Establishing Coherence:
The Right to Access to Medicines, Pharmaceutical Patents and the WTO Medicines Decision

by

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I. Introduction

"It is a well-known paradox of globalization that while it has led to increasing uniformization of social life around the world, it has also led to its increasing fragmentation - that is, to the emergence of specialized and relatively autonomous spheres of social action and structure. The fragmentation of the international social world has attained legal significance as it has been accompanied by the emergence of specialized and (relatively) autonomous rules or rule-complexes, legal institutions and spheres of legal practice."[1]

The era of globalization has had a fundamental impact on international relations and international law. From 1970 through 1997, the number of international treaties more than tripled[2]. This has lead to a situation where States are increasingly bound to treaties that may appear to include conflicting norms, *i.e.* a situation where adherence to one provision may lead to the violation of another. How to govern this fragmentation of international law is a challenge. The relationship between the right to access to medicines and protection of pharmaceutical patents is a current example of this ambitious task.[3]

The Agreement on Trade-Related Aspects of Intellectual Property Rights ("the TRIPS Agreement") created a global patent system that can be enforced, when necessary, through the World Trade Organization ("WTO") and its dispute settlement mechanism. Article 27 of the agreement stipulates that patents must be available also for pharmaceutical products and processes on a non-discriminatory basis.[4] Simultaneously, however, most WTO Members have other kinds of obligations that are arguably of more fundamental character – namely, human rights obligations. The right to health covered *e.g.* by Article 12 of the International Covenant on Economic, Social and Cultural Rights ("the ICESCR") concluded in 1966 obligates

[1] Koskenniemi 2006, paras. 7–8.

[2] Alvarez 2002, p. 216.

[3] For an in-depth research on the relationship between global patent protection and the right to access to medicines in international law, see Hestermeyer 2007.

[4] Article 27(1) of the TRIPS Agreement: "Subject to the provisions of paragraphs 2 and 3, patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application. [...] patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced."

contracting states to ensure access to affordable medicines.[5] The ICESCR has 160 Parties; over 80 percent of the Members of the WTO are simultaneously bound by both agreements.[6] The conflict between the TRIPS Agreement and the right to access to medicines has inspired a wealth of literature: while access to affordable medicines forms an integral part of the right to health, pharmaceutical patents tend to increase the prices of pharmaceuticals and may, thus, hinder access to medicines in developing countries.

The current health crisis related to HIV/AIDS and other epidemics in developing countries has highlighted the gap between the haves of industrialized countries and the have-nots of developing countries: approximately 90 percent of deaths due to infectious diseases occur in developing countries that represent 10 percent of the global pharmaceuticals market[7]. Human rights advocates have been calling for the supremacy of the right to access to medicines in relation to pharmaceutical patents. However, the fact is that the TRIPS obligations are more precisely formulated and backed up by an efficient dispute settlement mechanism, whereas the ICESCR and other agreements on human rights are drafted in broader terms and lack efficient enforcement systems.[8] Similarly, the right to access to medicines as a norm of customary international law seems to have no practical significance in trade negotiations.[9] Yet, at a time

[5] Article 12 of the ICESCR:"1. The States Parties to the present Covenant recognize the right of everyone to the enjoyment of the highest attainable standard of physical and mental health. 2. The Steps to be taken by the States Parties to the present Covenant to achieve the full realization of this right shall include those necessary for: (a) The provision for the reduction of the stillbirth-rate and of infant mortality and for the healthy development of the child; (b) The improvement of all aspects of environmental and industrial hygiene; (c) The prevention, treatment and control of epidemic, endemic, occupational and other diseases; (d) The creation of conditions which would assure to all medical service and medical attention in the event of sickness." Access to medicines is not mentioned in the ICESCR as an independent right. It is yet a critical component of the right to health both as a means of prevention, treatment and control of epidemic and endemic diseases and as a part of medical attention in the event of any kind of sickness. See Yamin 2004, p. 112.

[6] Hestermeyer 2007, p. 102; A list of Parties and signatories is available at http://treaties.un.org/Pages/ViewDetails.aspx?src=TREATY&mtdsg_no=IV-3&chapter=4&lang=en (last visited 26.3.2010). States have binding health-related obligations also through myriad other global and regional human rights instruments. See *e.g.* Article 12 of the Convention on the Elimination of All Forms of Discrimination Against Women, Article 24 of the Convention on the Rights of the Child, Article 5 of the International Convention on the Elimination of All Forms of Racial Discrimination, Article 16 of the African Charter on Human's and People's Rights ("Banjul Charter"), Article 11 of the European Social Charter, Article XI of the American Declaration on the Rights and Duties of Man and Article 10 of the subsequent Additional Protocol to the American Convention on Matters of Economic, Social and Cultural Rights ("Protocol of San Salvador"). In addition, access to medicines can be invoked in favour of various other human rights, such as the right to life (Article 6 of the International Covenant on Civil and Political Rights, "ICCPR"), rights to an adequate standard of living to social security, to education and to work, the right to benefits of scientific progress (Articles 6, 9, 13 and 15 of the ICESCR). Bearing in mind the indivisibility and interdependence of human rights, there is yet no need to further explain the significance of the right to health in relation to other human rights.

[7] World Health Assembly (resolution WHA56.27): *Intellectual property rights, innovation and public health* (2003), preamble, para. 3.

[8] Cullet 2006, p. 195.

[9] For an analysis of the right to access to medicines as a customary norm, see Hestermeyer 2007 p. 122 ff.

when approximately 17,6 million people in low- and middle-income countries die each year from communicable diseases and maternal and neonatal conditions[10] – the occurrence of which is far lower in developed countries – individuals in need of medicines should not be exposed to any additional burdens. Thus, the issue is how to strike a balance between global intellectual property protection and universal access to medicines – a task that literally turns into a life-and-death question with respect to pharmaceutical patents in developing countries.

The negative impact of pharmaceutical patents on access to medicines in developing countries was one of the central issues during the WTO Doha round. The well-known cases of South-Africa[11] and Brazil[12] generated a strong reaction from non-governmental organizations and international human rights organs that have been calling for exceptions to pharmaceutical patents on a public health basis as part of the reforms that should take place in the WTO context.[13] As the Sub-Commission on the Promotion and Protection of Human Rights put it,

> *"[...] since the implementation of the TRIPS Agreement does not adequately reflect the fundamental nature and indivisibility of all human rights, including [...] the right to health, there are apparent conflicts between the intellectual property rights regime embodied in the TRIPS Agreement, on the one hand, and international human rights law, on the other"*[14].

Faced with immense public pressure and obscurities related to the implementation of the agreement, WTO Members managed to adopt the *Declaration on the TRIPS Agreement and Public Health* at the 4th Ministerial Conference held in Doha in November 2001 ("the Doha Declaration"). In the declaration, WTO Members agree that the TRIPS Agreement does and should not prevent WTO Members from taking measures to protect public health[15]. The need to extend the deadline for least-developed country Members to apply provisions on pharmaceutical patents was recognized and the transitional periods have since been extended to

[10] Dutfield 2008, p. 107.

[11] For an overview of the case of South-Africa, see Nagan 2002.

[12] For an overview of the case of Brazil, see Lazzarini 2003.

[13] See *e.g.* Subcommission on the Promotion and Protection of Human Rights (resolution 2000/7): *Intellectual property rights and human rights*; Commission on Human Rights (resolution 2001/33): *Access to Medication in the context of pandemics such as HIV/AIDS*; World Health Assembly (resolution 28 May 2003): *Intellectual Property Rights, innovation and public health*; Oxfam: Oxfam Briefing Paper 4 (2001): *Priced out of reach – How WTO policies will reduce access to medicines in the developing world.*

[14] Subcommission on the Promotion and Protection of Human Rights (resolution 2000/7): *Intellectual property rights and human rights*, para. 2.

[15] Doha Declaration, para. 4.

January 2016[16]. Most importantly, the TRIPS Council was called upon to find a solution to the problem that many WTO Members lack the capacity to effectively utilize the exceptions to patent rights authorized by the TRIPS Agreement[17].

The adoption of the Doha Declaration thus launched a set of negotiations with the purpose of ensuring the ability of developing countries to use patented medicines in consistency with the TRIPS Agreement. In September 2003, after long negotiations and intensive politics, the General Council of the WTO adopted the *Decision on implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health* ("Medicines Decision"). The decision waives (*i.e.* temporarily suspends) certain obligations set out in Article 31 of the TRIPS Agreement. The provision concerns the use of patents without permission of the patent holder, a practice most often referred to as compulsory licensing. A WTO waiver means that a WTO Member will not initiate a complaint against another WTO Member, if the latter acts in accordance with the terms of the adopted waiver[18]. In December 2005, the General Council of the WTO adopted a decision to amend the TRIPS Agreement to make the Medicines Decision a permanent part of it[19]. This is done by inserting Article 31*bis*, which corresponds with the content of the Medicines Decision, to the TRIPS Agreement. The protocol amending the agreement was initially open for acceptance until the 1st of December 2007; the deadline was subsequently extended to the 31st of December 2009[20]. Meanwhile, the Medicines Decision applies to all WTO Members. The three texts, the TRIPS Agreement, the Doha Declaration and the Medicines Decision, now provide the main legal framework regulating the use of compulsory licenses as a public health safeguard protecting developing countries against the possible negative effects of pharmaceutical patents on access to medicines.

The conflict sketched out above, between pharmaceutical patents supported by the TRIPS Agreement and access to medicines as part of the human right to health, is an excellent example of fragmentation of international law – a situation where States are bound by obligations under different specialized systems that each establish their own principles and

[16] Ibid., paras. 6 and 7; Council for TRIPS: *Decision on the Extension of the Transition Period under Article 66.1 of the TRIPS Agreement for Least-developed Country Members for Certain Obligations with Respect to Pharmaceutical Products* (1 July 2002) and WTO General Council: *Decision on Least-developed Country Members – Obligations Under Article 70.9 of the TRIPS Agreement with Respect to Pharmaceutical Products* (12 July 2002). It should be noted, however, that some least-developed countries have nevertheless chosen to enforce patent systems despite the transitional periods they have been granted (Oh 2006, p. 30).

[17] Doha Declaration, para. 6.

[18] See also Article 56 of the Vienna Convention of the Law of Treaties.

[19] WTO General Council: *Amendment of the TRIPS Agreement* (8 December 2005).

[20] WTO General Council: *Amendment of the TRIPS Agreement – Extension of the period for the acceptance by members of the protocol amending the TRIPS Agreement* (21 December 2007). In order to replace the waiver, the amendment has to be formally accepted by two thirds of WTO Members in accordance with paragraph 3 of Article X of the Marrakesh Agreement.

institutions. Assessment of the phenomenon varies. Authors calling for coherence of international law have stated that the so-called sub-regimes or sub-systems of modern international law, such as WTO law and human rights law, must not be considered separate and self-contained regimes, as this kind of assumption would nullify the significance of general international law. Accordingly, even though a State can in theory contract out of all rules of international law, it cannot do that with respect to the system of international law, the maintenance of which requires a prohibition against the creation of sub-systems completely delinked from the rules of international law agreed upon elsewhere[21]. Others have given up on searching for unity and are calling for "weak compatibility between the fragments" of international law[22]. Institutional fragmentation is considered a natural expression of political plurality in a world where it is doubted that any legal unity existed in the first place. Having rejected the idea of any "abstract consistency", the proponents of this view believe that each special regime will continue speaking its own professional language and "seeks to translate that into a global Esperanto", while no overall solutions are available as to which system of law should be preferred in a particular situation[23].

The point of departure of this article is that no international regime can choose to exist in a legal vacuum – instead, all norms of international law can interact with each other. Similarly, international intellectual property regulation is applied in a context where the right to health is a well-established human right, codified in several human rights instruments. The feasibility of exclusive rights introduced by the TRIPS Agreement must, however, also be ensured as an important part of economic relations between WTO Members. The issue, therefore, is how to maintain coherence between the sets of norms examined. In the following, I will first examine the obligations imposed by the right to access to medicines and its relationship to and position in the TRIPS regime, in order to elucidate *why* these norms should be efficiently reconciled. I will continue by examining the content of the Medicines Decision – the amendment that was supposed to harmonize the TRIPS Agreement with the right to access to medicines – in order to provide a practical answer to the question of *how* to ensure that pharmaceutical patents do not hinder access to medicines in developing countries.

[21] Pauwelyn 2003, p. 9–10, 37–38.

[22] Fischer-Lescano and Teubner 2004, p. 1046. The authors present (p. 1024–1034) that with respect to pharmaceutical patents and the amendments made within the WTO, the organization managed to create an internal limitation on its own logic through the reformulation of a principle of health protection – an act that the authors describe as the internal achievement of the regime that allowed it to maintain its autonomy over conflicting regimes and laws.

[23] Koskenniemi & Leino 2002, p. 557, 578.

II. An Illusion of Incoherence?

2.1. The Right to Access to Medicines And the TRIPS Agreement

The obligations imposed by the right to access to medicines as part of the human right to health, and their position with respect to TRIPS obligations, can be approached by the well-known tripartite analysis of human rights: the obligations to respect, protect and fulfill. *The obligation to respect* is the negative dimension of the right to access to medicines, which requires States to refrain from interfering directly or indirectly with the enjoyment of the right.[24] This obligation is closely connected to the prohibition of retrogressive measures.[25] States must refrain from adopting legislation or policies that interfere with the enjoyment of any of the components of the right to health. They must thus take into account legal obligations regarding also the right to access to medicines, when entering into bilateral or multilateral agreements with other States, international organizations and other entities, such as multinational corporations.[26]

The introduction of pharmaceutical patents that have a price-increasing effect can constitute a violation of the obligation to respect the right to health if the regulation in question hinders access to medicines by increasing prices. It should be noted, however, that in accordance with the Doha Declaration, the TRIPS Agreement "shall be read in the light of the object and purpose of the Agreement as expressed, in particular, in its objectives and principles".[27] Pursuant to Article 7 of the TRIPS Agreement, the object of the agreement is to promote technological innovation "in a manner conducive to social and economic welfare, and to balance of rights and obligations". The provision is based on a proposal submitted by developing countries during the negotiations of the TRIPS Agreement and it represents a compromise between the global intellectual property protection, on the one hand, and the need to secure access technology in the South, on the other. It can well be used to legitimize exceptions to exclusive rights in order to strike a balance between the private and the public

[24] Dowell-Jones 2004, p. 29; ESCR Committee, General Comment 14, para. 33.

[25] ESCR Committee, General Comment 14, para. 32 (stating that if such measures are taken, "the State party has the burden of proving that they have been introduced after the most careful consideration of all alternatives and that they are duly justified by reference to the totality of the rights provided for in the Covenant in the context of the full use of the State party's maximum available resources").

[26] ESCR Committee, General Comment 14, para. 50. The UN Commission on Human Rights also called States to "refrain from taking measures which would deny or limit equal access for all persons to preventive, curative or palliative pharmaceuticals or medical technologies used to treat pandemics such as HIV/AIDS or the most common opportunistic infections that accompany them" in its resolution 2002/32 *Access to Medication in the Context of Pandemics such as HIV/AIDS* (para. 3[a]).

[27] Doha Declaration, para. 5(a). Similarly, in *The United States – Standards for Reformulated and Conventional Gasoline*, the Appellate Body stated (ch. 13) that if applying Article 31(1) of the VCLT (which refers to the object and purpose of a treaty) provides the answer, it does not need to apply other rules of international law.

interest.[28] Article 8 of the TRIPS Agreement ("Principles"), in turn, explicitly grants all WTO Members a right to adopt policies that promote public health as long as they are consistent with the agreement.[29] In addition to the significance of the provision in the interpretation of the TRIPS Agreement, it also means that a WTO Member challenging a measure adopted by another Member in pursuance of public policy objectives should have the initial burden of proof regarding inconsistency with the TRIPS Agreement. The claimant should also be conscious of the fact that if there ever were doubts that the requirement of consistency with the agreement could override public health measures, these doubts would have been removed by the Doha Declaration.[30]

Articles 7 and 8 of the TRIPS Agreement are of profound significance in the interpretation and implementation of the rights and obligations under the agreement.[31] Even though they do not give WTO Members an unlimited amount of room for exceptions to pharmaceutical patents, they nevertheless imply that TRIPS norms have not been meant to over-run the pre-existing human rights obligations of WTO Members.[32] The TRIPS Agreement should therefore be interpreted in a manner that does not constitute a retrogressive measure in relation to access to medicines. Simultaneously, one must bear in mind that pharmaceutical patents can also enhance the realization of certain important aspects of the right to health: namely, availability and quality of medicines[33].

Pharmaceutical patents contribute to the research and development of new medicines by making this profitable through an arrangement in which the inventor discloses and publicizes his invention to the society in exchange for the exclusive right granted by the State to exploit the invention for a fixed period of time. Patents are thus needed for sustainable availability of effective medicines. Similarly, the right to health requires health facilities, goods and services to be scientifically and medically appropriate and of good quality. This requires, *inter alia*, scientifically approved and unexpired medicines.[34] To this end, new medicines must undergo

[28] Correa 2007, p. 91–92, 103.

[29] Article 8(1) of the TRIPS Agreement: "Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement."

[30] Correa 2007, p. 108.

[31] Ibid., p. 92.

[32] Frankel has stated that the significance of the articles should not be exaggerated. She refers to the *Canada – Patent Protection of Pharmaceutical Products*, where the respondent invoked Article 8 in favor of its policies by claiming that said article supported liberal interpretation of permissible exceptions to patent rights. The panel, however, stated that the interpretation of the relevant articles must be a case-by-case factual analysis that does not equal to renegotiation of the basic balance of the agreement (Frankel 2006, p. 20–21).

[33] See ESCR Committee, General Comment 14, para. 12.

[34] Ibid., para. 12(d).

extensive clinical trials and other tests that demonstrate their efficacy and safety before the medicines are granted marketing authorizations. Many developing countries do not require this kind of data but approve a drug on the basis that it has been approved by a reliable authority in an industrialized country.[35] These clinical trials represent the lion's share of the research and development costs of new medicines: it has been estimated that the total average cost of developing a medicine is approximately USD 802 million, of which approximately USD 467 million represent clinical trial expenditures.[36] These expenditures are partly covered by the revenues pharmaceutical companies receive by selling their patented medicinal products. To summarize, instead of considering pharmaceutical patents as a mere hindrance to access to medicines, it should be remembered that a patent system is also conducive to the right to health.

The obligation to protect implies the "horizontal effectiveness" of the right to access to medicines, often known as the *Drittwirkung* of a right. This means that States must take all necessary measures to safeguard persons in their jurisdiction from infringements of the right by third parties – if a State is not in a position to realize the right itself, it must regulate private acts in order to ensure that individuals are not arbitrarily deprived of the enjoyment of their rights by other individuals.[37] The obligation to protect includes, *inter alia*, the duties of States to adopt legislation or to take other measures ensuring equal access to health care services provided by third parties and to ensure that privatization of the health sector does not constitute a threat to the availability and accessibility of medicines. Such omissions, as the failure to regulate the activities of individuals, groups and corporations so as to prevent them from violating the right to health, constitute a violation of the obligation to protect.[38]

Article 8 of the TRIPS Agreement allows WTO Members to take necessary measures in order to protect public health. The provision can be considered a policy statement that explains the rationale for measures taken under Articles 30 and 31 of the TRIPS Agreement that authorize exceptions to exclusive rights.[39] Article 30 allows exceptions to exclusive rights as long as they are kept limited, they do not unreasonably conflict with the normal exploitation of the patent and they do not unreasonably prejudice the legitimate interests of the patent owner.[40] In relation to pharmaceutical patents and access to medicines, exceptions of paramount nature

[35] Dutfield 2008, p. 117.

[36] DiMasi, Hansen & Grabowski 2003, p. 165–167.

[37] Craven 1995, p. 111–112.

