
>
> (c) social security, including if they are unable to support themselves and their dependents, appropriate social assistance.
>
> (2) The state must take reasonable legislative and other measures, within its available resources, to achieve the progressive realization of each of these rights.
>
> (3) No one may be refused emergency medical treatment[369].

i) The scope of the right to health in South Africa

Mr. Charles Ngwena, LLB, LLM, an associate professor in the Faculty of Law at Vista University (South Africa) and a senior research associate of the Centre for Health Systems Research and Development at the University of Orange Free State (South

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[368] Charles NGWENA, "The Recognition of Access to Health Care as a Human Right in South Africa: Is It Enough?", (2000) 5 *Health and Human Rights*, No.1, p.27.

[369] *Constitution of the Republic of South Africa*, Act No. 108 of 1996.

Africa), has attempted to delineate the scope of the right to health as laid down in the South African legislation[370]. He states that the South African right to health

> 'is enforceable against the state as well as individuals, [but] its importance lies in the former, not the least because the state had historically played a dominant role in maintaining an inequitable and iniquitous health care system'[371].

As we will see further in this section, human rights clearly play a very important role in renewing the South African legislation after such a long and painful denial. But not without regards to the best possible motivations and intentions, practical results of implementation policies will be the gage of success for policy and lawmakers, not the maximum extent of what the population potentially deserves according to the law. Is Section 27 robust enough to impose tangible obligations against the state? Professor Ngwena has a mitigated answer to that question. On the one hand, Section 27 may be accused of being another vague and imprecise provision that characterizes so well the field of international law, especially socioeconomic rights:

> "Its language is that of compromise and flexibility. It does not define the quantity or quality of health care services to be accessed. Though, like the [International Covenant of Economic, Social, and Cultural Rights] ICESCR, it imposes a mandatory injunction, it adopts a gradualist or incremental approach by requiring only *progressive* rather than immediate realization. It can even be argued that Section 27 is weaker than the ICESCR in that it requires recourse only to "available" rather than "the maximum of its available" resources, and thus insufficiently impresses upon the state the importance of deploying optimally all feasible resources, including international assistance"[372].

On the other hand, it logically cannot be said that Section 27 has unrealistic objectives affecting its credibility. Health care is a concept that is hardly quantifiable in terms of resources that a state would be obliged to provide for everyone of its citizens. The *United Nations Committee on Economic, Social, and Cultural Rights* has stated, when elaborating about the obligations arising from the *International Covenant of Economic, Social, and Cultural Rights (ICESCR)* that the principles for an efficient and fair

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[370] Charles Ngwena, loc. cit., note 368, p.31.
[371] Id., p.30.
[372] Id., pp. 30-31.

application of a national constitution should be left to courts[373], and it is widely accepted that provisions of the South African Bill of Rights must be interpreted generously[374]. Professor Ngwena suggests that the obligations under Section 27 "are neither open-ended nor without time constraints"[375]. He adds that "the state should, at the very least, begin by meeting minimal or basic needs as proclaimed, for example, in the *Alma-Alta Declaration*"[376]. Essential health services then, should be provided at international standards of diligence within a scheduled period of time.

Provided that the obligation arising from Section 27 has a progressive time-line to be implemented, this is good news for those who need the support of the state to enjoy minimal health services. The use of the terms "progressive realization of each of these rights" and "within its available resources" at Section 27 (2), was a clear indication that the limited resources of South Africa shall be taken into account by courts when determining where the state obligation regarding the provision of health care shall end. In a recent and famous case in South Africa, *Soobramoney* v. *Minister of Health*[377], the Constitutional Court had to interpret whether the appellant was entitled to be treated or not under Section 27(3) on the obligation to provide emergency care and the right to life included Section 11 of the *South African Constitution.* The appellant, who was in the final stages of chronic renal failure, had been receiving renal dialysis through the private health care system, but exhausted his funds. He was refused public assistance even considering that if no further dialysis was given to him he would not survive. Renal dialysis was heavily rationed through public health care, since only 30 percent of the demand for dialysis could be met.

The Constitutional Court stated that Section 27(3) was intended for sudden illness or unexpected trauma, not a chronic condition that has existed for years and would last until the end of the appellant's life. There was also the fact that South African resources were scarce, which rendered rationing as what was done in the case of the appellant, both inevitable and reasonable[378].

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[373] UNCESCR, *General Comment No. 3 of the United Nations Committee on Economic, Social and Cultural Rights*, Fifth Session, 1990, U.N. Doc. E/1991/23.
[374] *S* v. *Mhlungu* 1995 (3) SA867 (CC), 1995 (7) BCLR 793 (CC).
[375] Charles NGWENA, loc. cit., note 368, p.31.
[376] Id., p.31.
[377] (Kwa-Zulu Natal) 1997 (12) BCLR 1696 (CC).
[378] Charles NGWENA, loc. cit., note 368, p.33.

The *Soobramoney* case shows that when the enforcement of a socioeconomic right is claimed against the state, the availability of resources is a crucial consideration that ought to be considered by national courts. However, Professor Ngwena criticized the grounds on which this decision was taken, although he acknowledged that the grounds he favors would probably have given the same decision if the judges would have had applied them in *Soobramoney*:

> "[The Court] should not have shied away from its implicit constitutional obligation to inquire sufficiently into budgetary appropriations when dealing with enforcement of socioeconomic rights. In this regard, the Court failed to inquire whether priorities within the provincial and national governments' health care budgets were in consonance with its constitutional obligations"[379].

But the progressive nature of the realization of the government's obligations arising from the right to health has its limits. One of the most controversial actions of the South African government was that it restricted the use of Nevirapine to prevent the transmission of HIV from mothers to infants. The *Treatment Action Campaign (TAC)* brought a lawsuit against the government because it restricted the availability of Nevirapine in the public sector only to two pilot studies carried out in two hospitals for the whole country, and that was a violation of the right to health of the HIV-positive pregnant women and their unborn child[380]. The court agreed with the TAC, stating that

> "...the policy of restricting the availability of Nevirapine is unreasonable and a violation of the government's obligation to take reasonable legislative and other measures, within its available resources, to achieve the progressive realization of the right to access to health care services, including reproductive health care"[381].

2) Significance of Section 27 of the Constitution in South Africa

Although the obligation to provide health care may be limited by the availability of resources in South Africa, the way Section 27 has been drafted shows a strong will for

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[379] Id., p.34.
[380] George J. ANNAS, "The Right to Health and the Nevirapine Case in South Africa", in Sofia GRUSHIN, Michael A. GRODIN, Georges J. ANNAS, and Stephen P. MARKS, *Perspectives on Health and Human Rights*, Taylor and Francis Group, New York, 2005, p.498.
[381] Id., p.502.

significant improvement in the respect of human rights for all segments of the population. Section 27 is an affirmation of the confluence between civil/political rights and socioeconomic rights and, thus, challenges the classical liberal assumption that the latter are too polycentric and too politically charged to be amenable to adversarial adjudication[382]. Section 27 also seeks to redress the past by making a fundamental break with a health care system that had historically been saturated with unfathomable disparities[383]. Section 27 seeks to bring equality in the provision of health care, including the elimination of extraneous factors such as race, gender or HIV status case, but also the amelioration of other social disadvantages such as income and geographical location.

But indeed, South Africa has more people living with HIV/AIDS than any other country – an estimated 5.3 million, equal to 13 percent of the world's infected[384]. Since the government has done much regarding law and policy, these may no longer be the main impediments to universal access to health care. "Rather, South Africa's high burden of disease and trauma, extreme disparities in income, and general poverty are now the main constraints"[385]. Although the country has put in place a bold program for reforming the economy and the health care system, it is hostage in the short term to the constraining factors of historical neglect, extreme income differentials, and general poverty[386].

However, South Africa, perhaps because of its particular history, is one of the few countries to demonstrate an understanding of the holistic nature of human rights, and to underscore this understanding in its Bill of Rights[387]. The courts will now need to develop their own criteria based on the legal/policy framework formulated by the legislative authorities for a better enforcement of these rights. After having seen the extent of the right to health in the Constitution of South Africa, we will turn to two

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[382] Charles NGWENA, loc. cit., note 368, p.28.
[383] Id., p.28.
[384] REUTEURS AND BLOOMBERG, "Glaxo, Boehringer, cut a deal on AIDS drugs", *Business Report*, December 11th, 2003, available at: http://www.busrep.co.za/index.php?fSectionId=563&fArticleId=306011.
[385] Charles NGWENA, loc. cit., note 368, p.36.
[386] AFRICAN NATIONAL CONGRESS, "A National Health Plan for South Africa", Johannesburg, 1994.
[387] Charles NGWENA, loc. cit., note 368, p.38.

cases more specific to the access to essential drugs and which were largely publicized at the international level a few years ago.

3) Two Cases Brought in Front of South African Courts Regarding the Access to Essential Medicines

i) Pharmaceutical company lawsuit against the Government of South Africa about the compliance of the Medicines and Related Substances Act with the TRIPS Agreement on February 18th, 1998

South Africa has been involved in trade disputes with the U.S. and several European countries over its efforts to make medicines more affordable among its population, in attempting to respect its obligations at the international and national levels regarding the right to health. The most important and mediated dispute involved a new amendment of current patent law included in the *Medicines and Related Substances Act No. 90 of 1997*, especially at Section 15 c), which would provide the authority to issue compulsory licenses in a more efficient and timely manner and authorize parallel imports of medicines.

