TRADE AND HUMAN RIGHTS

EXPLORING THE IMPACT OF WTO LAW ON STATE CAPACITY TO PROTECT, PROMOTE AND FULFILL THE HUMAN RIGHT TO HEALTH

Master of Arts in Law and Diplomacy Thesis

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Since the institutionalization of the General Agreement on Tariffs and Trade in 1994, the World Trade Organization has become the drive for freer trade. However, critics of the organization have complained that free trade had become inconsistent with fair trade, and that the WTO had in fact prevented states from fulfilling their human rights obligations. One particular area of concern is health. In this paper, I will analyze the nexus between WTO law and the human right to health, in an effort to identify provisions that can, in fact, assist WTO members in fulfilling their human rights obligations vis-à-vis the right to health. In applying those provisions, however, WTO members and the dispute settlement body have showed an inconsistent stance in health-related disputes, which coincides with the involvement and influence of political lobbies. It is therefore essential, to guarantee a systematic application of WTO law, in a manner consistent with WTO members' human rights obligation in health, to institutionalize an interpretive approach to WTO law in light of the right to health. Such effort can be achieved only after the relevant international human rights bodies and the NGO community stop attacking the WTO, an attitude that has proved, thus far, counterproductive, but rather collaborate with it. This approach will not only ensure the respect for the human right to health in WTO law, but will also ensure that member states will reap the economic benefits of globalization the WTO has to offer.

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Since the institutionalization of the General Agreement on Tariffs and Trade (GATT) in 1994, the World Trade Organization (WTO) has become the drive for global free trade. According to Economists such as Nobel Prize winner Paul Samuelson, "[T]here is essentially only one argument for free trade or freer trade, but it is an exceedingly powerful one, namely: Free trade promotes a mutually profitable division of labor, greatly enhances the potential real national product of all nations, and makes possible *higher standards of living all over the globe*."[1] Such aspirational views have also been included in the Agreement Establishing the WTO, whereby the view of WTO members is to "rais[e] standards of living."[2] By doing so, it is reasonable to expect that free trade and the WTO will improve worldwide economic welfare of nations and the social welfare of the population. However, while trade has expanded, the list of least-developed countries has increased, from 42 in 1990 to currently 50 countries, including Bangladesh, Ethiopia, Haiti, Nepal, Senegal and Yemen.[3] The process of globalization has been found partly responsible for this widening of the poverty gap worldwide, by marginalizing the least-developed countries and exacerbating developmental problems,[4] and as a result, the WTO has become a target for criticism, not only by nongovernmental organizations, but also, as will be detailed later, by other intergovernmental institutions such as the Committee on Economic, Social and Cultural Rights or the Commission on Human Rights. The WTO has particularly been criticized for not only failing to protect, but actually diminishing human rights conditions in some of its member countries,

[1] Paul Samuelson, Economics 692 (9th ed. 1973), quoted in John Jackson, William Davey and Alan Sykes, *Legal Problems of International Economic Relations*, 4th ed. (St. Paul: West Group, 2002), 15.

[2] Agreement Establishing the World Trade Organization, Preamble.

[3] United Nations, *Current List of Least Developed Countries: Key Indicators* (accessed February 23, 2004); available from http://www.un.org/esa/policy/devplan/ldc03list.pdf

[4] Hussain Shihab, Permanent Representative of the Maldives, Address to the Third United Nations Conference on the Least Developed Countries, October 31, 2000 (accessed April 26, 2003); available from http://www.undp.org/missions/Maldives/stldc55.htm

specifically in the areas of labor and health. In this paper, we will therefore focus on the nexus between the WTO and the right to health, in order to determine how WTO law has affected states' capacities to fulfill their human rights obligations vis-à-vis the right to health.

The primary international human rights instrument that seeks to promote and protect the right to health is the International Covenant on Economic, Social and Cultural Rights (CESCR), to which 148 states are parties. Of these 148 states, it is important to note that 116 are also members of the WTO, with an additional 18 states which have applied for WTO membership. Further, although they have not ratified the Covenant yet, the 2 signatory states, members of the WTO, also have the obligation not to take measures that would affect the purpose of the Covenant (see Annex 1). For those 116 states parties to both regimes, it is essential to find a balance between their trade obligations and their human rights obligations in health, to ensure that abiding by the obligations of one system will not prevent them from respecting their obligations towards the other. WTO law, because it has required WTO members to adopt or amend domestic legislations in various areas, can be considered the most intrusive international legal regime, and it is probable that WTO law, in doing so, has had effects on non-trade related legislations, including socio-economic ones. In this paper, I will first analyze both institutional systems, in order to define what the right to health consists in, and to determine if and how WTO law can assist states in fulfilling their human rights obligations, and actually respect the right to health in its member states. We will then focus on the application of WTO agreements, specifically the General Agreement on Tariffs and Trade (GATT), Agreement on Trade-Related Aspects of Intellectual Property

Rights (TRIPS), and Agreement on Sanitary and Phytosanitary Measures (SPS), which have had, directly or indirectly, the greatest impact on the right to health and on public health policies. In these sections, I will particularly focus on the application of WTO law by the dispute settlement body of the organization, to determine whether, and if so, how it defers to domestic public health policies and the right to health. Finally, after having analyzed the application of WTO law and the inconsistencies of the dispute settlement body in doing so, I will turn to a more analytical approach to the problem, to determine how WTO law could respect member states' human rights obligations and effectively assist them in fulfilling them. To do so, I will discuss why an interpretive approach to WTO law in light of the right to health is not sufficient, whether it could be possible for the WTO to fully integrate human rights in its law, and in what ways human rights bodies in charge of monitoring the right to health can collaborate with the WTO.

I. INSTITUTIONAL BACKGROUND

1. Human rights instruments and definition of the right to health

a. International instruments

The right to health has been established as a fundamental human right of economic and social nature in a number of international human rights treaties. As soon as 1945, the United Nations (UN) Charter established the role of the UN as, *inter alia*, to "achieve international cooperation *in solving international problems of an economic, social***,** cultural or humanitarian character, and *in promoting and encouraging respect for human rights* and for fundamental freedoms for all without distinction as to race, sex, language or religion" (Art. 1.3). The UN's responsibilities also include the promotion of "higher standards of living" (Art. 55(a)) and of "solutions of international economic, social, *health*, and related problems" (Art. 55(b)). The principal international instrument to promote the human right to health is the International Covenant on Economic, Social and Cultural Rights (CESCR), which has thus far been ratified by 146 states, including Argentina (1986), Angola (1992), Brazil (1992), Canada (1976) and India (1979)[5] -- the U.S. signed the treaty in 1977 but has not, to this date, ratified it. According to Art. 12 of CESCR, states, by ratifying the treaty, "recognize the right of everyone to the enjoyment of the highest attainable standard of physical and mental health," and agree to take measures to protect the right to health, towards:

> "(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;

[5] Office of the High Commissioner for Human Rights (OHCHR), *Status of Ratifications of the Principal Human Rights Treaties* (accessed April 9, 2004); available from http://www.unhchr.ch/pdf/report.pdf. The states mentioned are also members of the World Trade Organization (WTO), against which complaints were filed with the WTO dispute settlement bodies. These cases will be elaborated in subsequent paragraphs.

> (c) The prevention, treatment and control of epidemic, endemic, occupational and other diseases;
> (d) The creation of conditions which would assure to all medical service and medical attention in the event of sickness." (Art. 12.2)

The right to health has also been included as a fundamental human right in the Universal Declaration of Human Rights,[6] a non-legally binding declaration adopted without a vote against by UN members in 1948. Children's right to health, specifically, is protected by Art. 24 of the Convention on the Rights of the Child, which also lists measures to be taken by states parties to protect it, i.e., the "provision of necessary medical assistance and health care … with emphasis on the development of primary health care" (Art. 24.2(b)).

b. Regional instruments

The recognition of the right to health as a fundamental human right has also been supported by its inclusion in regional human rights treaties. Indeed, it is guaranteed by the European Social Charter (Art. 11, 13), the Charter of Fundamental Rights of the European Union (Art. 35), the African Charter on Human and Peoples' Rights (Art. 16), and the Additional Protocol to the American Convention on Human Rights ("Protocol of San Salvador", Art. 10). Therefore, the right to health is a universal, justiciable right, not only in the international arena, but also in regional forums. However, and despite its legal recognition as a human right, the right to health has not been accepted by some as a fundamental one, with the same legal status as civil and political rights.[7] This lack of

[6] "Everyone has the right to a standard of living adequate for the health and well-being of himself and of his family, including food, clothing, housing and medical care and necessary social services …." Universal Declaration of Human Rights, Art. 25.1.

[7] "Although a fundamental human right, with the same international legal status as freedom of religion or the right to a fair trial, the right to health is not as widely recognized as these and other civil and political rights." United Nations (UN) Secretariat, Economic and Social Council, Commission on Human Rights, *The Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health: Report of the Special Rapporteur*, E/CN.4/2003/58, 2003, Para. II.38. Accessed April 7, 2004. Available from UNODS.

attention explains the lack of a clear definition as to what it consists of, and what states' obligations are.

c. What is the human right to health?

The international community seems to have become increasingly aware of its obligation to guarantee the right to health in the context of development -- out of the eight Millennium Development Goals developed by the United Nations Development Programme (UNDP) in September 2001, four goals are directly related to health, namely, to reduce maternal mortality and under-5 child mortality, and to reverse the spread of HIV/AIDS and ensure environmental sustainability by 2015.[8] As an economic and social right, the right to health is to be achieved progressively, according to the state's available resources (CESCR Art. 2).[9] However, no treaty clearly defines what the right to health consists in, what its scope is, and how to evaluate whether a state abides by its obligations. The Convention on the Rights of the Child lists states' responsibilities as including the provision of "necessary medical assistance and health care .. *with emphasis on the development of primary health care*."[10] Similarly, disease and malnutrition are to be fought, "including within the framework of primary health care."[11] In addition to primary health care, Art. 12 of CESCR and Art. 35 of the Charter of Fundamental Rights of the European Union [12] include the development of preventive health care as a

[8] United Nations Development Programme (UNDP), *Millennium Development Goals* (accessed April 08, 2003); available from http://www.undp.org/mdg/

[9] "Each State Party to the present Covenant undertakes to take steps, individually and through international assistance and cooperation, especially economic and technical, *to the maximum of its available resources*, with a view to achieving *progressively* the full realization of the rights recognized in the present Covenant …" CESCR, Art. 2.1.

[10] Convention on the Rights of the Child, Art. 24.2(b).

[11] Ibid, Art. 24.2(c).

[12] "The steps to be taken by the States Parties to the present Covenant to achieve the full realization of this right shall include those necessary for ... *the prevention*, treatment and control of epidemic, endemic, occupational and other diseases." CESCR, Art. 12.2(c).

component of the right to health. Similarly, Art. 10 of the San Salvador Protocol requires states to adopt certain measures "to ensure that right," including the "prevention and treatment of endemic, occupational and other diseases" (Art. 10.2(d)) and the "education of the population on the prevention and treatment of health problems" (Art. 10.2(e)).

In light of the above mentioned texts, and throughout this paper, the right to health will consist of a right to access to healthcare, i.e., the right to have access to both preventive and primary medical care. Such definition is consistent with the report of the Committee on Economic, Social and Cultural Rights, which, in August 2000, established that the right to health is an "inclusive right extending not only to timely and appropriate health care but also to the underlying determinants of health, such as access to safe and potable water and adequate sanitation, an adequate supply of safe food, nutrition and housing, healthy occupational and environmental conditions, and access to health-related education and information."[13] Although there seems to be consensus on what, at minimum, the right to health is, human rights treaties do not provide methods to evaluate a state's compliance with its obligations. On this particular issue, the Committee has indicated four principles to be used in evaluating the level of compliance, namely, the (1) availability, (2) accessibility, (3) acceptability (culturally acceptable) and (4) quality of health care.[14] Therefore, any state action that will threaten or prohibit, directly or indirectly, the availability of, access to, acceptability of, or quality of preventive and primary health care, is to be a violation of the human right to health. States' obligations,

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"Everyone has the right of access to *preventive health care* and the right to benefit from medical treatment under the conditions established by national laws and practices." Charter of Fundamental Rights of the European Union, Art. 35.

[13] UN Secretariat, Economic and Social Council, Committee on Economic, Social and Cultural Rights, *General Comment No. 14: The Right to the Highest Attainable Standard of Health (Article 12 of the International Covenant on Economic, Social and Cultural Rights*, E/C.12/2000/4, 2000, Para. 11. Accessed April 7, 2004. Available from UNODS. *General Comment No. 14* is reproduced in Annex 2.

[14] Ibid, Para. 12.

as per the classification of the Committee on Economic, Social and Cultural Rights,[15] shall include:

1. To respect the right to health, i.e., to not interfere with its realization (e.g., a state cannot legislate to limit or prevent the sale of essential medicines or access by the population to health care);
2. To protect the right to health, i.e., to prevent the dissemination of threats to health. This could include the implementation of national public health policies, the consideration of the effect on the health care system of resource allocation and of other, non-health related policies, or the setting up of maximum prices for essential medicine or of minimum sanitary measures to prevent dissemination of diseases;
3. To fulfill the right to health, i.e., to provide preventive and primary health care through public institutions as needed and as possible (e.g., maintaining public hospitals and providing at minimum emergency care, if at all possible for free).

Despite the lack of consensus on how to evaluate compliance, the right to health has been deemed to be justiciable by international bodies, such as the African Commission on Human and People's Rights,[16] as well as domestic courts.[17]

2. Health in international trade law

a. The World Trade Organization and General Agreement on Tariffs and Trade

The WTO was established in April 1994 upon completion of the General Agreement on Tariffs and Trade (GATT) Uruguay Round, and membership required

[15] Ibid, 33.
[16] Commission on Human Rights, E/CN.4/2003/58, 17.
[17] Minister of Health and Others v. Treatment Action Campaign and Others, CCT 8/02, 135.2(a) (Constitutional Court of South Africa, 2002).

acceptance of all WTO agreements (WTO Charter, Art. XIV) without reservations (WTO Charter, Art. XVI.5). The WTO currently has 146 members, including India, South Africa, the EC and the US. Because of the different levels of development of its members, WTO agreements contain provisions for differential treatment for developing countries,[18] and for financial and technical assistance for compliance with WTO obligations.[19] As part of international law, WTO law is subject to the Vienna Convention on the Law of Treaties and to "customary rules of interpretation of public international law" for matters of interpretation, as confirmed in Art. 3.2 of the Understanding on Rules and Procedures Governing the Settlement of Disputes (DSU).

The WTO's mandate, by providing a framework for free trade, is to "[raise] standards of living, ensuring full employment and a large and steadily growing volume of real income and effective demand,"[20] while taking into consideration the economic and development needs of its members,[21] thereby endowing WTO law with an economic and social agenda. However, no specific mention is made of human rights concerns -- the WTO was, actually, established in complete isolation from human rights organizations, and outside the auspices of the UN.[22] Further, it is important to note that there is no relationship agreement between the UN and the WTO, while there is between the UN and the IMF or the World Bank, its specialized agencies. This does not mean that by

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[18] "The least developed countries recognized as such by the United Nations will only be required to undertake commitments and concessions to the extent consistent with their individual development, financial and trade needs or their administrative and institutional capabilities." World Trade Organization (WTO) Charter, Art. XI.2.

[19] "The contracting parties shall … collaborate in analyzing the development plans and policies of less-developed contracting parties and in examining trade and aid relationships with a view to devising concrete measures to promote the development of export potential and to facilitate access to export markets." GATT Art. XXXVIII.2(c).

[20] WTO Charter, Preamble.

[21] General Agreement on Tariffs and Trade (GATT), Part IV "Trade and Development."

[22] Robert Howse and Makau Mutua, "Protecting Human Rights In a Global Economy," Rights & Democracy (accessed March 03, 2003); available from http://www.ichrdd.ca/frame.iphtml?langue=0.

ratifying WTO Agreements, states may breach their human obligations, since this would be contrary to the principle of *pacta sunt servanda* in international law, according to which states must enter into an agreement in good faith (Vienna Convention on the Law of Treaties, Art. 26).[23] Therefore, WTO law, which entered into force after the CESCR, must be considered as compatible with the CESCR, and trade obligations, compatible with economic, social and cultural rights obligations. However, the absence of a relationship agreement between the WTO and human rights bodies does indicate a possible lack of coordination between the two regimes, as will be evidenced in subsequent chapters. In relation with the right to health, Art. XX of the GATT ("General Exceptions") allows states to adopt and enforce measures that are necessary "to protect human, animal or plant life or health" (Art. XX(b)). The GATT therefore allows states to derogate from WTO law, in order to pursue bona fide public health goals. However, by virtue of being a WTO member, a state cannot derogate from any WTO agreement [24] -- members have to abide by all WTO agreements, whose obligations are cumulative. It is therefore necessary to examine the provisions of other WTO agreements, adopted by its decision-making bodies in 1994, specifically the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and the Agreement on Sanitary and Phytosanitary Measures (SPS).

b. Agreement on Trade-Related Aspects of Intellectual Property Rights

The purpose of the TRIPS Agreement is to harmonize members' intellectual property legislation (i.e., copyrights, trademarks, industrial designs and, of specific

[23] "Every treaty in force is binding upon the parties to it and must be performed by them in good faith." Vienna Convention on the Law of Treaties, Art. 26.

[24] "The agreements and associated legal instruments included in Annexes 1, 2 and 3 … are integral parts of this Agreement, binding on all Members." WTO Charter, Art. II.2.

interest to the right to health, patents), by establishing minimum standards of protection and requiring WTO members to adopt their domestic legislation accordingly.[25] It is important to note that the TRIPS Agreement was sponsored by the US delegation during the Uruguay Round[26] and strongly supported by the pharmaceutical industry.[27]

Specifically, the TRIPS Agreement contains provisions on the requirements for, and exceptions to, patentability (Art. 27) -- the latter includes "diagnostic, therapeutic and surgical methods for the treatment of humans and animals." The agreement does not, however, completely prohibit any use of a patented product without authorization from the right holder, such as compulsory licensing (Art. 31),[28] but seeks to restrict such practice. In light of the different levels of development of WTO members, the agreement contains provisions for technical and financial cooperation from developed countries (Art. 67), including to "support the establishment or reinforcement of domestic offices and agencies," and for transitional periods and arrangements -- as per Art. 65 and 66, developing and the least developed countries were granted transitional periods of five and ten years respectively, during which they "shall not be required to apply the provisions of this agreement" (Art. 66.1). It is to be noted that the WTO Ministerial Conference granted, in November 2001, an extension of their transitional period to the least

[25] "Members shall give effect to the provisions of the Agreement. Members may, but shall not be obliged to, implement in their law more extensive protection than is required by this Agreement … Members shall be free to determine the appropriate method of implementing the provisions of this Agreement within their own legal system and practice." Agreement on Trade-Related Aspects of Intellectual property Rights (TRIPS), Art. 1.1.