[38] ESCR Committee, General Comment 14, paras. 35 and 51. See also *Human Rights Guidelines for Pharmaceutical Companies in relation to Access to Medicines* drafted by the UN Special Rapporteur on the right to the highest attainable standard of health. Even though the guidelines are of non-binding character, they can be used as a guideline in order to specify the content of the obligation to protect.

[39] Gervais 2003, p. 121.

[40] Gervais 2003, p. 243–244; see also WTO Panel Report *Canada – Patent Protection of Pharmaceutical Products*, 17 March 2000.

allowed by the provision are 1) the use of an invention before the expiration of the patent in order to commercialize a generic version of the product immediately after the expiration of the patent (the so-called Bolar exception) and 2) parallel imports.[41] Article 31 of the TRIPS Agreement, in turn, allows for "other use without authorization of the right holder". Compulsory licenses referred to in this article can be granted in accordance with the conditions set forth in the provision *e.g.* in cases of national emergency.[42] Regardless of the fact that certain grounds are specifically referred to in the article, WTO Members can also determine other grounds for making exceptions to patent rights. Similarly, compulsory licenses can be conferred to import or to produce a patented product locally.[43] The conditions regarding the practice and their deficiencies that were addressed by the Medicines Decision are examined more closely below. However, taking into consideration the above mentioned provisions, it can be concluded that the TRIPS Agreement does not entail any legal impediments to States protecting the right to access to medicines. On the contrary, implementing any of the named practices is a question of political will. WTO Members can thus meet their obligation to protect access to medicines despite their obligation to grant patent protection to pharmaceutical products.

The obligation to fulfill requires States to, *inter alia*, "give sufficient recognition to the right to health in national political and legal systems, preferably by way of legislative implementation" and to ensure provision of health care for all.[44] States should actively implement policies and programs that enable individuals to enjoy access to underlying determinants of health where this has not been forthcoming through implementation of the previous two duties. The obligation to fulfill thus seems to remain a "catch-all" category the obligations of which require

[41] Based on current comparative law and other proposals made on the subject, Correa has defined the following additional exceptions: acts done privately and on a non-commercial scale and for non-commercial purpose; using the invention for research and experimentation and for teaching purposes; preparation of medicines for individual cases according to a prescription, and use of the invention by a third party who started – or undertook *bona fide* preparatory acts – before the application for the patent or its publication (Correa 2007, p. 303).

[42] Additional grounds specifically mentioned in Article 31 are a refusal by the patentee to voluntarily license its patent, the use of compulsory licenses to remedy anti-competitive practices or for public non-commercial use, such as educational intentions, or for dependent patents (Article 31[b], [c], [l]).

[43] Correa 1998, p. 210, 214. Sean Flynn has proposed developing countries to employ "access gap theory" for exploring when a patent holder is abusing its dominant position in the relevant market in a manner that justifies the issuance of compulsory licenses. Under this theory, a presumption on the existence of the preconditions for the issuance of compulsory licenses is present when there is a lack of access in society to a patented medicine needed to address an important public health problem and this deficiency is at least partly due to its significantly higher pricing when compared to a situation in a competitive market with reasonable royalties paid to the patent holder. Where these factors are present, the burden should be on the patentee to prove that it has promoted the lowest price possible consistent with receiving due reward for use of its invention *e.g.* by opening a licensing program that issues licenses at reasonable royalties to any potential competitor. This kind of policy converts the patent right from an exclusive property right (right to exclude) to a right to be paid in the specific situation where competition is needed to increase access to medicines (Flynn 2003, p. 538–539).

[44] ESCR Committee, General Comment 14, para. 39.

the mainstreaming of the right nationally on *e.g.* economic level.[45] With respect to the right to access to medicines, the obligation to fulfill requires States to take positive measures in order to foster research into health-related areas.[46] This can be considered as, *inter alia*, requiring States to subsidize research and development of new medicines.

Statistics indicate the unfortunate fact that medicines are currently developed only for diseases prevalent in developed countries, where their sales are most profitable. Less than 1 percent of the nearly 1400 medicines that were registered between 1975 and 1999 were for the treatment of tropical diseases that mainly occur in the southern hemisphere[47]. It is often pointed out that developing countries seem to benefit from research and development today mainly when the rich also suffer from the same diseases[48]. As noted by Sell, "market mechanisms to deliver innovation into the public domain fail spectacularly in the oligopolistic markets of the contemporary life sciences industries"[49]. However, the failure is not one of patents as such. In an economic sense, it is perfectly rational – whether or not admirable – to prioritize research in ways that generate most revenues. Thus, other ways than giving up on patent protection must be found that make up for the market failure, *i.e.* ways that make research and development of medicines needed for the treatment of "neglected tropical diseases"[50] economically feasible. Government subsidies are one alternative that can surely be considered as being consistent with the obligation to fulfill.

Finally, human rights obligations of third States must also be considered. All Members of the United Nations have pledged themselves to take both joint and separate action in cooperation with the organization for the solutions of international economic, social, health, and related

[45] Dowell-Jones 2004, p. 31–33.

[46] ESCR Committee, General Comment 14, para. 37.

[47] WHO: 10 facts on neglected tropical diseases (17 April 2007). In order to give a concrete example, it should be mentioned that while 95 percent of active TB cases occur in developing countries, no new medicines has been developed since 1967 (Dutfield 2008, p. 112–113).

[48] Commission on intellectual property rights, innovation and public health 2006, p. 77.

[49] Sell 2007, p. 43.

[50] Neglected tropical diseases ("NTDs") refer to diseases that affect circa 1 billion people (*i.e.* one out of six) in developing countries. Preventing, eliminating and eradicating these diseases is largely neglected due to the fact that they persist exclusively in the poorest populations of the world (WHO: 10 facts on neglected tropical diseases [17 April 2007]).

problems.[51] The Limburg Principles on the Implementation of the ICESCR note that "international co-operation and assistance pursuant to the Charter of the United Nations and the Covenant shall have in view as a matter of priority the realization of all human rights and fundamental freedoms, economic, social and cultural as well as civil and political".[52] The principle of international cooperation has been incorporated also to the ICESCR. Pursuant to Article 2(1) of the ICESCR, each Contracting State "undertakes to take steps, individually and through international assistance and co-operation, especially economic and technical, to the maximum of its available resources" in order to progressively realize all the rights included in the Covenant. The significance of the phrase has two diverging interpretations. On the one hand, it has been said to give rise to quite specific international obligations on the part of industrialized countries and to provide the foundations for the existence of a right to development. On the other hand, no legally binding obligation to provide aid to foreign countries has been read to the phrase.[53]

Yet, the UN Committee on Economic, Social and Cultural Rights ("ESCR Committee") formulates specific obligations for third States in relation to the right to health.[54] Accordingly, Contracting States must, *inter alia*, respect the enjoyment of the right to health in other countries and prevent third parties from violating the right to health in these countries, if they are able to influence them by way of legal or political means. They should also facilitate access to essential health goods in third countries when possible and provide needed aid. With respect to the conclusion of other international agreements, Contracting States should ensure that these instruments do not adversely impact upon the right to health and ensure that their actions as Members of international organizations take due account of the right to health.[55] These obligations can easily be applied also to the TRIPS Agreement. When examining the implementation of the Medicines Decision, it will become clear that access to patented medicines in the South can only be ensured if also industrialized countries implement the Medicines Decision appropriately. If the aim is to ensure that pharmaceutical patents do not hinder access to medicines, the above presented obligations of States to respect, protect and fulfill the right to access to medicines of their own citizens must be considered to constitute

[51]See Articles 55 and 56 of the Charter of the United Nations. See also Article 3 of the Declaration on the Right to Development: "1. States have the primary responsibility for the creation of national and international conditions favorable to the realization of the right to development; 2. The realization of the right to development requires full respect for the principles of international law concerning friendly relations and co-operation among States in accordance with the Charter of the United Nations; 3. States have the duty to co-operate with each other in ensuring development and eliminating obstacles to development. States should realize their rights and fulfill their duties in such a manner as to promote a new international economic order based on sovereign equality, interdependence, mutual interest and co-operation among all States, as well as to encourage the observance and realization of human rights. "

[52] The Limburg Principles, principle no. 29.

[53] Alston & Quinn 1987, p. 187.

[54] ESCR Committee, General Comment 14, para. 39.

[55] ESCR Committee, General Comment 14, para. 39.

only one side of the coin, while efficient assistance from industrialized countries forms the other. Assuming this kind of joint responsibility is in line with the fact that decisions that may have a reverse impact on the lives of millions are also made jointly in an international setting, *e.g.* in inter-state trade negotiations.

2.2. The Myth of a Self-Contained Regime

As pointed out above, the relationship between the obligations arising from the right to access to medicines and the TRIPS norms may not be as complex as it is often claimed to be – permissive norms corresponding to the obligations WTO Members have based on the access norm can, to some extent, be found in the TRIPS Agreement. Since the right to access to medicines is binding on all WTO Members as a well-established human rights norm, and since all States are expected to meet their obligations in good faith, it may *prima facie* seem difficult to find a strong legal justification for claims concerning the existence of conflict between these sets of norms. However, nothing in the TRIPS Agreement directly commands WTO Members to interpret TRIPS norms in consistency with the access norm. If the TRIPS regime, as part of the WTO, would constitute a "self-contained" regime, its norms could be interpreted solely from the perspective of trade and thus human rights could be ignored. In order to construe a legal justification for why TRIPS norms, that grant exclusive rights to medicinal compounds and products, should be interpreted harmoniously with the access to medicines norm, one has to examine the relationship between WTO law and public international law, the latter referring to the aggregate of norms regulating relationships between States.

A wealth of discussion exists over the applicability of public international law within the world trading system. The current opinion is spread across three main views, endorsing full, partial or no applicability of international law to trade disputes. Those who see the WTO as a closed legal system hold that as the jurisdiction and substantive mandate of WTO panels and the Appellate Body are strictly limited to claims under WTO governed agreements, only internal regulation of the organization should apply to the dispute resolution. Proponents of partial applicability of international law are willing to give WTO law a privileged status in relation to rules of public international law. They claim that the covered agreements should prevail against any attempt to introduce new rights or duties on behalf of other international rules. These privileged or autonomous positions nevertheless find little basis in the texts of the actual agreements and are not supported by the recent case law either.[56] In fact, the Appellate Body itself has stated that the WTO Agreement "is not to be read in clinical isolation from public international law".[57] It is undisputable that the mandate of WTO panels is to interpret WTO law and to determine

[56] Lindroos & Mehling 2006, p. 862–866.

[57] WTO Appellate Body Report, *The United States – Standards for Reformulated and Conventional Gasoline*, at 18.

whether a provision of the "covered agreements" has been violated.[58] Furthermore, in their decisions the panels "cannot add to or diminish the rights and obligations provided in the covered agreements" either.[59] Hence, the panels lack competence to reach a legal conclusion on violation or compliance with other treaties or customs, such as human rights norms. They cannot enforce or give effect to human rights provisions in a way that would add to or diminish WTO rights and obligations either.[60] However, this limited domain of the WTO does not mean that the WTO Agreement exists in a "hermetically sealed system, closed off from general international law and human rights law".[61] A distinction should be made between its jurisdiction and the applicable law: the limited jurisdiction of the panels does not limit the scope of law they may apply.[62]

The binding nature of the rules of general international law in the WTO is explicitly confirmed in Article 3.2. of the Dispute Settlement Understanding ("DSU"). Accordingly, the WTO covered agreements must be clarified "in accordance with customary rules of interpretation of public international law". WTO panels and the Appellate Body have in their decisions explicitly recognized the role of Articles 31 and 32 of the Vienna Convention on the Law of Treaties ("VCLT") with respect to Article 3.2. of the DSU. The provisions are generally accepted as embodying customary international law.[63] Therefore, even though not all WTO Members are parties to the VCLT, to the extent that these provisions reflect customary international law, they are binding on all Members.[64] In the following, the content of Article 31 of the VCLT is illuminated so as to explain why the right to access to medicines should be considered in the interpretation of the TRIPS provisions. It should be noted that each WTO Member has the right to make exceptions to pharmaceutical patents in consistency with Articles 30 and 31 of the TRIPS Agreement as well as the Medicines Decision despite their general obligation to protect intellectual property rights. Thus, making exceptions to intellectual property protection in order to ensure access to medicines would not as such "add to or

[58] According to Article 1.1 of the DSU, the DSU only applies to disputes brought pursuant to the consultation and dispute settlement provisions of the "covered agreements". Article 23(1) of the DSU also refers only to "covered agreements": "When Members seek the redress of a violation of obligations or other nullification or impairment of benefits under the covered agreements or an impediment to the attainment of any objective of the covered agreements, they shall have recourse to, and abide by, the rules and procedures of this Understanding."

[59] The DSU, Articles 3(2) and 19(2).

[60] Marceau 2002, p. 762–763; Pauwelyn 2001, p. 554. Petersmann has suggested *de lege ferenda* the enforcement of human rights through WTO dispute settlement system in order to exploit its strong enforcement mechanism. His suggestion, however, has faced strong opposition. See Petersmann 2002 and Alston 2002.

[61] Marceau 2002, p. 779.

[62] Pauwelyn 2001, p. 554–566; Koskenniemi 2006, paras. 44–45.

[63] WTO Appellate Body Report, *The United States – Standards for Reformulated and Conventional Gasoline* at 16; Lindroos & Mehling 2006, p. 867.

[64] Mitchell 2007, p. 807–808.

diminish the rights and obligations provided in the covered agreements" – something that the panels would be prohibited from doing by virtue of Articles 3(2) and 19(2) of the DSU.

In accordance with Article 31(1) of the VCLT, a treaty shall be interpreted in good faith and in the light of its object and purpose. Pursuant to Article 7 of the TRIPS Agreement, the object of the agreement is to promote technological innovation "in a manner conducive to social and economic welfare, and to balance of rights and obligations". Article 8 of the TRIPS Agreement, in turn, explicitly grants all States a right to adopt policies that promote public health as long as they are consistent with the agreement. Good faith interpretation of the agreement in the light of these articles would surely lead to a decision that adequately considers the right to access to medicines.

Pursuant to Article 31(3)(b) of the VCLT, any subsequent practice between the Parties to an agreement regarding its interpretation must also be considered when interpreting the treaty.[65] Thus, the Doha Declaration holds relevance in the interpretation of the TRIPS Agreement. It is a common, unanimous statement of all WTO Members regarding the interpretation of the TRIPS Agreement and, as such, must be considered as a subsequent practice. In paragraphs 1 and 2 of the declaration, WTO Members stress the need for the TRIPS Agreement to be part of an international action addressing public health problems affecting many developing countries. In paragraph 4, they agree that the TRIPS Agreement does not and should not prevent WTO Members from taking measures to protect public health – instead, the agreement can and should be interpreted and implemented in a manner supportive of Members' right to protect public health and to promote access to medicines for all. Moreover, WTO Members reaffirm in paragraph 5 that in applying the customary rules of interpretation of public international law, each provision of the TRIPS Agreement shall be read in the light of the object and purpose of the agreement as expressed in Articles 7 and 8.

In many respects, the Doha Declaration repeats the contents of the TRIPS Agreement and re-states matters that should have been considered in the interpretation of the treaty by virtue of the DSU already prior to the adoption of the declaration. The declaration has, in fact, been called "a politically convenient overstatement that turns blind eye to the principles of treaty interpretation"[66]. Nevertheless, as the juggling act between the rights of patent holders and the public interest is far from simple, the Doha Declaration brings an end to any possible speculation on the significance of public health needs in the application of the TRIPS Agreement. It should be considered an authoritative interpretation of the agreement, granting WTO Members an indisputable right to make exceptions to patent rights in order to realize an

[65] Article 31(3) of the VCLT:"There shall be taken into account, together with the context: (*a*) any subsequent agreement between the parties regarding the interpretation of the treaty or the application of its provisions; (*b*) any subsequent practice in the application of the treaty which establishes the agreement of the parties regarding its interpretation; (*c*) any relevant rules of international law applicable in the relations between the parties."

[66] Frankel 2006, p. 390.

individual's right to access to medicines. As such, it manifests the common will of the WTO and its Members to ensure coherence between the right to access to medicines and the TRIPS Agreement.

In accordance with Article 31(3)(c) of the VCLT, any relevant rules of international law applicable between the Parties must also be taken into account when interpreting a treaty. The words cover all sources of international law, including custom, general principles and, where applicable, other treaties.[67] The overall aim of the article is to promote coherence in international law: all treaties should be interpreted in good faith so as to avoid conflicts, taking into consideration all relevant rules between the Parties.[68] Accordingly, also WTO panels must consider *all* rules of international law that hold relevance in a given case.

General international law has been frequently considered by the DSB and the Appellate Body and its applicability to dispute settlement in the WTO is generally accepted[69]. It was affirmed *e.g.* in *Korea – Measures Affecting Government Procurement*. The panel took note to the content of Article 3.2. of the DSU and went on to state that "the relationship of the WTO Agreements to customary international law is broader than this. Customary international law applies generally to the economic relations between WTO Members. Such international law applies to the extent that the WTO treaty agreements do not 'contract out' from them. To put in another way, to the extent there is no conflict or inconsistency, or an expression in a covered WTO agreement that implies differently, we are of the view that the customary rules of international law apply to the WTO treaties and the process of treaty formation under the WTO"[70]. In the absence of any "contracting-out", the right to access to medicines as a customary norm should therefore also be considered when interpreting TRIPS provisions relating to pharmaceutical patents.

In addition to customary law, the WTO dispute settlement bodies have referred to rules derived from other treaties in numerous cases.[71] In Article 31(3)(c) of the VCLT, reference is made to "any relevant rules of international law applicable in the relations *between the parties*" (emphasis here). The question of which treaties can be used to interpret WTO obligations arises. A

[67] Koskenniemi 2006, para. 426(b). .

[68] Marceau 2002, p. 785–786; Marceau 2001, p. 1089. Koskenniemi refers to the principle of systemic integration, according to which Article 31(3)(c) of the VCLT requires the "integration into the process of legal reasoning – including reasoning by courts and tribunals – of a sense of coherence and meaningfulness." See Koskenniemi 2006, paras. 410–423.

[69] For a closer examination on the application of rules of general international law in the practice of the Appellate Body, see Pauwelyn 2003, p. 268–274.

[70] WTO panel report, *Korea – Measures Affecting Government Procurement*, para.7.96 (19 June 2000). The decision was not appealed. In addition, Lindroos and Mehling also point out in their study that the WTO dispute settlement organs have repeatedly relied on decisions of other international tribunals, including the ICJ, the European Court of Human Rights and the Inter-American Court of Human Rights as well as on the work of the international law commission (Lindroos & Mehling 2006, p. 871–873).

[71] Lindroos & Mehling 2006, p. 865.

narrow interpretation would require identical membership between the non-WTO treaty and the WTO-treaty. This, however, has several shortcomings. It would, *inter alia*, strongly limit the use of other international treaties by virtue of Article 31(3)(c) of the VCLT since identical memberships are rare in today's world. As WTO Membership grows, fewer international agreements will match its membership. Hence, a requirement of identical membership would lead to a paradoxical result that the WTO would on some level become more and more isolated from the system of international law as the amount of its Members increases. In addition, the Appellate Body seems to have adopted an approach that does not require identical membership: in *the United States – Shrimp*, it examined provisions of the Convention on International Trade in Endangered Species and several other environmental agreements that did not have identical membership with the WTO in order to define the term "exhaustible natural resources". The requirement of identical membership therefore seems to be unnecessary. An alternative approach would be to allow the use of treaties with potentially universal membership or to allow the use of norms that are not strictly binding on most States but nevertheless reflect the common intention of WTO Members by being agreed to or tolerated. On the whole, it seems that the treaty provision in question must be of relevance for the international community. The membership, however, is no guarantee of its authentic relevance.[72] Considering the nearly universal membership of the ICESCR (see above) and the wide coverage of other human rights agreements and the relevance of the norms contained by these agreements for everyone, there is little doubt of the ability of WTO panels to consider the right to access to medicines as formulated in the ICESCR when interpreting the scope of the patent protection granted for pharmaceuticals in the TRIPS Agreement.