Measures to ensure supply of more affordable medicines

15C. 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-

(a) notwithstanding anything to the contrary contained in the Patents Act, 1978 (No. 57 of 1978), determine that the rights with regard to any medicine under a patent granted in the Republic shall extend to acts in respect of such medicine which has been put onto the market by the owner of the medicine, or with his or her consent;

(b) prescribe the conditions on which any medicine which is identical in composition, meets the same quality standards and is intended to have the same proprietary name as that of another medicine already registered in the Republic, but which is imported by a person other than the person who is holder of the registration certificate of the medicine already registered and which originates from any site of manufacture of the original manufacturer as approved by the council in the prescribed manner, may be imported;

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

The adoption of this legal provision led to the court case involving PhRMA and 39 pharmaceutical firms against the Government of South Africa[388]. PhRMA and its members claimed that Section 15C contravened to sections 27 and 28 of TRIPS regarding non-discrimination and the respect of patent rights, as well as section 6 and 31 of TRIPS on parallel imports[389]. The Government of South Africa, for its part, alleged that Section 15C complied with the exigencies arising from TRIPS. Since Section 27(2) of TRIPS provides that in order to protect human health, member states may exclude inventions from patentability as long as the exclusion is not made merely because their law prohibits the exploitation of those inventions, this is likely to have been the case. The fact is that at that time, the *Doha Convention on TRIPS and Public Health*[390] and the *WTO General Council Decision of August 30th, 2003*[391], have not yet been formulated. This litigation seemed to have been the first test run for the TRIPS health safeguards and both parties and those who shared the same interests would take that opportunity to speak out and lobby about their interests.

The United States Government, in order to defend its strong national pharmaceutical industry, exercised a lot of pressure on the Government of South Africa in order to convince him to repeal Section 15C. On April 30th, 1999, the United States Trade Representative (USTR) put South Africa on the "Special 301" watch list that purports to "detail the adequacy and effectiveness of intellectual property protection" in countries throughout the world[392]. This report is only one of various documents formulated to monitor important foreign trade barriers to US exports. According to the *Consumer Technology Project* :

> "Being on the list itself is considered a trade sanction, because the U.S Government is advertising the country as an investment risk. But in my opinion, the lists are more significant as a source of information for U.S. Government policy. That is, being on the list is much less important that the bilateral pressures the U.S. Government applies to countries on the topics mentioned on the list"[393].

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[388] See *Notice of Motion in the High Court of South Africa*, case number 4183/98, Tranvaal Provincial Division, available at: http://www.cptech.org/ip/health/sa/pharmasuit.html.
[389] Id.
[390] Doha Declaration, op. cit., note 45.
[391] August 30th Decision, op. cit., note 18.
[392] James LOVE, "Notes on the USTR Watch Lists and Reports" July 15th, 1999, available at: http://www.cptech.org/ip/health/whatrlists.html.
[393] Id.

Moreover, on October 21st, 1998, Rep. Rodney Frelinghuysen from New Jersey introduced an omnibus appropriations law, H.R.4328 that became P.L. 105-277. This text intended to cut off aid to the Government of South Africa, "pending a Department of State report outlining its efforts to negotiate the repeal, suspension, or termination of Section 15C ..."[394]. PhRMA also participated in the lobbying, issuing frequent press releases and statements such as:

> "From the recent remarks and actions, the apparent intent of the Government of South Africa is to not only defend its diminishment of the effectiveness of patent protection in South Africa, but to urge other countries to similarly weaken patent protection for pharmaceutical products. Such a posture is plainly antagonistic to the concept of effective patent protection for pharmaceuticals, and is likely to give rise to a substantial diminishment of the effectiveness in protection not only in South Africa but elsewhere"[395].

However, a lot of pressure was also exercised by civil society on the U.S Government, PhRMA, and its members to drop the case against the South African Government. On February 23rd, 1999, Rep. Jesse Jackson Jr. introduces H.R. 772, the HOPE for Africa Bill, which among other things include Section 601 aiming to cut off funding to any department or agency that sought "through negotiation or otherwise, the revocation or revision of any Sub-Saharan African intellectual property or competition law or policy that is designed to promote access to pharmaceuticals or other medical technologies, as long as they comply with TRIPS"[396]. Major newspaper stories about the dispute also start to be published in mass media[397].

Thus, on December 1st, 1999, after considerable pressure from the public opinion, the USTR removed South Africa from its "Special 301" Watch List. Former President Clinton declared that from now on, the U.S would seek flexibility in the enforcement of drug patent laws when countries face a public health crisis[398]. This shift in American policy occurred after Vice-President Gore was "badgered at campaign stops by protesters who accused him of placing drug company interests ahead of the needs of

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[394] Id.
[395] Id.
[396] Id.
[397] See Merrill GOOZNER "Third World Battles for AIDS Drugs", *Chicago Tribune*, April 28th, 1999.
[398] Sabin RUSSELL, "Poor Nations Given Hope on AIDS Drugs New Policy Would Lower Prices", *San Francisco Chronicle*, December 3rd, 1999.

AIDS patients in Africa, where two-thirds of the 33.6 million people infected with the AIDS virus reside"[399]. As a counterpart, South Africa reaffirmed that it would abide by the WTO's TRIPS Agreement regarding access to essential drugs policies[400].

However, the lawsuit from the 39 pharmaceutical firms against the Government of South Africa went on for another two years before it was dropped. One of the decisive turns in the trial was when the *Treatment Action Campaign (TAC)* was granted the status of *amicus curiae,* or friend of the court, which authorizes the third party that has received this status to submit evidence or argument before the court[401]. This new status allowed the TAC, on April 10th, 1999, to submit a replying affidavit to PhRMA intended to establish evidence and provide information to the court that:

- There is no impermeable barrier between the private and public health care system in South Africa. The health system must be viewed as an integrated, interdependent, and complex whole;
- The alleged violations of intellectual property can in no way be said to threaten the viability or profitability of the research based pharmaceutical industry;
- There are examples of other developed and developing countries of legal measures promulgated to ensure the affordability, as well as safety and efficacy of medicines;
- An analysis of the factors behind recent drug company willingness to provide the South African Government with essential medicines at substantial discounts[402].

This was in response to PhRMA allegations that the *Medicines and Related Substances Control Act no.90 of 1997* :

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[399] Id.
[400] James LOVE, "Five Common Mistakes by Reporters Covering US/South Africa Disputes Over Compulsory Licensing and Parallel Imports", September 23, 1999, available at: http://www.cptech.org/ip/health/sa/mistakes.html.
[401] Theodora STEELE, *Replying Affidavit*, Treatment Action Campaign, High Court of South Africa, Case No. 4183/98, available at: http://www.tac.org.za/Documents/MedicineActCourtCase/affi0410.doc.
[402] Id.

- "will not result in cheaper medicines for a significant number of people because they mainly target the private sector, and because the offers of price reductions have already met the need for lower priced medicines and can protect the rights of the *amicus*' members to dignity, equality and access to health care services;
- violate intellectual property and trade mark rights that belong to the applicant and thereby threaten to jeopardize the international system of research, development, and marketing of medicines;
- are a violation of the WTO Agreement on Trade Related Aspects on Intellectual Property (TRIPS), and are not practiced in any country other than South Africa"[403].

Whether PhRMA trusted its argumentation or not, it decided, along with the 39 pharmaceutical firms, to drop the case under an extremely high amount of international pressure. Since *TRIPS*, even before the advent of the Doha flexibilities that came to clarify the issues at stake in this lawsuit, allowed compulsory licensing and parallel imports in order to cope with human health crisis, we doubt, strictly on legal terms, that PhRMA would have won this case and that the *Medicines Act* would have been declared illegal in regard to the TRIPS Agreement. Since there was no adversary adjudication from the High Court of South Africa, what mostly is significant about this case is the fierce and almost desperate contestation and denial from PhRMA members and the U.S. Government of public health safeguards included in the TRIPS Agreement, as well as basic and fundamental human rights that the South African population was entitled to.

ii) Complaint at South African Competition Commission against GSK and BI for excessive pricing of their ARVs medicines

In a much less mediated case but as significant as the victory over the 39 pharmaceutical firms, the AIDS Law Project, TAC and other civil society organizations had yet another opportunity to be delighted on how a South African legal body ruled over another issue of access to essential drugs. On September 19th, 2002,

[403] Id.

the AIDS Law Project issued a complaint with the Competition Commission against GlaxoSmithKline (GSK) and Boehringer Ingelheim (BI) on the behalf of four people living with AIDS, four health care workers, TAC, COSATU and its affiliate CEPPWAWU, alleging that that the two multinational pharmaceutical firms were unlawfully setting excessive prices for some of their ARVs, thus involving grave consequences for consumers. Two parties joined the complaint in February 2003, one police officer infected with AIDS who eventually died on June 16th, 2003, and an AIDS consortium representing more than a thousand individual and organizational members[404].

> "The excessive pricing of ARVs is directly responsible for premature, predictable and avoidable deaths of people living with HIV/AIDS, including both children and adults"[405].

There are four ARVs targeted by this complaint, namely AZT (branded as Retrovir), Lamivudine (branded as 3TC), AZT/Lamivudine (branded as Combivir), and Nevirapine (branded as Viramune)[406].

The complainants base their allegations on three provisions of the *Competition Act No. 89 of 1998:*

> **"8. Abuse of dominance prohibited**
>
> It is prohibited for a dominant firm to –
>
> (a) charge an excessive price to the detriment of consumers;
>
> (b) refuse to give a competitor access to an essential facility when it is economically feasible to do so;
>
> (c) engage in an exclusionary act, other than an act listed in paragraph (d), if the anti-competitive effect of that act outweigh its technological, efficiency or other pro-competitive, gain; or,
>
> (d) engage in any of the exclusionary acts, unless the firm concerned can show technological, efficiency or other pro-competitive gains which outweigh the anti-competitive effect of its act:

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[404] TREATMENT ACTION CAMPAIGN, "Competition Settlement Agreements Secure Access to Affordable Life-Saving Antiretroviral Medicines", *TAC Newsletter*, December 10th, 2003, available at: http://www.tac.org.za/newsletter/2003/ns10_12_2003.htm#TAC.

[405] COMPETITION COMMISSION OF SOUTH AFRICA, "Statement of Complaint in terms of Section 49 B(2)b) of the Competition Act of 1998", paragraph 17, available at: http://www.tac.org.za/Documents/DrugCompaniesCC/HazelTauAndOthersVGlaxoSmithKlineAndOthersStatementOfComplaint.doc.