[26] "The U.S. has long been among the leading advocates for stronger intellectual property rights in the trading community, based on at least a perception that US inventors and creators lose considerable sums due to lax protection overseas." Jackson, Davey and Sykes, 926.

[27] "The trade pact's key provisions," *Wall Street Journal*, December 02, 1994, A8.

[28] "Compulsory licensing is when a government allows someone else to produce the patented product or process without the consent of the patent owner." WTO, *Facts Sheet: TRIPS and Pharmaceutical Patents* (accessed April 7, 2004); available from http://www.wto.org/english/tratop_e/trips_e/factsheet_pharm02_e.htm.

developed countries until January 01, 2016.[29] Art. 66.1 of the agreement confirms the corollary of this provision, that is, those countries are not to be subject to the dispute settlement procedures for failure to comply with the agreement during the transitional period.

Pharmaceutical manufacturers have argued that the creation of a global intellectual property protection regime will create an attractive commercial environment worldwide, thereby increasing international trade and the transfer of knowledge and technology to less developed countries.[30] The TRIPS Agreement is also seen as an instrument that can promote the right to health worldwide, by allowing pharmaceutical manufacturers to recoup their investments in research and development, and by allowing them to re-invest in further research for new and improved medicines,[31] including, as pointed out by pharmaceutical companies, on tropical diseases that most affect developing countries. The agreement therefore tries to strike a balance between the financial interests of innovators and inventors (e.g., pharmaceutical companies), mostly

[29] "We also agree that the least-developed country Members will not be obliged, with respect to pharmaceutical products, to implement or apply Sections 5 and 7 of the TRIPS Agreement or to enforce rights provided for under these Sections until 01 January 2016, without prejudice to the right of least-developed country Members to seek other extensions of the transition periods as provided under Article 66.1 of the TRIPS Agreement." WTO Ministerial Conference, *Doha Declaration on the TRIPS Agreement and Public Health*, para. 7 (accessed February 2, 2003); available from http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm

[30] "Enhanced and global protection of intellectual property rights would foster technology and investment flows to developing countries, thus promoting their participation in trade and economic development." Carlos Correa, *Intellectual Property Rights, the WTO and Developing Countries* (New York, London: Zed Books Ltd., 2000), 23.

[31] According to estimates from the Pharmaceutical Research and Manufacturers of America (PhRMA), it takes an average of 10 to 15 years and $800 million to introduce a new medicine on the market. PhRMA, *Intellectual Property: Overview* (accessed March 03, 2003); available from http://www.phrma.org/issues/intprop/

"In order to provide medicines to poor people in developing countries, we first have to make sure the medicines exist. But new medicines won't continue to be developed absent strong intellectual property incentives, since investors will shy away from risky, expensive research it takes to come up with cures." Alan Holmer, President and CEO, PhRMA, Address to The Economist's Second Annual Pharmaceuticals Roundtable, November 20, 2002 (accessed April 7, 2004); available from http://www.phrma.org/publications/publications/20.11.2002.629.cfm.

in developed countries,[32] with human rights concerns in the areas of development, public health and the right to health in developing and the least-developed countries. This aspirational dimension is included in the TRIPS Agreement (Art. 7) -- the agreement should therefore respect the human right to health, and should potentially assist states, especially those that are parties to the relevant human rights treaties, to fulfill their obligations towards the right to health. In addition to the above, the agreement contains a provision to allow states to "adopt measures necessary to protect public health and nutrition" (Art. 8), thereby allowing derogations from general TRIPS obligations for public health purposes.

c. Agreement on Sanitary and Phytosanitary Measures

Finally, the SPS Agreement was adopted in 1994 to homogenize members' domestic sanitary regulations on foodstuffs, with a view to guarantee the protection of "human, animal or plant life or health,"[33] while minimizing negative impact on international trade. States are required to adapt their domestic regulations to the international standards and recommendations set up by, *inter alia*, the Food and Agriculture Organization (FAO) and the World Health Organization (WHO) (Art.2). However, WTO members are allowed to impose a higher level of sanitary protection, as they deem appropriate according to scientific evidence (Art. 3.3, 3.5). Like the TRIPS Agreement, the SPS Agreement acknowledges the financial, administrative and technological difficulties developing countries may encounter in implementing the agreement -- accordingly, it calls for assistance from developed countries (Art. 9, 10) and

[32] Approximately 74% of worldwide research and development is made in OECD countries, while only 6% is made in developing countries (Correa, 39).

[33] Agreement on Sanitary and Phytosanitary Measures (SPS), Preamble.

grants developing and the least developed countries a period of two and five years, respectively, to implement the agreement in their domestic legislation (Art. 14).

Sanitary and phytosanitary measures include all relevant laws and regulations that seek to protect human health and life "from risks arising from additives, contaminants, toxins or disease-causing organisms in food, beverages or feedstuffs" (Annex A, para.1.b). Such measures include, *inter alia*, "end product criteria, processes and production methods, testing, inspection, certification and approval procedures, quarantine treatment…, packaging and labeling requirements directly related to food safety." (Annex A, para. 1). For instance, according to the SPS Agreement, provisions to limit or ban imports of meat from Europe to the US, due to the spread of mad cow disease (BSE) and its transmission to humans as a fatal neurological disease, are permissible according to Art. 5.6 and 5.7 of the SPS Agreement.

The purpose of the SPS Agreement, however, is not to protect any sanitary regulations, but rather, to ensure that such regulations are necessary, i.e., to determine whether they are really protectionist measures in disguise. However, by encouraging states to adopt minimum standards and guarantee a minimum level of protection against health hazards due to the trade in foodstuff, the implementation of the SPS Agreement should assist WTO members in promoting the right to health. This is indeed confirmed in the preamble of the agreement [34] and, according to the WHO, since the entry into force

[34] "*Desiring* to improve the human health, animal health and phytosanitary situation in all Members." SPS Agreement, Preamble.

of the agreement in 1995, the SPS Committee has received over 100 specific trade-related concerns, of which approximately 30 are directly relevant to food safety.[35]

As demonstrated above, WTO Agreements recognize, in substance, a relationship between international trade and the right to health, and acknowledge the need to address health concerns by WTO member states, in a manner consistent with, not only the general principles of international law and international human rights law, but also with WTO law. WTO agreements are legally binding, and impose positive obligations to adopt domestic legislation to WTO standards. To support this, the WTO established a dispute settlement body, comprised of a Panel and an Appellate Body, which is quasi-judicial in nature and whose decisions are legally binding, at the cost of retaliatory sanctions against violators of WTO law.[36] This strict enforcement mechanism, which is notably absent from most human rights instruments, was set up as an incentive against the use of unilateral trade sanctions, a practice which, since 1994, has been, in effect, prohibited by the WTO.[37]

3. Nexus right to health / WTO law, and the role of non-governmental organizations

a. Increasing overlap between WTO law and human rights law

Both the human rights regime and the international trade regime were established after World War II, but due to the compartmentalized nature of the international legal system, they developed in isolation one from the other. Both regimes

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[35] WTO and World Health Organization (WHO), *WTO Agreements and Public Health: a Joint Study by the WHO and the WTO Secretariat* (Geneva: WTO, 2002), 65. Accessed April 7, 2004. Available from http://www.wto.org/english/res_e/booksp_e/who_wto_e.pdf

[36] Understanding on Rules and Procedures Governing the Settlement of Disputes (DSU), Art. 22.

[37] "In such cases [when Members seek the redress of a violation of obligations], Members shall not make a determination to the effect that a violation has occurred …, except through recourse to dispute settlement in accordance with the rules and procedures of this Understanding …." DSU, Art. 23.

have, as suggested by Thomas Cottier, evolved in such a way that they increasingly impact one another, leading to normative divergences and overlap between both systems.[38] Human rights law is aimed at protecting individuals from state abuses. While first generation rights, including civil and political rights, often restrict states' actions, the second generation of rights, including the right to health, imposes positive obligations on states, which have to take certain measures to respect, protect and fulfill those rights. From an individualistic approach to human rights, the human rights regime now recognizes the right to self-determination and the right to development, which are by nature group rights. While the scope of human rights has enlarged to protect groups or societies, international trade law has gradually narrowed its reach from protecting member states' trading rights (such as the "most favored nation" [MFN] status of members) to their private individuals and corporations. Whereas first generation trade agreements focused on the elimination of tariffs to promote free trade (GATT), the second generation sought to limit the use of non-tariff barriers by governments (e.g., subsidies). The third generation of agreements, since the Uruguay Round and the establishment of the WTO in 1994, has focused on limiting the potentially negative effects of domestic, non-trade regulations, on private actors in international trade, thereby protecting their interests. The inclusion of non-trade issues in WTO law, most notably that of intellectual property, has been mostly supported by private corporations which, in doing so, expect to protect their interests at the global level. The US pharmaceutical industry, for instance, had 625 registered lobbyists in Washington DC in 2001, and had a combined lobbying and campaign contribution budget in 1999 and 2000 of $197

[38] Thomas Cottier, "Trade and Human Rights: a Relationship to Discover," in *Journal of International Economics Law* 5, no. 1 (2002): 120-124.

million.[39] The implementation of the TRIPS Agreement was, in return, expected to bring between $2.1 and $14.4 billion in additional profits to pharmaceutical companies in developed countries.[40]

b. International trade, economic growth and the human right to health

Trade liberalization and WTO Agreements promoting it have been recognized as a tool in domestic poverty alleviation policies, based on their positive impact on economic growth.[41] The relationship is based, primarily, on the transfer of technology from industrialized to developing countries, the efficient re-allocation of factors of production within trading countries, and the increased real income generated. International trade allows for the greater access in domestic markets (for consumers and producers) to a wider base of technological knowledge, and such transfer of technology and access to innovations have been found to be the foundation of economic growth by Paul Romer,[42] by lowering a producer's costs of production, with the effect of lowering consumer prices. According to the same analysis, further economic growth can result from the spillover effect of technological advances in one industry or sector to another, thereby acting as a "catch-up bonus" for trading countries which can boost the

[39] Leslie Wayne and Melody Petersen, "A Muscular Lobby Rolls Up Its Sleeves," *New York Times*, November 04, 2001, BU1.

[40] Correa, 35.

[41] For reference on the relationship between trade and economic growth, please see:
Thomas Hertel, Christian Bach, Betina Dimaranan, and Will Martin, "Growth, Globalization, and Gains from the Uruguay Round," *World Bank Policy Research Working Paper no. 1614* (May 1996). Accessed April 7, 2004. Available from http://www.worldbank.org/research/trade/wp1614.html
Geoffrey Bannister and Kamau Thugge, "International Trade and Poverty Alleviation," *IMF Working Paper no. 01/54* (May 2001). Accessed April 7, 2004. Available from http://www.imf.org/external/pubs/ft/wp/2001/wp0154.pdf

[42] Paul Romer, "Endogenous Technological Change," in *Journal of Political Economy* 98 no. 5 (October 1990). Accessed April 7, 2004. Available from JSTOR

performance of other sectors in their economy.[43] Further, trade liberalization and WTO Agreements seek to eliminate, or at minimum reduce, the risks associated with trade, thereby encouraging foreign direct investments in trading countries, a particularly important factor of economic growth for developing countries.[44]

Trade liberalization has also been found to increase real income in trading countries, with a potentially particularly positive effect on the poor. Trade liberalization includes such policy reforms as the abandonment of border barriers to trade (e.g., tariffs, quotas) or of discriminatory treatment against imported products (e.g., taxes), effectively resulting in the availability of a greater variety of products at a lower price for consumers.[45] Specifically, a study of the distributional effects of Mercosur in Argentina conducted by Guido Porto for the World Bank showed, *inter alia*, that trade liberalization had had a "pro-poor distributional effect" in Argentina by eliminating tariffs that sought to protect domestic producers as opposed to consumers and the poor.[46] Further studies on the impact of trade liberalization on real income conducted by international organizations (including the World Bank), economists (such as Sachs and Warner)[47] and non-governmental organizations (NGOs) (including Oxfam) have proved a positive

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[43] Oscar Afonso, "The Impact of International Trade on Economic Growth" (PhD Working Paper no. 106, University of Porto, 2001). Accessed February 13, 2004. Available from http://www.fep.up.pt/investigacao/workingpapers/wp106.pdf

[44] According to a report published by the World Bank, capital flows to developing countries increased from less than $28 billion in the 1970s to $306 billion in 1997. Of these flows, the portion of official development aid (ODA) more than halved, while FDI (financial and technological). Paul Collier and David Dollar, *Globalization, Growth and Poverty: Building an inclusive world economy* (Washington DC: World Bank and Oxford University Press, 2002), 42. Accessed February 12, 2004. Available from http://econ.worldbank.org/prr/globalization/text-2857/

[45] Thomas Pugel, *International Economics,* 12th ed. (New York: McGraw Hill, 2004), 58-60.

[46] Guido Porto, "Using Survey Data to Assess the Distributional Effects of Trade Policy," *World Bank Working Paper no. 3137* (September 2003), 25-26 (accessed February 12, 2004); available from http://econ.worldbank.org/files/29916_wps3137.pdf

[47] Jeffrey Sachs and Andrew Warner, "Economic Reform and the Process of Global Integration," in *Brookings Papers on Economic Activity* 1995, no. 1 (1995): 1-118. Accessed February 12, 2004. Available from EconLit

correlation between the two. The effect of trade liberalization is therefore to allow consumers to consume beyond domestic producers' capacity to produce, but also to give them a greater variety of products at lower relative prices through competition and improved allocation of resources, both domestically and internationally.

However, it is necessary to acknowledge the "losers" from trade liberalization, and to limit the negative impact of trade on them. Indeed, according to the Solper Samuelson theory of trade, international trade, which affects product prices in perfect competition, has two unambiguous effects, namely, to raise the real return to the factor used intensively in the rising-price industry, while at the same time to lower the real return to the factor used intensively in the falling-price industry.[48] In the short-run at least, trade liberalization promoted by, *inter alia*, WTO Agreements can have a negative impact on workers and/or producers. In effect, while the number of persons living in absolute poverty has decreased by 14%, to approximately 762 million, in the period 1993-1998, and the rate of growth has increased on average, absolute poverty in less globalized developing countries has increased by 4%, to 437 million.[49] It is important to note that persons living in absolute poverty are to be found predominantly in rural areas of low-income countries, where "openness … is associated with greater inequality."[50] International trade has also been found responsible for the phenomenon of "immiserizing growth,"[51] whereby, in an effort to improve its terms of trade, a country will increase its volume of exports to compensate for their falling prices, leading to a further deterioration

[48] Pugel, 74.
[49] Collier and Dollar, *Globalization, Growth and Poverty: Building an inclusive world economy*, 50
[50] Ibid, 49.
[51] Jagdish Bhagwati, "Optimal Policies and Immiserizing Growth," in *American Economic Review* 59, no. 5 (December 1969): 967-970. Accessed April 7, 2004. Available from EconLit

of its terms of trade. Such phenomenon is a particular threat to countries relying on the exports of one or a few agricultural products, i.e., mostly in developing countries, and is a factor slowing down economic growth and development. In order to prevent, or at least minimize these negative effects of trade liberalization, economists and the World Bank have recommended the establishment of social safety nets, particularly to assist the most vulnerable parts of the population, ie, the poorest. Such social safety nets may include, but are not limited to, unemployment insurance programs, mandatory savings accounts, training programs, income support programs,[52] even bigger Governments.[53]

As a tool for poverty alleviation, WTO law can have a direct, positive impact on the human right to health. Indeed, economic growth and increased real income allows greater access to healthcare. Data from the World Bank Development Indicators show that, out of 97 developing countries with available data, 58 showed a positive causal relation between economic growth (measured in annual GDP growth) and per capita health care expenditures (measured in current US$), while 20 showed a negative causal relation (see Annex 3). It is therefore essential to acknowledge that WTO law, by promoting free trade and seeking to establish an environment conducive to liberalization and economic growth, can therefore be a very important tool to promote, protect and fulfill the human right to health in WTO member states. However, "absent supporting **health** and education services that **expand human capital**, the long-term dynamic gains of trade liberalization will be limited."[54]

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[52] Collier and Dollar, *Globalization, Growth and Poverty: Building an inclusive world economy*, 112-120.

[53] Dani Rodrick, "Why do more open economies have bigger governments?," in *Journal of Political Economy* 106, no. 5 (October 1998), 997-1033. Accessed February 23, 2004. Available from EconLit

[54] Bernard Hoekman, "Economic Development and the World Trade Organization After Doha," *World Bank Working Paper no. 2851* (June 2002), 5. Accessed February 12, 2004. Available from http://econ.worldbank.org/files/15652_wps2851.pdf

c. The role of non-governmental organizations

In short, while the human rights regime has broadened its scope, from the protection of the individual from the state to the promotion of peoples' rights by the state, the international trade law regime has narrowed its scope, from the promotion of tariff reductions by states to the imposition of non-trade standards onto domestic legislations to protect individuals' (or corporate) rights. Because of these tendencies, both systems have increasingly overlapped, and the nexus between WTO law and human rights, notably the right to health, has become increasingly apparent, even more so since non-governmental organizations (NGOs) have put it on their agenda. Although NGOs may have consultative status with UN and human rights bodies, no WTO provision explicitly allows WTO decision-making bodies to consult with NGOs, raising concerns about the organization's transparency. Most recently, NGOs have been permitted to submit *amicus briefs* to the WTO dispute settlement body,[55] and recent campaigns by organizations like Act Up or Third World Network have raised public opinion about the potential problems with the effect of current WTO law on the right to health, and on WTO members' ability to fulfill their human rights obligations.

Although the WTO mandate is not to promote human rights, including the right to health, but to promote free trade, the organization has evolved in such a way as to increasingly overlap with non-trade issues, including human rights and the right to health.

[55] "Each panel shall have the right to seek information and technical advice from any individual or body which it deems appropriate." DSU, Art. 13.2.