Finally, the *pacta sunt servanda* principle requires that "every treaty in force is binding upon the Parties to it and must be performed by them in good faith", as stated in Article 26 of the VCLT. States cannot contract out from this principle by establishing a new regime.[73] Even though human rights law cannot be given direct effect within the WTO, the adjudicating bodies of the organization must presume that WTO Members comply with their human rights obligations just as they are expected to do with all their international obligations at all times. The WTO law must thus be applied in good faith and in harmony with human rights law.[74] Any other kind of conclusion would essentially transform the organization into a "safe haven" for all WTO Members seeking to backtrack on obligations entered into elsewhere.

To conclude, WTO norms should be interpreted in consistency with general international law – a matter that is clearly manifested in the DSU. The panels have also adopted a clear approach to dispute settlement, signaling that the organization can hardly be considered a self-contained

[72] Marceau 2002, p. 780–782.

[73] Koskenniemi 2006, para. 176 (noting that it would only be possible if the regime was meant to create no obligations at all). See also Pauwelyn 2003, p. 37 where he presents that States cannot contract out of the system of international law due to the principle of *pacta sunt servanda* that could be considered a part of the *jus cogens*.

[74] Marceau 2002, p. 786.

regime, isolated from international law[75]. Further, the Doha Declaration should be considered a manifestation of the common will of WTO Members to maintain coherence between the right to access to medicines and exclusive rights covering pharmaceutical products. Despite the incompetence of the panels to enforce the right to access to medicines or to allow it to supersede and set aside a WTO provision, the access norm must be considered in the interpretation of the TRIPS norms. All in all, it has become clear above that WTO law does not operate in isolation from other rules of international law. As Lindroos and Mehling note, "the chimera of 'self-contained regime' remains a phantom with no legal basis in international law, a notion which, despite its persistent appearance in jurisprudential debate, is best confined to the lively world of myth and debate"[76].

2.3. Facilitating Coherence: Definition of Conflict of Norms

Interpreting TRIPS norms harmoniously with the pre-existing human rights norms is also in line with the principle of presumption against conflict, a widely accepted principle of treaty interpretation that allows for avoidance of conflicts. Accordingly, every new norm of international law, alike with norms of national legislation, is created within the context of pre-existing regulation. There is a presumption that this new norm builds upon and further develops existing law[77]. In other words, the strong presumption against normative conflict in international law appears as "the thumb-rule that when creating new obligations, States are assumed not to derogate from their obligations"[78]. Consequently, any deviation from existing law must be made in explicit language. When faced with two possible interpretations, the one that allows for harmonization of the two norms – and hence avoids conflict – ought to be preferred[79].

WTO Members have not contracted out of the access norm: the TRIPS Agreement is silent on the issue. Therefore, based on matters presented above, the TRIPS Agreement can well be interpreted in consistency with human rights norms. It would consequently be tempting to conclude that no normative conflict exists between the right to access to medicines and pharmaceutical patents. Nonetheless, one must first define what constitutes a "normative conflict" in order to see if reconciliation of the norms through interpretation is possible – namely, the presumption against conflict simply requires that an effort is made to interpret a new norm (here, a TRIPS-norm) in harmony with the existing law (here, the access norm) and that this kind of interpretation is feasible. If reconciliation between the two norms is not

[75] Lindroos & Mehlig 2006, p. 875.

[76] Ibid., p. 877.

[77] Pauwelyn 2003, p. 240.

[78] Koskenniemi 2006, paras. 37–38.

[79] Pauwelyn 2003, p. 240–241.

feasible, that is where the presumption ends.[80] Therefore, if it turns out that the TRIPS Agreement is in a normative conflict with the right to access to medicines, the norms can no longer be interpreted harmoniously as this would mean that the conflict would be solved in favour of the earlier rule (*i.e.* the access norm). One would, instead, need to resort to rules of conflict resolution.

Most norms of international law can be divided into obligations and rights. They can be further divided into four categories: norms obligating States to do something (commands), norms obligating States not to do something (prohibitions), norms granting States a right not to do something (exemptions) and, finally, norms granting States a right to do something (permissions).[81] These categories apply both to human rights norms, on the one hand, and the TRIPS norms, on the other. For States, the right to access to medicines constitutes both a command (obligation to respect, protect, fulfill and cooperate) and a prohibition (prohibition of retrogressive measures). The TRIPS Agreements similarly contains norms obligating (obligation to grant pharmaceutical patents) and prohibiting (prohibition of discrimination) States. However, these TRIPS commands and prohibitions are accompanied by flexibilities that are either permissions (*e.g.* Articles 30 and 31 examined above) or exemptions (*e.g.* rights of least-developed country Members not to enforce patents during the transitional periods, right to exclude certain subjects of patentability).

Conflict of norms in the strict sense can be defined as a situation in which "Party to the two treaties cannot simultaneously comply with its obligations under both treaties". [82] This narrow definition of conflict has been followed also in the WTO jurisprudence. In *Indonesia – Autos*, the panel stated that "in international law for a conflict to exist between two treaties [....] [their] provisions must conflict, in the sense that the provisions must impose mutually exclusive obligations [...]. Technically speaking, there is conflict when two (or more) treaty instruments contain obligations which cannot be complied with simultaneously"[83]. The Appellate Body has subsequently defined conflict as a situation "where adherence to the one provision will lead to a violation of the other"[84]. In accordance with the narrow definition of conflict, we have above arrived at a situation where no normative conflict exists between the right to access to medicines and pharmaceutical patents. Although the TRIPS Agreement obligates WTO Members to provide exclusive rights for pharmaceutical inventions, it also *exempts* them from

[80] Ibid., p. 242–244; Koskenniemi 2006, para. 42. Koskenniemi notes that there are no normative conflicts whose intrinsic nature makes them unsuitable for harmonization – anything can be harmonized as long as the will to harmonization is present between the Parties. However, if this will is not present, harmonization of the competing norms is no longer possible.

[81] Pauwelyn 2003, p. 159.

[82] Jenks 1953, p. 426.

[83] WTO Panel Report, *Indonesia - Certain Measures Affecting the Automobile Industry*, para. 14.28, footnote 649.

[84] WTO Appellate Body Report, *Guatemala - Anti-Dumbing Investigation Regarding Portland Cement from Mexico* (1998), para. 65.

certain obligations related to their enforcement and *permits* them to take necessary measures in order to protect public health. The right to access to medicines, in turn, *prohibits* States from taking retrogressive measures and *commands* them to exploit the flexibilities of the TRIPS Agreement when necessary for the protection of the right. WTO Members can thus comply with both agreements simultaneously by exploiting TRIPS flexibilities and no conflict of norms arises. Nonetheless, in order to comply with its human rights obligations, they no longer have a mere permission to execute exceptions to patents. Instead, it has an obligation to do so if the TRIPS Agreement is to comply with the access norm. What used to be a *may* has now turned into a *must*[85]. Exemptions and permissions have thus lost an integral part of their essence since WTO Members are now obligated to exploit these norms. This constitutes a "contradictory conflict" since both norms cannot be fully applied at the same time – a situation which is recognized as a conflict of norms in prevailing legal theory[86].

A wider definition of normative conflict has recently been supported by several scholars. It seems to lead to a requirement of complete harmony between international norms that can be considered cumulative, *i.e.* falling outside conflict. A mere possibility of inconsistency between divergent norms breaks this harmony. According to Pauwelyn, norms of international law conflict if they cannot be "applied together and without contradiction at all times"[87]. He defines conflict of norms as a relationship between two norms where "one norm constitutes, has led to or may lead to a breach of the other"[88]. Hestermeyer, albeit admitting that WTO law is not in systemic conflict (*i.e.* conflict between principles or goals rather than mere norms) with the human rights regime, has also assumed a broad definition of normative conflict. He concludes that the TRIPS Agreement conflicts with the right to access to medicines since a permission to exploit TRIPS flexibilities has now turned into an obligation to do so[89].

Even though genuine conflicts cannot be "interpreted away", conflict resolution and interpretation should not be completely distinguished from each other as rules always appear to be compatible or conflicting as a result of interpretation[90]. Therefore, before it is possible to establish whether TRIPS norms are in normative conflict with the right to access to medicines, the norms should be placed in their context. The main objective of any treaty interpretation is to identify the intention of the Parties. Taking in to consideration Articles 7 and 8 of the TRIPS Agreement, it is evident that efforts have been made for maintaining balance. Further, it

[85] Hestermeyer 2007, p. 176.

[86] Vranes 2006, p. 409. Vranes (p. 415) suggests the following definition of conflict: "There is a conflict between two norms, one of which may be permissive, if in obeying or applying one norm, the other one is necessarily or possibly violated."

[87] Pauwelyn 2003, p. 161.

[88] Pauwelyn 2003, p. 175 ff.

[89] Hestermeyer 2007, p. 174–181.

[90] Koskenniemi 2006, para. 412.

has been established above that the right to access to medicines must be considered in the interpretation of the TRIPS Agreement by virtue of the DSU, where reference is made to the VCLT. The Doha Declaration also reaffirms that the agreement should not hinder access to medicines. If norms granting exclusive rights would nonetheless be considered to conflict with the right to access to medicines on theoretical grounds and since the regimes in question have divergent objectives, these efforts for maintaining coherence through interpretation would be nullified.

A closer examination of the overall aim of the VCLT to promote coherence in international law and the presumption against conflict reveals the inherent striving for coherence in international law that can be attained through harmonious interpretation of divergent norms. States are presumed to perform all their international obligations in good faith pursuant to the *pacta sunt servanda* principle. It can consequently be presumed that States have also negotiated all their treaties in good faith, taking into account their existing obligations. In the absence of any evidence to the contrary, all States' obligations must be considered cumulative and should be read together[91]. It can be assumed that permissive norms have throughout time been included in treaties as well as domestic laws in order to allow for accumulation of norms and consistency between existing obligations and the new regulation. Similarly, norms permitting exceptions and norms exempting WTO Members from certain obligations of the TRIPS Agreement are aimed at maintaining unity between the pre-existing human rights obligations of States and the new intellectual property regulation. If, however, wide definition of conflict of norms is assumed, relationships between various sets of norms that were previously considered consistent with each other would most likely turn out conflicting. Interpreting these divergent norms so as to render them compatible would become even more difficult and these "sub-systems" could no longer coexist without the means of conflict resolution. This kind of conclusion would be contrary to the striving for coherence in international law and be especially detrimental in times of fragmentation of the international community and international relations.

To conclude, there is little reason to support a wide definition of conflict of norms in the present context. Instead, one must allow interplay between the norms examined. As formulated by Marceau, "if one believes that international commitments should be understood in the light of some coherent international legal order, one favors narrow definitions of conflicts, interpretations and applications of opposing norms that promote their harmonization"[92]. Coherence between the TRIPS Agreement and the right to access to medicines can be maintained as long as conflict is defined in accordance with the traditional view: as a situation where a State cannot simultaneously meet its obligations derived from two distinct norms. Since the permissive norms of the TRIPS Agreement ensure that WTO Members can still

[91] Marceau 2001, p. 1084, 1089.

[92] Marceau 2001, p. 1082–1083.

comply with obligatory norms enshrining access to medicines, no conflict exists between the norms examined. The often alleged incoherence between them has thus proven to be an illusion.

Since no normative conflict exists between the right to access to medicines and the TRIPS Agreement, the norms can and should be interpreted harmoniously in order to avoid conflict, in accordance with the presumption against conflict. WTO Members have an obligation to ensure access to medicines, as outlined above, and the TRIPS obligations must be interpreted accordingly. This requirement leads one to assume a human rights approach to the implementation of intellectual property regulation, meaning that human rights are employed as a guiding principle to the implementation and enforcement of exclusive rights[93]. It should be emphasized that a human rights approach to the implementation of these rights does not, however, mean that interpretation would be used to solve a conflict in favor of the relevant human right, *i.e.* it should not lead to *de facto* disregarding of exclusive rights. Instead, it must preserve the viability of both sets of norms under examination. A model for this kind of implementation of the Medicines Decision – a permissive TRIPS norm of key importance – is provided in the following.

III. Establishing Coherence: A Human Rights Approach to the Implementation of the Medicines Decision

3.1. In Search of a Golden Mean

The Medicines Decision – a result of the negotiations that followed the adoption of the Doha Declaration – forms an integral part of compulsory licensing as a means to ensure that the TRIPS Agreement does not hinder access to medicines. The aim of the decision is to ensure that the TRIPS Agreement does not hinder the right of WTO Members to adopt necessary measures for the protection of public health, as stated in paragraph 4 of the Doha Declaration. In the following, I will explore the practical implications of the right to access to medicines in the harmonious interpretation of the decision. As Eide put it, "what counts, in the end, is whether human rights are realized in practice – whether the standards and institutions serve to bring about the changes which are required in order to make it possible for all to enjoy all human rights" [94]. Nothing in the TRIPS Agreement obligates WTO Members to implement the Medicines Decision in a manner that best considers the right to access to medicines – the access norm, however, does. Nevertheless, as mentioned above, a human rights approach to the

[93] See Haracoglou 2008, p. 90–93 on the right to health as an interpretative principle in patent law and report of the High Commissioner of the Commission on Human Rights: *The impact of the Agreement on Trade-Related Aspects of Intellectual Property Rights on human rights* (2001).

[94] Eide 2001, p. 553.

implementation of the Medicines Decision should not undermine the integrity of the international patent system. The golden mean should, instead, be found in an implementation that ensures access to medicines in developing countries but simultaneously ensures that exclusive rights are adequately protected.

Representatives and proponents of the research based pharmaceutical industry often criticize exceptions to patent rights for strongly debilitating the position of right holders. Exceptions to patent rights in the auspices of the Medicines Decision have similarly been claimed to be detrimental to research and development of new medicines needed in developing countries.[95] These statements emerge from the *raison d'être* of patents which is to encourage innovations by rewarding the inventor with an exclusive right to exploit the invention for a predetermined period of time. If exceptions are repeatedly made to pharmaceutical patents covering medicines needed in developing countries, why would anyone contribute to their development as they will not receive any compensation for this work? This juxtaposition is inherent in the TRIPS context. Similarly, it was visible throughout the negotiations regarding the Medicines Decision.[96]

However, as pointed out above, today's patent protection is not contributing to research and development of medicines needed in developing countries anyway – these countries are likely to benefit only when developed countries with purchasing power suffer from the same diseases.[97] Further, research based companies are not relying on the rents they receive from developing countries in their research budgets. Some estimates suggest that only USD 1–1,5 billion per year of pharmaceutical budgets of companies based in the OECD may be dependent on developing country rents, while expenditures for research and development of these companies in 1995 were in the range of USD 25 billion and are substantially higher today.[98] A study prepared for the British Commission on intellectual property rights suggests that if developing countries gave no patent protection to pharmaceuticals at all, it would generate an aggregate loss of about one and a half billion dollars out of a total of USD 35 billion spent to research and development annually by the U.S. PhRMA companies. Circa 90 percent of the revenues these companies received in 2001 came from sales in the United States, Canada, Western Europe and Japan, while 0,3 percent came from sales in Africa.[99] Furthermore, research based companies spend on average only 15 percent of their revenues on research and development, while a much larger portion goes to administration and advertising (in developed countries).[100]

[95] Hoen 2006, p. 216.

[96] See Abbott [1] 2005 for a detailed presentation of the negotiations.

[97] Commission on intellectual property rights, innovation and public health 2006, p. 77; see footnote 47 above and the accompanying text.

[98] Abbott [1] 2005, p. 325 (note 58).

[99] Abbott [2] 2005, p. 420.

[100] Abbott [1] 2005, p. 325.

All things considered, markets of developing countries currently hold minor significance for research based companies. Exceptions to patents in the auspices of the Medicines Decision are thus unlikely to cause neither significant loss to right holders nor decrease research and development of medicines needed in developing countries. If re-diversion of medicines manufactured under compulsory licenses to the markets of developed countries is prevented, *status quo* of the research based industry in the pharmaceutical markets is preserved. A strict distinction must thus be made between patent protection in developed countries, on the one hand, and developing countries, on the other.

3.2. Compulsory Licensing Under Article 31 of the TRIPS Agreement

Article 31 of the TRIPS Agreement ("Other use without Authorization of the Right Holder") regulates the use of compulsory licenses. The provision comprehends use by a government or a third party authorized by the government. As mentioned above, the TRIPS Agreement does not set any specific grounds based on which compulsory licenses can be granted as long as the conditions set forth in Article 31 are followed. The Medicines Decision waives obligations set forth in paragraphs (f) and (h) of the provision which means that WTO Members are still obligated to follow most of the conditions set forth in the provision.[101] They are, *inter alia*, obligated to provide for judicial or another independent review by a higher authority on the legal validity of any decision related to unauthorized use of patents[102]. This means that right holders can still challenge the compliance of WTO Members with the requirements embodied in Article 31.

Pursuant to Article 31 of the TRIPS Agreement, each license has to be considered on its individual merits.[103] Efforts shall be made in order to obtain authorization from the right holder on reasonable terms and conditions, apart from cases of national emergency or other circumstances of extreme urgency. In case of a national emergency, the right holder must,

[101] In situations where government claims that it has lost "an expected benefit" as a result of actions of another government, it can initiate proceedings within the DSB regardless if a specific article has been breached. The purpose of this is to ensure that governments hold on to the commitments they make during multilateral trade negotiations (see TRIPS Agreement Article 64.2). These non-violation complaints are not applicable to disputes related to intellectual property rights. Thus, in order to initiate proceeding within the DSB, a WTO Member must address a specific provision of the agreement that the respondent has allegedly breached. Currently non-violation complaints have been excluded by a moratorium while WTO Members are searching for a permanent solution that would be acceptable to all parties. See *e.g. Implementation-Related Issues and Concerns*, Decision of 14 November 2001, Para 11.1.; *Doha Work Programme, Ministerial Declaration* of 18 December 2005, paragraph 45. Most countries are in favour of excluding matters related to intellectual property from the possibility of non-violation complaints altogether; others, *e.g.* the United States and Switzerland, claim that they are necessary in order to prevent WTO Members from getting around their TRIPS commitments (Sun 2004 p.142–143).

[102] TRIPS Agreement, Article 31(i).

[103] TRIPS Agreement, Article 31(a).

regardless, be notified as soon as possible after the unauthorized use.[104] The use of the patent shall be non-exclusive and non-assignable.[105] The scope and duration of the license must be limited to meet the purposes for which it was granted: it must be terminated when the circumstances that lead to its issuance cease to exist. Legitimate interests of licensees must nonetheless be protected: WTO Members shall guarantee that they also have access to justice on the basis of the relevant decision.[106] Patent holders are entitled to adequate remuneration pursuant to paragraph (h) of Article 31. In accordance with the Medicines Decision, this remuneration will be paid in the exporting WTO Member (see below). Any decision relating to the amount of remuneration must also be subject to judicial or other independent review in that Member.[107]

The most crucial condition set forth in Article 31 of the TRIPS Agreement is the requirement that compulsory licenses shall be granted "predominantly for the supply of domestic markets".[108] The provision limits the opportunities of developing countries with no local manufacturing capacity to utilize the mechanism. WTO Members are eligible for importing pharmaceuticals under compulsory licenses. This, however, is not possible from another Member that has granted the medicine a patent, unless the exporting country has manufactured the product under a compulsory license for its national demands to a larger extent.[109] Only few countries, *e.g.* India, Brazil and South-Africa, possess manufacturing capacity of generic medicines that could suffice to export. In order to be eligible as exporters, they would first have to issue a compulsory license "predominantly for the supply of domestic markets" pursuant to Article 31(f). Then, they would be allowed to export a part of the amount manufactured under the license to other countries in need. The limitations entailed by the provision are obvious. Another way to import generic medicines would be to import them from a non-WTO country

[104] TRIPS Agreement, Article 31(b). In accordance with paragraph 5(c) of the Doha Declaration, each WTO Member has the right to determine which circumstances qualify as a national emergency. Prior request is neither required for public non-commercial use nor in situations where licenses are granted to remedy anti-competitive practices (TRIPS Agreement, Article 31[b], [k]).