[406] Id., paragraph 17.1 to 17.4.

a. requiring or inducing a supplier or producer not to deal with a competitor;
b. refusing to supply scarce goods to a competitor when supplying those goods is economically feasible;
c. selling goods or services on condition that the buyer purchases separate goods or services unrelated to the object of a contract;
d. selling goods or services below their marginal or average variable cost;
e. buying up a scarce supply of intermediate goods or resources required by a competitor.

7. Dominant Firms

A firm is dominant in a market if—

(a) it has at least 45% of that market;

(b) it has at least 35%, but less than 45%, of that market, unless it can show that it does not have market power; or,

(c) it has less than 35% of that market, but has market power.

6. Restricted Application of Part B (abuse of a dominant position)

(1) Minister, in consultation with the Competition Commission, must determine--

(a) a threshold of annual turnover, or assets, in the Republic, either in general or in relation to specific industries, below which this Part does not apply to a firm; and

(b) a method for the calculation of annual turnover or assets to be applied in relation to that threshold.

(2) The Minister may make a new determination in terms of subsection (1) in consultation with the Competition Commission.

(3) Before making a determination contemplated in this section, the Minister, in consultation with the Competition Commission, must publish in the Gazette a notice—

(a) setting out the proposed threshold and method of calculation for purposes of this section; and,

(b) inviting written submissions on that proposal.

(4) Within six months after publishing a notice in terms of subsection (3), the Minister, in consultation with the Competition Commission, must publish in the Gazette a notice—

(a) setting out the threshold and method of calculation for purposes of this section; and

(b) the effective date of that threshold[407]".

The complainants argued that GSK and BI "engaged in excessive pricing of ARVs, to the detriment of consumers"[408], as prohibited by section 8(a) of the *Competition Act.* Moreover, it argued that GSK and BI both qualified as a "dominant firm" in regards of

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[408] Id., paragraph 17.

section 7 of the Act, thus engaging the mechanism laid down in section 8. Finally, the complainants also argued that GSK and BI have exceeded the threshold referred to in section 6 of the Act and provided in the *Government Notice 562 in Government Gazette 22128 dated March 9th, 2001*[409].

Whether by coincidence or feeling that it should act promptly since the decision of the Competition Commission would be soon, GSK issued a press release on October 16th, 2003, announcing that the originator company would go on with further price cuts on its ARVs[410]. Since the multinational firm held its commitments regarding cost savings in the manufacture of ARVs, the firm has reduced again its third world prices for ARVs destined for qualifying countries and organizations from US$ 0.90 to US$ 0.65 per day. Moreover, GSK has agreed to extend the voluntary license it has granted to Aspen Pharmacare in South Africa and Zimbabwe for the manufacture and sale of 3 ARVs, Combivir, Retrovir and Epivir. Until October 16th, 2003, the license could be used only by the public sector of these two countries. From now on, the voluntary license would apply to both private and public health care systems (although the price for the private health care system would remain much higher) and all countries in the Sub-Saharan area[411]. On the very same day, the Competition Commission issued its ruling in what was called a "stunning victory for access to cheaper drugs"[412].

> "The commission's decision goes far beyond the complaint laid by the TAC and 11 other complainants in September 2002, which argued that the two companies were charging too much"[413].

Mr. Brook K. Baker, a Health Gap member and a law professor at Northwestern University, affirmed that:

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[409] Id., paragraph 19.
[410] GLAXOSMITHKLINE, "GlaxoSmithKline takes further action to help the world's poorest fight HIV/AIDS", London, October 16th, 2003, available at: http://www.gsk.com/press_archive/press2003/press_10162003.htm.
[411] Id.
[412] HEALTH GAP, "AIDS Groups Laud Historic Decision Against Big Pharma in South Africa", *Health Gap press release*, October 17th, 2003, available at: http://lists.essential.org/pipermail/ip-health/2003-October/005453.html.
[413] Lynne ALTENROXEL, "AIDS drug firms face stiff penalties over pricing", *Johannesburg Star*, October 17th, 2003.

> "After this historic decision, drug companies will no longer have carte blanche to set monopoly prices. Big pharma's so-called 'discount prices' are a public relations sham"[414].

He further goes on by describing the legal significance of this precedent setting decision, since it represents the first good faith application of the *Doha Declaration on TRIPS and Public Health* prioritizing public health over absolute patent protection:

> "First, the decision validates three important theories. It clarifies: (a) that drug companies monopoly prices, even when partially discounted, can unnecessarily impede access to medicines; (b) that the refusal of drug companies to issue voluntary licenses to generic competitors can abusively impede competition; and (c) that the refusal to grant licenses can prevent manufacture of fixed-dose combination medicines, thereby complicating patient adherence to multi-pill treatment regimes.
>
> Second, the decision sets the stage not only for administrative penalties, it also permits the grant of a compulsory license that would permit the production of ARVs both for the internal South African market and for export to other developing countries. ... Because the South African license would remedy anti-competitive practices, it would not be subject to the WTO domestic-use rule nor would it be subject to the red tape procedural loopholes of August 30th Decision on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health.
>
> Finally, the decision indicates that South Africa is no longer going to suffer the fraudulent price reduction offers from big pharma, especially to the private sector... The difference [between public and private sector] is such that four people could be treated generically for each patient treated at the private sector price"[415].

In fact, the Competition Commission found that the firms contravened the law by refusing to grant voluntary licenses under reasonable conditions, thus abusing their dominant position. Specifically, the firms were found to be involved in three forbidden practices according to the law (1) denial to a competitor of an access to an essential facility; (2) excessive pricing; and (3) engagement in an exclusionary act[416]. This ruling from the Competition Commission implied a request to the tribunal to

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[414] AFRICAN NATIONAL CONGRESS, loc. cit., note 386.
[415] Id.
[416] CONSUMER PROJECT ON TECHNOLOGY, "Competition Commission finds pharmaceutical firms in contravention of the Competition Act", file compiled by the Consumer Project on Technology, 16 October 2003, available at: http://www.cptech.org/ip/health/sa/cc10162003.html, and *Competition Act No. 89 of 1998*, Section 8 (a), (b), and (c).

make "an order authorizing any person to exploit the patents to market generic versions of the respondents patented medicines or fixed dose combinations that requires these patents, in return for the payment of a reasonable royalty"[417]. But moreover on top of this, the Competition Commission recommended to the tribunal that 10 percent of the annual turnover of GSK's and BI's ARVs be paid as a penalty for each year they did not comply with the Competition Act. This ruling from the Commission, although not definitive since the tribunal was free to reverse these findings in its final ruling, would prove to be of strong influence if GSK and BI were ready to negotiate a settlement agreement with the complainants.

Of course, GSK and BI strongly rejected the Commission's findings that they charge excessive prices on ARVs. Mrs. Vicky Erich, the GSK spokesperson, claimed that their sale prices of ARVs in South Africa are among the lowest in the world[418]. She also defended GSK's position by affirming that GSK has issued a local license to Aspen Pharmacare to manufacture generics for the public and private sector, and that it lowered the price of ARVs more than once. BI also denied having abused its dominant position, and argued that the Commission's position was not consequent with another decision on a similar issue against the company a year before:

> "We shall avail ourselves of the opportunity, given by the commission, to discuss the matter further. This will be done as a matter of great urgency. We shall attempt to clarify what is behind this significant change in the interpretation of the act"[419].

BI further argues that Aspen Pharmacare was given rights to manufacture BI's product for the state sector, which requires a significant support from patent holders to provide health care relief to those who need it the most.

> "It is in this state sector of the market that the major need for anti-retrovirals exists, and it is for this reason that we have agreed to provide Aspen Pharmacare with a voluntary license to service this sector"[420].

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[417] CONSUMER PROJECT ON TECHNOLOGY, "Competition Commission finds pharmaceutical firms in contravention of the Competition Act", file compiled by the Consumer Project on Technology, 16 October 2003, available at: http://www.cptech.org/ip/health/sa/cc10162003.html.

[418] GLAXOSMITHKLINE, "GlaxoSmithKline Rejects Commission Findings", *SABC News*, October 17th, 2003, available at: http://www.sabcnews.com/economy/business/0,2172,67538,00.html.

[419] "Drug firm denies abusing position", *South Africa Mail and Guardian*, 17 October 2003, available at: http://lists.essential.org/pipermail/ip-health/2003-October/005451.html.

However, what GSK and BI omitted to mention is that the rate under which they licensed their products to Aspen Pharmacare was respectively 30% and 15% of the net sales of ARVs[421], when the standard rate for voluntary/compulsory licenses may be around 4% or 5%[422]. On December 11th, 2003, GSK and BI announced that they had agreed to allow the manufacture of cheap generic versions of their patented medicines to treat AIDS in South Africa. On that day, it was announced that the Competition Commission concluded a settlement agreement with GSK while it was getting closer to an agreement with BI. Essentially, GSK agreed to what it had already agreed in its first proposition to the Commission on October 16th, 2003, namely (1) to expand the voluntary license to Aspen Pharmacare in October 2001 in respect of the public sector to include private sector; and (2) to allow the licensees to export the ARVs to other Sub-Saharan countries[423].

More significantly, the agreement includes further concessions made by GSK that may substantially facilitate the access to essential drugs in South Africa, namely to (1) grant up to three more voluntary licenses on terms no less favourable than those granted to Aspen Pharmacare, based on reasonable criteria which include registration with the Medicines Control Council and the meeting of safety and efficacy obligations; (2) where the licensee has not have manufacturing capability in South Africa, GSK will allow the importation of the drugs for distribution in South Africa; (3) allow licensees to combine the relevant ARV with other antiretroviral medicines; and (4) charge royalties of no more than 5% of the net sales of the relevant ARVs[424]. To date, GSK has granted licenses for the manufacture and/or importation of its products to Aspen Pharmacare, Thembalami Pharmaceuticals, Feza Pharmaceuticals, Biotech Laboratories and Cipla-Medpro. However, among these companies, only Aspen and Cipla were being able to supply these medicines in December 2004[425]. According to

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[420] Id.
[421] TREATMENT ACTION CAMPAIGN, loc. cit., note 404.
[422] Supra, Part IV, chapter a)1).
[423] CONSUMER PROJECT ON TECHNOLOGY, "Competition Commission concludes an agreement with pharmaceutical firms", file compiled by the Consumer Project on Technology, December 10th, 2003, available at: http://www.cptech.org/ip/health/sa/cc12102003.html.
[424] Id.
[425] TREATMENT ACTION CAMPAIGN, "GlaxoSmithKline grants license to Cipla in accordance with Competition Commission settlement", *TAC electronic newsletter*, December 14th, 2004, available at: http://www.tac.org.za/newsletter/2004/ns14_12_2004.htm#grant.