"On 07 November 2000, and after consultation among all seven Members of the Appellate Body, we adopted, pursuant to Rule 16.1 of the *Working Procedures*, an additional procedure, *for the purpose of this appeal only*, to deal with written submissions received from persons other than parties and third parties to this dispute (the "Additional Procedure")." European Communities (EC) – Measures Affecting Asbestos and Asbestos-Containing Products, WT/DS135/AB/R, Para. 51 (Appellate Body Division, 2001). Accessed April 3, 2003. Available from WorldTradeLaw.net

Since the goal of the WTO is to participate in the effort to "[raise] standards of living," a similar goal to that of economic, social and cultural rights, it is to be expected that the WTO will not, at minimum, prevent its members, who are also parties to the relevant human rights treaties, to fulfill their human rights obligations. However, current application and interpretation of WTO law has raised serious questions about the organization's bona fide concern over health, as demonstrated by the implementation of the TRIPS Agreement.

II. THE AGREEMENT ON TRADE-RELATED ASPECTS OF INTELLECTUAL PROPERTY AND THE RIGHT TO HEALTH

1. The TRIPS Agreement and Access to medicine

a. The HIV/AIDS epidemic and other endemic diseases

The TRIPS Agreement was adopted as part of WTO law in 1994, before the explosion of the HIV/AIDS epidemic in developing countries. Nine years after its adoption, the WHO estimated the number of AIDS-related deaths to be approximately 3 million per year, including 2.4 million in Sub-Saharan Africa, while approximately one third of the world population has no access to essential medicines.[56] The HIV/AIDS epidemic has had far-reaching effects on the development of those countries, and in April 2001, the IMF and the World Bank called for greater assistance to affected developing countries, where HIV/AIDS has been proved to undermine productivity, security, education, health care, civil service systems, social cohesion, and political stability.[57] In addition to the HIV/AIDS epidemic, increasing resistance to existing drugs has led to a spread of malaria (which currently kills approximately 1 million persons a year) and tuberculosis. Despite the spread of these diseases, health care spending in the poorest countries remains approximately $57 billion short of the minimum required for good basic care,[58] thereby undermining individuals' enjoyment of their right to health in those affected areas.

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[56] WHO, *Essential Drugs and Medicines Policy* (accessed March 03, 2003); available from http://www.who.int/medicines/rationale.shtml

[57] Robert Hecht, Olusoji Adeyi and Iris Semini, "Making AIDS Part of the Global Development Agenda," *Finance & Development* 39, no. 1 (2002). Accessed April 13, 2004. Available from Expanded Academic ASAP.

[58] WHO, Commission on Macroeconomics and Health, *Macroeconomics and Health: Investing in Health for Economic Development* (Geneva: WHO, 2001), 168. Accessed April 7, 2004. Available from http://www3.who.int/whosis/cmh/cmh_report/report.cfm?path=cmh,cmh_report&language=english

b. Effect of intellectual property rights on prices of medicines

In response to this crisis, the General Assembly, in 2001, and the Commission on Human Rights, in 2003, have emphasized the role of access to medicine as a fundamental element in achieving the right to health.[59] Such access, however, has been made difficult due to the cost of medicines in the less-developed countries, where, frequently, individuals have to pay out of pocket for the medicine they need.[60] While the cost of the entire treatment against tuberculosis is estimated at $10,[61] the price of HIV tritherapy medicines, which cost up to $15,000 in the US and other western countries,[62] is still usually too high for the less-developed countries despite price differentiation.[63] In this respect, the World Bank Development Indicators, for example, show that per capita health expenditures in the least-developed countries averaged only $17.85 from 1994 to 2001, while public health expenditures have, on average, increased from 1.5% to 1.9% of GDP in the same period (see Annex 3). In 2000, among the 28 least-developed countries that are members of the WTO (or whose accession is in progress) and parties to the CESCR (24 of which are in Sub-Saharan Africa), per capita health expenditures ranged from $38 in the Solomon Island and $28 in Lesotho, to $3 in Burundi and $5 in Nepal. In South Saharan Africa, the region the most affected by the HIV/AIDS epidemic, average

[59] UN Secretariat, Economic and Social Council, Commission on Human Rights, *Access to Medication in the Context of pandemics Such as HIV/AIDS: Report of the Secretary-General*, E/CN.4/2003/48, 2003, Para. 2. Accessed April 7, 2004. Available from UNODS.

[60] WHO, *Macroeconomics and Health: Investing in Health for Economic Development*, 58-59.

[61] WHO, *New Global Plan to Stop the Spread of Tuberculosis* (accessed April 13, 2003); available from http://www.who.int/inf-pr/2001/en/pr2001-46.html.

[62] Sheila Davey, "Medicines for all, not just the rich," *Bulletin of the World Health Organization* 79, no. 4 (2001) (accessed April 3, 2003); available from http://www.who.int/docstore/bulletin/pdf/2001/issue4/news.pdf

[63] The cost of a one-year treatment for HIV/AIDS in the US, for instance, amounts to $10,000 to $15,000 per patient (Davey). Pharmaceutical manufacturers have therefore sold their products at reduced price in developing countries, to account for the currency rate and level of development -- Merck & Co., for instance, sells *Stocrin* (used in tritherapy) for as low as $346 per year per patient. Rachel Zimmerman and Mark Schoofs, "Merck to Cut Cost of AIDS Drug to Poorest Nations," *Wall Street Journal*, October 23, 2002, A2.

per capita health expenditure in 2001 amounted to approximately $11, down from $12 in 1995. In addition to that, the HIV/AIDS epidemic has become a drag on African economies, due to the impact on economies' human capital. In 1997, the World Bank estimated that AIDS was "reversing decades of progress in improving quality of life in developing countries."[64] For instance, in 2003, Bell, Devarajan and Gersbach found that "the AIDS epidemic will peak far in advance of the economic damage it will ultimately cause,"[65] as the disease is found to kill mostly young adults, thereby disrupting the "mechanisms through which human capital is transmitted and accumulated across generations."[66]

In light of this crisis, the Secretary General expressed his concern that "while in the past year prices have continued to decrease, the present cost of the least expensive anti-retroviral medicines continues to exceed the annual per capita gross domestic product of many least developed countries."[67] One may wonder whether the price increase is only transitional, or if it may be prevented when introducing patent protection, however, an analysis of the pharmaceutical industry shows that such impact is inherent to patent protection, with direct effects on consumption. The pharmaceutical industry is an oligopolistic one, i.e., highly concentrated within a few firms within the global industry, including Merck, GlaxoSmithKline, Pfizer, Aventis and Novartis, to name a few, and where scale economies are substantial, i.e., the average cost of producing each unit of

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[64] Martha Ainsworth and Mead Over, *Confronting AIDS: Public Priorities in a Global Economy* (Washington DC: World Bank, 1997), 42. Accessed February 12, 2004. Available from http://www.worldbank.org/aids-econ/confront/confrontfull/

[65] Clive Bell, Shantayanan Devarajan and Hans Gerbasch, "The Long-Run Economic Costs of AIDS: Theory and an Application to South Africa," *World Bank Policy Research Working Paper no. 3152* (October 2003), 92. Accessed February 12, 2004. Available from http://econ.worldbank.org/files/30343_wps3152.pdf

[66] Ibid, 93.

[67] Commission on Human Rights, E/CN.4/2003/48, Para. 10.

output falls as output increases. By nature, pharmaceutical companies therefore enjoy a quasi-monopolistic position in the world market, since they can control prices of their medicines. This is further reinforced by patent protection which grants a monopolistic power to the pharmaceutical company over its brand names' prices for the duration of the patent. On the other hand, studies have suggested that demand for medicines is relatively price inelastic compared to other commodities, i.e., the demand for pharmaceutical products is *relatively* insensitive to price increases.[68] However, it is important to note that demand for (therefore consumption of) medicines remains affected by prices, even in developed, or "rich," countries. Indeed, a study published by the Organisation for Economic Co-operation and Development (OECD) in 1993 showed the effect of increasing copayments on medicines, thereby effectively increasing their real price to consumers.[69] The study showed that, compared with an initial insurance copayment of 20%, a raise to 25% reduced demand by a quarter, while a raise to 95% reduced demand by 43%. Consistent with this finding, the population in developing countries, where few patients have insurance coverage and the majority of health-related expenses are paid out-of-pocket,[70] will be even more price sensitive, and increases in drug prices can only be expected to reduce their consumption. Since prices of patented drugs are higher than if set by the market, the increase in price results in loss of consumer welfare and in a

[68] Philippe Cullet, "Patents and Medicines: the Relationship Between TRIPS and the Human Right to Health," in *International Affairs* 79 no. 1 (January 2003): 141. In this analysis, the demand for pharmaceutical products is less sensitive to price increases in the "rich," developed countries than in the "poor" developing and least-developed countries.

[69] Organisation for Economic Co-operation and Development (OECD), Directorate for Education, Employment, Labour and Social Affairs, Employment, Labour and Social Affairs Committee, "Pharmaceutical Policies in OECD Countries: Reconciling Social and Industrial Goals," *Labour Market and Social Policy Occasional Paper no. 40* (April 2000), 15. Accessed February 12, 2004. Available from http://www.olis.oecd.org/OLIS/2000DOC.NSF/4f7adc214b91a685c12569fa005d0ee7/c125685b0057c558c12568c400331a1e/$FILE/00075948.PDF

[70] The WHO has found that, on average, 50% to 95% of medicines are paid by patients themselves in developing countries. WHO, *HIV-AIDS Antiretroviral Newsletter* No. 8 (December 2002) (accessed April 7, 2004); available from http://www.wpro.who.int/images/newspdf/nletter_ARV8_Dec2002.pdf

"routine underuse inherent in any well-functioning patent system."[71] There exist several definitions of what constitutes welfare loss, which may include only pure economic losses to the economy, i.e., how much more the patented drug costs consumers, but also the consumer's loss of variety and substitutes and foregone profits to local producers. In his analysis of the impact of the introduction of intellectual property protection on fluoroquinolone drugs (anti-bacterials) only, Chaudhuri calculated that the total annual welfare loss to the Indian economy would amount to US$713 million, including only US$50 million in foregone profits to local producers.[72] The violation of the "rule-of-fives," which stipulates that the most competitive, and therefore lowest, price is achieved when there are at least five therapeutic alternatives of five manufacturers, seems to be violated with the introduction of patent protection for medicines.[73]

Proponents of stronger patent protection often argue that 90 to 95% of medicines on the WHO list of essential medicines are off-patent, [74] therefore the implementation of the TRIPS Agreement will not affect their price or prevent their being copied by generic manufacturers. However, this argument has two shortcomings: firstly, the problem of pricing is all the most acute for those new medicines developed in response to increased resistance to older medicines, specifically in the cases of tuberculosis and malaria. In both cases, resistance has occurred from improper use of current drugs and from

[71] Michael Heller and Rebecca Eisenberg, "Can Patents Deter Innovations? The Anticommons in Biomedical Research," in *Science Magazine* 280, no. 5364 (May 1998): 698-701. Accessed February 12, 2004); available from http://www.sciencemag.org/cgi/content/full/280/5364/698

[72] Shubham Chaudhuri, Pinelopi Goldberg and Panle Jia, "Effects of Extending Intellectual Property Rights to Developing Countries: A Case Study of the Indian Pharmaceutical Market," *NBER Working Paper no. 10159* (December 2003), 1. Accessed February 12, 2004. Available from the National Bureau of Economic Research.

[73] WHO, *More Equitable Pricing for Essential Drugs: What Do We Mean and What Are the Issues?* (Geneva: WHO, 2001), 16. Accessed February 23, 2004. Available from http://www.globalhealth.org/assets/pdf/WHOA4.pdf

[74] European Federation of Pharmaceutical Industries and Associations (EFPIA), *Five Common Misunderstandings About Patents, TRIPS, Compulsory Licensing, Parallel Trade and Local Production* (accessed March 13, 2003); available from http://www.efpia.org/4_pos/access/5commisunderstandings.doc.

mutations of the disease. In the case of tuberculosis, for instance, the WHO has estimated that incidence of the disease has increased in Eastern Europe and Africa, after almost 40 years of decline,[75] as the result of an increase movement of people, of the HIV/AIDS epidemics, but also of the rise of "multi-drug resistant tuberculosis." At the same time, malaria has been found, in some areas, to have become "resistant to all affordable first-line therapies," while "few replacement drugs are being developed at affordable prices."[76] Secondly, although the TRIPS Agreement allows the use of patented drugs without authorization from the right-holder for domestic non-commercial purposes, such as compulsory licensing, in some cases of public health emergencies,[77] such use has been challenged by OECD countries against Argentina and Brazil.[78] Further, the requirement that compulsory licensing may be used primarily for domestic distribution prohibits those states in need of cheap medicines from buying them from generic manufacturers abroad, where compulsory licensing was issued.[79] The import, by the least-developed countries, of generics manufactured through compulsory licensing had been left unresolved by the WTO until August 2003, at which time the General

[75] WHO, *Fact Sheet No. 104: Tuberculosis* (accessed April 7, 2004); available from http://www.who.int/mediacentre/factsheets/fs104/en/

[76] WHO, Roll Back Malaria, *Facts on ACTs* (accessed April 7, 2004); available from http://www.rbm.who.int/cmc_upload/0/000/015/364/RBMInfosheet_9.htm

[77] "Each member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crisis, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency." Doha Declaration, Para. 5(c).

[78] Argentina - Patent Protection for Pharmaceuticals and Test Data Protection for Agricultural Chemicals, WT/DS171/1 (May 1999), Argentina - Certain Measures on the Protection of Patents and Test Data, WT/DS196/1 (June 2000) and Brazil - Measures Affecting Patent Protection, WT/DS199/1 (June 2000) (accessed from March 03, 2003); available from http://www.wto.org/english/tratop_e/dispu_e/distabase_wto_members1_e.htm . These complaints were brought to the WTO dispute settlement body by the United States and withdrawn after an agreement was reached between the parties.

[79] "Where the law of a Member allows for other use of the subject matter without the authorization of the right holder, including use by the government or third parties authorized by the government, the following provision shall be respected: (…) any such use shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use." TRIPS Agreement, Art. 31(f).

Council issued a decisions to allow such practice under specific circumstances.[80] However, it is important to note that, should the enforcement of the TRIPS Agreement in developing and the least-developed countries further reduce access to medicines to address public health crises, can therefore represent a "deliberate retroactive step" in promoting and enjoying the human right to health.

c. Promoting the right to health through development with the TRIPS Agreement?

Despite the price increase and underuse of medicines inherent to patent protection, it is important to note that patent protection has the potential to act as a developmental tool, and help promoting and fulfilling the human right to health, primarily by acting as an economic incentive for innovation, particularly on diseases affecting poor countries. Patent protection serves to compensate for the high cost of research and development (R&D) in the pharmaceutical industry, and R&D has, in turn, focused on diseases for which a substantial market exists, i.e., mostly on "rich country" diseases such as cancer or heart conditions.[81] The introduction of patent protection in developing countries is therefore expected to ensure a market for drugs targeted to them. The net result is that the profits realized by pharmaceutical companies from patent protection is to be considered a social benefit, thereby playing an important role in the fulfillment of the human right to health. Further, effective patent protection is considered to promote transfer of technology towards and innovations in developing countries,[82]

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[80] WTO General Council, *Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health* (August 2003) (accessed March 12, 2004); available from http://www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm . Please see Chapter IV(1)(c) below for details

[81] Jean Lanjouw, "A Patent Policy Proposal for Global Diseases," *Brookings Policy Brief no. 84*, 2001. Accessed April 7, 2004. Available from http://www.brookings.edu/comm/policybriefs/pb84.htm

[82] TRIPS, Art. 29.1

thereby contributing to their economic growth and development,[83] while the welfare loss is to be, therefore, transitional only. Finally, the introduction or reinforcement of an intellectual property regime may be expected to create a more favorable environment in developing countries for foreign pharmaceutical companies to invest there, with a potential spillover effect to other industries. In this respect, the World Intellectual Property Organization (WIPO) has noted an increase in foreign direct investment in India and Brazil after the implementation of intellectual property reforms in the 1990s.[84] Specifically, foreign direct investment has increased from approximately $938 million to $3.9 billion in India, and from $2 billion to $24.9 billion in Brazil, since 1994, after the entry into force of the WTO Agreements and TRIPS (see Annex 3). Simultaneously, per capita health expenditures have increased from $17 to $23 in India, and from $244 to $267 in Brazil. There is therefore evidence that the enforcement of intellectual property rights worldwide can play an important role in boosting pharmaceutical innovations, technological transfer and foreign direct investments in developing countries, thereby contributing to the fulfillment of the human right to health. These assumptions are further reinforced by the experience if the developed countries in the 1970s and 1980s, which, according to Professor Grabowski, Professor of Economics at Duke University, and a proponent of rapid implementation of the TRIPS Agreement, did see an increase in research and development.[85] Based on this and on the TRIPS provisions allowing states to "retain various policy instruments such as compulsory licensing and price controls for

[83] Romer.

[84] Kamil Idris, *Intellectual Property: A Power Tool for Economic Growth, An Overview*, 2nd ed. (Geneva: WIPO, 2003). Accessed April 7, 2004. Available from http://www.wipo.int/freepublications/en/intproperty/888/wipo_pub_888_1.pdf

[85] Henry Grabowski, "Patents, Innovation and Access to New Pharmaceuticals," in *Journal of International Economic Law* 5, no. 4 (2002): 849-860.

gaining access to new medicines in the case of national health emergencies," he argues for a rapid implementation of the TRIPS Agreement in the less developed countries, so as to allow them to develop their own research capacities in the long-run.

However, Grabowski's arguments suffer from one main shortcoming, namely, he bases his analysis on the success of stronger patent laws in OECD countries in the 1970s and 1980s, at a time when they were already economically developed, had the legislative and technical infrastructure to bear the costs of stricter patent law, and faced relatively little competition from non-OECD countries, a situation that represents a better starting position than that of the developing and least developed countries currently. In developing countries with little or no patent protection, the implementation of intellectual property rights on pharmaceutical products can have social costs that outweigh their benefits, and negatively impact the fulfillment of the human right to health. According to a World Bank economist, Julio Nogués, total welfare losses in some developing countries after full implementation of the TRIPS Agreement, i.e., Argentina, Brazil, Mexico, Korea and Taiwan, will amount to $3.5 to $10.8 billion.[86] This estimate was confirmed by later findings that, although countries' rates of development vary, the developmental effects of the TRIPS Agreement in countries that have implemented it have not been as promising as expected -- in Thailand for instance, there has been no significant increase in transfer of technology and in foreign direct investment, but pharmaceutical spending has increased at a higher rate than the overall medical spending.[87] As noted earlier, the enforcement of patent protection not only creates an incentive for innovation, but also generates an inherent underuse of medicines, as oligopolistic pharmaceutical companies

[86] Correa, 35.