[105] TRIPS Agreement, Article 31(d), (e).

[106] TRIPS Agreement, Article 31(c), (g).

[107] TRIPS Agreement, Article 31(j). Pursuant to Article 31(k), the obligation to pay adequate remuneration does not apply to cases where the license has been issued to remedy anti-competitive measures. Durojaye has even suggested the use of Article 31(k) and rules concerning anti-competitive measures as an alternative for the Medicines Decision. This would waive some of the essential conditions set forth on Article 31. However, it would also require interpreting pharmaceutical patents and a refusal to license as anti-competitive measures which exposes said suggestion to criticism. See Durojaye 2008, p. 30 ff.

[108] TRIPS Agreement, Article 31(f). According to paragraph (k) of Article 31, said condition does not concern situations whereby licenses have been issued to remedy for anti-competitive practices either.

[109] It is noteworthy, however, that some developed countries allow exceptions to patents without the limitation imposed by article 31(f); *e.g.* Patent Acts of Australia and New Zealand allow exports under an agreement with a foreign country to supply products required for the defence of that country (Correa 2002, p. 27).

that has not enforced patents for the product in question or where the term has expired[110]. In any case, finding a non-WTO country that possesses sufficient manufacturing capacity for exporting medicines remains a mere theoretical possibility.

The end of transitional period initially granted for developing countries highlighted the problem embodied in paragraph (f) of Article 31. India, for example, has been the most influential supplier of generic medicines for many developing countries. Its pharmaceutical industry is producing generic AIDS medicines for a half of the 700,000 HIV patients taking antiretroviral medicines in developing countries, at five percent of the price that pharmaceutical firms based in Europe or the United States charge for the same product[111]. India has managed to develop an extensive industry that produces generic medicines by not enforcing patents on pharmaceutical products and only allowing patents on manufacturing processes. This kind of policy encourages the search for cheaper and cheaper processes for the manufacture of pharmaceutical compounds[112]. Other WTO Members have previously been able to import medicines from India; in case the product in question would have been patented in their territory, they could have issued a compulsory license in accordance with Article 31. Medicinal products developed after January 2005 are, however, subject to patenting also in developing countries, including India[113]. Due to the requirement that the generic medicines were intended "predominantly for the supply of domestic markets", the end of the transitional period meant that it became difficult to obtain affordable versions of newly developed medicines.[114]

By failing to pay due attention to the needs of developing countries, Article 31 fails to redeem the promise of leaving all WTO Members enough room to adopt necessary measures in order to protect public health despite newly introduced intellectual property regulation. These deficiencies are addressed by the Medicines Decision. Several scholars have criticized the decision for not being faithful to the spirit of Doha; civil society groups and activists have

[110] Correa 2004, p. 20.

[111] Yalamanchili 2007, p. 211.

[112] Finland is also among the countries that did not enforce product patents on pharmaceuticals before the entry into force of the TRIPS Agreement. Said policy has resulted in a myriad of ongoing litigations between generic manufacturers and the holders of the original, so-called analogous process patents where the crux of the dispute is the scope of protection of these patents.

[113] See Articles 65.4; 70.8; 70.9 of the TRIPS Agreement. The end of transitional periods also meant that countries such as India started processing patent applications collected in its "mailbox" since January 1995. These medicines will be granted protection for the remainder of the 20-year term of filing date of the mailbox application. Hitherto, however, the processing has been slow and India has allowed the generic producers to continue supplying medicines already in production in January 2005 under certain conditions, *e.g.* upon payment of a reasonable royalty (Abbott & Reichman 2007, p. 945).

[114] Furthermore, paragraph (f) is discriminatory against WTO Members with smaller markets. In countries such as India, the UK or the United States, it is economically profitable to produce medicines under a compulsory license due to the large amount of potential consumers in the national markets. For Members with small sized domestic target groups, it is rather difficult to establish economically viable production if the product has to be "predominantly" sold in the domestic market of the licensee (Correa 2002, p.19).

described the Medicines Decision as a "gift bound in red tape"[115]. The question is: does the Medicines Decision and its implementation comply with the objective set forth in the Doha Declaration, *i.e.* does it secure the ability of countries with no manufacturing capacity to make effective use of compulsory licensing under the TRIPS Agreement for the protection of public health and access to medicines?

3.3. Exporting under Compulsory Licenses: Unnecessary Red Tape?

One of the controversies raised during the negotiations that followed the adoption of the Doha Declaration related to the question of which TRIPS provision the future decision should base on. Different alternatives, such as temporary solutions in which permission to manufacture medicines would be granted in individual cases, were presented. An alternative strongly advocated by NGOs and human rights organs was a system in which relevant exceptions would be legitimized under Article 30 of the TRIPS Agreement that allows for limited exceptions to patent rights.[116] However, the final system builds on Article 31 of the TRIPS Agreement and is, as described below, a rather complex system.

In order to initiate the procedure defined in the Medicines Decision, the importing country must make a notification to the TRIPS Council in which names and expected quantities of the products needed are specified. In case the importing WTO Member is not a least-developed country[117], it has to confirm in the notification that it has insufficient manufacturing capacities. This is a matter of self-assessment and the results cannot be challenged by any of the Members[118]. The importing country also has to confirm that it has granted or intends to grant a compulsory license to the pharmaceutical product patented in its territory in accordance with

[115] Durojaye 2008, p. 53–54.

[116] The representative of the WHO, for example, reminded the TRIPS Council in its meeting in September 2002 that the basic public health principle being followed in the solution to be found was that the people of a country that did not have the manufacturing capacity to produce a needed product should be no less protected by compulsory licenses and other provisions and safeguards in the TRIPS Agreement, nor face greater procedural hurdles in comparison to the people of a country capable of producing the product. Accordingly, the solution most consistent with this principle would have been the provision of a limited exception under Article 30 (Council for TRIPS, Minutes of meeting held in September 2002, para. 5). See also *e.g.* MSF: *Why Article 30 Will Work. Why Article 31 Will Not* (24 June 2002) and MSF, Oxfam, CPTech, Health Gap, Third World Network, & Essential Action, *Joint Letter to Members of TRIPS Council* (28 January 2002).

[117] Least-developed countries are defined by the UN Committee for Development Policy based on their gross national income per capita, human asset index and economic vulnerability index. For further information, see http://www.un.org/esa/policy/devplan/profile/criteria.html (last visited 18.1.2008).

[118] Correa 2004, p. 17, 29. Once it is established that such capacity has become sufficient to meet its needs, the system created by the Medicines Decision no longer applies. This is also assessed by the Member itself (see Annex of the decision). In the Chairperson's statement accompanying the Medicines Decision, Members are urged to provide information in the notification on how the establishment has been rendered. All notifications are brought to the attention of the TRIPS Council (see General Council Chairperson's statement, 13 November 2003, para. 5).

Article 31 of the TRIPS Agreement. The Medicines Decision waives its obligation to pay remuneration – the compensation is paid in the exporting WTO Member[119]. All other conditions set forth in Article 31 remain valid. Due to the extension of the transitional periods[120], least-developed country Members may regardless be excluded from obligations related to compulsory licensing. This follows from a possible decision by a government to refrain from offering legal protection to pharmaceutical patents.[121]

National legislation and Article 31 of the TRIPS Agreement, apart from paragraph (f), determine the course of proceedings also in the exporting country. This means that the interested supplier first has to ask for a voluntary license in accordance with Article 31(b). It can be argued that the exporting WTO Member is entitled to consider the situation in the importing country as an emergency or to recognize its public non-commercial use; then, it is possible to accelerate the process by ignoring this step[122]. The duration of the license is determined by the government of the exporting country. Pursuant to Article 31(g), legitimate interests of the licensees must be adequately considered. Thus, the duration of the license should allow enough time to recoup production costs. According to paragraph 3 of the Medicines Decision, adequate remuneration pursuant to Article 31(h) of the TRIPS Agreement shall also be paid in the exporting WTO Member, taking into account the economic value of the unauthorized use to the importing State. The generic company will thus compensate the use of the patent to the right holder. The competent national authority is responsible for determining the appropriate amount of compensation. The exporting State is only allowed to grant a license for the manufacture of the amount needed by the eligible importing country[123]. Thus, the importing Member must establish its exact needs when making the final agreement with the license holder.

Prevention of re-exportation is of crucial significance for the protection of patent rights. Parallel imports of generic medicines manufactured under the system are thus not allowed. All WTO Members must take reasonable measures in order to prevent re-exportation of these medicines.[124] The requirement of identifying the products produced under the system set out in the Medicines Decision also enhances the prevention of re-exportation: suppliers must distinguish such products through special packaging, shaping or colouring of the original product. Such a distinction is to be feasible and have no significant impact on price. It applies to both formulated pharmaceuticals and active ingredients produced and supplied under the system. Finished products using such active ingredients are also covered by this obligation: in

[119] The Medicines Decision, para. 3.

[120] See footnote 16 above.

[121] The Medicines Decision, para. 2(a).

[122] Correa 2004, p. 19, 21.

[123] The Medicines Decision, para. 2 (b)(i).

[124] The Medicines Decision, paras. 4 and 5.

case developing countries manufacture generic medicines locally, they have to make these products identifiable.[125]

The final step of the procedure is that the licensee shall post technical information, *i.e.* the quantities of products supplied to each destination and the distinguishing features of these products, to a website before the shipment begins.[126] Similarly, the exporting WTO Member must notify the TRIPS Council of the grant of the license, including the conditions attached to it.[127]

Pursuant to Article 31(i) of the TRIPS Agreement, the legal validity of any decision relating to the authorization shall be subject to judicial review or other independent review by a higher authority in the involved WTO Member. This means that a patent holder has an opportunity to hamper the actions taken under the Medicines Decision in both countries involved – an opportunity that is well catered for under an Article 31 based solution. The Medicines Decision has been called a complex system satiated with several administrative conditions to fulfil that hinder the effective implementation of the decision[128]. The legislation implementing the decision in Canada, for example, has been criticized for permitting dilatory litigation as it grants the patent holder the right to petition for various reasons other than grounds related to the possible misuse of the system[129]. Correa has noted that a patent owner may exploit the complex system and exercise its rights under relevant national laws so as to block all use of the patent – a situation which effectively transforms the application of the Medicines Decision into a conflict between the country demanding access and the patent owner unwilling to supply[130]. The question arises: are these administrative hurdles turning the Medicines Decision into an excessively complex system that protects the rights of patent holders at the expense of access to medicines in developing countries?

[125]The Medicines Decision, para. 2(b)(ii). In the General Council Chairperson's statement accompanying the Decision, "Best practices" guidelines have been established (Attachment to the statement). There, examples are given of policies companies have used in order to prevent diversion of products donated. Correa has suggested that the obligation to distinguish is not absolute: if it would not be feasible or would have significant impact on price, it could not be required under the Medicines Decision (Correa 2004, p. 23). However, distinguishing products is a part of a normal manufacturing procedure and as such it cannot be assumed to constitute an unreasonable burden for the generic manufacturer.

[126] The Medicines Decision, para. 2(b)(iii).

[127] The Medicines Decision, para. 2(c).

[128] Abbott & Reichman 2007, p. 934; see also *e.g.* MSF 2006: *Neither expeditious, nor solution: The WTO August 30th decision is unworkable*.

[129] Lazo 2007, p. 266. A license issued in Canada may be terminated if *e.g.* the generic company fails to maintain or update the relevant webpage, fails to notify the relevant parties during the exporting process or fails to pay the remuneration in time (The Jean Chrétien Pledge to Africa, Section 21.14).

[129] Correa 2007, p. 339.

[130] Ibid, p. 339.

The obligation of all States to protect the right to access to medicines and the duty of Third States should be considered here. Accordingly, also WTO Members must ensure that third parties do not curtail the right to access to medicines. This obligation also extends to the implementation process of the Medicines Decision. As stated in the Maastricht Guidelines on Violations of Economic, Social and Cultural Rights, Contracting States themselves "are responsible for violations of economic, social and cultural rights that result from their failure to exercise due diligence in controlling the behaviour of such non-State actors"[131]. The legislation implementing the decision must thus ensure efficiency of the system. If it turned out that patent holders tried to abuse the system and prevent exportation of medicines manufactured under it, any laws enabling such behaviour should be amended in consistency with the human rights obligations of the States involved. One important practical matter is whether patent holders are provided with an opportunity to obtain an injunction against the execution of the license decision for the duration of the possible appellate procedure. If this is possible, right holders may have the means to hinder the procedure to an unreasonable extent. Thus, when implementing the Medicines Decision, WTO Members should – in consistency with their obligation to protect and duty to cooperate – avoid any provisions that may lead to an unnecessary interference with the utilization of the decision.

> Correa has also referred to the difficulties faced in the Philippines. 120 applications for compulsory licenses were filed under the former Philippine patent law, out of which 51 compulsory licenses were granted. The appellate procedure, however, hindered the execution of the licenses. The beneficiary companies were not able to market their product during this appellate procedure. The delay also caused the dismissal of 23 applications while 14 applications were dismissed due to a compromise agreement between the parties. 8 applications were dismissed because the patent expired while the procedure was still pending. Up until 2003, only one compulsory license applied for during the old patent legislation had been executed – the application had been lodged in 1991 and the execution took place in December 2001.[132]

The fact that the Medicines Decision was achieved by amending Article 31 of the TRIPS Agreement ensures that the rights of patent holders are adequately protected. It does not necessarily imply inefficiency of the decision – as long as WTO Members meet their obligation to protect access to medicines and draft their laws accordingly. It may also be that basing any exportation on Article 31 better justifies the action in the eyes of patent holders and thus increases their willingness to cooperate under the system. Finally, the Medicines Decision is without prejudice to other flexibilities WTO Members have under the TRIPS Agreement[133]. This means that *e.g.* exceptions allowed under Article 30 still remain available.

[131] Maastrict Guidelines, para. 18.

[132] Correa 2004, p. 7.

[133] The Medicines Decision, para. 9.

In the following, main issues of the Medicines Decision are tackled by using the implementing regulations of Canada[134] ("Jean Chrétien Pledge to Africa"), the EC[135] ("EC regulation") and Switzerland[136] ("Gesetzesänderung") as concrete examples of the policies WTO Members have adopted at national level.[137] These Members have implemented the decision and they also have the capacity to export medicines under the system established. In addition, some of the solutions proposed in the U.S. amendment ("Life Saving Medicines Export Act") will be used as examples even though the bill never became a law[138]. What are alternatives that should be chosen if WTO Members are to meet their obligations to respect, protect and fulfil the right to access to medicines?

3.4. Eligible Importing Countries

3.4.1. Treatment of WTO Members

The first essential issue is which countries are eligible to use the system established by the Medicines Decision. Paragraph 6 of the Doha Declaration was intended to solve the problems of WTO Members "with insufficient or no manufacturing capacities in the pharmaceutical sector". Defining eligible importer countries proved divisive. Developing countries supported the definition given in the declaration, whereby determination of eligibility would be made case-specifically. The EC and the United States, in turn, were interested in limiting the amount of prospective importing countries. Using national income as a determinant or creating a predetermined list of eligible importing countries based on the level of local production capacity were options suggested during the negotiations.[139]

Under the Medicines Decision, only least-developed country Members are automatically eligible for importing generic medicines. Other WTO Members can notify the TRIPS Council if they intend to use the system. This is a precondition for being eligible to import generic medicines that have been manufactured under the system. The notification may be unqualified or it can

[134] Chapter 23 of the Canadian Patent Act (Bill C-9): An Act to amed the Patent Act and the Food and Drugs Act (The Jean Chrétien Pledge to Africa), assented to 14th of May 2004.

[135] Regulation (EC) No 816/2006 of the European Parliament and the Council of 17 May 2006 on compulsory licensing of patents relating to manufacture of pharmaceutical products for export to countries with public health problems.

[136] Bundesgesetz vom 25. Juni 1954 über die Erfindungspatente (Patent Gesetz, PatG), Article 40(d), 40(e).

[137] Among other countries that have implemented the Medicines Decision are India, South-Korea, Norway and China. See Consumer Project on Technology: http://www.cptech.org/ip/wto/p6/index.html (last visited 10.4.2010).

[138] See The United States: The Proposed Life Saving Medicines Export Act (http://www.govtrack.us/congress/bill.xpd?bill=s109-3175 [last visited 10.4.2010]).

[139] Abbott [1] 2005, p. 326–327.

be limited to certain exceptional circumstances, such as national emergencies[140]. Further, pursuant to Article 2(a)(ii) of the Medicines Decision, other than least-developed country Members must make a determination that they have insufficient or no manufacturing capacity in the pharmaceutical sector for the products in question once they have decided to import medicines under the system. The criteria for this determination are set out in the annex to the decision. The matter is in the discretion of the officials of the importing WTO Member[141]. Manufacturing capacity covers both technical aspects (*i.e.* availability of technology, trained personnel, equipment, access to raw material etc.) and economic feasibility of production. The notification is declaratory, *i.e.* it does not have to be approved by a WTO organ. The Chairman's statement accompanying the Medicines Decision encourages WTO Members to include in the notification the information on the methodology they have used for assessing their manufacturing capacity – this, however, has no legal impact on the actual content of the decision[142]. The implementing legislations of Canada, the EC and Switzerland, for example, all give the importing WTO Member the power to determine whether it qualifies for importing the medicine in question while least-developed country Members are automatically considered eligible[143]. Thus, no prior limitations have been set for the eligibility of a WTO Member to utilize the Medicines Decision.

3.4.2. Treatment of Non-WTO-Countries

Treatment of non-WTO countries lacking sufficient manufacturing capacity is an issue not covered by the Medicines Decision. It can be argued that exporting medicines to a non-WTO country constitutes a limited exception to patent rights and as such is allowed under Article 30 of the TRIPS Agreement. However, the Medicines Decision is silent on the issue. Requiring

[140] The Medicines Decision, para. 1(b).

[141] Annex of the Medicines Decision, para. 2: "For other eligible importing Members insufficient or no manufacturing capacities for the product(s) in question may be established in either of the following ways: (i) the Member in question has established that it has no manufacturing capacity in the pharmaceutical sector; or (ii) where the Member has some manufacturing capacity in this sector, it has examined this capacity and found that, excluding any capacity owned or controlled by the patent owner, it is currently insufficient for the purposes of meeting its needs. When it is established that such capacity has become sufficient to meet the Member's needs, the system shall no longer apply."

[142] Correa 2004, p. 17–18. It should be noted that several WTO Members notified the TRIPS Council that they will not use the system as importing countries and some made a statement that in case they would use it, it would only be in cases of national emergency or extreme urgency. Practically, all OECD countries are not using the system as importing States, including all members of the EC (the Medicines Decision, para. 1 [b]). Abbott has explained this as a factor that made the EC to concede to an approach that set no prior limitations for possible exporter countries. The EC was primarily concerned on the possible price erosion and low-priced imports in developed countries – along with the control mechanism and the statement that developed countries would not employ the system as importers, the rights of patent holders seem to be adequately taken into account (Abbott [1] 2005, p. 329).

[143] Jean Chrétien Pledge to Africa, Section 21.04(3)(d)(iii); EC Regulation, Article 4; Gesetzesänderung, Article 40(d)(1).

membership in the WTO as a precondition for benefiting from the established system would, in any case, be unreasonable from a human rights perspective. In order to take steps towards the realization of universal access to patented medicines, all prospective exporting WTO Members should tackle this question when implementing the decision. Membership in the WTO has not been set as an absolute precondition for utilizing the Medicines Decision in the implementing legislations under examination[144]. Certain restrictive conditions have nonetheless been set *e.g.* in the EC.