Mr. Nathan Geffen, national director of the Treatment Action Campaign, supporters of human rights should be jubilant with the announcement of this agreement:

> "Today, December 10th, is International Human Rights Day. It is also TAC's fifth birthday. With the announcement of the South African government treatment plan a few weeks ago and this agreement today, there is real hope for people with HIV/AIDS, their friends and family in the months ahead that they can get life saving medicines. Five years of struggle are resulting in the rights of people with HIV/AIDS being realized"[426]

4) 2005 amendments to South African Patent Law

Last but not least concerning South Africa, a few amendments to its patent legislation were proposed in 2005. These amendments mainly concern the procedure to patent biological material and traditional knowledge in South Africa[427]. As stated in the Memorandum on the objects of the Patent Amendment Bill, 2005, this patent bill will seek to fix two loopholes in the patent legislation, namely the fact that the *Patents Act of 1978* "does not empower the registrar of patents to refuse, invalidate or revoke an application for a patent which does not disclose or wrongfully discloses the origin of the biological material upon which the invention is based"[428]. Moreover, it will also seek to facilitate the sanctioning of "non-disclosure or wrongful disclosure of biological material results in the registration of patents which do not meet the criteria for patenting"[429].

More particularly, the proposed amendments may affect directly the access to essential drugs in South Africa considering the fact that given the absence of detailed patent examinations, the *AIDS Law Project* and the TAC have proposed that "a system of pre-grant opposition, similar to that found in the *Indian Patents Act, 1970* (as amended), be incorporated in through the amendment of section 34 of the act"[430]. If the proposed

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[426] Philippe RIVIÈRE, "At last, generic anti-AIDS medicine for Sub-Saharan Africa", *Le Monde Diplomatique*, December 2003, available at: http://mondediplo.com/2003/12/19aids.
[427] *Patents Amendment Bill no. [17-2005]*, Republic of South Africa, p.4.
[428] Id., p.4.
[429] Id., p.4.
[430] AIDS LAW PROJECT and the TREATMENT ACTION CAMPAIGN, *Joint Submission: Patents Amendment Bill [B 17-2005]*, 25 July 2005, availale at http://www.tac.org.za.

amendments by the AIDS Law Project and TAC are adopted, section 34 would read as follows (amendments underlined):

> "The registrar shall examine in the prescribed manner every application for a patent and every complete specification accompanying such application or lodged at the patent office in pursuance of such application and if it complies with the requirements of this Act, he or she shall accept it if the following steps have been completed:
>
> (1) He or she has caused notice of the application for the patent to be published in the *Government Gazette* not less than six months prior to the date upon which the application is accepted;
> (2) All interested parties, including those acting solely in the public interest, have been provided the opportunity to make written submissions setting out the manner in which the patent application does not comply with any provision of this Act; and
> (3) He or she has provided written reasons justifying the acceptance of the patent application, notwithstanding the submissions advanced in terms of subsection (2)."[431]

The AIDS Law Project and the TAC are also seeking to expand the grounds for patent revocation in the law. They point out that there should be a procedure to revoke patents granted on the grounds of unlawfully obtained bioprospecting results. Thus, they proposed to add a new paragraph to section 61(1):

> (j) That at the time of the lodging of the statement in terms of section 30(3A), the applicant for the patent did not have title or authority to make use of the indigenous biological resource or genetic resource or of the traditional knowledge or traditional use, and the relevant invention was directly derived from an indigenous biological resource or a genetic resource, and/or that the invention was based on or derived from traditional knowledge or traditional use"[432].

Furthermore, the *AIDS Law Project (ALP)* and the TAC proposed that South Africa undertake "a comprehensive review of its patent legislation to enable the development of an appropriate patent regime within the bounds of both what is permitted in terms of international trade law and what is required by international human rights law and the Constitution"[433]. ALP and TAC further claim that considering the level of development, the burden of disease and the industrial strategy regarding generics, patentees are still overprotected in South Africa. This situation could be corrected by

[431] Id, pp. 5-6.
[432] Id., p.6.
[433] Id., p.6.

the integration of health safeguards provided by *TRIPS*, the *Doha Declaration on TRIPS and Public Health*, and the *WTO General Council Decision of August 30th, 2003*. In order to do so, ALP and TAC proposed further amendments to the South African patent legislation:

- Expand the category of state officials who may use an invention for public purposes, and provide a default procedure for compulsory licensing in this case if the patentee and the state official fail to come to an agreement in this regard (section 4);
- Ensure the possibility to issue a compulsory license to deal with a health emergency, whether by the Minister of Health, the Minister of Industry, or the executive council responsible for health in a province (new section 4A);
- Limit the granting of patents in respect of new uses and new forms of known substances (section 25);
- Abolish 'TRIPS-plus' patent protections included in section 56 by allowing a private person, including companies, to apply for a compulsory license;
- Ensure the exportation of generic pharmaceutical products to markets with no or insufficient manufacturing capacity (new section 56B);
- Ensure the revocation of a patent when the grant of a voluntary/compulsory license has not allowed to prevent abuses resulting from the exclusive rights conferred by a patent, provided that at least two years have expired since the grant of such license (section 61); and
- New definitions should be included in the patent act to clarify the amendments proposed above[434].

[434] Id., p.7.

VI- ANALYSIS OF THE MEANS OF COMPLIANCE AND TENDANCIES REGARDING THE RIGHT TO HEALTH AT THE NATIONAL LEVEL

So far, among the countries studied, only Canada, India, and the European Union have taken action to modify their legislative framework in order to comply with the *TRIPS Council Decision of August 30th, 2003*[435]. South Africa has been pressured by civil society to undertake a legal reform concerning the export of generic drugs[436], but it must deal with the provision of ARVs to its own population first before thinking of providing other developing countries with insufficient manufacturing capacity. So far, the U.S. and Brazil have not demonstrated an intention to modify their compulsory licensing regime to allow the export of generic drugs to developing countries. Canada, India and the European Union have adopted similar regimes for the export of generic drugs although they also include important differences.

The U.S., although it does not seem to intend to establish the suggested mechanisms in the Doha negotiations, put forward a 15-billion initiative over 5 years, the *Presidents Emergency Plan for AIDS Relief -(PREPFAR)*, in May 2003. However, the initiative is significantly limited by not allowing generic drugs to be purchased under that initiative, therefore strongly affecting its purchase power. PREPFAR remains rather controversial since it limits safety approval standards to those used by the FDA or other stringent regulatory authorities, and it is also limited to a list of fifteen countries, "which upsets anyone associated with a country not on the list"[437]. Moreover, the adoption of a special regime for exports of generic essential drugs to countries affected by HIV/AIDS, as provided by the Doha documents, seems to be a more appropriate and efficient long-term approach to countering the spread of the pandemic.

The developing countries studied in part V of this analysis have all adopted health safeguards in their intellectual property law in order to favour universal access to essential medicines within their jurisdiction, as found in chapter b) of Part VI of this analysis.

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[435] August 30th Decision, op. cit., note 18.
[436] AIDS LAW PROJECT and the TREATMENT ACTION CAMPAIGN, loc. cit., note 430.
[437] WIKIPEDIA, "Definition of 'PREPFAR'", from Wikipedia, the Free Encyclopaedia, available at: http://en.wikipedia.org/wiki/President%27s_Emergency_Plan_For_AIDS_Relief.

Moreover, radically opposed to the spirit of the Doha negotiations, there are attempts to further strengthen the minimum standards of intellectual property protection provided by *TRIPS*[438]. These attempts, if successful, would diminish the capacity of the countries adopting such policies in favour of increased access to essential medicines. These attempts are summarized in chapters c) and d) of this part of the analysis.

Part VI will identify four key legal elements that need to be adapted to right to health requirements in order to carry out a successful and fair distribution of essential drugs worldwide. The first is compliance with the *August 30th Decision of the TRIPS Council*, which is becoming crucial for the next generation of medicines, since TRIPS is now applied in most countries with the infrastructures required to manufacture essential drugs beginning in the year 2005. The second key element is the adoption of laws by developing countries that favour universal access to essential drugs. No matter how many legal measures developed countries might adopt to help poorer countries distribute essential medicines, they will not produce any positive benefit if developing countries themselves do not adopt corresponding measures. The third and fourth key elements are measures that need to be closely monitored since they seek to increase patent protection, the use of FTAs and the loosening of patentability criteria. These elements negatively affect universal access to essential medicines, and decrease the scope of the latest developments brought to TRIPS and the WTO concerning public health.

Chapter a) Compliance with the August 30th Decision of the TRIPS Council

1) Countries covered by the compulsory licensing regime

The Canadian and Indian compulsory licensing regimes for the export of generic drugs cover all states with insufficient manufacturing capacities, whether they belong to the WTO or not. However, the developing countries not part of the WTO that do not qualify as a least developed country (LDC) according to UN standards will be disadvantaged compared to countries with the same income level that are part of the

[438] TRIPS, op. cit., note 8.

WTO. The former will be treated as mid-income countries such as Czech Republic, meaning generic manufacturers wishing to contract with such countries will need to go through supplementary bureaucratic measures before they obtain their compulsory license. However, the Canadian law entitles NGOs to contract with Canadian generic manufacturers with the permission of the government of the importing country, while only governments will be entitled to contract with generic manufacturers under the Indian law.