[87] WHO, *Globalization, Trade and Public Health: Tools and Training for National Action* (New Delhi: WHO, 2001), 9.

limit their output (and therefore the availability of their products to consumers) to the one that will generate the most profits.[88] Further, Lanjouw and Chaudhuri, among others, have analyzed the R&D engendered by TRIPS and patent protection on "poor country" diseases, and have found a limited correlation between the two. Specifically, Lanjouw analyzed 90% of R&D in India, and found that only 16% targets tropical diseases (of which only 19.7% is research for new medicines), while 46.2% targets developing countries' diseases generally.[89] More generally, her findings show that effective patent protection has thus far failed to boost R&D on tropical and poor country diseases,[90] thereby imposing higher prices of medicines on developing and the least developed countries, while failing to address their specific medical needs. The systematic implementation of strong patent protection without incentives, or obligations, to invest in poor country diseases R&D will therefore fail to promote and protect the human right to health in developing and the least developed countries. It has therefore been argued that "protection of foreign intellectual property rights in the South … advances global efficiency if the prospects for productivity gain through R&D are sufficiently bright, but for modest potential advances in knowledge world welfare actually is higher when the South *fails* to enforce patent protection."[91]

Finally, it is important to acknowledge the highly political dimension of intellectual property rights in the context of globalization, and the attempts by developing

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[88] For reference, please see Edwin Mansfield and Gary Yohe, *Microeconomics*, 11th ed. (New York: Norton & Company, 2004), 361-369.

[89] Jean Lanjouw and Iain Cockburn, "Do patents matter?: Empirical evidence after GATT," *NBER Working Paper no. 7495* (January 2000), 18. Accessed February 12, 2004. Available from the National Bureau of Economic Research.

[90] Lanjouw, "A Patent Policy Proposal for Global Diseases."

[91] Judith Chin and Gene Grossman, "Intellectual Property Rights and North-South Trade," *NBER Working Paper no. 2769* (November 1988), 16. Accessed February 12, 2004. Available from the National Bureau of Economic Research.

countries' governments to protect their domestic pharmaceutical companies. Indeed, some developing countries have developed a thriving pharmaceutical manufacturing capacity based on a complete lack or limited scope of patent protection. The Indian pharmaceutical industry, for instance, includes such companies as Cipla, with sales in the amount of $364 million in 2003 (up from $316 million in 2002), and which exports to the Americas (32%), Europe (23%) and Africa (19%),[92] and Dr. Reddy's Laboratories, with sales of $368 million in 2002-2003 (up from $365 million the previous year), 64% of total revenue derived from sales abroad (sales to North America represent 32% of total revenue), and with R&D in the amount of 7.6% of revenues.[93] Brazil has also benefited, in the past, of a weak patent regime – Brazil is the eighth largest pharmaceutical market in the world, however 70% of the market is dominated by multinational pharmaceutical companies. Domestic manufacturers, however, are specialized in generic products.[94] Even if resistance may be politically driven in an effort to protect domestic generic manufacturing industries, the social costs of patent protection, in terms of limited output of medicines by oligopolistic manufacturers, higher prices of medicines, and limited R&D on tropical and poor country diseases, are nonetheless real and need to be addressed, in order to ensure the enjoyment of the human right to health. In the case of India, whose generic manufacturing industry stands to lose with the implementation of strong patent protection for foreign medicines, Chaudhuri has estimated a loss of

[92] Cipla, *Annual Report 2003* (accessed February 23, 2004); available from http://www.cipla.com/aboutus/annualreport/PDF/CIPLA ANNUAL REPORT 2003.pdf

[93] Dr. Reddy's Laboratories, *Annual Report 2003* (accessed February 23, 2003); available from http://www.drreddys.com/site/annualreport2003/Annual_Report_2003_full.pdf

[94] University of Texas, *Brazil Pharmaceutical Industry* (accessed February 23, 2003); available from http://uts.cc.utexas.edu/~spam/

approximately Rs. 2.3 billion (US $50.7 million) to manufacturers, while consumer welfare stood to drop by Rs. 29.7 billion (US $655million).[95]

2. WTO interpretation of the TRIPS Agreement

a. India - A restricted interpretation of the TRIPS Agreement

The least developed and developing countries were not to be subject to complaints for violation of the TRIPS Agreement until the end of the transition period. However, several cases were brought to the US International Trade Commission and/or to the WTO dispute settlement body, regarding the use of compulsory licensing and the implementation of the agreement by developing countries during the transition period. In 1997, the WTO's decision in the India - Patent Protection for Pharmaceutical and Agricultural Chemical Products Case (India Patent Case)[96] represented a blow to developing countries, inasmuch as it showed the WTO's intent to limit states' options to choose how to implement the TRIPS Agreement domestically. Until 1994, India's patent regime protected processes but not products, which allowed Indian generic manufacturing industry to flourish and allowed India to provide cheaper generics to a greater portion of its population.[97] India joined the WTO upon its inception in January 1995, and agreed to the TRIPS Agreement in exchange for concessions in the agricultural

[95] Chaudhuri, Goldberg and Jia, 32

[96] India - Patent Protection for Pharmaceutical and Agricultural Chemical Products, WT/DS50/R (Panel, September 1997), WT/DS50/AB/R (Appellate Body Division, December 1997). Accessed March 03, 2003. Available from WorldTradeLaw.net.

[97] "The Indian pharmaceutical industry today is in the front rank of India's science-based industries with wide ranging capabilities in the complex field of drug manufacture and technology. A highly organized sector, the Indian Pharma Industry is estimated to be worth $4.5 billion, growing at about 8 to 9 percent annually (…). The pharmaceutical industry in India meets around 70% of the country's demand for bulk drugs, drug intermediate, pharmaceutical formulations, chemicals, tablets, capsules, orals and injectibles (…). Technologically strong and totally self-reliant, the pharmaceutical industry in India has low costs of production, low R&D costs, innovative scientific manpower, strength of national laboratories and an increasing balance of trade." Pharmaceutical and Drug Manufacturers, *Indian Pharmaceutical Industry Overview* (accessed April 25, 2003); available from http://www.pharmaceutical-drug-manufacturers.com/pharmaceutical-industry/

and textile areas from developed countries.[98] As a developing country, India also requested, and was granted, a five-year period to adapt its domestic legislation to the agreement. Although developing countries are not required to provide full protection until the end of their transition period, they are required, under Art. 70.8, to take provisional measures towards that end, by providing, *inter alia*, for patent applications to be filed and duly recorded (but not examined or granted) as soon as 1995. This "mailbox" provision was implemented in India, and, by October 1997, 1,924 applications had been recorded.[99] The US, however, considered such procedure insufficient to comply with the TRIPS Agreement, on the basis that India failed to guarantee exclusive marketing rights (as per Art. 70.9). In its report, the Appellate Body first reiterated that countries which were granted a transition period were "*entitled*" to delay the application of the TRIPS Agreement,[100] and that WTO members remained free to "determine how best to meet their obligations under the TRIPS Agreement within the context of their own legal systems."[101] However, its interpretation of Art. 70.8 ("mailbox procedures") and 70.9 (exclusive marketing rights during the transition period) is more problematic -- the Appellate Body relied on implicit criteria set by Art. 70.8 to conclude that India's procedures were not sufficient to comply with the agreement,[102] and to request India to "bring its legal regime for patent protection on pharmaceutical and

[98] During the Uruguay Round, developed and developing countries engaged in a series of negotiations for the drafting and implementation of WTO agreements on various trade-related issues, resulting in the "Grand Bargain". In the course of negotiations, developing countries agreed to the TRIPS Agreement, which they mostly objected to, in exchange for concessions on agriculture and textiles from the developed countries. Suman Dubey, "India agrees to expand textile trade with US and EU, change patent laws," *Wall Street Journal*, January 03, 1995, 10.

[99] India Patent Case, Appellate Body, Para. 4.

[100] Ibid, Para. 58.

[101] Ibid, Para. 59.

[102] "What precisely is the means for filing mailbox applications that is *contemplated* and required by Art. 70.8(a)?" Ibid, Para. 54.

agricultural chemical products into conformity with India's obligations under Art. 70.8 and 70.9 of the TRIPS Agreement", prior to the expiration of its transition period.[103] India, as a developing country, was entitled to a five-year transitional period to fully comply with the TRIPS Agreement, i.e., to "bring its legal regime for patent protection … into conformity with [its] obligations." However, in light of the differential treatment to be accorded to developing countries in WTO law, one may wonder if the strict interpretation of the agreement in the India Patent Case was warranted, and if deference could have been given to its public health policies, in accordance with Art. 8 of the TRIPS Agreement, GATT Art. XX(b), and the Preamble of the WTO Charter.

b. Canada - Denial of the public health policy argument

The interpretation of Art. 8 and Art. 31, specifically on the use of compulsory licensing to pursue public health goals, by the Appellate Body in the Canada - Patent Protection of Pharmaceutical Products Case (Canada Patent Case) in March 2000,[104] shows not only a strict interpretation of the agreement, but a refusal to consider exceptions for public health reasons, thereby effectively ignoring states' obligation to promote the right to health. In this case, the EC contested the patent protection regime of Canada, which allowed for the use of patented drugs without authorization of the patent-holder, for the development of generic medicines before expiration of the patent. Such policy was based on Canada's public health policy goal, to ensure that generics could be tested for regulatory review before exhaustion of patents, so as to start distribution as soon as patents expired (such procedure, in the US, is called the "Bolar exception").[105]

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[103] Ibid, Para. 98.

[104] Canada - Patent Protection of Pharmaceutical Products, WT/DS114/R (Panel, March 2000). Accessed April 8, 2003. Available from WorldTradeLaw.net.

[105] Ibid, Para. 7.3.

Although the Panel agreed that such practice (also called fast-tracking) was not inconsistent with the TRIPS Agreement,[106] it found that the *stockpiling* of generics for six months before exhaustion of patents, so as to start distribution immediately upon patent expiration, was inconsistent with the TRIPS Agreement.[107] This case is especially important because, while India did not base its arguments on public health necessity, but rather relied on its transition period, Canada did claim that its regulation was permitted under Art. 8 of the TRIPS Agreement, as follows:

> "In the view of Canada … one of the key goals of the TRIPS Agreement was a balance between the intellectual property rights created by the Agreement and other important socio-economic policies of WTO Member governments. Art. 8 elaborates the socio-economic policies in question, with particular attention to health and nutritional policies."[108]

It is first arguable whether a "balancing test" should apply among human rights, which are, by definition, "inalienable." If, *arguendo*, one is of the view that human rights, including health and development, are not absolute, but are to be balanced against each other and, so as to ensure proportionality between competing rights and obligations, [109] the WTO Panel, in the present case, the Panel's response evidences just how, with the TRIPS Agreement, the WTO has become an obstacle for states to pursue public health policies and protect the right to health. The EC argued that the balance between intellectual property rights and socio-economic policies had been negotiated in the final text of the agreement, whose purpose is solely "to lay down minimum requirements for

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[106] Ibid, Para. 7.84.
[107] Ibid, Para. 8.1.
[108] Ibid, Para. 7.24.
[109] Please refer to the European Court of Human Rights (ECHR), which has applied a "balancing test" between human rights in the following cases:
Case of Goodwin v. the United Kingdom, 16/1994/463/544 (ECHR, 1996) (on balancing the right to freedom of expression and disclosure in the general interests of the administration of justice)
Case of Jersild v. Denmark, 36/1993/431/510 (ECHR, 1994) (on balancing the protection of the reputation or rights of others and the right to impart information)
(accessed February 12, 2004); available from HUDOC.

the protection and enforcement of intellectual property rights."[110] Article 8 was, the EC contended, only aspirational in nature and without legal content. The Panel went further than the EC in its rejection of the public health argument, by brushing Canada's argument off and not addressing the claim at all, thereby effectively refusing to interpret the TRIPS Agreement in light of public health concerns. This case confirms that, when evaluating compliance with the TRIPS Agreement, the WTO will not use health as an "interpretive principle,"[111] but will instead textually and narrowly interpret the agreement to strengthen domestic patent laws beyond the minimum required and downplay public health policies. For states parties to the CESCR and human rights instruments that guarantee the right to health, such interpretation is bound to limit their options to protect the right to health, potentially making them violators of their human rights obligations.

3. Why such a strict interpretation?

a. Vienna Convention on the Law of Treaties

In order to understand the rationale for such implementation, it is necessary to look at the general rules of interpretation in public international law, and to the source of the TRIPS Agreement. According to Art. 31 of the Vienna Convention on the Law of Treaties, international treaties are to be interpreted in light of their "object and purpose." The WTO dispute settlement bodies are therefore required to interpret the TRIPS Agreement according to its purpose, i.e., in such a way as "to reduce distortions and impediments to international trade," and to provide "effective and adequate intellectual

[110] Ibid, Para. 7.25, 7.26.

[111] Gregg Bloche, "WTO Deference to National Health Policy: Towards an Interpretive Principle," *Journal of International Economic Law* 5, no. 4 (2002): 825-848. In this essay, Gregg Bloche contends that the WTO has adopted health as a *de facto* systematic interpretive principle (827), when applying the GATT, SPS Agreement and TRIPS Agreement alike. In this paper, however, I argue that such interpretive approach is lacking in cases involving the TRIPS Agreement.

property rights."[112] The purpose of the TRIPS Agreement is therefore to harmonize global intellectual property regimes towards minimum standards that include (1) the existence of administrative and legislative procedures to guarantee the enjoyment of such rights by inventors, (2) the guarantee of protection for a period of twenty years from the date of filing the application. The agreement's purpose, as stated in its preamble and text, is *not* development, however, it is important to note that, as a WTO Agreement, it recognizes "the basic principles of GATT 1994,"[113] including its purpose to raise standards of living, and "the underlying public policy of national systems for the protection of intellectual property, including *developmental* and technological objectives."[114]

b. Influence of private actors and lobbies

It is important to remember that the agreement had been heavily lobbied for by the US pharmaceutical industry and strongly supported by Europe and Japan. Although there are long-run economic benefits to the introduction of intellectual property protection, the TRIPS Agreement was established to protect the private, financial interests of multinational, private actors in trade. Indeed, it was estimated that profits from patent rights and royalties to US pharmaceutical companies amounted to $36.5 billion in 2002, i.e., over half of the world's total.[115] The pharmaceutical industry benefits from a strong lobbying power, and its strong support for a harmonized world patent protection regime is reflected in the US strong stance regarding the implementation of the TRIPS

[112] TRIPS Agreement, Preamble
[113] Ibid.
[114] Ibid.
[115] Ron Chepesiuk, "Will the Developing Countries Ever Get Access to Cheap Life Saving Medicines?," *Daily Star*, August 5, 2003 (accessed February 23, 2004); available from http://www.thedailystar.net/2003/08/05/d30805150289.htm

Agreement, and its refusal to loosen its terms. Lobbying efforts by the US pharmaceutical industry are to be traced back to 1980, when Pfizer management started mobilizing US companies to make intellectual property a leading issue in US trade policy.[116] Negotiations on the TRIPS Agreement did not start until 1989, however, by then, the Pharmaceutical Research and Manufacturers of America (PhRMA) had been lobbying the US Congress to enact "the intellectual property revisions of the Omnibus Trade bill that would strengthen the hand of the US Government in urging all of our trading partners to respect [pharmaceutical companies'] rights in inventions and trademarks," and that eventually resulted in Section 301 of the Trade Act of 1974 (more on the substance and implementation of Section 301 below).[117] The intense lobbying from the pharmaceutical industry relied on the need to provide worldwide protection of intellectual property in order to guarantee the continued development of new medicines. It has been argued, however, that, in the US, high R&D costs may be "unnecessarily inflated" in the US, when taking into account (1) the low levels of R&D reinvestments as opposed to high levels of marketing investments, (2) the tax deductions pharmaceutical companies benefit from based on R&D, and (3) the subsidization of R&D by patients as "consumers of health insurance."[118] Such "inflation" of R&D costs may cast a shadow on the bona fide social interests of pharmaceutical companies. Coincidentally, also, the countries against which the US started procedures for non-compliance with the TRIPS Agreement, were listed on the PhRMA's "Priority Watch List Countries", i.e., countries

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[116] Wikipedia, *Agreement on Trade-Related Aspects of Intellectual Property Rights* (accessed February 23, 2004); available from http://en.wikipedia.org/wiki/Agreement_on_Trade-Related_Aspects_of_Intellectual_Property_Rights#Background_and_History

[117] Julio Nogués, "Patents and Pharmaceutical Drugs: Understanding the Pressures on Developing Countries," in *Journal of World Trade* 24, no. 6 (December 1990): 84.