The EC regulation defines all least-developed countries as eligible importers regardless of their membership in the WTO.[145] It yet sets a strict criterion for the eligibility of other non-WTO countries: pursuant to Article 4 (c), "any country that is not a member of the WTO, but listed in the OECD Development Assistance Committee's list of low-income countries with a gross national product per capita of less than USD 745, and has made a notification to the Commission of its intention to use the system as an importer, including whether it will use the system in whole or in a limited way", is eligible to import medicines manufactured under the system. Thus, the scope of eligible non-WTO countries is strongly limited in Europe where the initial wish to set a predetermined criteria for eligible countries based on national income seems to be held on to in relation to non-WTO countries. This can be criticized for its possible negative effects on access to medicines in certain countries.

For example, Turkmenistan is eligible for official development assistance as it is listed by the OECD as a low middle income country with a per capita gross national income between USD 936 and USD 3 705.[146] However, the country is not a Member of the WTO.[147] It is thus not eligible to receive any medicines manufactured under compulsory licenses from the territory of the EC. Surely, Turkmenistan does not possess manufacturing capacity of generic medicines sufficient to secure access to medicines for its people. If the government of Turkmenistan wanted to provide its population access to patented medication that otherwise is unaffordable, it would have to turn to other potential exporters as the Members of the EC have excluded themselves from this kind of action. This situation is untenable from the perspective of the

[144] In Switzerland, eligible country is a country "das über keine oder ungenügende eigene Herstellungskapazitäten auf pharmazeutischem Gebiet verfügt und diese Produkte zur Bekämpfung von

Problemen der öffentlichen Gesundheit benötigt, insbesondere im Zusammenhang mit HIV/Aids, Tuberkulose, Malaria und anderen Epidemien". Only countries that have notified the TRIPS Council that they will not use the system or that they will only use it in extreme circumstances are excluded from eligibility (Gesetzesänderung, Articles 40[d][1] and 40[d][2]).

[145] EC regulation, Article 4(a).

[146]See OECD list of countries eligible for official development assistance, available at http://www.oecd.org/dataoecd/62/48/41655745.pdf (last visited 16.2.2010).

[147] List of WTO Members available at http://www.wto.org/english/theWTO_e/whatis_e/tif_e/org6_e.htm (last visited 16.2.2010).

goals all EC members have accepted by being Members of the United Nations and parties to various human rights conventions.[148]

When implementing the Medicines Decision, WTO Members should not set restrictive conditions for potential importing countries based on their membership in the WTO. All countries should have the right to utilize the Medicines Decision for the protection of access to medicines. Needless to say, this entails obligations also: they should have a duty of preventing re-exportation of the medicines in accordance with the decision (see section 3.6.6. below). Such duties can, however, easily be established through license agreements – thus, patent rights would be respected just as they are if the importer is a WTO Member. Finally, Article 30 of the TRIPS Agreement remains applicable and there are no clear reasons why a WTO Member could not export medicines to a non-WTO country under the article[149].

3.4.3. Position of Non-Governmental Organizations

NGOs and international organizations are responsible for the supply and distribution of pharmaceutical products in many developing countries that are short of working local governance. The Medicines Decision is silent on whether these organizations are entitled to request importation of patented medicines under the decision. However, in the implementing legislations of Canada and the EC, other than governmental entities are also specifically mentioned. Pursuant to the EC Regulation, evidence of a specific request from the importer must be attached to the license application. A request made by a non-governmental organization or a UN body or other international health organization acting with the formal authorization of the importing country qualifies for this purpose[150]. Similarly, products manufactured in Canada can be sold to a non-governmental entity authorized by the government of the importing country[151]. In the proposed U.S. amendment, non-governmental

[148] In Canada, for example, eligible countries are listed in different schedules based on their economic status and WTO membership. Schedule 4 includes non-WTO countries that are eligible for official development assistance. The scope of eligible countries is hence rather wide considering that the OECD list of countries eligible for official development assistance includes upper middle income countries that had per capita gross national income of up to USD 11 455 dollars in 2007.

[149] Abbott & Reichman 2007, p. 958. The authors refer to the resolution adopted by the European Parliament on the TRIPS Agreement and access to medicines. In paragraph 10 of the resolution, the parliament "calls on the Council to adopt a Joint Policy Statement with Parliament to the effect that WTO Members remain free to use all exceptions from the TRIPS Agreement under their domestic patent laws to authorise production and export to address public health needs in importing *Members* (emphasis added) and asks the Council to ensure that the Commission refrains from taking action to interfere with these proceedings.

[150] EC Regulation, Article 6(3)(f)(ii) and (iii).

[151] Jean Chrétien Pledge to Africa, Section 21.04(2)(f). The requirement of permission from the government of the importing country has been criticized in Canada (Elliot 2007, p. 53).

agencies were referred to for supportive purposes which would have seemingly left them in a less independent position[152].

NGOs should be encouraged to promote the use of the system established by the Medicines Decision in countries where they are largely responsible for the provision of medicines. They may often have more accurate information on how the system can best be utilized in these countries. They may also have more knowledge on the needs of the local population. Some scholars have gone as far as claiming that generic companies should be permitted to enter into an importation agreement directly with NGOs, provided that the NGO in question supplies medicines to the eligible importing country[153]. Despite the advantages of this suggestion, it would be questionable to allow NGOs to act independently of the government as only States have the ability to take measures needed for the prevention of re-exportation (*e.g.* custom clearance). Therefore, in order for a country to be able to utilize the Medicines Decision, its government has to be willing to cooperate. This, in turn, is an obligation of every State for the realization of access to medicines. Including non-governmental agencies in the legislation implementing the Medicines Decision for supporting purposes is nevertheless essential and represents an up-to-date view on the measures that are required for ensuring universal access to medicines – a mission that can only be completed through efficient cooperation between all stakeholders involved.

3.5. Scope And Coverage of Products and Diseases

In paragraph 1 of the Doha Declaration, WTO Members "recognize the gravity of the public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics". Paragraph 4 refers to public health and access to medicines without any further qualifications while in paragraph 6, reference is made to "WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector". Even though no limitations are set in the declaration, some WTO Members presented that the future decision should be limited only to medicines used for the treatment of diseases specifically named in the declaration. For home countries of major research based pharmaceutical companies, this would have been a way to minimize the amount of revenues eroded.[154] The United States insisted on limiting the applicability of the Medicines Decision to the diseases named in paragraph 1 of the Doha Declaration.[155] Similarly, the representative of Australia claimed that the declaration clearly articulated the scope and coverage of the future decision. Accordingly, the future decision should only cover medicines

[152] Life-Saving Medicines Export Act Section 298(b)(1), Section 298(c)(2)(F).

[153] Lazo 2007, p. 264.

[154] For the different suggestions presented in the negotiations, see Abbott [1] 2005, p. 327–334.

[155] See *e.g.* Council for TRIPS, Minutes of meeting held in November and December 2002, para. 34 (where the inability of the U.S. delegation to agree to the consensus reached on the scope of diseases is expressed).

for the treatment of HIV/AIDS, tuberculosis, malaria and other epidemics. Additional products like active ingredients or diagnostic kits should only be included in the agreed criteria if they were related to the diseases specifically mentioned[156].

Limiting the scope of diseases seems incomprehensible – after all, diseases individuals in developing countries suffer from are not limited to those that can be classified as epidemics. Non-communicable conditions such as cardiovascular disease, cancer, diabetes and respiratory and musculoskeletal diseases are major causes of death also in developing countries[157]. Similarly, medicines on the WHO list on essential medicines are increasingly for the treatment of chronic diseases such as cancer and diabetes[158]. Newer, more effective medicines for these conditions are and will be patented also in the future. In the light of the human right to health, it is impossible to justify why compulsory licenses should only apply to infectious diseases of epidemic nature. As pointed out by Abbott and Reichman, "there is no public health justification for denying access to treatment for certain diseases because trade officials have decided that some diseases should be on (or off) an official list"[159].

"Pharmaceutical products" as defined in paragraph 1 of the Medicines Decision mean "any patented product, or product manufactured through a patented process, of the pharmaceutical sector needed to address the public health problems as recognized in paragraph 1 of the Doha Declaration", including "active ingredients necessary for its manufacture and diagnostic kits needed for its use". The word "especially" used in paragraph 1 of the Doha Declaration implies that diseases specifically named in the declaration are mere illustrations. No exhaustive list is presented in the declaration. Thus, the Medicines Decision cannot be interpreted as limiting the scope of diseases either. It neither limits the use of the system to certain types of products nor makes its applicability dependent on their characterization as *e.g.* essential medicines. The decision may also be applied to a patent covering a pharmaceutical formulation or a process for its manufacture. Vaccines are not specifically named in the decision but by using *e contrario* deduction, one can conclude that had the drafters wanted to exclude them, they would have explicitly done so – after all, vaccines are produced by the pharmaceutical industry and they are used to solve public health problems.[160] All in all, no limiting conditions have been set in the Medicines Decision regarding the scope of products or diseases.

[156] Council for TRIPS, Minutes of meeting held in September 2002, para. 30. See also statement supporting this view by the representative of Japan. The EC and the United States favored a term of "constructive ambiguity" in order to find a desirable solution to the problem by interpretation. Ibid., paras. 15 and 44.

[157] See World Health Report 2002, Annex Table 3. Accordingly, 45,9 % of the total amount of deaths was due to noncommunicable conditions in 2001.

[158] WHO: 10 facts on essential medicines (22 October 2007).

[159] Abbott & Reichman 2007, p. 937. See also Abbott [1] 2005 on the relevant negotiations.

[160] Correa 2004, p. 10–11.

In consistency with the Medicines Decision, neither the EC nor Switzerland has nationally limited the scope of pharmaceutical products or diseases the decision can be used for.[161] Canada, in turn, has limited the applicability of the decision to patented products that were on the WHO list of essential medicines and were patented in Canada at the time of the adoption of the national amendment. The decision also applies to antiretroviral medicines that were then approved for sale in Canada.[162] These products are listed in the annex (Schedule 1) to the national amendment.[163] The Governor in Council may amend the list by removing or adding a medicine, a dosage form, strength or a route of administration of a medicine "that may be used to address public health problems afflicting many developing countries and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics" on the recommendation of the Minister of Health who is assisted by an advisory committee.[164]

The Canadian policy narrows down the applicability of the Medicines Decision and is problematic for at least two reasons. Firstly, taking this kind of retrogressive measures in relation to the Medicines Decision violates the obligation also touching upon Canada to ensure that its acts do not adversely impact on access to medicines in third States. As pointed out by Richard Elliot, "by introducing a limited list of products in its implementing legislation, Canada, which had repeatedly indicated it would wait for a multilateral solution to be agreed at the WTO, has unilaterally undermined that consensus"[165]. Secondly, a lot of discretionary powers are given to national officials. It is clear that a great deal of lobbying takes place around leading politicians wherefore politicizing an essential issue such as the one at hand is at least questionable. To conclude, WTO Members should not introduce any limitations as to the scope and coverage of products and diseases in the implementing legislation – instead, the Medicines Decision should, as a starting point, apply to all pharmaceutical products needed to address public health problems.

[161] In the EC, "pharmaceutical product" is defined as "any product of the pharmaceutical sector, including [...] active ingredients and diagnostic kits ex vivo." (EC Regulation, Article 2). In Switzerland, reference is made to "pharmazeutisher Producte [...] zur Bekämpfung von Problemen der öffentlichen Gesundheit benötigt, insbesondere im Zusammenhang mit HIV/Aids, Tuberkulose, Malaria und anderen Epidemien" (Gesetztsänderung, Article 40d1).

[162] Elliot 2007, p. 47.

[163] Jean Chrétien Pledge to Africa, Section 21.02.

[164] Ibid., Section 21.03 (a)(i). Since the passage of the legislation, the list in Schedule 1 has been amended twice in response to requests from generic manufacturers and NGOs: in September 2005 to add a fixed-dose combination AIDS drug containing the antiretroviral drugs zidovudine (AZT), lamivudine (3TC) and nevirapine (NVP) (a fixed-dose combination of which was subsequently manufactured by generic producer Apotex), and again in September 2006 to add the anti-influenza antiviral oseltamivir (marketed by the patentee under the brand-name Tamiflu). In each case, what had been repeatedly represented as being a simple process, turned out to be slow and complex. In fact, it took months before the government acted in consequence of repeated urging by NGOs and would-be manufacturers (Elliot 2007, p. 49).

[165] Elliot 2007, p. 48.

3.6. Procedural Issues

3.6.1. Prior Negotiations

In accordance with Article 31(b) of the TRIPS Agreement, the interested supplier first has to ask for a voluntary license. In Canada, the EC and Switzerland, prior negotiations are expected to take place at least 30 days prior to the filing of the application[166]. Pursuant to the proposed U.S. amendment, request for a voluntary license was to be performed at least 60 days before the submission of the application[167]. Interpreting this to constitute "a reasonable period of time" within the meaning of Article 31(b) of the TRIPS Agreement seems unreasonable for its part: it practically means that a person is denied access to medicines while it is obvious that the additional 30 days will do little for the achievement of a voluntary license agreement between the patent holder and the generic producer. Thus, the definition of "reasonable" should not exceed 30 days.

As previously mentioned, the exporting WTO Member can be entitled to consider the situation in the importing country as an emergency or to recognize its public non-commercial use; then, it is possible to accelerate the process by passing the prior negotiations[168]. After all, the exportation takes place for the control of a health crisis in the recipient country, not in the exporting Member. However, from the national amendments examined only the EC regulation specifically allows for this kind of interpretation[169]. Further, evidence of efforts that have been made in order to obtain a voluntary license is to be attached to the application pursuant to all national implementing legislations under examination[170]. In the absence of a specific mention on the possibility not to perform a prior request, the patent holder may challenge the issuance of a compulsory license for violating the requirement set forth in Article 31(b) if no prior negotiations have occurred within a set period of time. It is thus desirable to provide for an explicit opportunity in the national legislation to pass the prior negotiations in case of outbreaks of epidemics that require immediate action.

[166] EC Regulation, Article 9 (1), Jean Chrétien Pledge to Africa, Section 21.04(3)(c), Gesetzesänderung, Article 40e.

[167] Life-Saving Medicines Export Act, Section 298(2)(F).

[168] Correa 2004, p. 19, 21.

[169] EC Regulation Article 9 (2): "The requirement in paragraph 1 shall not apply in situations of national emergency or other circumstances of extreme urgency or in cases of public non-commercial use under Article 31(b) of the TRIPS Agreement."

[170] During the process that lead to the adoption of the Jean Chrétien Pledge to Africa in Canada, suggestions were made according to which the patent holder would have obtained a right to block the issuance of a compulsory license if it agreed to match the terms of the agreement between the importing country and the generic producer (Elliot 2007, p. 43). This kind of provision would have been unreasonable for generic producers and unnecessary when considering that patent holders have the chance to voluntarily license their patent when the required prior request is performed.

3.6.2. Notification from the Importing Country

Pursuant to paragraph 2 of the Medicines Decision, the importing country has to make a notification to the TRIPS Council in which names and expected quantities of the products needed are specified. It also has to confirm that, if the pharmaceutical is patented in its territory, it has granted or intends to grant a compulsory license in accordance with Article 31 of the TRIPS Agreement and the provisions of the decision. Determining which patents are required in both countries and their legal status is difficult and time-consuming. A compulsory license covering all patents related to a specific product to be acquired, whether identified or not, is an advantageous solution to this problem. This is possible if the license is applied for in cases of national emergencies when no prior request from the patent holder is required pursuant to Article 31(b). This kind of comprehensive coverage would include *e.g.* processes and possible indications of the medicine.[171]

Where prior negotiations with the patent holder are required, *i.e.* when the compulsory license is granted in other situations than those exempted from said obligation, there is regardless a need to recognize all patents related to the pharmaceutical product in question. In addition, right holders must in any case be notified as soon as reasonably possible after the unauthorized use, regardless of whether prior request has been performed[172]. The relevant patents must thus be recognized eventually. This is when assistance from developed countries is needed in order to secure effective implementation of the Medicines Decision. In the proposed U.S. amendment, for example, establishment of a separate office in connection with the national Patent and Trademark Office was suggested that would have *e.g.* assisted in the identification of covered patents[173]. This model should be followed either in all exporting countries separately or on international level as a common enterprise.

In article 67 of the TRIPS Agreement, developed countries commit themselves to cooperate and assist developing and least-developed country Members technically and financially in order to facilitate the implementation of the agreement. In order to offer technical assistance and capacity building for the implementation of WTO rules, the organization announced Integrated Framework for Trade-Related Technical Assistance to Least-developed Countries in 1996 which brings together six international agencies, including UNCTAD and UNDP. The rationale for this framework is to, *inter alia*, offer support for WTO-related aspects of a country's development strategy as well as to assist with the costs of the implementation of WTO obligations. The technical assistance programs carried out to serve this purpose have often been criticized for being inadequate and inefficient. However, since the Doha Round was launched in 2001, donors have provided more funding for the programmes and the WTO Secretariat has

[171] Correa 2004, p. 39.

[172] TRIPS Agreement, Article 31(b).

[173] Life-Saving Medicines Export Act Section 298(c)(1)(b)(i).

also improved in delivering its part.[174] Providing something similar to solve possible technical problems in countries that are willing to utilize the Medicines Decision might face, is an idea worth looking into. This kind of action would increase the effectiveness of the Medicines Decision: it would, first of all, familiarize the system in general and lower the political threshold for its use. It would also accelerate the procedure and thus enable more rapid reactions to emergency situations.

Importing countries, in turn, must ensure that the procedure for obtaining a compulsory license in their jurisdiction remains sufficiently simple. In case the receiving country has not enforced a patent on the product in question, the country only has to contact a generic producer and negotiate an agreement that meets its needs. The situation is more complex, if the country has enforced a patent on the needed product. In many countries, decisions concerning compulsory licensing require the involvement of various government departments and agencies. This prolongs and complicates the procedure in the importing country. In order to facilitate coherence and coordination, WTO Members should explore other available alternatives. Establishing a separate multi-agency committee that is responsible for decision-making, for example, can provide the necessary means for simplifying the procedure[175]. All in all, activeness also on behalf of the importing country is important. While much depends on the political will of its government to employ the system, importing countries will nevertheless also need technical assistance in using the Medicines Decision.

3.6.3. Determination of the Amount of Medicines Needed

It is difficult to estimate the amount of medicines that eventually need to be exported: the developments of health crises are hard to foresee. When making the notification to the TRIPS Council, the importing WTO Member must only specify the *expected* quantity of pharmaceuticals needed.[176] Reference to "expected" quantities means that it does not need to establish its exact needs before the conclusion of the actual license agreement: nothing in the decision prevents a WTO Member from modifying the notified quantity over time if its needs change or are specified.[177] The decision does not establish any form or template for the notification regarding the expected quantities either. Thus, the importing WTO Member is left with certain room for discretion. It could, for example, define the quantities needed by reference to a quantity of pharmaceutical product X sufficient to treat X number of patients

[174] Shaffer 2005, p. 660–661.

[175] Oh 2006, p. 28.

[176] The Medicines Decision, Article 2(a)(i).

