Pharmaceutical Patents, Global Health and the TRIPS Agreement

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1. Abbreviations

AIDS	Acquired Immunodeficiency Syndrome
BILL	The Medicines and Related Substances Bill
CAMR	Canada's Access to Medicines Regime
DSU	The Dispute Settlement Understanding
GATT	The General Agreement on Tariffs and Trade
HIV	Human Immunodeficiency Virus
IPRs	Intellectual Property Rights
IP	Intellectual Property
LDCs	Least Developed Countries
MFN	Most-Favoured Nation
SAMMANDRA	South African Medicines and Medical Devices Regulated Authority Act
TRIPS	The Agreement on Trade-Related Aspects of Intellectual Property Rights
USTR	The United States Trade Representative
VCLT	The Vienna Convention of the Law of Treaties
WHO	World Health Organization

2. Introduction

The problem of pharmaceutical patents and access to medicines is a difficult one. While insufficient infrastructure, lack of well-trained medical personnel and tariffs on drugs are contributing factors, high drug prices are being blamed as one of the main reasons for access problems.[1]

High drug prices are sought by pharmaceutical companies because research and development of new drugs are extremely costly and risky, and competition on the pharmaceutical market has intensified over the last years.[2] A pharmaceutical company may expend millions of dollars on clinical trials to gain approval from the United States Food and Drug Administration, before the product enters the market.[3] At the same time a company relies on only a few successful and profitable drugs and profits derived from sales of drugs that are still covered by patent.[4] Expiry of patent sets off generic competition and erodes profits.[5] With pharmaceutical patents, the companies are able to cover their research costs and foster future innovation.[6] If companies were not guaranteed high levels of protection, there would be little incentive for investments in innovative drugs.[7] The United States affords high levels of intellectual property (IP) protection.[8] The United States also pursues infringers to ensure a patent owner's profits are not eroded.[9] In contrast, other countries do not afford that high level of IP protection or do not properly pursue infringers.[10] The incentive for American companies to enter the markets of countries, where intellectual property rights (IPRs) are not granted, or if granted, are not properly enforced, is naturally low. The company would face profit losses due to infringing products on the market.[11]

To harmonize the varying levels of IP protection among countries, the World Trade Organization (the WTO) [12] members adopted the Agreement on Trade-Related Aspects of

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[1] Graham Dutfield, Delivering Drugs to the Poor: Will the TRIPS Amendment Help? 34 Am. J.L. & Med. (2008) 107-08; Kristina M. Lybecker, The Economic of Access to Medicines: Meeting the Challenges of Pharmaceutical Patents, Innovation, and Access for Global Health. 53 Harvard Int. Law Journal (2011) 25-43.
[2] Dutfield, ibid., 117; Lybecker, ibid., 31, 34.
[3] Dutfield, ibid.
[4] Lybecker, ibid., 32; see generally Marcia Angell, The Truth About the Drug Companies, N.Y. Rev. Books (July 15, 2004).
[5] Dutfield, ibid., 117.
[6] Christopher Lea Lockwood, Biotechnology Industry Organization v. District of Columbia: A Preemptive Strike Against State Price Restrictions on Prescription Pharmaceuticals, 19 Alb. L. J. Sci.&Tech. (2009) 143, 148-49.
[7] Robert Bird & Daniel R. Cahoy, The Impact of Compulsory Licensing on Foreign Direct Investment: A Collective Bargaining Approach, 45 Am. Bus.L.J., (2008) 283, 285.
[8] Lockwood, *supra* fn 6, 148-49.
[9] Stefan Kirchanski, Protection of U.S. Patent Rights in Developing Countries: U.S. Efforts to Enforce Pharmaceutical Patents in Thailand, 16 Loy.L.A. Int'l & Comp.L.Rev. (1994) 569-70, 582.
[10] Baris Karapinar & Michelangelo Temmerman, Benefiting from Biotechnology: Pro-Poor Intellectual Property Rights and Public-Private Partnerships, 27 Biotech. L. Rep. (2008) 189, 198.
[11] Kirchanski, *supra* fn 9, 571-72.
[12] World Trade Org., http://www.wto.org (22/05/2013). The WTO "is the only global international organization dealing with the rules of trade between nations." What Is the WTO? World Trade Org., http://www.wto.org/english/thewto_e/whatis_e/whatis_e.htm (22/05/2013). The WTO currently comprises 159 countries, referred to as member countries. WTO membership. World Trade Org., http://www.wto.org/english/thewto_e/whatis_e/tif_e/org6_e.htm (22/05/2013).