[118] Sarah Joseph, "Pharmaceutical Corporations and Access to Drugs: The "Fourth Wave" of Corporate Human Rights Scrutiny," in *Human Rights Quarterly* 25, no. 2 (May 2003): 431-2, 440.

it deemed to have low patent protection, including Argentina, Pakistan, India, Brazil and South Africa.[119] The influence of private multinational corporations has also potentially influenced the WTO into adopting a very restrictive, non-interpretive application of the agreement, with the effect to limit the types of initiatives states can take to protect the right to health (i.e., compulsory licensing). The TRIPS Agreement has therefore become an obstacle to the enjoyment of the right to health, by (1) limiting the access to new medicines, primarily in developing countries, (2) hindering efforts, in less-developed countries, to use exception provisions to pursue national public health policies, and (3) requiring resource re-allocation to establish administrative and legislative patent regime.

c. Resource allocation in the less-developed countries

Access to medicines, it is important to acknowledge, is also severely hampered by the lack of infrastructure in the developing and least developed countries, an argument often raised by the pharmaceutical industry to explain why the introduction of patent protection in and of itself will not prevent access to medicine.[120] However, because of the current state of the infrastructure in developing countries (or lack whereof), the implementation of the TRIPS Agreement can be expected to require the re-allocation of often scarce resources to the administration, enforcement and monitoring of a strong patent regime, while the technology required for pharmaceutical R&D may remain out of their reach, preventing them from developing their own R&D and manufacturing capacity. Rasiah, specifically, has analyzed the effect of TRIPS on the infrastructure of

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[119] PhRMA, *2004 PhRMA Special 301 Submission* (accessed April 7, 2004); available from http://www.phrma.org/international/resources/2004-02-12.582.pdf

[120] PhRMA, *Healthcare in the Developing World* (accessed March 12, 2003); available from http://world.phrma.org/index.html

International Federation of Pharmaceutical Manufacturers Associations (IFPMA), *Intellectual Property and Patents* (accessed April 7, 2004); available from http://www.ifpma.org/Issues/issues_intell.aspx

developing countries, based on a classification of countries according to their Basic Infrastructure Index (BII), High Tech Infrastructure Index (HII), including intellectual property office and administration, and Residents Patents Index (RPI).[121] His analysis of the developing countries' capacity to enforce TRIPS leads to the following classification:

	BII	HII	RPI	Example
Newly Industrialized Economies (NIEs)	HIGH	HIGH	HIGH	Hong Kong Brazil India
Second-Tier NIEs	HIGH	LOW	LOW	Argentina Indonesia China Thailand Kenya
Less Industrialized Developing Economies (LIDEs)	LOW	LOW	LOW	Bangladesh Cote d'Ivoire Nicaragua

According to this classification, NIEs, having existing technological infrastructures and institutions, have the capacity to implement the TRIPS Agreement (although implementation may be slowed down for political reasons), whereas second-tier NIEs and LIDEs will face many more technological and institutional difficulties implementing it and enjoying the benefits from it, including the enjoyment of the human right to health to the population. As far as LIDEs are concerned, Rasiah argues:

[121] The Basic Infrastructure Index (BII) determines an economy's capacity to target resources for high technological development, while the High Tech Infrastructure Index (HII) determines the generation of innovation in an economy, influenced by the number of scientists and engineers. Rajah Rasiah, "TRIPS and Capability Building in Developing Economies: Critical Issues," in *Journal of Contemporary Asia* 33, no. i3 (August 2003). Accessed February 12, 2004. Available from Expanded Academic ASAP.

> "Not only will compliance [with TRIPS] be a serious issue, they lack the resources even to participate in the definition and future direction of the TRIPS … Most of the remaining LIDEs neither demonstrate the infrastructure support – basic and high tech – institutions nor the innovation capabilities to reverse the technological gap emerging between them and the developed economies. The TRIPS Agreement may aggravate the situation as these economies will now have to divert scarce resources to meet enforcement conditions."[122]

Rasiah's analysis is further supported by the World Bank's estimates of the costs of establishing an intellectual property regime, which can reach, on average, US$1.5 million, for the judicial systems, customs, patent office, and enforcement.[123] In this respect, WIPO has acknowledged the financial difficulties in implementing an intellectual property regime in developing countries:

> "Almost all IPOs [intellectual property offices] suffer from financial constraints and the difficulty of recruiting and retaining qualified staff members for their operations. The problem of limited resources is particularly acute in the developing world and means that intellectual property offices are often not able to provide adequate services to users of the intellectual property systems in those countries."[124]

By requiring states to re-allocate their resources towards intellectual property protection, the WTO, in cases involving the poorest countries, will require states to choose between their trade obligations and their human rights obligations, a problem strongly criticized by the Committee on Economic, Social and Cultural Rights in December 2001,[125] when it stated that "any intellectual property regime that makes it more difficult for a state party to comply with its core obligations in relation to *health,* food, education, especially, or any other right set out in the Covenant, is inconsistent with the legally binding obligations of the state party."

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[122] Ibid.

[123] "Patently Problematic," *The Economist*, September 12, 2002. Accessed February 23, 2004. Available from The Economist.

[124] Idris.

[125] UN Secretariat, Economic and Social Council, Committee on Economic, Social and Cultural Rights*, Substantive Issues Arising in the Implementation of the International Covenant on Economic, Social and Cultural Rights: Human Rights and Intellectual Property,* E/C.12/2001/15, 2001, Para. 12 (December 2001). Accessed April 2, 2003. Available from UNODS

Developing countries have been criticized for failing to take the necessary steps required under Art. 2 of CESCR, i.e., to "achiev[e] progressively the full realization" of economic, social and cultural rights, including the right to health, particularly in view of their military expenditures. Indeed, under Art. 2 of CESCR, and as supported by the Committee on Economic, Social and Cultural Rights in General Comment No. 3,[126] states parties to the CESCR are subject to an "obligation of conduct" that requires them to take the necessary steps "as expeditiously and effectively as possible"[127] towards the realization of the right to health. In this view, re-allocation of public resources from health to the military would, indeed, violates the Covenant. In order to address this issue, it is relevant to compare public health and military expenditures among the 65 developing and least developed countries that are members of the WTO (or whose accession is in process), and parties to the CESCR. The following statistics are derived from the comparison between the public health expenditures and military expenditures, expressed in percentage of GDP, for these 65 countries after the entry into force of the WTO Agreements, i.e., between 1994 and 2001 (See, Annex 3). A table summarizing these comparisons is attached herewith as Annex 4.

For developing countries with available data, a comparison between 1994 and 2000 shows 33 countries kept their health spending higher than their military one, while 7 shifted from a military-oriented spending allocation to a health-oriented one (relatively speaking). While 20 countries remained relatively military-oriented, it is interesting to note that 15 of them increase their health spending between 1994 and 2000, with the

[126] UN Secretariat, Economic and Social Council, Committee on Economic, Social and Cultural Rights, *General Comment No. 3: The Nature of States Parties Obligations (Art. 2, Par. 1 of the Covenant)*, E/C.12/1991/23, 1990, Para. 1. *General Comment No. 3* is reproduced herewith as Annex 5.

[127] Ibid, Para. 9

simultaneous decrease in the military spending of 4 of them (including, *inter alia*, Cambodia and Egypt). On the whole, of the 27 relatively military-oriented countries in 1994, 7 reversed this trend while the rate of decrease in military spending has outpaced the one in health spending in 4 countries, an evidence of better resource allocation (e.g., Angola and Azerbaijan), and 15 have actually increased their health spending (e.g., Nigeria, Cambodia). On the other hand, of the 38 relatively health-oriented countries, only 5 reversed the trend (e.g., China), while the rate of decrease in military spending has outpaced that in health spending in 2 countries (Albania and Croatia), and 14 have actually increased their health spending (e.g., Senegal, Bolivia, the Gambia). Assuming that less health spending is worse except if the rate of decrease is outpaced by the rate of decrease in military spending, then, compared to 1994, only 23 developing countries are relatively worse off in 2000, while 42 are relatively better off. Although the allocation of resources between health and military spending may not be considered optimal by some, it is important to realize that there has actually been a better resource allocation between by governments of developing and least developed countries after the entry into force of the WTO, and one can only hope that the trend will continue.

Based on the WTO's strong enforcement mechanism and the possibility of retaliatory measures, poor states which have to choose where to allocate their resources will predictably, although not necessarily so, opt for trade-related obligations, at the expense of their human rights obligations. The agreement favors, at least at the present time, only those multinational corporations in developed countries which already had research, development and manufacturing capabilities before the entry into force of the agreement. Pharmaceutical companies have argued that the entry into force of the TRIPS

Agreement and the implementation of a strong patent regime will allow an increased transfer of technology from developed to developing countries, allowing them, in the long-run, to develop their own, targeted, R&D capacity, at what time local innovators will also be able to enjoy the economic benefits of a patent protection. However, when analyzing the number of patents filed in developing countries (see Annex 3), it is clear that, thus far, it has benefited primarily companies in developed countries. Since 1994, over 7.8 million patent applications have been filed in developing countries that are members of the WTO and parties of the CESCR, including approximately 125,000 filed by residents of the same countries, compared to over 7.7 million filed by non-residents (see Annex 3). Some countries which have already implemented the TRIPS Agreement and strengthened their patent regime have seen an increase in patent filing, mostly by non-residents. By 2000, Argentina saw a 32% increase in non-resident applications (from 5,035 in 1997 to 6,634 in 2001) while resident applications have declined from 824 to none. In Brazil, non-resident patent applications have increased by 181% since 1995 (from 23,040 to 64,645 in 2000), while the number of resident applications has been declining from 2,757 to 41. In India, resident applications have increased by 818% since 1996 (from 6,632 to 60,852 in 2000), while resident applications have fallen by 95% (from 1,660 to 90). China, however, has seen an increase in both resident and non-resident applications, by 154% and 205% respectively.

According to the WTO Charter, trade liberalization is intended to raise standards of living among trading countries, however, and while acknowledging the share of responsibility of developing countries in resource misallocation and lack of infrastructure, the current benefits of increased patent protection seem to be to

corporations in developed countries, with no significant improvement in, or even with a worsening of, welfare in developing countries. The limited or lack of welfare benefits in developing countries, and the economic, welfare and human cost of establishing a patent regime seem, at least for now, to defeat efforts to enhance the enjoyment of the human right to health and even proponents of the TRIPS Agreement have agreed that "trade that advantages only an elite few without contributing to a society's wider economic development, including reduction in poverty and raising of incomes, is unlikely to promote public health and well-being."[128]

The conflict between the TRIPS Agreement and the human right to health, in addition to raising some economic and legal questions, also poses moral and ethical concerns. As a human right, the right to health is protected by international law binding upon the 148 countries that have ratified the CESCR. The obligation to protect human rights, including economic and social ones, does not only fall onto parties to the CESCR, but to UN members, according to the UN Charter. Indeed, Art. 3 of the Charter requires states to cooperate in "promoting and encouraging respect for human rights", while Art. 55 requires the UN, as an organization, to promote "higher standards of living, full employment, and *conditions of economic and social progress and development***.**" Although intellectual property rights may be considered a private, human right,[129] and

[128] Bloche, 830.

[129] The right to property has been recognized as a human right in international human rights law, as included in the CESCR and regional human rights instruments:

"The state Parties to the present covenant recognize the right of everyone to benefit from the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author." CESCR, Art. 15(1)(c)

"Every natural or legal person is entitled to the peaceful enjoyment of his possessions. No one shall be deprived of his possessions except in the public interest and subject to the conditions provided for by law and by the general principles of international law." ECHR, Art. 1

"(1) Everyone has the right to the use and enjoyment of his property. The law may subordinate such use and enjoyment to the interest of society. (2) No one shall be deprived of his property except upon

therefore innovators, and pharmaceutical companies, are entitled to protection for their discoveries, no human right is absolute, and a balancing test must be used between the right to health and the right to protection for scientific material and discoveries. Art. 4 of CESCR provides that:

> "The States Parties to the present Covenant recognize that, in the enjoyment of those rights provided by the State in conformity with the present Covenant, the State may subject such rights only to such limitations as are determined by law only in so far as this may be *compatible with the nature of these rights and solely for the purpose of promoting the general welfare in a democratic society*."

Art. 4 of CESCR therefore recognizes the possible need to balance rights and to limit the exercise of one human right, say of the right to property, to protect the individual right to health, so long as it is compatible with the nature of the right to health and solely for the purpose of promoting the general welfare in a democratic society. Such authorization, however, shall be "proportional, i.e., the least restrictive alternative must be adopted where several types of limitations are available," and "of limited duration and subject to review."[130] This provision is supported by Art. 5 of CESCR, so long as the limitation of the right to property to protect the right to health is not imposed "to a greater extent than is provided for in the present Covenant." This provision therefore allows state parties to CESCR to limit the right to intellectual property to respond to health crises in an effort to protect the right to health and to pursue a specific public health policy.

Further, it is the responsibility of all UN members to promote human rights, including those of economic and social nature, and including through international

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payment of just compensation, for reasons of public utility or social interest, and in the cases and according to the forms established by law. (3) Usury and any other form of exploitation of man by man shall be prohibited by law." American Convention on Human Rights, Art. 21.

"The right to property shall be guaranteed. It may only be encroached upon in the interest of public need or in the general interest of the community and in accordance with the provisions of appropriate laws." African Charter on Human and Peoples' Rights, Art. 14.

[130] Committee on Economic, Social and Cultural Rights, *General Comment No. 14*, E/C.12/2000/4, Para. 29.

cooperation, as required by the Committee on Economic, Social and Cultural Rights.[131] In cases of conflict between members' obligations under the UN Charter and their obligations under "any other international agreement, their obligations under the present Charter shall prevail." This provision, found in Art. 103 of the UN Charter, is one of the elements that give the Charter the constitutive instrument of the international community,[132] and ensures that no prior or subsequent international treaty would trump the principles of the UN Charter. By law, no international agreement may therefore violate, or impose obligations that would violate, the principles and obligations of the UN Charter, including human rights obligations. Further, in accordance with the principle of *pacta sunt servanda* enshrined in the Vienna Convention on the Law of Treaties and the UN Charter (Art. 2.2), a state may not enter into international agreements with a view to derogate from its other international obligations, including those imposed by the UN Charter. Accordingly, the Sub-Committee on the Promotion and Protection of Human Rights reminded governments, in Resolution 2001/21, of "the primacy of human rights obligations under international law over economic policies and agreements."[133] The interpretation of the UN Charter therefore confirms that, in case of conflict between the human right to health and other obligations that are not included in the UN Charter, the human right to health should prevail.

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[131] Committee on Economic, Social and Cultural Rights, *General Comment No. 3*, E/C.12/1999/23, Para. 14.

[132] Thomas Franck, "Is the UN Charter a Constitution?" (accessed April 14, 2004); available from http://edoc.mpil.de/fs/2003/eitel/95_franck.pdf. In this essay, Franck argues that the UN Charter contains the four elements of a constitutive instrument, namely, (1) pervasive perpetuity, since it lacks a provision for withdrawal, (2) indelibleness, since it does not allow reservations and is difficult to amend (Art. 108-109), (3) primacy (Art. 103), and (4) institutional autochtony, since it establishes organs for decision-making and independent administration.

[133] UN Secretariat, Economic and Social Council, Commission on Human Rights, *Resolution 2001/21, Intellectual Property and Human Rights*, E/CN.4/2002/2, E/CN.4/Sub.2/2001/40, 2001, Para. 3. Accessed April 02, 2003. Available from UNODS.

It is therefore clear that, taking into account the potential benefits from trade and intellectual property protection, and the state of the economies and current public health crises in developing and the least developed countries, the benefits from TRIPS to the latter are largely outweighed by its economic, human and social costs. The choice faced by the less-developed countries between their obligation to protect the right to health and their trade obligations is therefore morally reprehensible and unacceptable.

In order to better understand how the WTO affects the right to health, and states' capacities to meet their human rights obligations to health, it is also necessary to examine the WTO dispute settlement bodies' interpretation of other health-related WTO agreements, including the GATT and the SPS Agreement, to determine whether the right to health has been used as an interpretive principle in WTO dispute settlements, or if WTO law generally undermines the right to health.

III. THE RIGHT TO HEALTH AS AN "INTERPRETIVE PRINCIPLE" IN WTO LAW

1. Case studies - Application of the GATT and SPS Agreement

a. EC - Measures Affecting Asbestos and Asbestos-Containing Products Case (EC Asbestos Case)[134]

The Agreement on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) has proved controversial for its intrusive nature on domestic policies and regulations, by imposing domestic legislative and regulatory changes on WTO members. The purpose of the agreement is to harmonize sanitary regulations among WTO members, according to international standards and guidelines, and members are required to adapt their regulatory system accordingly. As an incentive to do so, domestic regulations that conform to those standards will automatically be deemed consistent with WTO law, in accordance with Art. 3.2 of the SPS Agreement.[135]

The EC Asbestos Case was filed in 1998 by Canada against the ban by EC member states on the import of asbestos and products containing asbestos. The ban was premised on scientific studies showing that such products, because of their carcinogenic nature, were a threat to public health, and was therefore consistent with the European countries' human rights obligation to protect the right to health, i.e., to prevent the spread of diseases among the population. Because it was based on scientific evidence, the ban was permissible according to Art. 3.3 and 5.8 of the SPS Agreement. However, Canada challenged the necessity of such a drastic measure when it thought the same public health policy goal could be achieved in a less trade-restrictive manner, an argument rejected on

[134] EC - Measures Affecting Asbestos and Asbestos-Containing Products, WT/DS135/R (Panel, September 2000), WT/DS135/AB/R (Appellate Body Division, March 2001). Accessed March 15, 2003. Available from WorldTradeLaw.net.

[135] "Sanitary … measures which conform to international standards, guidelines or recommendations shall be deemed to be necessary to protect human … life or health, and *presumed* to be consistent with the relevant provisions of this Agreement and of GATT 1994." SPS Agreement, Art. 3.2.

appeal by the Appellate Body, based on the necessity to protect human health and life.[136] The Appellate Body further asserted that no quantification of the risk to human life was necessary,[137] and that "it is undisputed that WTO members have the right to determine the level of protection of health that they consider appropriate in a given situation."[138] In doing so, the dispute settlement body imposed only a low level of scientific and empirical evidence on states to justify their trade-restrictive public health policies, clearly assisting them in promoting the right to health. Most importantly, it also spelt out the interpretive approach it has developed in handling such health cases, i.e., that "the objective pursued by the measure is the preservation of human life and health through the elimination, or reduction, of the well-known, and life-threatening, health risks posed by asbestos fibres. *The value pursued is both vital and important in the highest degree.*"[139]

In the EC Asbestos Case, the WTO dispute settlement body affirmed its intention to defer to domestic public health policies, thereby formally adopting health as an interpretive principle in WTO law.[140] Such procedure clearly contrasts with the narrow, trade-restricted interpretation of the TRIPS Agreement described earlier, and fully supports domestic public health policies. In the EC Asbestos Case specifically, such interpretive approach included (1) using a broad definition of what "like products" are, which allowed the Appellate Body to declare that all asbestos-containing products pose a

[136] GATT, Art. XX(b).
[137] EC Asbestos Case, Appellate Body, Para. 167.
[138] Ibid, Para. 168.
[139] Ibid, Para. 172.
[140] However, in order to qualify as exceptions to pursue public health policy goals, under Art. XX(b) of the GATT, domestic measures have to be bona fide, i.e., not be protectionist measures in disguise.

threat to health (although not all represented the same level of threat), and (2) broadening the scope of the necessity for (i.e., lack of alternative to) a public health regulation.[141]

b. EC - Measures Concerning Meat and Meat Products (Hormones) Case (EC Hormones Case) [142]

The EC Asbestos Case was a victory for public health advocates, inasmuch as it firmly established the deference given to domestic health policies in interpreting GATT and SPS provisions, and confirmed the WTO's use of health as an interpretive principle of WTO law. In contrast, the ruling on the EC Hormones Case was a defeat for public health and human rights advocates. In 1996, the US requested the WTO to analyze the EC's measures on certain meat products, which included the ban on administering growth promotion toxins (hormones) to farm animals, and on selling, marketing and importing cattle and meats containing such toxins. These measures were considered to violate WTO law, on the basis that they were not based on scientific evidence, but rather on consumers' concerns over hormones in beef. It is to be noted that the Scientific Group on Anabolic Agents in Animal Production (or Lamming Group), established by the EC in 1984, refuted the risk to human health posed by the ingestion of such meats,[143] but the Committee of Enquiry into the Problem of Quality in the Meat Sector (established by the EC in 1988) later endorsed the ban on the use of hormones for non-therapeutic reasons, as "the only way to restore consumer confidence in the meat sector."[144] In its report, the Appellate Body agreed that "the risk assessment could set out both the prevailing view

[141] "In our view, France could not reasonably be expected to employ *any* alternative measure if that measure would involve a continuation of the very risk that the Decree seeks to "halt." Such an alternative measure would, in effect, prevent France from achieving its chosen level of health protection." EC Asbestos Case, Appellate Body, Para. 174.