[177] Abbott & Reichman 2007, p. 933.

over a period of X amount of time.[178] The exporting WTO Member is not bound by the amount indicated in the notification according to the Medicines Decision either. Yet, only the amount necessary to meet the needs of the importing party may be manufactured under the license pursuant to Article 2(b)(i) of the decision. The "amount necessary to meet the needs" of the importing country may nevertheless be established on the basis of several criteria depending on the degree to which the needs of the importing country can be determined *ex ante* – thus, it does not necessarily imply recourse to the notification.[179]

The national implementing legislations of Canada and the EC nonetheless only allow manufacture of the amount specified in the notification to the WTO or, if the importing country is not a WTO Member, to other relevant entity.[180] This makes it even more important to prefer flexible formulations already at the notification stage – otherwise, the amount imported may turn out insufficient. Furthermore, an application for a compulsory license lodged in Canada must set out the maximum quantity of the pharmaceutical to be manufactured and sold for export under the authorization[181]. Canada does not provide for a chance to modify the license in order to export additional quantities to meet the needs of the importing country either. This can lead to the requirement of renewing the entire administrative procedure in order to obtain a new compulsory license for any possible increases in the products needed, regardless of their magnitude. Needless to say, this is inconsistent with a human rights approach to the implementation of the Medicines Decision.

The EC, instead, provides for an opportunity to revise the conditions of the license if necessary in accordance with a simplified and accelerated procedure. In case the amount exported turns out to be insufficient, the importing country must notify the competent authority of the matter. The licensee must then file a new application that contains relevant information regarding the amount of pharmaceuticals manufactured and the importing country. If prior negotiations would normally be required, this obligation is waived if the amount requested does not exceed 25 percent of the amount granted under the original license[182]. In accordance with the proposed Live Saving Medicines Act, the generic manufacturer would have notified the competent official on insufficiency of the estimated quantity. Then, the amount could have

[178] Abbott & Puymbroeck 2005, p. 24. The authors suggest the following text for the notification: "Based on its present evaluation of its public health needs, [Member] expects to import [quantity(ies)] of [pharmaceutical product name(s)]. However, because it is not possible to predict with certainty the extent of its public health needs [Member] reserves the right to modify the foregoing estimate as necessary or appropriate."

[179] Correa 2004, p. 21.

[180] Jean Chrétien Pledge to Africa, Section 21.05(2)(b); EC Regulation, Article 8(2). In the United States, it was suggested that an estimate of the quantities of the products to be exported as well as a stipulation that the amount manufactured and exported does not exceed the amount necessary to meet the needs of the country would be required by virtue of Section 298(c)(2)(B) of the proposed amendment.

[181] Jean Chrétien Pledge to Africa, Section 21.04(2)(c).

[182] EC Regulation, Article 16 (4).

been adjusted to the quantity proposed by the licensee unless there would have been compelling evidence that the proposed quantity was excessive[183]. The EC has thus comparatively preferred a more limited approach.

Although the European approach does not allow for great flexibility, it is reasonable from the perspective of all parties involved. The importing country and the applicant should be able to assess the necessary amount at least to some extent in advance – otherwise, the situation becomes legally insecure for patent holders. During prior negotiations, they need to have as accurate information as possible on the exception that will be made to their rights in case they refuse to deal. In addition, the model proposed in the United States is unclear with respect to the burden of proof. What constitutes "compelling evidence"? Who has the burden of proof? It would be unreasonable to expect the patent holder to provide this evidence, taking into consideration that the product may be exported to a country the existence of which they are hardly aware of. It is, in any case, important to allow revision of the license if needed. Otherwise, States and generic manufacturers have to be overly cautious when making the notification or filing the national application which would delay the process.

3.6.4. Adequate Remuneration

According to paragraph 3 of the Medicines Decision, adequate remuneration pursuant to Article 31(h) of the TRIPS Agreement shall be paid in the exporting WTO Member, taking account of the economic value of the unauthorized use to the importing State. This means that the competent authorities in the exporting Member determine the amount of compensation paid by the licensee to the patent holder. Since the purpose of a pharmaceutical patent is to generate income for its holder who can exploit the exclusive right in its products or license the patent to another party, it is understandable that the issue of remuneration is of relevance when making exceptions to patents. In order for an exception to these rights to be as limited as possible, the patentee must receive adequate compensation. At the same time, however, attention should be paid to the effect these royalties have on the price of the exported product. The price must remain reasonable. The UNDP estimates royalties of four percent or less of the generic sales price, depending on the circumstances and the economic value of the medicine to the importing country, to be an appropriate policy of remuneration.[184] Due to the price effect of this kind of royalty rate, developing countries may find it unreasonable. For example, Thailand, that issued compulsory licenses to certain medicines during years 2006 and 2007, had initially, without any success, offered a royalty of 0,5 percent to the patent holders in order to obtain voluntary licenses.[185]

[183] Life-Saving Medicines Export Act, Section 298(d)(5).

[184] UNDP: Human Development Report 2001, p. 108.

[185] Abbott & Reichman 2007, p. 953.

The policy of four percent introduced by the UNDP seems to be followed in several countries. For medicines exported from the area of the EC, the remuneration shall, in case of a national emergency or other circumstance of extreme urgency and in cases of public non-commercial use, be a maximum of four percent of the total price paid by the importing country or another entity. In other cases, compensation shall be determined taking account of the economic value of the authorized use to the importing country or countries, as well as the humanitarian or non-commercial circumstances relating to the issuance of the license.[186] In Switzerland, the remuneration must take account of the economic value the license has to the importing country, as well as the level of development and health in that country, and the humanitarian urgency with respect to the need of medicines. The Federal Council determines the appropriate royalty rate.[187]

In Canada, the Governor of Council determines the royalty rate. When doing so, the humanitarian and non-commercial reasons underlying the issuance of the license are considered.[188] Separate guidelines have been established for the determination of the royalty rate. The rate is dependent on the Human Development Index ("HDI") of the importing country assessed by the UNDP. There is a sliding scale of 0,02 percent up to four percent: most developing countries would be required to pay less than three percent royalties, whilst the rate would be less than one percent for most countries in Africa.[189] The Federal Court may on the application of the patent holder order payment of a rate greater than this, if it is dissatisfied with the original royalty rate. When doing so, it must take into account the reasons underlying the issuance of the license and the economic value of the use of the invention to the recipient country.[190] It should be noted that Article 31(j) of the TRIPS Agreement as such demands that any decision relating to the remuneration is subject to judicial review or other independent review by a competent authority in that WTO Member. Therefore, the provision mentioned does not add anything to the rights of patent holders.

The most detailed formulas for the determination of the appropriate royalty rate are found in the proposed U.S. Life Saving Medicines Act. The competent authorities would determine the royalty rate considering factors such as 1) the need of the licensee to make a reasonable return that is sufficient to sustain continued operations, and 2) the need for low-cost pharmaceutical products of the people in the importing country. The maximum royalty rate would be four percent of the commercial value of the supply agreement. Alternative royalty rate formulas that

[186] EC Regulation, Article 9.

[187] Gesetzesänderung, Article 40e(5).

[188] Jean Chrétien Pledge to Africa, Section 21.08(1); 21.08(2). In the original draft of the bill, the government had proposed a flat 2 percent royalty rate for the patent holder. However, the industry association for pharmaceutical patent owners objected to this proposition (Elliot 2007, p. 45).

[189] Oh 2006, p. 32.

[190] Jean Chrétien Pledge to Africa, Section 21.08(4) - 21.08(7).

utilize the HDI ranking of the recipient country are then presented from which the competent official would choose the most appropriate one. Exportation to least-developed countries would, in accordance with the formulas established, lead to royalties below 0, 5 percent.[191] It is important to fix the royalty rates as clearly as possible in order to accelerate the issuance of the license. Including these formulas in the implementing legislation increases transparency; this is why the proposed U.S model seems most adequate. Due to the economic interests underlying the entire issue, unambiguous rules are necessary.

The global patent system has been a joint venture of developed countries and, as presented above, there are reasons to hold on to this venture. Since these exclusive rights are of economic nature, respecting the rights of the inventors of pharmaceuticals exported under the Medicines Decision is possible by ensuring that they receive adequate remuneration. The recipient country may, nonetheless, claim that it cannot afford this kind of compensation. Would it then not be in the interests of all parties that the government of the exporting WTO Member would subsidize this action in the form of development assistance (without decreasing the amount of other public development aid)? In case the exporting WTO Member would also be a developing country, international organizations offering development assistance could come to the rescue. A fund could also be created for this purpose in connection with the WTO secretariat. WTO Members could decide on a fixed amount of royalties, say four percent, which would be paid to the patent holder. After all, providing medicines would be an efficient means of development assistance and it would thus promote the search for solutions of international economic, social, health and related problems in the spirit of Articles 55 and 56 of the UN Charter. Similarly, it would be consistent with Article 2(1) of the ICESCR, according to which Contracting States must "take steps, individually and through international assistance and cooperation, especially economic and technical," for the realization of the rights recognized in the Covenant[192]. At the same time, the money spent could be considered the price that must be paid in order to maintain the international patent system created by the TRIPS Agreement.

[191] Life-Saving Medicines Export Act, Section 298 (e). The proposed act includes detailed formulas for the calculation of the royalty rate. For example, if the name of the importing country would have been on the HDI maintained by the UNDP, the royalty rate would have been determined as follows: (total number of countries listed on the HDI + 1 – the numerical rank on the HDI of the country to which the pharmaceutical product is to be exported) / (total number of countries listed on the HDI) × 0,04. In case the importation would have taken place in *e.g.* Tanzania, which is a country of low human development, the royalty rate in accordance with this formula would be (178 – 159) / 178 × 0,04 = 0,0043. In comparison, exportation to Kazakhstan, a country of medium human development, would have generated the patent holder royalties with the rate of 0,0237. If there would have been only one patentee, the total monetary value of the license agreement would have been multiplied by this royalty rate obtained; in case of several patentees entitled to compensation, the amount would have been divided by the number of patentees. HDI rankings are available at http://hdr.undp.org/en/statistics (last visited 11.4.2010).

[192] See also ESCR Committee, General Comment 3, paras. 13 and 14. In the latter, the committee emphasizes that "in accordance with Articles 55 and 56 of the Charter of the United Nations, with well-established principles of international law, and with the provisions of the Covenant itself, international cooperation for development and thus for the realization of economic, social and cultural rights is an obligation of all States. It is particularly incumbent upon those States that are in a position to assist other in this regard."

3.6.5. Making Exportation Economically Efficient

In order for the system established by the Medicines Decision to work, it has to be economically efficient. Generic producers in both developed and developing countries have argued that, in addition to those of procedural character, economic barriers prevent their participation in the arrangements under the Medicines Decision. After all, they share with the research-based industry the common motivation of serving the interests of their shareholders[193]. As pointed out by Lazo, no matter how altruistic a generic company may be, or how severe a pandemic – like AIDS – may become, failure to incorporate greater financial incentives will render the implementing legislation in question useless in the fight to improve the life or death problem of access to medicines in developing countries.[194] This means that there has to be a sustainable operational framework for anyone willing to apply for a license and decent economic incentives for the manufacture of the generic product. The requirement of economic efficiency hence seems to lead to two requirements: firstly, the license has to remain valid for a period of time sufficient to recoup the production costs. Secondly, the amount of medicines ordered and manufactured under the license has to be large enough. These conditions are interdependent: a license valid for the lifetime of the patent fails to encourage generic production if the amount manufactured remains limited.

It is important that enough time is granted for the production and marketing of the generic product and for the recovery of the costs of this process. In many cases, this may require a license for the lifetime of the patent. Otherwise, producing generic medicines is economically insecure and incentives for such action remain low.[195] Pursuant to Article 31(c) of the TRIPS Agreement, the scope and duration of a compulsory license must be limited to the purpose for which it was granted. The Medicines Decision does not amend this requirement. In the EC and Switzerland, no prior limitations as to the duration of the license have been set, but it has been restated that the duration shall be limited.[196] Canada, instead, has assumed a different kind of approach: an authorization granted under the Jean Chrétien Pledge to Africa is valid for a period of two years beginning on the day on which the authorization was granted.[197] In the proposed Life Saving Medicines Act, the term of a compulsory license issued under the

[193] Commission on Intellectual Property Rights, Innovation and Public Health 2006, p. 120.

[194] Lazo 2007, p. 241.

[195] Correa 1998, p. 214.

[196] EC Regulation Article 10(3), Gesetzesänderung Article 40e(2).

[197] Jean Chrétien Pledge to Africa, Section 21.09.

Medicines Decision expires on the date that is the earliest of seven years after the date of issuance of the license.[198]

The generic producer incurs the costs of producing the exported medicine. These include *e.g.* the costs of reverse-engineering the pharmaceutical in question, presumably without any assistance from the patent holder. In addition, the generic producer must pay the royalties set in the exporting WTO Member.[199] Setting limitations for the duration of the license that are not required under the Medicines Decision forms an additional disincentive for generic producers to consider using the system: financial costs and risks associated with obtaining the required regulatory approvals and scaling up production appear greater than the short-term revenues that could be made under the contract. The alternative of applying for a new license includes additional costs and opportunities for the patent holder to intervene in the procedure, thus decreasing its value as a true alternative.[200] Therefore, setting unreasonable limitations for the duration of the license should be avoided.

In addition to the duration of the license, the amount of medicines manufactured under a compulsory license must be as large as possible for the action to be profitable. Contrary to original medicines, generic medicines should be produced with high volume and low margin returns. In order to ensure high volume of medicines manufactured, the importing countries should pool their purchasing power in order to bargain down the prices of pharmaceuticals. The wording in paragraph (2)(b)(i) of the Medicines Decision "only the amount necessary to meet the needs of the eligible importing member(s)" implies that it is possible to incorporate the needs of several eligible importing countries under one license. In the EC regulation, reference is also made to "importing country or countries"[201]. This seems to enable exporting to several countries under one license. The proposed Life Saving Medicines Act, in turn, would have taken a step forward by specifically addressing the issue of combined license applications. The national authority could have established procedures to permit a combined license application from more than one eligible country or issued a multi-country license if appropriate[202].

There is plenty of potential in allowing combined license applications. Many developing countries suffer the same public health problems and lack the necessary manufacturing

[198] Life-Saving Medicines Export Act, Section 298(d)(3)(a). Pursuant to paragraph (c), termination of the license would have naturally been possible prior to this date on a petition from the original patent holder if the circumstances that lead to the issuance of the license cease to exist and it appears probable that such circumstances will not reoccur.

[199] See Lazo 2007, p. 271–274 (suggesting that one possible way of reducing the costs would be to motivate the patent holder to cooperate by rewarding such action by higher royalty rates).

[200] Canadian HIV/AIDS Legal Network 2006, p. 4.

[201] EC Regulation, Articles 6(3)(d) and 10(2).

[202] Life Saving Medicines Act, Section 298(c)(3).

capacity. At the same time, they may not have sufficient information on the possibility of importing generic medicines. Cooperation could improve the ability of these countries to obtain medicines under Medicines Decision. In consequence of pooling their purchasing power, States could additionally obtain medicines at lower prices. However, the Medicines Decision requires each importing WTO Member to make a notification to the TRIPS Council which means that each importing Member would yet have to notify its intentions to the Council. Allowing exportation to several countries under the same license is nevertheless a practical way of improving the economic efficiency and accelerating the procedure of obtaining a license. After all, the importing countries have the same legal right to import medicines and the same legal duties imposed by the Medicines Decision. Since there are no legal obstacles for allowing combined licenses, it would be important to explicitly provide for this opportunity in the implementing legislations in order to avoid obscurity.

In order to better cater to the needs of developing countries, an exception related to the ban of re-exportation was included in paragraph 6 of the Medicines Decision. Where a developing or a least-developed country Member is a party to a regional trade agreement at least half of which consists of countries presently on the UN list of least-developed countries, re-exportation is allowed. The obligation to obtain an additional export license is waived to the extent necessary to enable exportation of a pharmaceutical produced or imported under the Medicines Decision to another developing or least-developed country that is a party to this regional trade agreement and shares the health problem in question[203]. This exception does not allow the generic producer to supply medicines for other States than those that are eligible to import medicines in accordance with the decision; it only allows re-exportation by the original importer. The new importing country also has to issue a compulsory license pursuant to Article 31 of the TRIPS Agreement in case the imported product is covered by a patent in its territory. In addition to these restraints, it is worth remembering that most least-developed countries are situated in Africa. The exception in question is thus relevant only in relation to some regional trade agreements in Africa.[204]

In their article, Abbott and Reichman sketch the establishment of a Regional Pharmaceutical Supply Centre ("RPSC") inside a loose trade association which would have at least six least-developed country Members. The RPSC could organize the procurement of pharmaceuticals needed to fulfil the demand of as many as twelve countries. It would act on behalf of its buyer governments that would now be in a better position to obtain low prices after having pooled their purchasing power. The RPSC would first make efforts to obtain voluntary licenses from patent holders who might be more willing to cooperate with a larger amount of buyers. If it

[203] The Medicines Decision, para. 6(i).

[204] The EC insisted that the solution should be limited to what is effectively Sub-Saharan Africa. It rejected proposals that would have made it unnecessary for importing countries to separately issue compulsory licenses. In addition, developing countries considered the provision for assistance in the creation of regional patents as a part of an EU strategy to support its pharmaceutical industry (Abbott & Reichman 2007, p. 942).

would fail to negotiate a voluntary license, it could purchase the product abroad under the system established by the Medicines Decision. The system established by the decision could also be used for importing active ingredients to be used for the manufacture of pharmaceutical products in the importing countries. Through cooperation, developing countries could hence increase local production facilities.[205]

The proposal of Abbott and Reichman is one example of innovative thinking that expands the use of the Medicines Decision without requiring any legislative reforms. All it calls for is cooperation between States that employ the decision. Similar suggestions should be presented in the WTO context and, more importantly, they should be put into action. It is somewhat ironic that in a world where millions of people lack access to medicines, one obstacle for efficient use of the Medicines Decision could be the small size of relevant markets.

3.6.6. Diversion of Medicines

In order for the Medicines Decision to serve its purpose, medicines manufactured under compulsory licenses must be diverted to individuals who lack access. This issue of appropriate diversion of medicines has two dimensions: internal and external. From the perspective of an effective patent regime and patent holders, the most central issue with respect to the Medicines Decision is the external aspect of diversion: re-exportation of medicines manufactured under the decision must be prevented. This is also important for the beneficiaries of the system, *i.e.* individuals lacking access to affordable medicines. Otherwise, someone else is taking advantage of their suffering and the humanitarian concerns underlying the system are left unresolved. It is understandable that preventing re-exportation was one of the main issues during the negotiations – after all, it is the only way to ensure that patent protection is not eroded in the developed countries.[206]

Preventing re-diversion of medicines requires cooperation. It is undisputable that if the products manufactured in the auspices of the Medicines Decision are re-diverted to the markets of developed countries, the rights of patent holders are infringed in an illegitimate manner.

[205] Abbott & Reichman 2007, p. 974–977. During the negotiations preceding the adoption of the Medicines Decision, the representative of Switzerland suggested an additional instrument of voluntary public tender procedure. In a voluntary public tender procedure the WTO Member with insufficient manufacturing capacity could be assisted in the examination of the offers by another organization with the necessary expertise and the know-how to choose the best offer (for example, the WTO or the WHO). A voluntary public tender would ensure wide participation of potential suppliers in the process and as such is a proposition worth looking into (Council for TRIPS, Minutes of meeting held in June 2002, para. 106).

[206] See *e.g.* Council for TRIPS, Minutes of meeting held in September 2002. The representative of Switzerland, for example, stated that safeguards against diversion were most important to his delegation (Council for TRIPS, Minutes of meeting held in September 2002, para. 82). It should be noted that the TRIPS Agreement as such obligates Members to prevent the importation of any infringing goods into their territory (TRIPS Agreement, Articles 28 and 44.1).

According to paragraph 4 of the Medicines Decision, importing WTO Members must take reasonable measures in order to prevent re-exportation. In addition, all importing WTO Members must ensure the availability of effective legal means to prevent importation that is inconsistent with the decision. Concrete actions range from efficient custom clearance to injunctions and liability for compensation. If a WTO Member considers that such measures are insufficient, the matter can be reviewed in the TRIPS Council[207]. It should yet be noted that developed countries are expected to assist the importing WTO Members in the prevention of re-diversion by providing them with technical and financial assistance[208]. Further, developed countries pledge to cooperate and assist developing countries technically and financially in order to facilitate the implementation of the TRIPS Agreement in Article 67 of the agreement. These are commitments that must be taken seriously, if the wish is to create efficient patent protection globally.