Unfortunately, under European Union policies, only governments of WTO member-states (and not NGOs) will be entitled to contract with European Union generic drug manufacturers. This is unacceptable from a human rights perspective, since the international obligations regarding universal human rights arising from the *Covenant on Economic, Social and Cultural* Rights, as well as the *Alma-Alta Declaration,* still stand whether the population of a particular country belongs to the WTO or not. This means that any generic manufacturer from a European Union member country will be unable to sell generic drugs to a non-WTO country.

2) Limit of time for negotiations with the brand-name manufacturer

Countries require the generic manufacturer to negotiate a voluntary license with the brand-name manufacturer before the competent national authority may issue a compulsory license. If after "a reasonable period of time", no agreement has been reached between both manufacturers, then a compulsory license will be issued by the appropriate national authorities.

In Canada, the meaning of a "reasonable period of time" will be no longer than 30 days. This contrasts starkly with the six-month period in India. There is no time-line provided in the European Union policies, leaving a lot of uncertainty about when one will have the right to claim a compulsory license. The Indian law's designation of six months as "a reasonable period of time" appears far too long a period to conclude negotiations, especially for the provision of essential drugs to poor populations in urgent need. This will allow an unjustified extension of the monopoly of the patent holder into countries with insufficient manufacturing capacities for pharmaceuticals,

since this compulsory period of negotiations will likely be used to delay the introduction of generic drugs in the relevant markets.

3) Scope of medicines and diseases covered by the compulsory licensing regime

Both India and the European Union provide an unlimited scope regarding the patented medicines that may be exported under their compulsory licensing regime. Canada however, limits the scope of Bill C-9 to 46 products based on the WHO list of essential medicines for HIV/AIDS, tuberculosis and malaria. This is much too narrow, there are many other diseases affecting poor countries for which cures are unaffordable. Canada is certainly not in the right position to decide which medicines are most needed in the developing world.

4) Safety requirements for exported drugs when there is no reference product sold in the market of the exporting country

Canada and the European Union demonstrate flexibility when there is no reference product sold in their national market. When sufficient clinical data is provided individually on ARV agents constituting a FDC (sometimes three or four different agents are in one FDC), the threshold for safety approval will be reached in Canada. In the European Union, information from other jurisdictions, university studies or international programs on drug safety may be sufficient for approval of generic drugs for exports with no reference product sold within the European Union jurisdiction.

Since India has a large poor population, most of the generic products exported are also used within their own borders. Therefore, there is often a reference product to conduct bioequivalence studies. Moreover, as seen in the previous chapter, Indian pharmaceutical manufacturers make extensive use of the WHO pre-qualification program for drug safety requirements.

5) Confusion of compulsory licensing for exports to developing countries and former compulsory licensing regimes in force prior to the advent of TRIPS and regional trade agreements such as NAFTA

Until the early nineties, some countries such as Canada extensively used compulsory licenses for pharmaceuticals. Fifteen years later, Canada can again claim the merit of being one of the first developed countries to modify its national legislation. Bill C-9, in force since 2005, complied with the *Decision of the General Council of August 30th, 2003 on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health.* Although the main mechanism of Bill C-9 is compulsory licensing, this new regime should not, however, be confused with the former compulsory licensing regime providing a "local working" requirement for pharmaceuticals. This approach was repealed under U.S. pressure to comply with *NAFTA* and *TRIPS* in the early nineties. This is crucial since the brand-name pharmaceutical industry sees Canada's compulsory licensing system in an extremely negative light, and has convinced both levels of government that broad compulsory licensing provisions would significantly hurt Canada's international reputation[439]. Whether this fear is justified or not, the debate should not harm the new compulsory licensing regime for exports to developing countries provided in Bill C-9, especially considering the urgency of the situation. Moreover, if Canada's reputation should be affected at the international level, it would be by not implementing the *TRIPS General Council Decision of August 30th, 2003*, and not by complying with its responsibilities towards developing nations regarding the right to health.

Chapter b) Health safeguards in intellectual property legislation at the national level favouring the access to essential medicines in developing countries

In intellectual property law, health safeguards are crucial in developing countries. Yet, due to the high number of poor people even in the populations of developed countries, such safeguards are necessary to ensure adequate access to essential medicines for all. The countries we studied in part V all have such safeguards to different extents.

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[439] Gold, E. Richard and al. Gene Patents: Past-Time for Reform, McGill University, (submitted).

In Brazil, if the Federal authorities declare in an act of law that if there is a case of national emergency or public interest, and that the patentee or his/her licensee does not meet the demand from the public, "a temporary *ex-officio* non-exclusive compulsory license for the exploitation of a patent may be granted"[440]. This provision was used in the latest attempt by the Brazilian government to grant a compulsory license and seems to have appropriate grounds to do so, since the "local working" requirement[441] likely contravenes article 27(1) of TRIPS, which forbids discrimination in the enjoyment of patent rights whether the products are imported or locally produced. However, that picture may be significantly changed if the *Bill No. 22/03* exempting pharmaceutical products for the prevention and treatment of AIDS from patentability ever enters into force.

In India, for drugs marketed prior to March 2005, there was much less need to use health safeguards since only methods or processes of manufacture were patentable, as opposed to the product itself. However, concerning drugs for which patents will be registered after March 2005, health safeguards are essential to ensure access to medicines since patents on products are granted after that date. Section 84 of the *Patent Act No. 39 of 1970* allows the Controller of Patents to grant a compulsory license on a drug to any person who requests it if it has not been made available to the public at a reasonable price, at least three years after the patented drug has been put on the market. In this case, the standard on which to decide whether a compulsory license may be granted or not is pricing. "Reasonable pricing" will undoubtedly be linked to the capacity of the population to pay, thereby ensuring that essential drugs will not be available only to rich segments of the society.

South Africa is the only country studied that has included the right to access to health care in its constitution. It requires actions from the government to ensure the highest attainable standard of health for all. Although this obligation is clearly limited by the available resources of the state, it goes as far as examining budgetary appropriations when dealing with enforcement of socioeconomic rights, a practical implementation of right to health obligations in national law which is unseen in any other national jurisdiction under study. In line with the South Africa Constitution, the government

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[440] Law 9279/86, op. cit., note 264, article 71.
[441] Id., article 68.

may "prescribe conditions for the supply of more affordable medicines in certain circumstances so as to protect the health of the public"[442], including compulsory licensing and parallel imports of patented medicines.

Public health safeguards in the application of intellectual property law in countries such as Canada and the United States (although they are not as crucial as in Brazil, India and South Africa for the survival of their nationals due to lower poverty among their populations, broader public health insurance programmes, or private insurance) should nonetheless be used as "watchdogs" to maintain fair access to medicines. In Canada, the *Patent Act* offers three ways to limit patent rights considering public policy concerns, i.e. in cases where the patentee abuses his/her exclusive rights under his/her patent, through the government use of a patented invention against an adequate consideration, and through the *Patented Medicine Prices Review Board*, if patented medicines are sold at a price that, in the board's opinion, is excessive. In that last case, the board may order the patentee to pay a fine or reduce the price of the medicine to an extent that will offset the amount of the excessive revenue received[443].

The United States, however, is reluctant to adopt measures preventing abusive pricing of pharmaceuticals within their jurisdiction. For the federal government, there are only two mechanisms to derogate from the patent rules: 1) through government "march-in rights" for publicly-funded inventions, if an invention is not being made reasonably accessible to the public; and 2) through a broad government use provision, where the federal government can use any patent or copyright, but where the right holder is entitled to compensation. The other legal tool encouraging a form of price control over pharmaceuticals is via the *Hatch-Waxman Act*. It supports the entry on the market of generic products by allowing bioequivalence studies to be used for safety approval requirements. But still, this Act allows a patent extension of five years to cope with the time a drug remains in the development pipeline, and of two and a half years if a generic manufacturer challenges the patent. And although these national public health safeguards are not as permissive as those in the other countries studied, the U.S. government seems to lack the will to use them when the opportunity arises. This was

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[442] *Medicines and Related Substances Act No. 90 of 1997*, section 15C.
[443] Robert G. HOWELL and al, *Intellectual Property Law: Cases and Materials*, Edmond Montgomery Publications Limited, Toronto, 1999, p.1014.

demonstrated in the Cipro case and through the request made under the *Bayh-Dole Act* to the Clinton and Bush administrations to contract with the WHO for the provisions of essential medicines to developing countries. At the state level, although the use of the eminent domain for patents as a health safeguard may provoke some debate on the access to affordable medicines issue in general, it seems to lack credibility.

Many of these public health safeguards are defendable under the *TRIPS Agreement.* In fact, while TRIPS created many obligations in developing countries, some of which were also new in developed countries, this treaty also allows WTO Member countries to legitimately adopt regulations that ensure a balance between the minimum standards of patent protection and the public good.

> "... they can adopt measures which are conducive to social and economic welfare (article 7 of the TRIPs Agreement), such as those necessary to protect public health, nutrition and the public interest in sectors of vital importance for their socio-economic and technological development. Countries can also adopt measures to prevent the abuse of intellectual property rights (Article 8.1 and 8.2 of the TRIPs Agreement)[444]".

Professor Jerome Reichman also explained that:

> "[C]ountries could also attempt to trigger the safeguards implicit in Articles 7 and 8 in one of two ways. The least destructive approach would be to convince the Council for TRIPS itself to recommend narrowly described waivers to meet specified circumstances for a limited period of time. This approach would strengthen the mediatory powers of the Council for TRIPS and help offset the problems arising from the inability of that body to quash or stay request for consultations and dispute-settlement panels launched by trigger-happy governments.
>
> Alternatively, developing country defendants responding to complaints of nullification and impairment under Article 64 might invoke the application of Articles 7 and 8(1) to meet unforeseen conditions of hardship. This defense, if properly grounded and supported by factual evidence, could persuade the Appellate Body either to admit the existence of a tacit doctrine of frustration recognized in the Vienna Convention on the Law of Treaties. Either way, overly aggressive complainants could wind up with what amount to a judicially imposed waiver[445]".