[142] EC - Measures Concerning Meat and Meat Products (Hormones), WT/DS26/R/USA (Panel, August 1997), WT/DS26.48/R (Appellate Body, January 1998). Accessed March 15, 2003. Available from WorldTradeLaw.net.

[143] EC Hormones Case, Panel, Para. II.28.

[144] Ibid, Para. II.31.

representing the "mainstream" scientific opinion, as well as the opinions of scientists taking a divergent view (…). By itself, this does not necessarily signal the absence of a reasonable relationship between the SPS measure and the risk assessment, especially where the risk involved is life-threatening in character and is perceived to constitute *a clear and imminent threat to public health and safety.*"[145] Such assertion does give states the possibility to act preemptively, even based on marginal scientific data, so as to avoid the spread of diseases among the population, especially if the risks of exposure may result in irreparable injury to the population's well-being. However, both the Panel and the Appellate Body rejected the EC's public health argument, on the basis that risk assessment cannot rely solely on consumer concerns rather than scientific evidence.[146] Further, the WTO rejected proof of cancer induced by hormones in laboratory mice, as a proof of risk to human beings.[147] In doing so, it is arguable that "the WTO removed the ability of governments to take precautionary action to protect against risks strongly suggested, but not proven, by scientific evidence,"[148] a reasoning that contradicts para. 194 of the Appellate Body Report itself on the acceptance of non-mainstream scientific evidence. Interestingly enough, in the US, Sec. 409 of the Federal Food, Drug, and Cosmetic Act (1997), usually referred to as the Delaney Clause, prohibits the use of any additive in processed food, if it is found to induce cancer in man *or animals*.[149] A very

[145] EC Hormones Case, Appellate Body, Para. 194.

[146] EC Hormones Case, Panel, Para. 8.134.

[147] Patti Goldman, J. Martin Wagner and Barry Castlemann, "Trading Away Public Health," in *Multinational Monitor*, October 1999. Accessed February 23, 2004. Available from Expanded Academic ASAP

[148] Ibid.

[149] Relevant sections of the Federal Food, Drug and Cosmetic Act, 21 USCS Para. 348 (1999):

Sec. 409(b)(1): "Any person may, with respect to any intended use of a food additive, file with the Secretary a petition proposing the issuance of a regulation prescribing the conditions under which such additive may be safely used."

Sec. 409(c)(3): "No such regulation shall issue if a fair evaluation of the data before the Secretary -

strict interpretation of the same clause was upheld by the Ninth Circuit Court of Appeals in 1992, in a case brought against the Environmental Protection Agency, and by the US Supreme Court in 1993, when it refused to hear arguments to overturn the latter decision.[150] Domestically, therefore, the US has adopted a "zero-risk" approach to the use, in processed food, of certain substances that may cause cancer in animals, consistently with the precautionary principle approach denied to the EC in the EC Hormones Case by the WTO.

Both the above cases reveal that, in interpreting the provisions of the GATT and SPS Agreement, the WTO dispute settlement body has given a high level of deference to domestic public health regulations, when applied in a non-discriminatory manner and with the good faith purpose of protecting human health and life. Although the EC lost the Hormones Case, it is important to acknowledge that the burden of proof was on the EC to establish the existence of a potential risk to human health, a burden of proof that it failed to meet,[151] instead relying on the "precautionary principle" applied to health.

(A) fails to establish that the proposed use of the food additive, under the conditions of use to be specified in the regulation, will be safe: *Provided*, That **no additive shall be deemed to be safe if it is found to induce cancer when ingested by man or animal**, or if it is found, after tests which are appropriate for the evaluation of the safety of food additives, to induce cancer in man or animal, **except** that this proviso shall not apply with respect to the use of a substance as an ingredient of feed for animals which are raised for food production, **if the Secretary finds** (i) that, under the conditions of use and feeding specified in proposed labeling and reasonably certain to be followed in practice, such additive will not adversely affect the animals for which such feed is intended, **and (ii) that no residue of the additive will be found** (by methods of examination prescribed or approved by the Secretary by regulations, which regulations shall not be subject to subsections (f) and (g)) **in any edible portion of such animal after slaughter or in any food yielded by or derived from the living animal**

(accessed February 23, 2004); available from Congressional Universe.

[150] For reference, please see Cornell University, *Pesticide Management Education Program* (accessed April 7, 2004); available from http://pmep.cce.cornell.edu/issues/delaney-pr-195.html

[151] EC Hormones Case, Appellate Body, Para. 206.

2. Limitation of the interpretive approach: the precautionary principle

a. Relevance of applying the precautionary principle to health-related cases

Just like the implementation and enforcement of the TRIPS Agreement are not only an economic or human problem, but also a political one, the ban on exports based on GATT Art. XX and the SPS Agreement interpretation is not only a matter of scientific data and human health, but also of domestic policy. Indeed, the WTO disputes mentioned above have had a highly political dimension, as, specifically, the European Union has attempted to continue to protect its domestic agricultural producers. It may therefore not be easy to disassociate political from the public health motivations, however this chapter will focus on the enjoyment of the human right to health, and specifically on the right of individuals to state intervention and protection, i.e., the state's duty to take measures to prevent the dissemination of threats to health.

What seems most problematic in the interpretative approach used by the WTO in the EC Hormones Case is its refusal to accept the "precautionary principle" argued by the EC in support of its ban. This principle is premised on uncertainty, and requires that, "where there is a threat of actual or potential irreversible damage, lack of full scientific certainty should not be used as a reason for postponing measures to avoid or minimize the threat."[152] The human right to health requires states, *inter alia*, to respect and protect the right to health and the well-being of the population. Inherent to this obligation is the necessity, for states, to evaluate potential threats to public health and take preventive, or precautionary, measures to fulfill this obligation. This is not only relevant to a ban on potentially carcinogenic foodstuffs to humans as in the EC Hormones Case, but also to

[152] Farhana Yamin, "Biodiversity, Ethics and International Law," in *International Affairs (Royal Institute of International Affairs)* 71, no. 3 (1995): 532.

the ban on US beef following the most recent mad cow disease outbreak in December 2003 (e.g., by South Korea, Singapore and Taiwan), or to bans of imports of other agricultural products (from developed and developing countries) if they are found unsafe for consumers. In such cases, the same issues of determining whether import restrictions are bona fide or protectionist in nature remain. The precautionary principle in the public health arena is even more necessary and essential, as health hazards may take years to be recognized as such, in the meantime potentially causing irreparable injury to individuals, including long-term disability or death. Although applying the precautionary principle to health-related matters seems logical and inherent to states' obligations to protect the right to health, international law has, thus far, acknowledged its validity only in environmental law, and has not become part of customary international law.

b. Rationale for rejecting the precautionary principle in WTO cases

The principal argument against accepting the precautionary principle is its imprecise nature, and the potential for states to use such precautionary measures for political purposes, to protect their domestic producers.[153] This conflict between international law's rejection of the precautionary principle and the need for preventive measures in health-related cases has most recently been part of the debate over the adoption of the precautionary principle in agricultural biotechnology, specifically on genetically modified organisms, and will presumably resurface in the WTO in the context of the US complaint against the EC's ban on the import of genetically modified

[153] Henry Miller and Gregory Conko, "Precautionary Principle Stalls Advances in Food Technology," in *Washington Legal Foundation* 15, no. 32 (2000). Accessed March 23, 2003. Available from LexisNexis.

organisms.[154] The EC Hormones Case represents a defeat for public health advocates, specifically for advocates of the precautionary principle to protect human life and health. The SPS Agreement, however, contains a provision for the use of precautionary regulations only for a *temporary* period (Art. 5.7), an argument rejected in the EC Hormones Case because the EC's regulations were to be permanent. The Appellate Body acknowledged that the precautionary principle is "regarded by some as having crystallized into a general principle of customary international *environmental* law." However both the Panel and the Appellate Body restrained from considering whether the precautionary principle has, indeed, become a rule of customary international law, to be applied in WTO law with regard to health-related regulations.[155] Further, the Appellate Body rejected its application in international trade law, based on the lack of " a *clear textual directive* [to] relieve a panel from the duty of applying the normal (i.e. customary international law) principles of treaty interpretation (…)."[156] It therefore appears that the WTO's integration of the "precautionary principle" could only be done after it has been recognized as a customary international norm in the international legal regime.

3. Basis for using the right to health as an interpretive principle

In applying the GATT and SPS Agreement, the WTO has clearly expressed its deference to domestic health regulations, when adopted with a bona fide intent to protect human health and life. Such approach clearly assists states in protecting the right to

[154] Since 1999, individual governments of member states to the European Union have had to approve genetically modified seeds and foods before they can be imported on their territory, imposing a ban on the import of those products to the EU. Estimated losses to, *inter alia*, US corn farmers amount to $300 million per year. The United States has been expected to bring a complaint to the WTO, on the basis that "the ban is purely political and based on no scientific finding of risk." However, to this date, no complaint has been filed. Michael Schroeder, "US-EU Trade Fight Isn't Over, Just Sidetracked," *Wall Street Journal*, March 14, 2003, A8.

[155] EC Hormones Case, Appellate Body, Para. 123.

[156] Ibid, Para. 124.

health through public health policies, not by integrating protection of the right to health within WTO law, but by refraining from imposing limits on the regulations states can adopt. It is relevant to note that such deference to health policies and concerns, i.e., the consideration of the effects of the implementation of WTO Agreements on the right to health when reviewing complaints, has so far lacked from the interpretation and implementation of the TRIPS Agreement, which has focused on the evaluation of patent regimes and their efficiency in guaranteeing intellectual property protection to innovators and pharmaceutical companies. This may be partly explained by the involvement, in the drafting of the SPS Agreement and in case review, of the WHO.[157] Such cooperation has certainly had an impact on the interpretive approach of the GATT and SPS Agreement by the WTO dispute settlement body, and has ensured that these agreements could not be used to prevent states from fulfilling their obligation to promote the right to health. It is therefore possible that greater collaboration between human rights bodies and the WTO, or the adoption by the WTO of a human rights approach in the drafting of agreements and review of complaints, could resolve the conflicts between the implementation of the TRIPS Agreement and the right to health (and human rights generally), if not to promote a human rights-based approach to drafting and implementing WTO law, but at minimum to ensure that WTO law respect the right to health and is not applied in such a way as to force states to choose between their health and trade obligations. The issue of cooperation between the WTO and human rights bodies will be discussed below.

[157] The WHO has observer status with the WTO, along with the World Bank and the UN Conference on Trade and Development (UNCTAD), among others. WTO, *Members and Observer* (accessed April 7, 2004); available from http://www.wto.org/english/thewto_e/whatis_e/tif_e/org6_e.htm.

Health has been awarded greater "value" than economic *interests*, and has been found "both vital and important in the highest degree." This approach is consistent with the fact that, not only the costs of healthcare necessary to address public health crises in developing countries usually require a resource re-allocation from other development activities,[158] but rather health itself has increasingly been viewed as an economic factor of production, since poor health has been found to be a source of "loss of valuable skills and experience, and decline in productivity and enterprise profits."[159] However, current WTO jurisprudence shows an inconsistent approach to health-related issues by its dispute settlement body. Whereas in GATT and SPS cases, the dispute settlement body has supported states in fulfilling their obligation to protect the right to health, it has thus far rejected this interpretive approach in cases involving the TRIPS Agreement. In addition to being inconsistent with its own interpretive principle, the WTO, in doing so, is inconsistent with the recommendations of the Committee on Economic, Social and Cultural Rights which, in December 2001, took it upon itself to "identify some of the key human rights principles deriving from the Covenant that are required to be taken into account in the development, interpretation and implementation of contemporary intellectual property regimes."[160] In light of the *de facto* interpretive approach of WTO law in GATT and SPS cases, one may wonder how such approach could be used in TRIPS cases, and whether it could, or should, eventually lead to an integrative human

[158] Bell, Devarajan and Gerbasch.
[159] Desmond Cohen, "Human Capital and the HIV Epidemic in Sub-Saharan Africa," *International Labour Organisation (ILO) Working Paper No. 2* (June 2002), Preface. Accessed April 14, 2004. Available from http://www.ilo.org/public/english/protection/trav/aids/publ/wp2_humancapital.pdf
[160] Committee on Economic, Social and Cultural Rights E/C.12/2001/15, Para. 2.

rights-based approach to WTO law, as recommended by the Committee on Economic, Social and Cultural Rights.[161]

[161] "The Committee considers of fundamental importance the integration of international human rights norms into the enactment and interpretation of intellectual property law." Ibid, Para. 18.

IV. SHOULD WTO LAW INTEGRATE THE RIGHT TO HEALTH?

1. Including the right to health in the WTO agenda

a. Role of international human rights bodies

As discussed earlier, human rights law and international trade law evolved in isolation from each other. However, with the expanding of human rights law to groups and peoples, and the simultaneous narrowing of WTO law to protect private individuals' rights, both systems have overlapped, including in the area of health. Such overlap, coined "Trade and …" by Joel Trachtman,[162] is not unique to the right to health, but has occurred between international trade law and labor rights[163] and the environment.[164] The WTO dispute settlement body has increasingly deferred to states' public health policies in evaluating the permissibility of their domestic regulations under WTO law, but it has failed to do so in applying the TRIPS Agreement. The question is whether such interpretive approach to WTO law to defer to the right to health could be implemented in non-SPS and non-GATT cases. My answer is yes, and the combined role of international human rights bodies and of NGOs is essential to this end.

In the specific area of the right to health, international human rights bodies have raised concerns over the exclusion of human rights bodies from the drafting of economic

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[162] Joel Trachtman, "Institutional Linkage: Transcending 'Trade and …'," in *American Journal of International Law* 96, no. 1 (2002): 77.

[163] The WTO has been criticized for not including the protection of labor standards within its agreements, and for the accession of certain states that have a record of violation of labor standards (e.g., China). For reference, please see:

WTO, *Trade and Labour Standards, Subject of Intense Debate* (accessed April 14, 2004); available from http://www.wto.org/english/thewto_e/minist_e/min99_e/english/about_e/18lab_e.htm

Gary Burtless, "Workers Rights: Labor Standards and Global Trade," in *Brookings Review* 19, no. 4 (Fall 2001). Accessed April 14, 2004. Available from Expanded Academic ASAP.

[164] E.g., United States – Import Prohibition on Certain Shrimp and Shrimp Products, WT/DS58/RW (Panel, June 2001), WT/DS58/23 (Appellate Body Division, November 2001). Accessed February 12, 2004. Available from WorldTradeLaw.net. In this case, the WTO reviewed the US prohibition on the import of shrimps from countries that failed to meet the US environmental standards for shrimp fishing and the protection of sea turtles. The Panel and Appellate Body found that the US prohibition was permitted under Art. XX of the GATT.

agreements, and about the potentially negative effects of WTO law on human rights obligations. In December 2001, the Committee on Economic, Social and Cultural Rights warned that "any intellectual property regime that makes it more difficult for a state to comply with its core obligations in relations to health, food education, especially, and any other right set out in the [CESCR], is inconsistent with the legally binding obligations of the State Party."[165] In the same report, the Committee "confirms its willingness to discuss the issues identified in this statement with relevant actors and its availability to assist State Parties *and intergovernmental organizations* [including the WTO], in this process." Similarly, the Sub-Commission on the Promotion and Protection of Human Rights requested, in August 2001, that the UN High Commissioner for Human Rights "seek observer status within the World Trade Organization for the ongoing review of the TRIPS Agreement."[166] Earlier, in November 1999, the Committee had communicated with the WTO Ministerial Conference its concerns that "the realms of trade, finance and investment are in no way exempt from human rights principles,"[167] and that it had "become increasingly aware of the extent to which economic policies and practices affect the ability of states to fulfill their [human rights] treaty obligations." The particular relationship between the implementation of the TRIPS Agreement and human rights has also been endorsed by the UNDP in its *Human Development Report 1999*: the UNDP issued a strong warning against the negative consequences of the agreement on food

[165] Committee on Economic, Social and Cultural Rights E/C.12/2001/15, Para.12.