A closer examination of the global patent system reveals that its gains are anything but distributed equally: ten developed countries account for 84 percent of global resources spent on research and development annually, and receive 91 percent of global cross-border royalties and technology license fees.[209] In total, industrial countries account for the vast majority – 97 percent – of patents worldwide. For example, only 31 of the 26 088 applications for patents filed in 1997 under the auspices of the African Intellectual Property Organization were from residents of Africa while only seven of 25 731 applications registered that year by the African Regional Industrial Property Organization were filed by residents.[210] Considering this unequal distribution of the advantages of a global patent system, it would only be reasonable to hold the governments who benefit the most liable for the expenses caused by measures that secure the rights of patent holders. Why should developing countries, that have no resources to secure their citizens access to very basic commodities, allocate their resources to the maintenance of a patent system that is more or less a joint venture of developed countries – an enterprise that they did not want in the first place and that at present hardly benefits them at all?

Although the Medicines Decision only addresses the external dimension of diversion of medicines, a few words can be said regarding its internal aspect. After all, the arrival of medicines manufactured under the system to the importing country as such can be considered a mere first step, while just distribution within that country forms the second step. The importing States are responsible for providing appropriate channels of distribution that ensure effective diversion of medicines within their territory. Here, the physical accessibility of medicines is of significance: medicines must be within safe reach for all sections of the population[211]. Similarly,

[207] The Medicines Decision, para. 5.

[208] The Medicines Decision, para. 4.

[209] Correa 2007, p. 91.

[210] World Bank: World Development Report 2000/2001, p. 184–185.

[211] ESCR Committee, General Comment 14, para. 12 (b).

any price decreases attained with the help of the Medicines Decision must be directly visible in the sales price of these medicines. This means that the government should not include any additional taxes in their prices. Instead, it must ensure affordability of the imported medicines for all[212]. All this requires working governance. Since NGOs can participate in the distribution of the medicines manufactured under the decision, this is a choice a country ought to look into if its own capability turns out to be insufficient. Invoking defences based on the level of development in this connection is unacceptable as ensuring internal diversion of medicines is less a matter of resources than a matter of political will.

IV. From Normative to Political Coherence

As established above, the Medicines Decision leaves WTO Members sufficient room to strike a balance between the public interest and the private rights under examination. Efficiency of the decision depends on the approaches assumed on the national level – how the obligations arising from the right to access to medicines are put into practice when implementing the decision. WTO Members must choose the alternatives that best ensure that pharmaceutical patents do not hinder access to medicines in developing countries; some examples have been given above. As Hestermeyer commented the implementation of the Medicines Decision, "the adoption of such legislation is not just laudable, but a way to comply with the obligation to cooperate"[213]. As another matter, all WTO Members should accept the protocol amending the TRIPS Agreement in order to make the Medicines Decision a permanent part of the agreement. So far, a very limited amount of countries have done this, among these, only few developing countries[214].

Although WTO Members have been given an opportunity to meet their obligations to respect, protect and fulfil the right to access to medicines despite protection of pharmaceutical patents, they have, for the time being, been unwilling to do so by utilizing the Medicines Decision. So far, only Ruanda has notified the TRIPS Council of its intention to import medicines from a Canadian generic manufacturer[215]. The reasons underlying this passivity are most often claimed to be of political nature: governments of developing countries are unwilling to publish their

[212] Ibid.

[213] Hestermeyer 2007, p. 169.

[214] These are (in chronological order) the United States, Switzerland, El Salvador, Rep.of Korea, Norway, India, Philippines, Israel, Japan, Australia, Singapore, Hong Kong (China), China, the EC, Mauritius, Egypt, Mexico, Jordan, Brazil, Morocco, Albania, Macau (China), Canada, Bahrain, Colombia, Zambia, Nicaragua and Pakistan (WTO: Members accepting amendment of the TRIPS Agreement, last visited 11.3.2010).

[215] Council for TRIPS: *Notification under paragraph 2(a) of the Decision of 30 August 2003 on the Implementation of the paragraph 6 of the Doha Declaration – Rwanda* (19 July 2007); *Notification under paragraph 2 (c) of the Decision of 30 August 2003 on the Implementation of Paragraph 6 of the Doha Declaration – Canada* (8 October 2007). See also Intellectual Property Quarter Update 2005.

intentions to exploit the flexibilities in the TRIPS Agreement as they are worried about its possible negative impact on foreign investment in their country and any additional political pressure it may cause[216]. These fears have been nourished by the policies of some developed countries. For example, when Thailand issued three compulsory licenses from November 2006 through February 2007 to manage the costs of providing universal access to antiretroviral medicines (that amount to up to ten percent of the national budget), it found itself faced with immense political pressure. The United States placed the country on its "Priority Watch List"[217], stating that regardless the fact that the licenses issued were in consistency with the TRIPS Agreement, the lack of transparency and due process exhibited in Thailand represented a serious concern. The Trade Commissioner of the European Commission claimed that the actions taken could lead to the isolation of Thailand from "the global biotechnology investment community" and that a systematic policy of applying compulsory licenses whenever medicines exceed certain prices, was inconsistent with the agreement[218]. The hostilities targeted at the government of Thailand are neither legally supported by the TRIPS Agreement nor the subsequent regulation, which, on the contrary, specifically elucidates that "the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health"[219]. What is even more important, these hostile actions violate the obligation of third States to cooperate by virtue of Articles 55 and 56 of the UN Charter and Article 2(1) of the ICESCR. The Thai government was wise to declare its intention to bring a claim to the WTO dispute settlement body, if trade sanctions were wrongfully imposed – there is little doubt that it would win a possible dispute on TRIPS-compliance of its licensing for government use[220].

Finally, it should be noted that compulsory licenses represent a last resort to access to patented medicines. Voluntary licensing should be encouraged since patent holders may be willing to cooperate. For example, when the Canadian generic producer Apotex Inc. requested voluntary licenses from the pharmaceutical companies that hold patents covering the pharmaceuticals that are exported to Ruanda, all right holders expressed interest in the exploitation of their patents under a humanitarian initiative. They agreed to a royalty rate of zero percent, while their main concern was to ensure that the medicines would not be re-diverted from the original recipient country. Boehringer Ingelheim Pharmaceuticals Inc., one of the four pharmaceutical companies involved, went even further by offering a voluntary license that would have, *inter alia*, been valid for the entire patent life of the product, as opposed to the two year term provided by Canadian law. Furthermore, it permitted Apotex Inc. to extend the license to other developing countries in addition to Ruanda by way of a simple letter of intent to the patent

[216] Oh 2006, p. 31.

[217] "Priority Warch List" is one category a country can fall to by virtue of Section 301 of the US Code that allows unilateral measures if a country is denying adequate protection of intellectual property rights.

[218] Abbott & Reichman 2007, p. 947; 949–951.

[219] Doha Declaration, para. 4.

[220] Abbott and Reichman 2007, p. 956.

holder.[221] As noted by Oh, prior negotiations with pharmaceutical companies constitute an integral part of the government's strategy to cope with its public health crisis also in Malaysia. These companies have become more cooperative, since authorized government use took place in the country between 2003 and 2005.[222] It is thus not merely imaginary to claim that one day voluntary cooperation between the actors involved will result in affordable patented medicines in countries lacking manufacturing capacity. In the meanwhile, the Medicines Decision can be employed as a band-aid solution which allows for coherence between the right to access to medicines and pharmaceutical patents. Either way, what is required at the moment are politics that are consistent with the normative regulation underlying the access dilemma.

Unfortunately, it seems that the recent developments in international intellectual property regulation point in the opposite direction. Among these are bilateral and regional free trade agreements: by February 2010, 462 regional trade agreements had been notified to the GATT/WTO.[223] Also issues of intellectual property protection are increasingly settled outside the WTO: several bilateral and regional agreements contain provisions that may hinder the use of the flexibilities in the TRIPS Agreement described above.[224] This hinders access to medicines. It thus seems that matters related to access to pharmaceutical patents in developing countries, should be negotiated in multilateral settings, where weaker States can be backed up by the wider international community. Intellectual property protection is unsuited to be regarded as a matter falling exclusively within the scope of an economic "sub-system" of international law. It has become evident in the TRIPS era that exclusive rights have an impact on fundamental human rights and therefore they are a matter of the human rights "sub-system" also. As such, intellectual property rights, at least to the extent they concern pharmaceutical products, should be negotiated in multilateral settings where human rights advocates are also able to express their concerns. Then, coherence in international law is more likely to remain.

V. Conclusions

In my article, I have explored whether coherence can be maintained in international law between the right to access to medicines and pharmaceutical patents introduced by the TRIPS Agreement. The TRIPS Agreement contains certain flexibilities that enable WTO Members to meet their obligations arising from the right to access to medicines. Further, the TRIPS

[221] Intellectual Property Quarter Update 2005, p. 6.

[222] Oh 2006, p. 28.

[223] WTO: Regional Trade Agreements (http://www.wto.org/english/tratop_e/region_e/region_e.htm [last visited 6.4.2010]).

[224] For a critical view on the regional and bilateral free trade agreements, see *e.g.* Drahos 2007 and Sell 2007. For a review of the intellectual property provisions used in FTAs concluded by the United States, see *e.g.* Vivas-Eugui 2003 (concerning the Free Trade Area of the Americas).

Agreement should be interpreted in consistency with human rights law pursuant to the customary rules of interpretation guiding the construction of the agreement. Since WTO Members can exploit the permissive norms of the TRIPS Agreement in order to follow the obligatory norm of the right to access to medicines, no conflict of norms exists between the two and they should be interpreted harmoniously in accordance with the presumption against conflict. The Medicines Decision constitutes a permissive norm that plays a central role in this kind of reconciliation. By assuming a human rights approach to its implementation, WTO Members can simultaneously ensure that access to medicines is not hindered by pharmaceutical patents in developing countries and maintain an efficient patent system that is also in the best interest of the world community.

As presented above, ensuring access to medicines necessitates the use of compulsory licenses. This inevitably erodes patent protection. However, a clear distinction must be made between developed and developing countries. Policies relating to exclusive rights in the former must be distinguished from policies assumed in the latter. Despite the formal creation of global intellectual property system, it has become evident that it will take time before global exclusive rights can be enforced in practice. For this to happen, people living in developing countries must afford to provide this kind protection. Unfortunately, it seems unlikely that this will occur within the foreseeable future. For the time being, different standards of protection must be followed in developing and developed countries. Using compulsory licenses in practice means that the scope of public domain is expanded at the expense of exclusive rights. It hence seems that the scope of public domain should remain wide in the southern hemisphere whereas it is increasingly limited in the North. However, there seems to be no alternative available for this double standard, since the models developed and upheld in industrialized countries fail to meet the reality in the developing world.

As mentioned in the beginning of this article, the relationship between the right to access to medicines and exclusive rights enshrined by the TRIPS Agreement is an excellent example of the consequences of fragmentation in international relations. However, any legal fragmentation caused by this phenomenon can be ruled by means of the existing international norms. In my study, I have provided an example of how two divergent systems of international law can interact with each other in a manner that preserves coherence in international law. The Medicines Decision must be considered an affirmation of this kind of cross-fertilization between different sets of rules. The phenomenon in question is not a mere coincidence but a natural consequence of the emergence of divergent international institutions and structures within international law that by its nature favours coherence and presumes norms to be cumulative. Allowing for interplay between norms of divergent "sub-systems" of international law provides a counterforce to the general phenomenon of fragmentation. As Cassese has stated, "it shows that at least at the normative level the international community is becoming more integrated and – what is even more important – that such values as human rights and the

need to promote development are increasingly permeating various sectors of international law that previously seemed impervious to them"[225]. Further, it ensures the surveillance of diverging regimes simultaneously which is most often in favour of the entire international community.

As a final remark, it should be emphasized that patents are not the main issue in relation to the right to access to medicines. The overwhelming poverty of individuals, absence of state health care financing, lack of medical personnel and distribution infrastructure are also issues of high importance[226]. Furthermore, the current health crisis in the South is influenced by certain matters of even more fundamental character such as ecological and social conditions, including the lack of education and gender issues [227]. All these issues are related to poverty that, needless to say, is the most fundamental problem underlying the access dilemma but one that cannot be resolved as easily as the relevant patent policies can be altered. The access dilemma can only be solved one piece at a time. Ensuring that pharmaceutical patents do not hinder access to medicines must thus be considered as one of the pieces in the puzzle of global public health. Yet, other pieces must be collected and put in their places as well. It must be borne in mind that the current public health crisis prevailing in the developing world is a sum of hundreds of individuals facing a human tragedy each day. As put by the Commission of Macroeconomics and health, "fighting disease will be the truest test of our common capacity to forge a true global community. There is no excuse in today's world for millions of people to suffer and die each year for lack of USD 34 per person needed to cover essential health services. A just and far-sighted world will not let this tragedy continue"[228].

[225] Cassese 2005, p. 45.

[226] Commission on Intellectual Property Rights, Innovation and Public Health 2006, p. 202.

[227] Commission on Macroeconomics and Health 2001, p. 74–76.

[228] Ibid., p. 110.

TABLE OF REFERENCES

Literature

Abbott, Frederick M. [1]: The WTO Medicines Decision: World Pharmaceutical Trade and the Protection of Public Health. 99 American Journal of International Law 317 (2005).

Abbott, Frederick M. [2]: Managing the Hydra: The herculean task of ensuring access to essential medicines. In: Maskus, Keith E. & Reichman, Jerome H.: International Public Goods and Transfer of Technology. Cambridge University Press. Cambridge 2005.

Abbott, Frederick M. & van Puymbroeck, Rudolph: Compulsory Licensing for Public Health, A Guide and Model Documents for Implementation of the Doha Declaration Paragraph 6 Decision, World Bank Working Paper No. 61 (2005). Accessible at http://www-wds.worldbank.org/external/default/WDSContentServer/WDSP/IB/2005/08/30/000012009_20050830130225/Rendered/PDF/334260rev0pub.pdf (last visited 8.11.2008).

Abbott, Frederick M. & Reichman, Jerome H.: The Doha Round's Public Health Legacy: Strategies for the Production and Diffusion of Patented Medicines Under the Amended TRIPS Provisions. 10 Journal of International Economic Law 921 (2007).

Alston, Philip & Quinn, Gerard: The Nature and Scope of States Parties' Obligations under the International Covenant on Economic, Social and Cultural Rights. 9 Human Rights Quarterly 156 (1987).

Alvarez, Jose E.: The New Treaty Makers. 25 Boston College International and Comparative Law Review 213 (2002).

Vivas-Eugui, David: Regional and bilateral agreements and a TRIPS-plus world: the Free Trade Area of the Americas. Quaker United Nations Office TRIPS Issue Papers 1 (2003). Accessible at http://www.quno.org/economicissues/intellectual-property/intellectualLinks.htm#QUNOPUB (last visited 16.11.2008).

Correa, Carlos M.: Patent Rights. In: Correa, Carlos M. & Yusuf, Abdulqawi A.: Intellectual Property Rights and International Trade: The TRIPS Agreement. Kluwer Law International. London 1998.

Correa, Carlos M.: Implications of the Doha Declaration. World Health Organization (2002). Accessible at http://www.who.int/medicinedocs/index.fcgi?sid=q7hObeB79ee80ca700000000474ca8a4&a=d&d=Js2301e (last visited 18.1.2008).

Correa, Carlos M.: Implementation of the WTO General Council Decision on Paragraph 6 of the Doha Declaration. World Health Organization (2004). Accessible at http://www.who.int/medicines/areas/policy/WTO_DOHA_DecisionPara6final.pdf (last visited 18.1.2008).

Correa, Carlos: Trade Related Aspects of Intellectual Property Rights. A commentary on the TRIPS Agreement. Oxford University Press. New York 2007.

Craven, Matthew C.R.: The International Covenant on Economic, Social and Cultural Rights. A Perspective on its Development. Clarendon Press. Oxford 1995.

Cullet, Philippe: Patents and Medicines. The Relationship between TRIPS and the Human Right to Health. In: Gruskin, Grodin, Annas and Marks (eds.): Perspectives on health and human rights. Routledge. London 2006.

DiMasi, Joseph A. et al.: The Price of Innovation: New Estimates of Drug Development Costs. 22 Journal of Health Economics 151 (2003).

Dowell-Jones, Mary: Contextualising the International Covenant on Economic, Social and Cultural Rights : Assessing the economic deficit. Martinus Nijhoff. Leiden Boston 2004.

Drahos, Peter: Four Lessons for Developing Countries from the Trade Negotiations over Access to Medicines. 28 Liverpool Law Review 11 (2007).

Durojaye, Ebenezer: Compulsory Licensing and Access to Medicines in Post Doha Era: What Hope for Africa? Netherlands International Law Review p. 33 - 71 (2008).

Dutfield, Graham: Delivering Medicines to the Poor: Will the TRIPS Amendment help? 34 American Journal of Law and Medicine 107 (2008).

Eide, Asbjørn: The Obstacles and Goals to be Pursued. In: Eide, Krause and Rosas: Economic, Social and Cultural Rights A Textbook. Martinus Nijhoff Publishers. The Netherlands 2001.

Elliot, Richard: Delivering on the Pledge: Global Access to Medicines, WTO Rules, and Reforming Canada's Law on Compulsory Licensing for Export. Vol. 3 Issue 1 McGill International Journal of Sustainable Development Law & Policy 23 (2007).

Fischer-Lescano, Andreas & Teubner, Gunther: Regime Collisions: The Vain Search for Legal Unity in the Fragmentation of Global Law. 25 Michigan Journal of International Law 999 (2004).

Flynn, Sean: Legal Strategies for Expanding the Access to Medicines. 17 Emory International Law Review 535 (2003).

Frankel, Suzy: The WTO's Application of the Customary Rules of Interpretation of Public International Law to Intellectual Property. 46 Virginia Journal of International Law 365 (2006).

Gervais, Daniel: The TRIPS Agreement – Drafting History and Analysis. 2nd edition Sweet & Maxwell Ltd. London 2003.

Haracoglou, Irina: Competition Law and Patents. A Follow-on Innovation Perspective in the Biopharmaceutical Industry. Edward Elgar. Cheltenham 2008.

Hestermeyer, Holger: Human Rights and the WTO. The Case of Patents and Access to Medicines. Oxford University Press. New York 2007.

Hoen, Ellen 't: TRIPS, Pharmaceutical Patents, and Access to Essential Medicines. A Long Way From Seattle to Doha. In: Gruskin, Grodin, Annas and Marks (eds.): Perspectives on health and human rights. Routledge. London 2006.

Jenks, Wilfred: Conflict of Law-Making Treaties. 30 British Yearbook of International Law 401 (1953).

Koskenniemi, Martti: Fragmentation of International Law: Difficulties Arising from the Diversification and Expansion of International Law. Report of the Study Group of the International Law Commission. Fifty-eighth session of the International Law Commission. UN Doc A/CN.4//L.682 (13 April 2006).

Koskenniemi, Martti & Leino, Päivi: Fragmentation of International Law? Postmodern Anxieties. 15 Leiden Journal of International Law 553 (2002).

Lazo, Jennifer A.: The Life-Saving Medicines Export Act: Why the Proposed U.S. Compulsory Licensing Scheme Will Fail to Export Any Medicines or Save Any Lives. 33 Brooklyn Journal of International Law 237 (2007).

Lazzarini, Zita: Making Access to Pharmaceuticals a Reality: Legal Options Under TRIPS and the Case of Brazil. 6 Yale Human Rights & Development Law Journal 103 (2003).

Lindoos, Anja & Mehling, Michael: Dispelling the Chimera of 'Self-Contained Regimes' International Law and the WTO. 16 (5) The European Journal of International Law 857.