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[444] Carlos M. CORREA, loc. cit., note 15, p.3-4.
[445] Peter K. YU, "TRIPS and Its Discontents", (2005) *Legal Studies Research Paper Series*, Research Paper No. 03-03, Michigan State University College of Law, p.14.

Section 27(2) of TRIPS also provides patentability exceptions under motives related to *ordre public*. Although *ordre public* may be a broad notion, section 27(2) reveals that it is not limited to security reasons; it also relates to the protection of human, animal, or plant life or health and may be applied to inventions that may lead to serious prejudice to the environment[446]. However, this exception does not appear to be sufficient, according to Professor Carlos M. Correa, to justify such an exclusion from patentability, except in limited circumstances[447].

Moreover, we would like to underscore that competition law may also be used in most jurisdictions to counter the use of a patent that unduly prevents access to the patented invention to the detriment of the consumers. Through competition law remedies, courts may dispose of a relatively large range of measures that would cope with an "abuse of dominant position" from a patent holder, such as financial penalties, compulsory licenses under the conditions they deem appropriate, or simply revoking the patent. South Africa has successfully used competition law to promote access to essential drugs as analysed in part V, chapter c).

Chapter c) The Use of Free Trade Agreements to Extend Patent Protection

Obviously, developing countries have been much concerned about the increased protection required by TRIPS and its harmful impact not only in the area of health, but also concerning agriculture, environment, education and culture. To make matters worse, developing countries discontent did not end up with the *TRIPS Agreement*:

> "Today, many developed countries have sought to ratchet up their protection by negotiating around the TRIPS Agreement, seeking what commentators have called "TRIPS-plus" protection"[448].

The *Trade Promotion Authority Act of 2002* requires the U.S. Government to respect the *Doha Declaration on Public Health* during the negotiations of free-trade agreements (FTAs). Nonetheless, the most recent FTAs show that the U.S. Government has chosen not only to maintain its hard line on protection of patent

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[446] Carlos M. CORREA, loc. cit., note 15, p.12.
[447] Id.
[448] Peter K. YU, loc. cit., note 445, p.10.

rights, but also to increase patent protection and expand patent terms above what is required by *TRIPS*, through the patenting of new uses of known molecules, among other things. In fact, apart from intellectual property treaties to which the parties to a free-trade agreement with the U.S. are subjected, and which are always duly reported in the first provisions of such an agreement, little consideration has been given to other treaties that may be affected by that FTA, especially regarding access to medicines and the right to health. Among the states that are party to a FTA with the U.S., only Bahrain, Morocco and CAFTA required the express recognition of a party's right to benefit from the so-called Doha solution, while the *Doha Declaration on the TRIPS Agreement and Public Health* is recognized in the preamble of the U.S.-Chile FTA.

This is not surprising, since the latest trend of FTAs concluded by the U.S. government constitute a clear attempt to prevent the other state party to use Doha mechanisms in order to react to public health crises. For example, the U.S.- Australia FTA allows the export of generic drugs to a third party only for marketing approval purposes if a patent is still valid in the jurisdiction of that party[449], clearly contravening the spirit of the *Doha Declaration on the TRIPS Agreement and Public Health* and the *Decision of the TRIPS Council on the Implementation of Paragraph 6 of the Doha Declaration on TRIPS Agreement and Public Health of August 30th, 2003.* Other measures included in most FTAs involving the U.S. affect the implementation of access to essential drugs policies. These measures include preventing marketing approval of a product when the patent of the reference product is still valid; limited grounds for patent revocation; abolishment of pre-grant opposition procedure; patent term extension if a marketing approval takes more than a defined time-line; and, protection of clinical data for the term of the whole patent plus a five year period after patent exhaustion.

What is also disturbing to developing countries that reluctantly joined the *TRIPS Agreement* to avoid unilateral trade sanctions is that they find themselves in no better position, as far as unilateral sanctions are concerned, than they were had they not signed the *TRIPS Agreement:*

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[449] *U.S.- Australia Free-Trade Agreement*, section 17.9.6, signed on May 18th, 2004.

> "Because most of the items negotiated under the bilateral and plurilateral agreements were considered outside the scope of the TRIPS Agreement, the Agreement would not shield less developed countries from trade sanctions"[450].

But even more problematically, the recent trend of FTAs came at a time when the intellectual property system was closely watched by the civil society in the developed world. Until recently, intellectual property was not of popular interest. Considering this new perspective and the concerns over expanding intellectual property rights in developed countries, it is very difficult to find it

> "...timely to harmonize and elevate international standards of patent protection – even if that were demonstrably beneficial – when there is so little agreement in the U.S. itself on how to rectify a dysfunctional apparatus that often seems out of control"[451].

Nevertheless, the Doha mechanisms are voluntary. Such measures do not constitute a breach of international trade obligations with sanctions under the WTO. There are no mechanisms in the international trade framework that aim to re-equilibrate a bilateral agreement where one party would have misled the other through its dominant position during the negotiations. However, such provisions clearly constitute a breach of international obligations regarding the right to health, including the responsibility that rich states have towards developing states regarding the access to essential medicines. That is why developing countries need to be sensitised, informed and supported during the negotiations for a free-trade agreement in order not to give away their entitlements under international law. The U.S. is currently negotiating a FTA with the South African Customs Union (SACU), a regional trade union regrouping South Africa, Botswana, Lesotho, Namibia and Swaziland, a region widely affected by HIV/AIDS, malaria, tuberculosis and many other diseases. On July 2nd, 2003, eight NGOs highlighted in a letter to U.S. President George W. Bush, the necessity to exclude intellectual property from the negotiations over a U.S – SACU Free Trade Agreement, because it will likely limit the ability of these countries to adopt appropriate measures to fight HIV/AIDS and other serious health problems[452]. The negotiations on this very

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[450] Peter K. YU, loc. cit., note 445, p.10.
[451] Id., p.11.
[452] "Letter from Eight NGOs to President Bush Asking for the Exclusion of Intellectual Property from the South African Customs Union FTA", accessible at: http://www.cptech.org/ip/health/trade/sacu/ngos07022003.html.

important FTA, at least regarding access to essential drugs, are not completed yet. Hopefully, provisions generating human rights violations will be dropped from that agreement, despite the recent trend in the conclusion of FTAs.

Chapter d) The loosening of patentability criteria in order to expand the length of patent monopoly on pharmaceutical products

Pressure to expand patentability criteria has occurred not only through FTAs that include "TRIPS-plus" requirements, but also through the industry lobbying governments to reform their intellectual property law, such as in India[453]. India considered allowing the patenting of new uses or dosages of an already known molecule, thus significantly increasing the possibility of extending the length of a patent over 20 years. Another form of expression is the frivolous patent claims that have occurred in the U.S. because of a lax application of patentability criteria[454].

In India, in order to avoid the "evergreening" of patents, the authorities have decided to prevent the patentability of new uses of already known molecules by clarifying the definitions of "inventive step", "new invention", and "pharmaceutical substance"[455]. In the U.S., although they are now preventing patent listing for drug packaging, drug metabolites and intermediate forms of a drug, they are still allowing patents on new uses of a drug[456].

Canada also allows the patentability of new uses of known molecules. Since this issue is not specifically covered by the law, such as in India, it is up to the patent authorities and the courts to rule on the matter, through the interpretation of the patentability criteria of "novelty" and "inventive step". In a case that now constitutes precedent, the Supreme Court of Canada had to rule on whether a new use of a known product for which the patent was already exhausted should be granted another patent, according to the definition of "invention" in section 2 of the *Patent Act*[457] in *Shell Oil Co.* v.

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[453] Supra, Part V, chapter b)2).
[454] Supra, Part IV, chapter b)2)i).
[455] *Patents Amendment Act No. 15 of* 2005, section 2 f), g), and h).
[456] Supra, Part IV, chapter b)2)i).
[457] Patent Act, op. cit., note 97.

Canada (Commissioner of Patents)[458]. That decision ruled that the "invention" at stake in the claims was the newly discovered properties of that product, and not the composition of that product itself. Therefore, it was not necessary for the Court that the composition of the known product be new, as long as the new properties of that product demonstrate novelty and inventive step[459].

No matter what road patent authorities or national courts may take to justify or prevent the patentability of the new use of a known product to extend patent term, it remains a political choice dictated by a wide spectrum of interests. However, we think such a decision as whether or not to grant a patent on new uses of known molecules is a choice that needs to be addressed independently by every national government, with no pressure exercised by any other trade partner in taking that decision. Moreover, specifically regarding essential medicines, patent claims evaluation should be more focused on the significance of the improvement of a molecule instead of the expectation of profits arising from its new use. Regarding *TRIPS*[460] and the associated Doha documents[461], a state-member is entirely justified to prevent the patenting of new uses on known products. Accordingly, countries entering FTA negotiations and considering implementing patents on new uses of known products should carefully examine how patent term extension might affect their national industry and the well being of their population.

> "The *TRIPS Agreement* does not define what an "invention" is; it only specifies the requirements that an invention should meet in order to be patentable. This leaves Member countries considerable freedom to determine what should be deemed an invention, and to exclude from patentability any substance which exists in nature[462]".

Thus, TRIPS may allow enough "policy space" for developing countries to be able to push for an interpretation of the substance of the agreement that will meet their needs "while preserving the national autonomy appropriately reserved to them during the

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[458] [1982] R.C.S. 536.
[459] Id., paragraph 31.
[460] TRIPS, op. cit., note 8.
[461] August 30th Decision, op. cit., note 18, Doha Ministerial Declaration, op. cit., note 44, and Doha Declaration, op. cit., note 45.
[462] Carlos M. CORREA, loc. cit., note 15, p.19.

negotiation process"[463]. The ambiguities included into TRIPS may be used by developing countries to counter the continuous expansion of intellectual property rights, and may even allow them to get back what has been lost in the recent battles regarding uniform intellectual property protection.