[166] OHCHR, Sub-Commission on the Promotion and Protection of Human Rights, *Resolution 2001/21: Intellectual Property and Human Rights*, 53rd session, 26th meeting, August 2001 (accessed April 7, 2004); available from http://www.unhchr.ch/huridocda/huridoca.nsf/Documents?OpenFrameset

[167] UN Secretariat, Economic and Social Council, Committee on Economic, Social and Cultural Rights, *Statement of the United Nations Committee to the Third Ministerial Conference of the World trade Organization*, E/C.12/1999/9, 1999, Para. 2. Accessed April 12, 2003. Available from UNODS.

security, indigenous knowledge,[168] bio-safety and access to health care. International human rights bodies have therefore been fully aware of the nexus between WTO law and its effect on states' capacity to fulfill their human rights obligations (including vis-à-vis the right to health). However, whereas the WTO has cooperated with the WHO, it has thus far failed to seek cooperation with human rights bodies, and has not granted them observer status.

b. Role of nongovernmental organizations

At the same time, NGOs have rallied public opinion on the nexus between WTO law and the human right to health, including Global Trade Watch (which runs projects on the TRIPS Agreement and access to medicines),[169] Consumer Project on Technology (which presented a report to the Joint Secretary of the WHO and WTO for its workshop on differential pricing for medicines)[170], or Health GAP, a US non-profit focused on access to medicines in the context of HIV/AIDS,[171] notwithstanding other, non-trade related human rights organizations with a globalization office (such as Amnesty International or Human Rights Watch). Although NGOs have been particularly notorious for the disaster of the 1999 Seattle Ministerial Conference,[172] and their accountability remains open to be debated,[173] NGO pressure has contributed to developments in the application of the TRIPS Agreement with regard to the right to health, although other

[168] The TRIPS Agreement has also raised problems regarding the issuance of patent to Western pharmaceutical companies, for traditional medicines, such as herbal remedies, used for generations in local communities. The WTO has, thus far, received no complaint on this issue. "Patently Problematic," *The Economist*

[169] Global Trade Watch (accessed April 25, 2001); available from http://www.citizen.org/

[170] Consumer Project on Technology (accessed April 25, 2003); available from http://www.cptech.org/.

[171] Health GAP (accessed April 25, 2003); available from http://www.healthgap.org/.

[172] Third World Network, *The Seattle Debacle: What Happened and What Next?* (accessed April 25, 2003); available from http://www.twnside.org.sg/title/focus13.htm

[173] For further reading on governance and accountability of NGOs and transnational networks, please see Jonathan Fox and David Brown, Ed., *The Struggle for Accountability: The World Bank, NGOs and Grassroots Movements* (Cambridge: MIT Press, 1998).

factors have also accounted for these changes, such as the rallying of developing countries around Brazil, in an effort to gain bargaining power against developed countries.

A specific case at hand is the Brazil - Measures Affecting Patent Protection Case (Brazil Patent Case),[174] filed in June 2000 by the US. In an effort to increase the transfer of technology in its pharmaceutical industry, a purported goal of the TRIPS Agreement and an argument used by pharmaceutical multinationals to seek greater patent protection, Brazil required, as of 1996, "local working" for the enjoyment of exclusive patent rights, i.e., in the absence of local manufacturing for a product patented in Brazil, the Brazilian government would grant a license to a local pharmaceutical company to manufacture the same products without authorization of the right holder.[175] The US argued that this regulation violated the TRIPS Agreement, inasmuch as it did not support free trade (i.e., imports to Brazil) but local production. For background, Brazil's compulsory licensing is estimated to have allowed it to save over $500 million in AIDS medicines from 1997 to 2001, and to freely distribute cheap generic version of foreign AIDS medication.[176] The Brazilian policy also includes, *inter alia*, intensive negotiations with multinational pharmaceutical companies, for the sale of HIV/AIDS medicines at heavily discounted prices, i.e., at a price where pharmaceuticals just recover their costs. It is important to note that Brazil's granting of compulsory licenses to local manufacturers has also been based on the outcome of these negotiations, in accordance with Art. 31(b) of the TRIPS

[174] Brazil - Measures Affecting Patent Protection, Request for the Establishment of a Panel by the United States, WR/DS199/3 (WTO Panel, 2001). Accessed April 03, 2003. Available from WorldTradeLaw.net

[175] TRIPS Agreement, Art. 31(f).

[176] Helen Cooper, "US Drops WTO Claim Against Brazilian Patent Law," *Wall Street Journal,* June 26, 2001, B7.

Agreement.[177] In later cases, Brazil was able to negotiate reduced prices for AIDS medicines with patent-holders (down by as much as 80%) by threatening to issue licenses.[178] By the year 2000, the Clinton Administration had adopted Executive Order 13,155 on "Access to HIV/AIDS pharmaceuticals and medical technologies," according to which measures taken by developing countries to address the HIV/AIDS epidemic should not be challenged by the US,[179] and in June 2001, the Bush Administration eventually withdrew its complaint to the WTO, after activist organizations, including, but not limited to, Act Up,[180] Oxfam [181] and Third World Network,[182] informed public opinion on the effect of the TRIPS Agreement on access to medicines. In fact, the withdrawal is said to have been motivated by the administration's desire to "mute criticism from AIDS activists and developing countries."[183] Faced with similar pressure from NGOs and the negative effect on their public relations efforts, 39 pharmaceutical multinationals abandoned a similar case against South Africa (which sought to import generic medicines from countries where they had been manufactured through compulsory licensing, a practice called "parallel import," generally prohibited in patent law).

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[177] "Patently Problematic," *The Economist*

[178] Miriam Jordan, "Brazil to Break Roche Patent on AIDS Drug," *Wall Street Journal,* August 23, 2001, A3. Brazil's policy is to negotiate reduced prices for ADIS drugs with manufacturers and patent-holders. In March 2001, as a result, an agreement was entered between Brazil and Merck & Co. to reduce prices of two AIDS drugs it manufactures. Similarly, Brazil negotiated with Roche for reduced prices for *Viracept,* an anti-retroviral drug -- after six months of negotiations, Brazil eventually issued compulsory licenses for the local manufacturing of the drug. It is to be noted that, through negotiations with developing countries, pharmaceutical manufacturers sell patented drugs for very little, or no, profit. GlaxoSmithKline, for instance, provides the AIDS drug *Combivir* to African countries for a price of $730 per year per patient, while the drug is sold for $6,289 per year per patient in the US (Harris Gardiner, "Adverse reaction: AIDS Gaffes in Africa comes back to haunt drug industry at home," *Wall Street Journal,* April 23, 2001, A1).

[179] Office of the President, *Access to HIV/AIDS Pharmaceuticals and Medical Technologies*, Executive Order 13155, May 10, 2000.

[180] ACT UP (accessed April 25, 2003); available from http://www.globaltreatmentaccess.org/content/press_releases/01/040901_AEB_PR_BRA_USG_html.

[181] Oxfam (accessed April 25, 2003); available from http://www.oxfam.org/English/pdfs/pp020710_no26_generic_competition_briefing_paper.pdf.

[182] Third World Network (accessed April 25, 2003); available from http://www.twnside.org.sg/trade.htm or http://www,twnside.org.sg/hum.htm.

[183] Cooper, B7.

Because of the current HIV/AIDS epidemic in developing countries, especially in Sub-Saharan Africa, efforts of NGOs have focused on raising public awareness on the negative effects of the TRIPS agreement on a specific aspect of the right to health, i.e., access to medicine. However, considering the success such campaigns have had, it is reasonable to expect that continued pressure from the NGO community may result, in the long run, in an increasing deference to domestic public health policies, and to an increasing deference to the right to health as a systematic, interpretive principle of WTO law.

c. The Doha Declaration - Towards a systematic interpretive approach?

The need to interpret WTO law, specifically the TRIPS Agreement, with deference to the right to health and the pursuance of public health policies, has already been accepted by the WTO Ministerial Conference, by unanimity, in November 2001, during the WTO Doha Round. According to the Declaration, the least developed countries have been granted an extension of the transition period until January 01, 2016 (their initial transition period was due to expire on January 01, 2005).[184] While the same provision explicitly waives TRIPS obligations for the least developing countries with respect to pharmaceutical products, the WTO also stated:

> "We affirm that the Agreement *can and should* be interpreted and implemented in a manner *supportive of WTO Members' right to protect public health* and, in particular, to promote access to medicines for all." [185]

Critics of the Declaration argue that it is only a reiteration of provisions already present in the TRIPS Agreement, and that, since the Ministerial Conference did not follow the amendment procedure established in Art. 71 of the TRIPS Agreement, it has

[184] Ibid, Para. 7.
[185] Ibid, Para. 4.

no legal value. However, I will argue that the Declaration does have a legal value, in accordance with the decision of the International Court of Justice (ICJ) in the *Australia & New Zealand v. France* case (Nuclear Test Case) in 1974.[186] In this case, the ICJ found that unilateral declarations may, under some circumstances, form the basis for legal obligations, if (1) the state issuing the declaration has the intent to be bound by it, and (2) the declaration is made public, and publicly. In the Nuclear Test Case, declarations by the French President and Prime Minister, among other Ministers, according to which France would stop nuclear tests in the area, and made publicly to the Australian and New Zealander governments, were found to meet those criteria. Similarly, the Doha Declaration, although not made unilaterally by one state, was adopted by unanimity by the WTO's Executive body, the Ministerial Conference. The Declaration also reiterated earlier provisions which were already legally binding, although not fully implemented, therefore repeating the intent of WTO members to abide by those provisions. If, *arguendo*, one is not convinced of the legal value of the Declaration, the Declaration still requires WTO members and dispute settlement body to systematically adopt an interpretive approach to the TRIPS Agreement,[187] "in a manner supportive of WTO Members' right to protect public health," in much the same way as the Panel and Appellate Body have done so in interpreting the GATT and SPS Agreement. Such declaration therefore meets the requirements of Art. IX of the WTO Charter, according to which only the Ministerial Conference or the General Council may adopt an interpretation of the WTO agreements, to be adopted by a 3/4 majority of members. The pressure from human rights bodies and NGOs has therefore succeeded, thus far, in

[186] Australia & New Zealand v. France, 1974 ICJ 253,457, 46-50 (International Court of Justice, 1974)
[187] Doha Declaration, Para. 4.

obtaining a public acceptance of an interpretive approach to WTO law, specifically of the TRIPS Agreement, in light of the right to health and access to medicine, a practice that can only assist states in promoting the right to health.

The Doha Declaration, although it granted an extension to the developing and the least-developed countries to implement the TRIPS Agreement, failed to resolve the issue of import/export of generic drugs and other pharmaceutical products manufactured through compulsory licensing to developing and the least-developed countries which face public health crises. Cullet has argued that for those countries without the local manufacturing capacity to produce cheaper generics (e.g., Botswana), the implementation of the TRIPS Agreement in generic exporting countries such as India or Brazil may already restrict their access to cheaper medicines.[188] A complete prohibition to import them would have dramatic consequences on access to medicines in the poorest countries, effectively reducing the population's capacity to enjoy their human right to health. Further, the abandonment of the complaints against Brazil and South Africa shows a "forced restraint" on developed countries, but do not provide precedents for potential future cases. The 2003 decision of the WTO General Council on the implementation of para. 6 of the Doha Declaration sought to establish a system to allow "eligible importing members" (i.e., the least-developed countries and other member states after notification to the TRIPS Council in cases of extreme national emergency) to import generic pharmaceuticals in cases of national emergency and for "non-commercial use" only (Art. 1(b)), effectively granting manufacturing countries a waiver of TRIPS Art. 31(f) for exports to eligible countries. The decision also requires (1) importing states to "take reasonable measures within their means, proportionate to their administrative capacities

[188] Cullet, 154

and to the risk of trade diversion to *prevent re-exportation of the products* that have actually been imported into their territories under the system,"[189] and (2) other member states to take measures to prevent parallel import in their territory.[190] Finally, the decision also provides that measures taken in conformity with the trading system it lays out "shall not" be challenged in the WTO.[191] The question of the legal effect of the decision, which had arisen with the Doha Declaration earlier, can be addressed in much the same way as that of the Doha Declaration. However, Art. 11 of the decision indicates the view by the Council of its legally-binding aspect, as the decision seems to be a first step towards an amendment of the TRIPS Agreement.[192] By validating the present decision as legally-binding until the TRIPS Agreement is amended, the WTO General Council has not only acknowledged the deficiencies of the agreement as is, but has also confirmed the legally-binding aspect of the Doha Declaration.

d. National patent regimes and the TRIPS Agreement

Because, as analyzed earlier, the enforcement of intellectual property rights, including patents, can have, and has had, social benefits and can support the enjoyment of the right to health, it is preferable, in the long-run, to implement a systematic patent regime worldwide. However, and in accordance with Art. 30 of the TRIPS Agreement, such regime and possible exceptions to it should "not unreasonably prejudice the legitimate interests of the patent owner, taking into account of the legitimate interests of third parties," including patients themselves. A better balance between the systematic

[189] *Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health*, Art. 4

[190] Ibid, Art. 5

[191] Ibid, Art. 10

[192] "This Decision, including the waivers granted in it, shall terminate for each Member on the date on which an *amendment to the TRIPS Agreement* replacing its provisions takes effect for that Member." Ibid, Art. 11

implementation and enforcement of a patent regime and the enjoyment of the human right to health can, and should, therefore be achieved, as supported by the OECD in 2000.[193] Such balancing may be achieved through various ways, including price controls, compulsory licensing for countries with a manufacturing capacity, price subsidization, or greater public funding for R&D. These solutions, however, have been found to be problematic for different reasons: Price controls could prevent the entry of certain manufacturers if the price is set too low,[194] compulsory licensing has already been challenged in the WTO, as would potentially be price subsidization under the WTO Agreement on Subsidies and Countervailing Measures, while public funding for R&D has been found less efficient than private one, especially in light of the neo-liberal economic agenda.[195] Two other measures, however, have been proposed to re-establish a fairer balance between private and public health interests, namely price differentiation and differential patent regimes.

Price differentiation must involve partnerships with the private sector, to negotiate and establish different prices for the same medicines, depending on the specific needs of a country and its price sensitivity for medicines. As a result, the developing and the least developed countries that are unable to ensure the right to health, and where the demand for medicine is price elastic (i.e., where the population is highly sensitive to changes in prices), private firms would charge a lower price for the medicines necessary to address a public health crisis/epidemic. Such system, analyzed by Watal for a WTO report in

[193] "Health policy's main concern is to optimise the level and distribution of pharmaceuticals at an affordable level while industrial policy ought to foster innovation in the light of public expenditure constraints." OECD, *Pharmaceutical Policies in OECD Countries: Reconciling Social and Industrial Goals*, 9.

[194] Lanjouw, "A Patent Policy Proposal for Global Diseases"

[195] Suzanne Scotchmer, "The Political Economy of Intellectual Property Treaties," *NBER Working Paper no. 9114* (August 2002), 14. Accessed March 3, 2004. Available from the National Bureau of Economic Research.

2001,[196] has been found to result in a win-win situation for consumers, the state and the cooperating private firm, by promoting greater access to life-savings medicines while creating a new market for distribution, thereby promoting the human right to health and investor profitability. This solution was also promoted in 2001 by both the WTO and the WHO, which proposed criteria to determine which countries and medicines could benefit from this system (priority should be given to life saving medicines). However, the viability and efficiency of such system would depend on market segmentation worldwide, as domestic consumers would presumably pressure private pharmaceutical firms to lower their domestic prices to the lowest one worldwide, as has happened in the U.S. with the import of medicines from Canada. The absence of a mechanism to prevent this phenomenon would presumably have the reverse effect, i.e., the homogenization of prices to the highest worldwide. Therefore, mechanisms for "controlling arbitrage or domestic political pressure" will be necessary, eg, controls of exports of medicines from lower-priced markets and/or control of imports into higher-priced markets. It is relevant to note that these requirements have been proposed by the WTO General Council in its August 2003 decision on the trade of generics manufactured through compulsory licensing (see Art. 4-5). In addition to import/export restrictions on such medicines, labeling and marking requirements are also required under the General Council's decision (Art. 2(b)(2)), in order to be readily identifiable. This requirement is consistent with the WHO/WTO proposal,[197] but *de facto* requires trade restrictions, under the GATT Art.

[196] Jayashree Watal, "Workshop on Differential Pricing and Financing of Essential Drugs, Background Note" (Geneva: WHO Secretariat, 2001), 11-22 (accessed February 23, 2004); available from http://www.who.int/medicines/library/edm_general/who-wto-hosbjor/wto_background_e.doc

[197] WHO, *More Equitable Pricing for Essential Drugs: What Do We Mean and What are the Issues?* (Geneva: WHO Secretariat, April 2001), 26 (accessed February 23, 2004); available from http://www.who.int/medicines/library/edm_general/who-wto-hosbjor/equitable_pricing.doc

XX(b) exception clause. However, this system would also result in a win-win situation by allowing private pharmaceutical companies to charge higher prices in countries with lower demand price elasticity for medicines (i.e., "rich" countries), and achieving "the economies of scale necessary to make [their] drugs affordable to countries like Uganda or Tanzania."[198]

Lanjouw, of the National Bureau of Economic Research, has proposed a policy model for such price and patent regime differentiation system, based on amendments to the current US patent registration system.[199] The current procedure provides for US innovators first to obtain a patent in the US, then to file for a "Foreign Filing License" (FFL) to be able to file for patent abroad. According to Lanjouw's model, when filing for FFL in the US, the patent holder would be required to certify that, for a given medicine and in a given country, he/she will not attempt to restrict the manufacture and use of this particular drug by suing for patent infringement in this particular country. In so doing, the US patent holder will, *de facto*, choose one market where to protect its intellectual property right, and will presumable choose the market with the highest revenues. It is important to note the limitation of this proposal, however, since, not only does it require segmented markets, but it also requires highly concentrated ones in either the rich or the poor countries.

Finally, another solution is that of differentiating patent regimes, and possibly lowering the current standard set by the TRIPS Agreement to meet the specific conditions and needs of WTO member states. Such differentiation would be permitted under WTO law, since the WTO does not impose the implementation and enforcement of a given

[198] "The Right Fix?" *The Economist*, September 1, 2003. Accessed March 12, 2004. Available from The Economist.

[199] Lanjouw, "A Patent Policy Proposal for Global Diseases"

system within each member states, but rather gives flexibility to develop a system according to member states' needs and capacity. Such solution has been promoted by Scotchmer, of the National Bureau of Economic Research, on the basis that such asymmetric protections may be more efficient than universal protections,[200] and by Deardorff, who showed, when analyzing patent protection in the North and the South, that:

> "Protection in the South might not be optimal for either Southerners alone, or for the world as a whole, since the deadweight loss in the South might outweigh the worldwide benefits of getting more inventions."[201]

Some have gone further than differentiation of protection, and have advocated either for developing countries to not "commit themselves to rich-world systems of intellectual property right protection unless such systems are beneficial to their needs,"[202] or for developed countries to "allow their property to be copied or used without cost and often without authorization," since "copying creates additional consumers."[203] Short of a return to the pre-TRIPS Agreement era, such differentiation of intellectual property protection would therefore mean an amendment of the TRIPS Agreement to lower the minimum standard protection required. Associated with this proposal is the need for technical assistance to developing and the least-developed countries, not in providing medicines under private-public partnership agreement (which, again, provides the good, but does not guarantee the enjoyment of the human right to health), but in establishing a patent protection regime in these countries, as supported by Chin, of the National Bureau of Economic Research:

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[200] Scotchmer, 4

[201] Scotchmer, 6

[202] "Patently Problematic," *The Economist*

[203] Katz and Shapiro, quoted in Murray Fulton, "The Economics of Intellectual Property Rights: Discussion," in *American Journal of Agricultural Economics* 79, no. 5 (December 1997). Accessed March 3, 2004. Available from Expanded Academic ASAP

> "[If intellectual property rights do increase global efficiency and welfare, then] the North ought to be willing and able to compensate the South for any losses that it would incur in the course of providing such protection."[204]

2. Towards a rights-based approach?

a. Integrating human rights in WTO law?