Marceau, Gabrielle: Conflicts of Norms and Conflict of Jurisdictions. The Relationship between the WTO Agreement and MEAs and other Treaties. 35(6) Journal of World Trade 1081 (2001).

Marceau, Gabrielle: WTO Dispute Settlement and Human Rights. 13 (4) European Journal of International Law 753 (2002).

Mitchell, Andrew D.: The Legal Basis for Using Principles in WTO Disputes. 10 Journal of International Economic Law 795 (2007).

Nagan, Winston P.: International Intellectual Property, Access to Health Care, and Human Rights: South Africa v. United States. 14 Florida Journal of International Law 155 (2002).

Oh, Cecilia: Compulsory Licenses: Recent Experiences in Developing Countries. Vol 1, Nos 1/2 International Journal of Intellectual Property Management (2006).

Pauwelyn, Joost: The Role of Public International Law in the WTO: How Far Can We Go? 95 American Journal of International Law 535 (2001).

Pauwelyn, Joost: Conflict of Norms in Public International Law. Cambridge University Press. Cambridge 2003.

Sell, Susan K.: TRIPS-Plus Free Trade Agreements and Access to Medicines. 28 Liverpool Law Review 41 (2007).

Shaffer, Gregory: Can WTO Technical Assistance and Capacity-Building Serve Developing Countries? 23 Wisconsin International Law Journal 643 (2005).

Sun, Haochen: The Road to Doha and Beyond: Some Reflections on the TRIPS Agreement and Public Health. 15 (1) European Journal of International Law 123 (2004).

Vivas-Eugui, David: Regional and bilateral agreements and a TRIPS-plus world: the Free Trade Area of the Americas. Quaker United Nations Office TRIPS Issue Papers 1 (2003). Accessible at http://www.quno.org/economicissues/intellectual-property/intellectualLinks.htm#QUNOPUB (last visited 16.11.2008).

Vranes, Erich: The Definition of 'Norm-Conflict' in International Law and Legal Theory. 17 European Journal of International Law 395 (2006).

Yalamanchili, Vijay: State of India's TRIPS-Compliant Patent Regime. 26 Biotechnology Law Report 211 (2007).

Yamin, Alicia Ely: Not just a Tragedy: Access to Medications as a Right under International Law. 21 Boston University International Law Journal 101 (2004).

Other Private Publications

Canadian Hiv/AIDS Legal Network: The Jean Chrétien Pledge to Africa and its impact on improving access to HIV/AIDS treatment in developing countries (2008). Accessible at http://www.aidslaw.ca/publications/interfaces/downloadFile.php?ref=696 (last visited 10.10.2008).

Consumer Project on Technology: Patent Exception for Exports to Address Health Needs (Legislation to Allow for the Export of Pharmaceuticals Produced under Compulsory License). Accessible at http://www.cptech.org/ip/wto/p6/index.html (last visited 23.1.2009).

Intellectual Property Quarter Update: Rwanda and Canada: Leading the Implementation of the August 2003 Decision for Import/Export of Pharmaceuticals Produced Under Compulsory License. 3 Intellectual Property Quarter Update 5 (2007).

Accessible at www.ciel.org/Publications/IP_Update_3Q07.pdf (last visited 10.10.2008).

Maastrict guidelines on Violations of Economic, Social and Cultural Rights. Maastricht 1997. Accessible at http://www1.umn.edu/humanrts/instree/Maastrichtguidelines_.html (last visited 24.10.2008).

MSF: Why Article 30 Will Work. Why Article 31 Will Not (2002). Accessible at http://www.accessmed-msf.org/fileadmin/user_upload/medinnov_accesspatents/WhyArticle30willworkwhyArticle31willnot_2002.pdf (last visited 5.8.2008).

MSF, Oxfam, CPTech, Health Gap, Third World Network, & Essential Action, Joint Letter to Members of TRIPS Council (28 January 2002). Accessible at http://www.accessmed-msf.org/resources/key-publications/key-publication-detail/Article/joint-letter-to-the-trips-council-january-2002/ (last visited 5.8.2008).

MSF: Neither Expeditious, Nor Solution: The WTO August 30th Decision Is Unworkable (2006). Accessible at http://www.msf.ch/fileadmin/user_upload/uploads/communiques/images_2006/pdf/came_Neither_expeditious_nor_a_solution_-_August_30_and_the_JCPA_single_page.pdf (last visited 28.10.2008).

Oxfam: Priced Out of Reach: How WTO Patent Policies Will Reduce Access to Medicines in the Developing World. Oxfam briefing paper 4 (2001). Accessible at http://www.oxfam.org.uk/resources/policy/health/index.html (last visited 24.10.2008).

Official sources

Decisions, declarations and resolutions

Council for TRIPS: Decision on the Extension of the Transition Period under Article 66.1 of the TRIPS Agreement for Least-developed Country Members for Certain Obligations with Respect to Pharmaceutical Products. IP/C/25 (1 July 2002). Accessible at http://www.wto.org/english/tratop_e/trips_e/art70_9_e.htm (last visited 24.10.2008).

UN Commission on Human Rights (resolution 2001/33): Access to Medication in the context of pandemics such as HIV/AIDS. UN Doc. E/CN.4/RES/2001/33 (71st meeting, 20 April 2001). Accessible at http://www.unhchr.ch/huridocda/huridoca.nsf/Documents?OpenFrameset (last visited 24.10.2008).

UN Commission on Human Rights (resolution 2002/32): Access to Medication in the Context of Pandemics such as HIV/AIDS. UN Doc. E/CN.4/RES/2002/32 (49th meeting, 22 April 2002). Accessible at http://www.unhchr.ch/huridocda/huridoca.nsf/Documents?OpenFrameset (last visited 24.10.2008).

UN High Commissioner of Human Rights: The impact of the Agreement on Trade-Related Aspects of Intellectual Property Rights on human rights. Report of the High Commissioner. UN Doc. E/CN.4/Sub.2/2001/13 (27 June 2001). Accessible at http://documents-dds-ny.un.org/doc/UNDOC/GEN/G01/143/45/pdf/G0114345.pdf?OpenElement (last visited 24.10.2008).

UN Sub-Commission on Human Rights (resolution 2000/7): Intellectual Property Rights and Human Rights. UN Doc. E/CN.4/SUB.2/RES/2000/7. 25th meeting (17 August 2000). Accessible at http://www.unhchr.ch/Huridocda/Huridoca.nsf/0/c462b62cf8a07b13c12569700046704e?Opendocument (last visited 12.10.2008).

World Health Assembly (resolution WHA56.27): Intellectual property rights, innovation and public health. 56th World Health Assembly (28 May 2003). Accessible at http://ftp.who.int/gb/archive/pdf_files/WHA56/ea56r27.pdf (last visited 20.10.2008).

WTO General Council: Implementation-Related Issues and Concerns. WTO Doc. WT/MIN(01)/17 (14 November 2001). Accessible at http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_implementation_e.htm#trips (last visited 24.10.2008).

WTO General Council: Declaration on the TRIPS Agreement and Public Health. WTO Doc. WT/MIN(01)/DEC/W/2 (14 November 2001). Accessible at http://www.wto.org/English/thewto_e/minist_e/min01_e/mindecl_trips_e.htm (last visited 24.10.2008).

WTO General Council: Decision on Least-developed Country Members – Obligations Under Article 70.9 of the TRIPS Agreement with Respect to Pharmaceutical Products. WTO Doc. WT/L/478 (12 July 2002). Accessible at http://www.wto.org/english/tratop_e/trips_e/art70_9_e.htm (last visited 24.10.2008).

WTO General Council: Decision on Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health. WTO Doc. WT/L/540, Corr.1 (1 September 2003). Accessible at http://www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm (last visited 23.10.2008).

WTO General Council: Doha Ministerial Declaration. WTO Doc. WT/MIN(05)/DEC (18 December 2005). Accessible at http://www.wto.org/english/thewto_e/minist_e/min05_e/final_text_e.htm#non_viol (last visited 13.1.2008).

WTO General Council: Amendment of the TRIPS Agreement. WTO Doc. WT/L/641 (8 December 2005). Accessible at http://www.wto.org/english/tratop_e/trips_e/wtl641_e.htm (last visited 25.10.2008).

WTO General Council: General Council´s Chairperson's statement. Excerpt from the minutes of the General Council meeting 30 August 2003. WTO Doc. WT/GC/M/82 (13 November 2003). Accessible at http://www.wto.org/english/tratop_e/trips_e/gc_stat_30aug03_e.htm (last visited 3.2.2009).

WTO General Council: Amendment of the TRIPS Agreement – Extension of the period for the acceptance by members of the protocol amending the TRIPS Agreement. WTO Doc. WT/L/711 (21 December 2007). Accessible at http://www.wto.org/english/tratop_e/trips_e/pharmpatent_e.htm (last visited 24.10.2008).

Other Official Publications and Documents

Commission on Intellectual Property Rights, Innovation and Public Health: Public Health, Innovation and Intellectual Property Rights. WHO 2006. Accessible at http://www.who.int/intellectualproperty/report/en/index.html (last visited 24.10.2008).

Commission on Macroeconomics and Health: Investing in Health for Economic Development (2001). Accessible at http://www.paho.org/English/HDP/HDD/Sachs.pdf (last visited 6.2.2009).

Council for TRIPS: Minutes of meeting held in the Centre William Rappard 17–19 September 2002. IP/C/M/37 (11 October 2002). Accessible at http://www.wto.org/english/tratop_e/trips_e/intel6_e.htm (last visited 24.10.2008).

Council for TRIPS: Minutes of meeting held in the Centre William Rappard on 25-27 and 29 November, and 20 December 2002. IP/C/M/37 (5 February 2003). Accessible at http://www.wto.org/english/tratop_e/trips_e/intel6_e.htm (last visited 24.10.2008).

Council for TRIPS: Minutes of meeting held in the Centre William Rappard 4–5 June. IP/C/M/40 (22 August 2003). Accessible at http://www.wto.org/english/tratop_e/trips_e/intel6_e.htm (last visited 24.10.2008).

Council for TRIPS: Notification under paragraph 2(a) of the Decision of 30 August 2003 on the Implementation of the paragraph 6 of the Doha Declaration – Rwanda. IP/N/9/RWA/1 (19 July 2007). Accessible at http://www.wto.org/english/tratop_e/trips_e/public_health_notif_import_e.htm (last visited 23.10.2008).

Council for TRIPS: Notification under paragraph 2 (c) of the Decision of 30 August 2003 on the Implementation of Paragraph 6 of the Doha Declaration – Canada. IP/N/10/CAN/1 (8 October 2007). Accessible at http://www.wto.org/english/tratop_e/trips_e/public_health_notif_export_e.htm (last visited 23.10.2008).

Limburg Principles on the Implementation of the International Covenant on Economic, Social and Cultural Rights, UN. Doc. E/CN.4/1987/17, Annex. 9. Human Rights Quarterly 122 (1987).

OECD list of countries eligible for official development assistance. Accessible at http://www.oecd.org/dataoecd/62/48/41655745.pdf (last visited 16.2.2010).

UNDP: Human Development Report 2001: Making New Technologies Work for Human Development.

UNDP: Human Development Indices: A statistical update 2008 – HDI Rankings. Accessible at http://hdr.undp.org/en/statistics (last visited 14.8.2008).

UN Committee on Economic, Social and Cultural Rights: General comment 3: The Nature of States Parties obligations (Article 2, par. 1). 5th Session (1990). UN Doc. 14/12/1990. Accessible at http://www.unhchr.ch/tbs/doc.nsf/(symbol)/CESCR+General+comment+3.En?OpenDocument (last visited 25.10.2008).

UN Committee on Economic, Social and Cultural Rights: General comment 14: The right to the highest attainable standard of health (Article 12). 22nd Session, 11 August 2000. UN Doc. E/C.12/2000/4 Accessible at http://www.unhchr.ch/tbs/doc.nsf/(symbol)/E.C.12.2000.4.En (last visited 25.10.2008).

UN Development Policy and Analysis Division: The criteria for identifying Least Developed Countries. Accessible at http://www.un.org/esa/policy/devplan/profile/criteria.html (last visited 18.1.2008).

UN Special Rapporteur on the right to highest attainable standard of health: Human Rights Guidelines for Pharmaceutical Companies in relation to Access to Medicines. Accessible at www2.ohchr.org/.../Guidelinesforpharmaceuticalcompanies.doc (last visited 10.4.2010).

UN Treaty Collection: International Covenant on Economic, Social and Cultural Rights. Status as at 26.3.2010. Accessible at http://treaties.un.org/Pages/ViewDetails.aspx?src=TREATY&mtdsg_no=IV-3&chapter=4&lang=en (last visited 26.3.2010).

The United States: The proposed Life Saving Medicines Export Act: GovTrack.us. S. 3175~109th Congress (2006): Life-Saving Medicines Export Act of 2006. GovTrack.us (database of federal legislation). Accessible at <http://www.govtrack.us/congress/bill.xpd?bill=s109-3175> (last visited 9.10.2008).

WHO: World Health Report 2002. Accessible at http://www.who.int/whr/2002/en/whr2002_annex3.pdf (last visited 9.10.2008).

WHO: 10 facts on neglected tropical diseases. Accessible at http://www.who.int/features/factfiles/neglected_tropical_diseases/en/index.html (last visited 24.10.2008).

WHO: Selection of essential medicines. Accessible at http://www.who.int/selection_medicines/list/en/ (last visited 20.8.2008).

World Bank: World Development Report 2000/2001: Attacking poverty. Accessible at http://web.worldbank.org/WBSITE/EXTERNAL/TOPICS/EXTPOVERTY/0,,contentMDK:20194762~pagePK:148956~piPK:216618~theSitePK:336992,00.html (last visited 3.12.2008).

WTO: List of WTO Members, accessible at http://www.wto.org/english/theWTO_e/whatis_e/tif_e/org6_e.htm (last visited 16.2.2010).

WTO: Members accepting amendment of the TRIPS Agreement, accessible at http://www.wto.org/english/tratop_e/trips_e/amendment_e.htm (last visited 11.3.2010).

WTO: Regional Trade Agreements. Accessible at http://www.wto.org/english/tratop_e/region_e/region_e.htm (last visited 6.4.2010).

Relevant Domestic Legislation

Canada: Use of Patents International Humanitarian Purposes to Address Public Health Problems ("Jean Chrétien Pledge to Africa"). Patent Act, Section 21. Accessible at http://laws.justice.gc.ca/en/showdoc/cs/P-4/bo-ga:s_21_01//en#anchorbo-ga:s_21_01 (last visited 24.10.2008).

The European Communities: Regulation (EC) No 816/2006 of the European Parliament and the Council of 17 May 2006 on compulsory licensing of patents relating to manufacture of pharmaceutical products for export to countries with public health problems. Accessible at http://eur-lex.europa.eu/LexUriServ/site/en/oj/2006/l_157/l_15720060609en00010007.pdf (last visited 24.10.2008).

Switzerland: Zwangslizenzen für die Ausfuhr pharmaceutische Producte. Bundesgesetz über die Erfindungspatente (25 June 1954), Articles 40d and 40e. Accessible at http://www.admin.ch/ch/d/sr/2/232.14.de.pdf (last visited 9.10.2008).

Case Law

WTO Appellate Body: Guatemala-Anti-Dumbing Investigation Regarding Portland Cement from Mexico. WTO Doc. WT/DS60/AB/R, para. 65 (5 November 1998). Accessible at http://www.wto.org/english/tratop_e/dispu_e/ab_reports_e.htm (last visited 24.10.2008).

WTO Appellate Body Report: United States – Standards for Reformulated and Conventional Gasoline. WTO Doc. WT/DS2/AB/R (5 May 1996). Accessible at http://www.wto.org/english/tratop_e/dispu_e/ab_reports_e.htm (last visited 29.12.2008).

WTO Panel Report: Canada-Patent Protection of Pharmaceutical Products. WTO Doc. WT/DS114/R (17 March 2000). Accessible at http://www.wto.org/english/tratop_e/dispu_e/7428d.pdf (last visited 5.9.2008).

WTO Panel Report: Korea – Measures Affecting Government Procurement. WTO Doc. WT/DS163/R (1 May 2000). Accessible at http://www.wto.org/english/tratop_e/dispu_e/cases_e/ds163_e.htm (last visited 24.10.2008).

WTO Panel Report: Indonesia–Certain Measures Affecting the Automobile Industry. WTO Doc. WT/DS54/R, WT/DS55/R, WT/DS59/R, WT/DS64/R (2 July 1998). Accessible at http://www.wto.org/english/tratop_e/dispu_e/cases_e/ds54_e.htm (last visited 24.10.2008).

International Agreements

Additional Protocol to the American Convention on Human Rights in the Area of Economic, Social and Cultural Rights. 17 November 1988. OAS Treaty Series No. 69. Accessible at http://www.oas.org/juridico/English/treaties/a-52.html (last visited 24.10.2008).

African (Banjul) Charter on Human and Peoples' Rights. 18th assembly of heads of State and Government, 27 June 1981. OAU Doc. CAB/LEG/67/3. Entered into force 21 October 1986. Accessible at http://www.achpr.org/english/_info/charter_en.html (last visited 24.10.2008).

Agreement on Trade-Related Aspects of Intellectual Property Rights. Annex 1C of the Marrakesh Agreement Establishing the World Trade Organization. 15 April 1994. Accessible at http://www.wto.org/english/docs_e/legal_e/legal_e.htm#TRIPs (last visited 24.10.2008).

Charter of the United Nations (26 June 1945, effective 24 October 1945). Accessible at http://www.un.org/aboutun/charter/ (last visited 25.10.2008).

Convention on the Elimination of all Forms of Discrimination against Women. GA Resolution 34/180. UN Doc. A/34/46, 18 December 1979 (entered into force 3 September 1981). Accessible at http://www.un.org/womenwatch/daw/cedaw/text/econvention.htm#intro (last visited 24.10.2008).

Convention on the Rights of the Child. GA resolution 44/25. UN Doc. A/44/49, 20 November 1989 (entered into force 2 September 1990). Accessible at http://www.unhchr.ch/html/menu3/b/k2crc.htm (last visited 24.10.2008).

Dispute Settlement Understanding. Annex 2 of the Marrakesh Agreement Establishing the World Trade Organization. 15 April 1994. Accessible at http://www.wto.org/english/docs_e/legal_e/legal_e.htm#TRIPs (last visited 24.10.2008).

European Social Charter. 18 October 1961. Accessible at http://conventions.coe.int/Treaty/EN/Treaties/Html/035.htm (last visited 24.10.2008).

International Covenant on Civil and Political Rights. GA Resolution 2200A (XXI). UN Doc. A/6316, 16 December 1966 (entered into force 23 March 1976). Accessible at http://www.unhchr.ch/html/menu3/b/a_ccpr.htm (last visited 24.10.2008).

International Covenant on Economic, Social and Cultural Rights. GA Resolution 2200A (XXI). UN Doc. A/6316, 16 December 1966 (entered into force 3 January 1976). Accessible at http://www.unhchr.ch/html/menu3/b/a_cescr.htm (last visited 24.10.2008).

International Convention on the Elimination of all Forms of Racial Discrimination. GA Resolution 2106 (XX). UN Doc. A/6014, 21 December 1965 (entered into force 4 January 1969). Accessible at http://www.unhchr.ch/html/menu3/b/d_icerd.htm (last visited 24.10.2008).

Marrakesh Agreement Establishing World Trade Organization. 15 April 1994. Accessible at http://www.wto.org/english/docs_e/legal_e/04-wto_e.htm (last visited 24.10.2008).

Vienna Convention on the Law of Treaties (23 May 1969, entered into force 27 January 1980). United Nations, Treaty Series, vol. 1155, p. 331. Accessible at http://untreaty.un.org/ilc/texts/instruments/english/conventions/1_1_1969.pdf (last visited 25.10.2008).