Intellectual Property Rights (TRIPS or TRIPS Agreement).[13] The aim of the agreement was "the protection and enforcement of intellectual property rights" among countries and the promotion and transfer of technologies.[14]

Least developed countries (LDCs) lack the resources to ensure protection and enforcement of those rights, and higher levels of IP protection maintain high levels of drug prices.[15] Citizens in poor countries simply cannot afford the high prices. Therefore, a constant tension remains between the interests of pharmaceutical companies to obtain profits from patented pharmaceuticals and the needs of poor countries to obtain affordable drugs.[16]

To ease that tension, TRIPS left open the possibility of compulsory licenses and parallel importation for use by developing countries and LDCs to obtain necessary drugs.[17] Criticism of TRIPS and ambiguities of certain terms led to the adoption of the Doha Declaration.[18] The aim of the Doha Declaration was to highlight the importance of facilitating access to medicines, to address the public health issues of developing countries and LDCs and to clarify the options for those countries to promote transfer of technology and pharmaceutical products.[19] Despite TRIPS and the Doha Declaration, access to pharmaceuticals for poor countries still remains difficult. Since a 2003 decision of the TRIPS Council allows non-producing LDCs to import pharmaceuticals, only Canada has used this option to provide drugs to Rwanda.[20]

This note provides background on the TRIPS Agreement and its public health-related declaration and decisions. It analyses and interprets in detail the current available TRIPS options with reference to the Vienna Convention of the Law of Treaties , casts light on the pharmaceutical industry's position and concludes by stating that the TRIPS options are no sustainable solution to the current access problem.

[13] Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 108 Stat. 4809, 869 U.N.T.S. 299 [hereinafter TRIPS or TRIPS Agreement].
[14] Ibid., Art. 7.
[15] Jerome H. Reichman, Comment, Compulsory Licensing of Patented Pharmaceutical Inventions: Evaluating the Options, 37 J.L. Med. & Ethics (2009) 247, 248.
[16] Bird & Cahoy, *supra* fn 7, 283.
[17] TRIPS and Pharmaceutical Patents: Fact Sheet, Exceptions, World Trade Org., available at http://www.wto.org/english/tratop_e/trips_e/factsheet_pharm02_e.htm#exceptions (22/05/2013).
[18] World Trade Organization, Ministerial Declaration of 14 November 2001 on the TRIPS Agreement and Public Health, WT/MIN(01)/DEC/2, 41 I.L.M. 755 (2002) [hereinafter Doha Declaration]; Haochen Sun, The Road to Doha and Beyond: Some Reflections on the TRIPS Agreement and Public Health, 15 Eur. J. Int'l L. (2004) 123, 125.
[19] Doha Declaration, *supra* fn 18, para. 1-5.
[20] Pascal Lamy, Dir.-Gen., World Health Org., Address at the 11th Annual International Generic Pharmaceutical Alliance Conference in Geneva (Dec. 9, 2008), available at http://www.wto.org/english/news_e/sppl_e/sppl111_e.htm (22/05/2013).