> "In sum, the TRIPS Agreement has provided many reasons why less developed countries are dissatisfied with the current international intellectual property system. However, the Agreement *alone* does not result in the current state of dissatisfaction. New developments, such as the increasing use of TRIPS-plus free trade agreements as well as the growing use of technological protection measures, have made the system even more unbearable[464]".

PART VII – CONCLUSION

It was demonstrated in this analysis that measures consequent with the right to health and universal access to essential medicines were adopted successfully at the national level in most of the countries studied, due to the room for interpretation given by the provisions of the *TRIPS Agreement* and the *Doha Declaration.* We say successfully since those measures often had to be strongly supported by civil society organizations, or government officials, against the intense lobbying of the brand-name pharmaceutical industry and some developed countries. It may lead as far as litigation in front of WTO panel or a national court, as it was the case for Brazil and South Africa. Even if the WTO DSU had been used primarily by developed countries, as the Agreement matures, less developed countries have begun to use the process more frequently. As Professor William Davey pointed out:

> "In the first five years of the system's existence, developing countries initiated by themselves roughly one-quarter of the consultation requests. In the four and one-half years from 2000 to June 2004, developing countries initiated 62% of the consultation requests – more than doubling their relative share of initiations. ... Thus, in the last few years developing countries have become more frequent users of WTO dispute settlement, both in absolute and relative terms. Interestingly, the majority of those cases have involved developing country respondents. That is to say, developing countries seem to have found the WTO dispute settlement system to

[463] Peter K. YU, loc. cit., note 445, p.12.
[464] Id., p.11.

> be a useful mechanism to deal with a wide range of trade disputes – using it not only against developing countries, but also in their trading relations with other developing countries[465]".

In light of what we discovered through our research, we suggest that the right to health is reconcilable with intellectual property protection as long as the previous has precedence over the former. It seems that this assumption is also shared by an increasing number of stakeholders. However, this does not include the U.S., more inclined to defend the interests of their powerful pharmaceutical industry, which explains their recent propensity to prevent states from adopting measures commanded by the right to health and the access to essential medicines through the conclusion of FTAs.

An efficient enforcement of intellectual property rights might need to be paired with considerations from other fields, such as human rights. As long as strict enforcement of patents on essential medicines will not be balanced by human rights interests and will let millions of people affected by diseases suffer and die without treatment, there will be no legitimacy to the manner which patents on medicines are enforced for most of the world's population. As stated by an author from the Center for Study of Responsive Law:

> "Of all the grotesque inequities that prevail in the world, that of health is arguably the most offensive"[466].

At the moment, poorest countries' populations are denied treatment through unfair international intellectual property agreements pushed by the greed of western businesses and governments. There are no valid reasons why this issue should not be addressed. The arguments for the limitation of access to treatment in poor countries seem dubious at best. Supporters of strong intellectual property protection claim that if patented drugs are produced by generic companies to supply poor countries, incentives for pharmaceutical firms to market new medicines, which benefit not only the poor but the whole population, will be significantly endangered. In reality, because of their lack

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[465] Peter K. YU, loc. cit., note 445, p.16.
[466] Amir ATTARAN, "Human Rights and Biomedical Research Funding for the Developing World: Discovering State Obligations under the Right to Health", (1999) 4 *Health and Human Rights*, no.1, p.27.

of resources, poor countries should represent a minimal share of brand-name pharmaceutical manufacturers' market. They simply cannot buy patented essential drugs. If brand-name manufacturers do not significantly supply poor markets anyway, why would they be opposed to the generic industry manufacturing those medicines and get from 1% to 5% of the net sales of the copycat product?

> "Two important questions, in this context, are (a) the extent to which the income generated by patents in the developing world is actually invested to develop the medicines needed by the poor; and (b) whether the granting of patents in developing countries, under conditions substantially similar to those applicable in developed countries, is essential to provide incentives for industry's global R&D activities[467]".

Many drugs are important for both developed and developing countries. However, developing countries also have different needs than developed countries for many other diseases. The diseases of the poor attract very little investment by large pharmaceutical companies, since they are not promising sources of profit. Between 1975 and 1997, only 13 of 1223 new chemicals entities, or 1% were for the treatment of tropical diseases[468]. "Of the annual health-related research and development worldwide, only 0.2% goes for pneumonia, diarrhea and tuberculosis – yet these account for 18% of the global disease burden[469]". Moreover, the contribution to R&D arising from less developed countries or regions is negligible in global terms:

> "For instance, Africa – one of the regions where the problems of access to drugs are more severe – only accounts for around 1.3% of world pharmaceutical sales[470]".

Moreover, there is increasing evidence that global welfare is not improved under a uniform world-wide system of pharmaceutical product patents. Indeed, Professor F. M. Scherer's analysis reveals that

> "global welfare is maximized by letting low-income nations free-ride on the patented inventions of first-world nations over a wide range of negative new product development

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[467] Carlos M. CORREA, « Public Health and Intellectual Property Rights », paper partially based on the study prepared by the author for the *Commission on Macroeconomics and Health*, 2001, p.9.
[468] Id.
[469] Id.
[470] Id., p.14.

> impacts if one accepts the reasonable premise that the marginal utility of income is appreciably higher in poor nations than in rich nations[471]".

Other authors are claiming that IP rewards beyond what is necessary to spur innovation, and even that IP may be a drag to innovation:

> "One complaint is that intellectual property rewards inventors beyond what is necessary to spur innovation. Another is that intellectual property is a drag to innovation, rather than a spur, since it prevents inventions from being used efficiently, especially in creating further innovations. A third complaint is that some inventions should not be protected at all but, instead, be supported by public sponsors[472]".

Thus, these authors have identified alternative mechanisms to reward innovation, such as public funded research and prizes[473]. From a long-term perspective, the use of compulsory licensing, whether to supply a national market or for exports, may not be enough to ensure universal access to essential medicines. The use of the terms "exceptional circumstances", "national emergency", or "extreme urgency", plus the fact that importing countries need to justify themselves through notification, according to the *August 30th Decision,* clearly demonstrate the exceptional character of those measures[474]. However, even if the bureaucratic burden can prove to be rather heavy, public health safeguards provided in *TRIPS* and the Doha documents need to be fully used for the time being, before another mechanism is agreed on by all the stakeholders and is implemented where people need it. Because India, the largest provider of cheap medicines to the developing world, needs to comply with *TRIPS* starting in 2005, the use of this public health safeguard will become crucial for the treatment of millions of people, since Bangladesh is the only country not subject to the WTO until 2016 that is able to produce generic drugs for the developing world[475]. Since India was supplying medicines to about 50% of the AIDS-inflicted people in the developing world,

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[471] F. M. SCHERER, « A Note on Global Welfare in Pharmaceutical Patenting », (2004) 27 *The World Economy*, 1127-1142, 1137.
[472] Nancy GALLINI and Suzanne SCOTCHMER, « Intellectual Property : When Is It the Best Incentive System? », (2002) 2 *Innovation Policy and the Economy*, Adam Jaffe, Joshua Lerner and Scott Stern, Cambridge, Mass., MIT Press, 51-72.
[473] See id., and Steven SHAVELL and Tanguy VAN YPERSELE, « Rewards versus Intellectual Property Rights", (2001) 44 *Journal of Law and Economics*, 525-547.
[474] Marie CARPENTIER and René CÔTÉ, « La Déclaration de Doha sur la santé publique : la bonne prescription ? Une perspective historique sur le débat concernant la protection par brevet des médicaments », (2005), 46 *Les Cahiers de Droit*, no.3, 746.
[475] THE INDEPENDANT, "Bangladesh eyes huge medicine market in Africa", business news, available at: http://independent-bangladesh.com/news/mar/29/29032005bs.htm#A0.

countries like Bangladesh will not be able to take over entirely its production of generic drugs. Developing countries will need WTO members to produce cheap generic medicines and make them available as soon as possible under *TRIPS* public health safeguards.

Other reward-based mechanisms must be put in place to replace the patent system, at least regarding essential medicines. In the U.S. H.R. 417, or the *Medical Innovation Prize Fund Act*, is a new bill that would separate the markets of innovation and of the provision of essential pharmaceutical products by creating a fund to compensate new inventors when they make available a new and useful product for consumers. H.R. 417 "would change the paradigm for financing medical R&D and pricing prescription drugs in the United States":

> "Rather than rely on high drug prices as the incentive for R&D, the bill would directly reward developers of medicines, on the basis of a drug's incremental therapeutic benefit to consumers, through a new Medical Innovation Prize Fund. ... The Bill, by rewarding only truly innovative products that provide new therapeutic benefits to consumers, would also dramatically reduce wasteful expenditures such as those on research, development and marketing of me-too drugs"[476].

This legislation, if adopted, would prevent massive expenditure on marketing pharmaceutical products and on me-too drugs, which bring very little net social benefits, and instead adequately reward truly innovative medicines. Innovators would be rewarded from the Fund, which would be financed by 0.5% of U.S. GDP, and products would become generics immediately following FDA approval. Inventors would still obtain a patent and be free to use it, until the FDA approves a new medicine[477]. Breaking the link between drug prices and R&D would greatly increase equitable access to medicines. H.R. 417 would also provide minimal funding for orphan drugs, thus fixing another major flaw in the current patent system.

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[476] *H.R.417 – The Medical Innovation Prize Fund Act*, Summary by the Office of Rep. Sanders, available at: http://www.cptech.org/ip/health/hr417/hr417-summary.pdf.
[477] Id.

Moreover at the international level, numerous experts from different fields formulated a proposal for a new global medical R&D treaty in 2002. Among other things, this R&D treaty would seek to prevent

> "A growing web of multilateral, regional, bilateral and unilateral trade agreements and policies [that] focus nearly exclusively on measures that expand the scope and power of intellectual property rights, or reduce the effectiveness of price negotiations or controls"[478].