The Economist, in 2003, stated:

> "As they stand, the WTO's rules leave the vast majority of poor, disease-ridden countries in a pickle. They cannot afford to buy the patented versions of essential drugs; they do not have the resources to make cheaper generic versions; and they cannot import generics, because the countries that make them are not allowed to export them."[205]

Since then, the Doha Declaration and the General Council's 2003 decision have attempted to address the particular tension between the TRIPS Agreement and the human right to health, by seeking a "healthy" balance between private interests and the social costs of patent regimes. Since public health and the right to health have been adopted as an interpretive principle in WTO law, one may wonder whether the WTO could and should go further, by integrating health in its decision-making process and adopting a rights-based approach to WTO law. Such approach was advocated by the Committee on Economic, Social and Cultural Rights in its letter to the WTO Ministerial Conference in November 1999, in which it called for human rights norms to "shape the process of international economic policy formulation."[206] Earlier, in August 1999, the UN Sub-Commission on the Promotion and Protection of Human Rights had called for steps to be taken to "ensure that human rights principles and obligations are fully integrated in future negotiations in the World Trade Organization."[207]

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[204] Chin, 26

[205] "The Right Fix?" *The Economist*

[206] Committee on Economic, Social and Cultural Rights, E/C.12/1999/9, Para. 5.

[207] OHCHR, Sub-Commission on the Promotion and Protection of Human Rights, *Resolution 1999/30: Trade Liberalization and its Impact on Human Rights*, 51st session, 33rd meeting, August 1999, Para. 4

Such a rights-based approach to decision-making in the WTO seems to be warranted by the actions of some non-state actors which have influenced WTO law without consideration for the effect of new agreements on the right to health, as did pharmaceutical companies with the TRIPS Agreement. Indeed, integrating the right to health in WTO law would, at a minimum, ensure that it could not threaten the right to health by, for instance, requiring states to choose between fulfilling their WTO obligations and their human rights ones. It may not be possible to avoid completely such a choice. But the implementation of WTO Agreements in the face of public health crises, and the impact on a state's capacity to promote and protect the human right to health, has proved problematic, and a balancing test needs to be made between private and social costs/benefits to ensure that the TRIPS Agreement not only promotes intellectual property rights and private benefits but also sustainable economic development in the developing and the least-developed countries through promoting access to medicine and transfer of technology. Whereas the current approach is generally to interpret WTO law in the manner that will have the least negative impact on the right to health, a rights-based approach would also give the WTO the responsibility to promote the human right to health. The WTO, as an international governmental *organization*, would not accept such responsibility for two reasons: the first legal reason is that, according to human rights treaties and the Vienna Convention on the Law of Treaties (Art. 1), this responsibility is clearly within individual *states* only, and although the General Assembly adopted, in March 1999, the Declaration on the Responsibility of Individuals and Groups

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(accessed April 02, 2003); available from http://www.unhchr.ch/huridocda/huridoca.nsf/Documents?OpenFrameset

of Society to Protect Human Rights,[208] such declaration has not been made into a treaty yet, and is not legally binding. Secondly, and for practical purposes, it would be inefficient to have human rights specialists involved in the drafting of WTO law, whose purpose remains, first and foremost, economic, i.e., to promote and create an environment conducive to free trade. It is important to note that the above does, in no way, justify violations of international human rights law by *individual* WTO member states, which, in their individual capacity, are the bearers of international human rights obligations. However, the isolation of the WTO from human rights bodies, especially since it has clearly been strongly influenced by private multinational corporations, has had, as demonstrated earlier, dramatic consequences on states' capacity to fulfill their obligations towards the right to health. And whereas the WTO preamble suggests that international trade law seeks a balance between economic and social interests, the balance has certainly tilted in favor of economic interests, as alluded to by Bloche.[209] Such imbalance must be corrected, and an interpretive approach is not sufficient.

b. Corporate initiatives and partnerships with the public sector

In response to attacks on its undue influence on WTO law and the consequences on the right to health, specifically on access to medicine, multinational pharmaceutical companies have emphasized their role in private/public partnerships. The Pharmaceutical Research and Manufacturers of America (PhRMA) confirms that, between 1998 and 2001, US pharmaceutical manufacturers donated over $1.9 billion in financial assistance

[208] UN Secretariat, General Assembly, *Resolution 53/144: Declaration on the Rights and Responsibility of Individuals, Groups and Organs of Society to Promote and Protect Universally Recognized Human Rights and Fundamental Freedoms*, 53rd session, 85th plenary meeting, March 1999. Accessed April 22, 2003. Available from UNODS.

[209] "Trade that advantages only an elite few without contributing to a society's wider economic development, including reduction in poverty and raising of incomes, is unlikely to promote public health and well-being." Bloche, 830.

and medicine donations to developing countries,[210] with $564 million donated in 2001 alone. Merck & Co., for instance, has collaborated with the World Bank, the WHO and UNICEF to donate certain medicines to developing countries,[211] while GlaxoSmithKline provided AIDS care training to South Africa from 2000 to 2002.[212]

However, these initiatives have two shortcomings: firstly, they tend to be limited in time, and may not be sustainable once programs are completed. Secondly, while multinational corporations have, at least publicly, supported states in protecting the right to health through these initiatives, pharmaceutical manufacturers' associations have simultaneously advocated a reinforcement of the TRIPS Agreement. The Doha Round did, as a result, stall on the issue of granting differential treatment for developing countries, and specifically on the scope of Art. 31(f) of the agreement, whereby compulsory licensing must be granted for *domestic* purposes, thereby preventing generic manufacturers to export cheap medicines to developing countries with parallel import. As reviewed earlier, this issue was eventually addressed in August 2003 by the WTO General Council in favor of the developing countries' pharmaceutical needs, evidencing a potential shift in the WTO to address the human rights dimension of international trade, at least with reference to health. Further, the US and the EU have tried to implement "TRIPS Plus" regulations, i.e., they require states to adopt intellectual property

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[210] PhRMA, *Global Partnerships: Humanitarian assistance programs of the pharmaceutical industry in developing nations* (accessed March 03, 2003); available from http://world.phrma.org/Phrma_2001Booklet.pdf.

[211] Merck & Co. has collaborated with the WHO, the World Bank and UNICEF since 1987 to fight "river blindness", an African endemic disease, by donating *Mectizan* to developing countries. Merck, *Corporate Social Responsibility: Access to Medicines in the Developing World* (accessed April 7, 2004); available from http://www.merck.com/about/cr/policies_performance/social/medicines_developing.html.

[212] GlaxoSmithkline has collaborated with local governments to fight lymphatic filariasis (aka "elephantiasis") in African countries through drug donation programs. GlaxoSmithKline, *Global Community Partnerships* (accessed April 7, 2004); available from http://www.gsk.com/community/about.htm.

regulations that are more strict than those required by the TRIPS Agreement in order for them to receive trade concessions or development assistance.[213] The bona fide of corporations, whose social initiatives, additionally, may not be regulated under national or international law, is therefore questionable, and without assurances of good faith and the sustainability of those initiatives, other options should be sought.

Finally, although such partnerships and corporate programs can allow pharmaceutical companies to assist developing countries in promoting public health policies while continuing to campaign for strong patent regimes worldwide, it is important to note that such programs actually do not necessarily promote the human right to health. Indeed, Shue argues that the human right to health is one of the basic rights, along with food and security, without which the enjoyment of any other human right is not possible.[214] According to his analysis, these basic rights are also defined by the "rational basis for justified demand of something *socially guaranteed*,"[215] and are to be differentiated from the provision of the good of the right when not socially guaranteed. With respect to health, the provision of cheap medicines through public-private

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[213] Section 2411 of the US Code 19 allows the United States Trade Representative (USTR) to impose unilateral sanctions against states that it perceives unjustifiable undermine US trade. USC 19, Sec. 2411, specifically allows the Trade Representative to take such action against states that do not offer high enough intellectual property protection, even when those states meet the standards set up by the TRIPS Agreement, thereby legalizing "TRIPS Plus" actions. Relevant sections of the Code are as follows:

"If the United States Trade representative determines under section 2414(a)(1) of this title that an act, policy, or practice of a foreign country is unjustifiable and burdens or restricts United States commerce, the Trade Representative shall take action authorized in subsection (c) of this section, subject to the specific direction, if any, of the President regarding any such action …" 19 USC, Sec. 2411(d)(3)(A).

"An act, policy or practice is unreasonable if the act, policy or practice, while *not necessarily in violation of, or inconsistent with,* the international legal rights of the United States, is otherwise unfair and inequitable." 19 USC, Sec. 2411(d)(3)(A).

"Acts, policies, and practices that are unreasonable include, but are not limited to, any act, policies, or practices, or any combination of acts, policies, or practices, which denies fair and equitable provision of adequate and effective protection of intellectual property rights *notwithstanding the fact that the foreign country may be in compliance with the specific obligations of the Agreement on Trade-Related Aspects of Intellectual Property Rights*." 19 USC, Sec. 2411(d)(3)(B)(II).

(accessed April 23, 2003); available from http://www4.law.cornell.edu/19/2411.html

[214] Henry Shue, *Basic Rights* (Princeton: Princeton University Press, 1982)

[215] Ibid, 14.

partnerships does indeed provide the good (the medicines), but does not provide any social guarantee for its distribution; according to Shue's analysis, these strategic partnerships are therefore not sufficient to promote the human right to health. In this paper, and with reference to the three-part definition of the human right to health (see Chapter I), these partnerships allow states to fulfill the third part of the definition, without addressing the first two parts.

3. Institutional options?

a. Observer status for international human rights bodies at the WTO

Although free trade does have a positive impact on economic growth and a role to play in poverty reduction, and therefore can contribute to the enjoyment of the human right to health, WTO Agreements have also proved to hinder states' capacity to fulfill their human right obligation to promote health, especially in developing countries. Where the influence of lobbies is less sensitive, as in the implementation and interpretation of the GATT and of the SPS Agreement, the decision was left to the dispute settlement body to interpret WTO law in a manner consistent with the right to health and states' human rights obligations. However, where the influence of corporate interest groups has been most important, as in the drafting and implementation of the TRIPS Agreement, the results have been dramatic, and some states, because of the re-allocation of resources or of their economic incapacity to ensure access to health care, have become violators of their human rights obligations, a situation that could presumably be worsened with the implementation of "TRIPS Plus" agreements.[216] In

[216] "TRIPS Plus" agreements refer to multilateral and/or bilateral agreements that require much stronger intellectual property rights requirements than those required by the TRIPS Agreement. For reference, please see GRAIN, *"'TRIPS Plus' Through the Back Door* (accessed April 7, 2004); available

order to ensure that WTO law will, at a minimum, not prevent states from fulfilling their human rights obligations, it is essential for the WTO to cooperate with human rights bodies. The Committee on Economic, Social and Cultural Rights, in December 2001, invited such cooperation. However, without the political will of WTO members, this invitation has not been taken upon yet.

A possible way to collaborate would be for the WTO to grant observer status to human rights bodies, such as the Committee on Economic, Social and Cultural Rights, in accordance with Art. V of the WTO Charter -- such procedure, however, requires the political will of WTO members, which may be obtained by pressure from public opinion, the NGO community and/or international human rights bodies. One way of obtaining the political will would be for NGOs to increase pressure on WTO members. If no observer status is accorded, another possibility would be to establish a Committee on Trade and Human Rights, or Trade and the Right to Health, within the WTO, in much the same way as the Committee on Trade and the Environment was established in 1994. The parameters used to determine the mandate of this Committee were, first and foremost, the acknowledgement that "the WTO is not an environmental protection agency,"[217] therefore the Committee could only examine the potential effect of trade on the environment, and vice versa. The result has been that, according to WTO data, no measure taken under an environmental agreement that affects trade has been challenged in the WTO.[218] Collaboration between the WTO, environmental agencies and other non-

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from http://www.grain.org/docs/trips-plus-en.pdf. Oxfam America, *TRIPS Plus Provisions* (accessed April 7, 2004); available from http://www.oxfamamerica.org/advocacy/art5391.html.

[217] WTO, *Parameters Guiding the Work of the Committee on Trade and Environment* (accessed April 7, 2003); available from http://www.wto.org/english/tratop_e/envir_e/guiding_e.htm

[218] Ibid.

state actors has therefore been successful, and could be taken as an example by human rights bodies.

b. Explaining the current failure to collaborate

It is also necessary to find the reasons why such collaboration between human rights bodies and the WTO have failed with regard to the right to health. One explanation may be the political pressure from NGOs and human rights bodies, a pressure which is actually a "double-edged sword." Indeed, concern may grow within the WTO over the effect of such collaboration over the day-to-day functioning of the organization and its ability to promote free trade, especially in light of the attacks on the WTO. For instance, in 2000, the WTO reacted strongly to reports of the Special Rapporteur to the Sub-Commission on Human Rights on the impact of the WTO on human rights; a relevant passage of the report stated that "for certain sectors of humanity, particularly the developing countries of the South, the WTO is a veritable nightmare."[219] Whereas an aggressive approach may have been necessary to put the respect for the right to health and other human rights on the WTO's agenda, a strategic collaborative approach may be now required in order to entice collaboration from the WTO. Such collaboration is an absolute requirement for ensuring that the WTO does take into account the positive and, more importantly, the negative impact WTO law may have on human rights, in this specific case on the human right to health. Indeed, whereas, at the micro-level, a compartmental approach to the various areas of international law may be necessary and more efficient, no international agreement functions in a vacuum, and there are, at the

[219] UN Secretariat, Economic and Social Council, Sub-Commission on the Promotion and Protection of Human Rights, *Globalization and Its Impact on the Full Enjoyment of Rights: Preliminary report submitted by J. Oloka-Onyango and Deepika Udagama, in accordance with Sub-Commission resolution 1999/8*, E/CN.4/Sub.2/2000/13, 2000, Para.13. Accessed April 7, 2004. Available from http://www.unhchr.ch/huridocda/huridoca.nsf/Documents?OpenFrameset

macro-level, overlaps between agreements. Should collaboration not happen, these overlaps will fail to be addressed, and the international legal system as a whole would be unsustainable and further weakened and destabilized.

Further, whereas collaboration between the WTO and human rights bodies to protect the right to health is necessary, some developing countries may be wary of the influence of human rights bodies in areas other than health. Indeed, for violators of human rights treaties, particularly in the area of labor standards, the collaboration between both bodies may result in the use of trade incentives or sanctions to promote and protect human rights among WTO members. Such effect has already been visible with the conditions for granting "Generalized System of Preference" status to developing countries, a pro bono practice permissible under Art. XVIII of the GATT.[220]

In light of the fruitful collaboration between the WTO and other international organizations, including the WHO,[221] the International Labor Organization (ILO)[222] or the United Nations Environment Programme (UNEP),[223] it is therefore possible for human rights bodies to cooperate with the WTO so as to ensure that WTO law will not threaten the right to health, and be an additional obstacle to the enjoyment of this right by individuals, especially in the less-developed countries. For this, the scope of this collaboration will need to be clearly defined to respect the organization's mandate, so as

[220] The Generalized System of Preference is a voluntary program by which developed countries may grant preferential trade concessions to developing countries without reciprocity, in order to assist those countries in their efforts to develop through free trade.

[221] WHO and WTO, *WTO Agreements and Public Health: a Joint Study by the WHO and the WTO Secretariat*.

[222] WTO, *Trade and Labour Standards, Subject to an Intense Debate*.

[223] WTO, *Elements of Cooperation Between the WTO and UNEP* (accessed April 14, 2004); available from http://www.wto.org/english/news_e/pres99_e/pr154_e.htm

to convince the WTO and developing countries that international trade law will not become an international enforcement mechanism to ensure the human right to health.

CONCLUSION

The World Trade Organization was established for the sole purpose of promoting freer trade among its members, however, it does have socio-economic aspirations, as its preamble confirms. WTO law was drafted in such a way that it provides options for states to pursue free trade while protecting the human right to health. However, the application and interpretation of these same provisions has been more problematic, especially in those areas where lobbies are the most active and powerful, with the effect that WTO members which are parties to the relevant human rights conventions have seen their efforts to respect, protect and fulfill their obligations vis-à-vis the right to health undercut by trade regulations. When, mostly in the cases of developing and least-developed countries, states have been obliged to re-allocate their resources to comply with WTO law, they have sometimes become violators of their human rights obligation to protect the right to health. It is therefore essential, in order for those states that are members of the WTO and parties to the international human rights instruments that guarantee the right to health to be able to fulfill their obligations in both regimes, formally to recognize the right to health as, at a minimum, an "interpretive principle" of WTO law. This goes beyond the customary rules of interpretation of international law, as codified in the Vienna Convention on the Law of Treaties, which requires that international treaties shall be interpreted in accordance with their object and purpose. However, it has been successfully done in GATT and SPS cases by the WTO dispute settlement body. It is all the more important to formalize and institutionalize this principle, as the actions of private actors and some governments have proved detrimental to the right to health, with, most recently, the implementation of "TRIPS Plus"

agreements. The confrontational approach taken by both the NGO community and international human rights bodies has proved efficient in putting the nexus between WTO law and the right to health on the WTO's agenda. However, such approach has also probably been the reason for the denial of observer status to, *inter alia*, the Committee on Economic, Social and Cultural Rights, or the UN High Commissioner for Human Rights. Such collaboration, in addition to be possible, is essential to ensure that WTO law will, at a minimum, respect the human right to health. Cooperation between the WTO and non-trade intergovernmental organizations has already proved successful, most specifically in the area of the environment. It is urgent for the human rights community, including NGOs and intergovernmental organizations, to stop condemning the WTO, and instead use its regime and cooperate with the organization in an effort both to protect the right to health among its members and to assist in their economic development.