This draft treaty[479], which is a work in progress, represents a collaborative effort over the past two years. At its core is an obligation to finance medical research and development, linked with a country's GDP. The proposed treaty would provide minimal financing for neglected diseases. It would also provide drastic changes for financing R&D:

> "While virtually all of today's trade agreements focus exclusively upon purchase of medicines at high prices as the sole method of financing R&D, the Draft R&D Treaty takes a much broader view. Acceptable methods of finance include such items as direct public funding, tax credits or other expenditures, philanthropic spending, research funding obligations imposed on sellers of medicines, purchases of relevant medical products (to the degree that such expenditures induce investments in medical R&D), and innovation prizes (to the degree that such prizes induce investments in medical R&D)"[480].

This draft treaty would work similarly to the Kyoto Treaty on climate change, since it would assign credits for socially important projects. Excess credits could be traded between states to satisfy the treaty obligations. Credits could be granted for a wide range of projects, such as R&D for neglected diseases and priority projects, free and open source public databases, technology and capacity transfers to developing countries, preservation and dissemination of traditional medical knowledge, and exceptionally useful public goods[481]. Such a mechanism would reduce inequities in biomedical research funding between diseases prevalent in rich countries and those prevalent in poor countries.

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[478] *Request to Evaluate Proposal for New Global Medical R&D Treaty*, Letter to the World Health Assembly Executive Board and the World Health Organization Commission on Intellectual Property Rights, Innovation and Health, February 2005, p.2, available at: http://www.cptech.org/workingdrafts/24feb05WHOen.pdf.

[479] *New Global Medical R&D Treaty* available at: http://www.cptech.org/workingdrafts/rndtreaty4.pdf.

[480] *Request to Evaluate Proposal for New Global Medical R&D Treaty*, op. cit., note 456, p.2

[481] Id., p.3.

> "An estimated 93 percent of the world's burden of preventable mortality (measured as years of potential life lost) occurs in the developing world. Yet, of the $30 billion global investment in health research in 1986, only 5 percent or $1.6 billion was devoted specifically to the health problems of developing countries. For each year of potential life lost in the industrialized world, more than 200 times as much is spent on health research as is spent for each year lost in the developing world"[482].

However, such radical changes for financing innovation brought by this draft treaty and by its counterpart at the national level, H.R. 417, although they both work towards increasing the respect of the right to health and other human rights, are difficult to adopt, considering that such a global treaty needs to be negotiated by the state parties. For now, considering the urgency to make treatments available for HIV/AIDS, malaria, tuberculosis and other diseases affecting poor countries, we may need to improve the current system with Doha while working on further changes to be brought to innovation and patent protection rules.

The *TRIPS* public health safeguards are very important because of the symbol they represent. Since international trade is increasingly integrated in international development and international relations in general, market forces undoubtedly affect an increasing number of other fields, where they are in breach of other rights and entitlements. Regarding the case of international trade of essential medicines, it is the right to health and access to essential medicines that is affected. What makes the access to patented essential medicines an issue more than a symbol is that a huge proportion of humankind believes it is totally unacceptable to let millions of people die without treatment only in order for transnational corporations to increase their already enormous profits. *TRIPS* public health safeguards and, more importantly, their further interpretation through the Doha documents constitute an express recognition that when free trade rules negatively affect human rights, an amendment to these trade rules is necessary, thus giving consideration to human rights in a forum exclusively devoted to international trade. Such reasoning may lead to the consideration of other fields in the international trade forum and the formulation of trade rules, such as culture and environment protection. This would seem obvious and natural since free trade and the

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[482] COMMISSION ON HEALTH RESEARCH FOR DEVELOPMENT, "Health Research: Essential Link to Equity in Development", Oxford University Press, London, 1990, p.29.

WTO were believed to be intended to spread democracy, human rights, and good western values around the globe.

In order to ensure that human rights are respected, follow-up devices could be put in place, such as universal human rights indicators. These human rights indicators could work similarly to those used by the United Nations Development Programme (UNDP) to calculate the level of human development in different countries. In order to carry out their evaluation, the UNDP uses four simple indicators: life expectancy at birth, the adult literacy rate, school enrollment rates, and the average annual income per person[483]. According to an author, human rights indicators

> "...could show the status of a particular human rights situation, reveal whether a situation is getting better or worse owing to a policy change, and guide the formation of better policy"[484].

Developing indicators for human rights compliance may not be simple, considering the difficulty to conceptualize human rights, political and cultural divergences, and lack of resources for a state to implement and to monitor measures promoting human rights. States are reluctant to submit their human rights behavior to scrutiny by other states, and vice-versa.

> "It is not obvious that the rich normative concepts of human rights can be turned into policy evaluation tools that are adequately responsive to the complexities of policy-making situations"[485].

Concerning the right to health and the access to essential medicines, we propose that the pricing of essential medicines (which is directly linked to intellectual property and public health safeguards), amongst others, should constitute an essential indicator to assess the extent of the compliance to the right to health in a given jurisdiction.

What remains certain is the fact that access to essential medicines, like ozone depletion and global warming, is a problem that initially needs to be addressed globally, since

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[483] Kate RAWORTH, "Measuring Human Rights", in Sofia GRUSHIN, Michael A. GRODIN, Georges J. ANNAS, and Stephen P. MARKS, *Perspectives on Health and Human Rights*, Taylor and Francis Group, New York, 2005, p. 393.
[484] Id., p.395.
[485] Id.

different members of the international community are either responsible or the victims of high prices of essential medicines. This is where the proposed international treaty on R&D and the TRIPS/Doha public health safeguards stand. And then, states of the international community have room to adopt measures consequent with the right to health, such as *H.R. 417 – The Medical Innovation Prize Fund Act* and others like those adopted by Canada, the European Union, Brazil, India, and South Africa that we saw in parts IV and V of this analysis. To favor the adoption of those two levels of measures, we propose that the bridge between human rights law and international trade law be established or strongly reinforced, depending whether one considers that this bridge is already established or not. This might be done by delineating the extent to which developed countries are responsible towards developing states concerning the implementation of the right to health and other human rights.

It is an evident fact of state practice that states do routinely finance foreign projects for promoting health and other aspects of social welfare[486]. For example, one author mentions that "each year donor states plan how much they shall disburse abroad in health aid; this information is then shared with recipient states, who budget that same amount as revenue for their domestic health budget"[487]. The author further concludes that such practice equals to a tacit acceptance of a duty to assist internationally[488]. Moreover, article 2 of the *International Covenant on Economic, Social and Cultural Rights* states that the state parties must

> "...take steps, individually and through international assistance and cooperation... to the maximum of its available resources, with a view to achieving progressively the full realization of the rights recognized in the present Covenant by all appropriate means, including particularly the adoption of legislative measures".

However, according to another author, article 2 makes the *ICESCR* "a catalogue of imperfect obligations and nevertheless establishes duties to specify, without undue delay, what steps will be taken, and when; what forms of assistance will be sought and from whom; what resources will be allocated; and at what pace the right will be

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[486] A. ATTARAN, loc. cit., note 451, p.34.
[487] Id., p.34.
[488] Id., p.35.

progressively realized"[489]. We have two observations concerning what is mentioned above about the responsibility or the duty for a state to act in order that the right to health is adequately implemented in another state. First, it seems that the "duty to assist internationally" other states is not limited to foreign aid but also includes the formulation of policies that do not prevent the respect, the protection and the fulfillment of the right to health in other countries[490]. The second observation is that since neither the Security Council nor the United Nations in general is a party to the *ICESCR*, economic sanctions could hardly be undertaken legally as a human rights violation[491]. Because the *ICESCR* provides no sanctions of its own in case of non-compliance to its provisions, their efficient implementation remains difficult to achieve.

In order to cope with this situation, the concepts of human rights and development should be joined. Since human rights are about the normative constraints on power relations to ensure human dignity and the elimination of repressive and oppressive processes, and development objectives focus more on material conditions and distributional arrangements that allow people to benefit from economic processes to improve their condition, human rights and development have evolved on parallel and non-intersecting tracks[492]. However, the introduction of human rights in development can be justified in numerous ways. An interesting rationale supporting this assumption is social justice, as defined by the Human Rights Council of Australia, for which primary importance is given to eliminate social disparities and inequalities in access to health. A human rights based approach to development may be explained such as following:

> "...a body of human international rights law is the only agreed international framework which offers a coherent body of principles and practical meaning for development cooperation, [which] provides a comprehensive guide for appropriate official development assistance, for the manner in which it should be delivered, for the priorities that it should address, for the

[489] Stephen P. MARKS, "Human Rights in Development: The Significance for Health", in Sofia GRUSHIN, Michael A. GRODIN, Georges J. ANNAS, and Stephen P. MARKS, *Perspectives on Health and Human Rights*, Taylor and Francis Group, New York, 2005, p.99.
[490] Id., p.100.
[491] Stephen P. MARKS, loc. cit., note 62, p.371.
[492] Stephen P. MARKS, loc. cit., note 489, p.95-96.

> obligations of both donor and recipient governments and for the way that official development assistance is evaluated"[493].

Since current development is carried out globally through trade and the access for a local industry to foreign markets, it seems to us that the application of the human rights based approach to the international trade framework is perfectly valid. This would inculcate some humanity and democracy into the legal framework for international trade. Applied to the case of access to essential medicines, it would constitute a solid base for an increased utilization of the TRIPS/Doha public health safeguards, as well as a further reform of the patent system concerning essential medicines.

We hope that this analysis will further and enhance the influence of human rights law, and especially the right to health, in international and national policymaking, since article 14 of the *Universal Declaration on Bioethics and Human Rights* of October 19th, 2005, reaffirms that health is "essential to life itself," and that it "must be considered as a social and human good"[494].

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[493] THE HUMAN RIGHTS COUNCIL OF AUSTRALIA, *The Rights Way to Development: A Human Rights Approach to Development Assistance*, Sydney, Australia, 1995.

[494] Subject to linguistic and editorial modifications, the Declaration is available at: http://www.unesco.org/shs/bioethics.

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