3. The Agreement on Trade-Related Aspects of Intellectual Property Rights

The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS or TRIPS Agreement) is an international agreement administered by the WTO.[21] It was negotiated at the end of the Uruguay Round of the General Agreement on Tariffs and Trade (GATT) in 1994 and signed on April 15, 1994.[22] It is the most comprehensive agreement on IP to date. Its purpose is to harmonize the different levels of IP protection across country borders in order to foster free movement of innovation and technology by setting minimum global standards for most forms of IPRs based on the prevailing standards of the developed countries.[23] It is binding to all WTO members, and its ratification is a compulsory requirement for the WTO membership.[24] Any country seeking access to the international trade markets opened by the WTO membership must enact IPRs as mandated by the TRIPS Agreement. Under TRIPS, each WTO member is required to adapt its domestic laws to provide at least the minimum standards of protection set forth in the agreement.[25] The principle of territoriality of patent protection, however, still requires the inventor to seek a patent from the member country in which he wishes patent protection.[26] The TRIPS Agreement constitutes Annex 1C[27] of the WTO Agreement[28]. The annexes of the WTO Agreement contain all specific multilateral agreements that were concluded in the Uruguay Round.[29] The WTO Agreement itself is a short agreement containing 16 articles that set out the framework of the WTO as an international organization.[30]

a) Dispute Settlement and Principles for Interpreting TRIPS

According to TRIPS Art. 64, disputes between member countries are resolved through the WTO's Dispute Settlement Body[31], a strengthened version of the earlier GATT dispute settlement system[32].

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[21] TRIPS, *supra* fn 13.
[22] Ibid.
[23] Ibid., Art. 7 (stating that the objective of the agreement is the promotion of innovation and transfer of technology); Michael Finger, The WTO's Special Burden on Less developed Countries, 19 Cato Journal (2000) 429 (stating that the minimum rights cover (1) what is patentable, (2) the right of the patent holder, (3) permissible exceptions to those rights, (4) patent term).
[24] TRIPS, *supra* fn 13, Art. 1(3); WTO Agreement Art. II(2), 33 I.L.M., 1144 (TRIPS is a central component of the WTO Agreement and TRIPS binds all Members).
[25] Adrian Otten & Hannu Wager, Compliance with TRIPS: The Emerging World View, 29 Vand. J. Transnat'l L. (1996) 391, 392 (outlining the main features of the TRIPS Agreement).
[26] Frederick Abbott et al., The International Intellectual Property System: Commentary and Materials (1999) 602 (stating that under the concept of territoriality, a "creator must obtain protection in each territory where protection is considered necessary"); John Gladstone Mills III, A Transnational Patent Convention for the Acquisition and Enforcement of International Rights, 84 J. Pat. & Trademark Off. Soc'y (2002) 83, 92.
[27] TRIPS, *supra* fn 13.
[28] Marrakesh Agreement Establishing the World Trade Organization, opened for signature Apr. 15, 1994, 33 I.L.M. at 1144, reprinted in 1867 U.N.T.S. 3 (1994) [hereinafter WTO Agreement], available at http://www.wto.org/english/docs_e/legal_e/04-wto.pdf (22/05/2013).
[29] Ibid.
[30] Ibid.
[31] Otten & Wager, *supra* fn 25, 392; TRIPS, *supra* fn 13, Art. 64 (incorporating the general dispute settlement provisions of the WTO Agreement into the TRIPS Agreement).
[32] Otten & Wager, ibid., 411-12 (the dispute settlement system versus its predecessor under GATT). The General Agreement on Tariffs and Trade (GATT), an instrument created in 1947, set forth the basic rules governing

Annex 2 of the WTO Agreement contains the procedures and rules that apply to the current WTO dispute settlement system (the Understanding on Rules and Procedures Governing the Settlement of Disputes, referred to as the Dispute Settlement Understanding or DSU)[33]. This system was created as part of the WTO Agreement during the Uruguay Round[34]. Unlike other agreements on IPR, TRIPS has a powerful enforcement mechanism, and states can be disciplined through the WTO's dispute settlement mechanism.[35]

The DSU states in Art. 3.2 that the dispute settlement system is intended to clarify the provisions of the WTO Agreement "in accordance with customary rules of interpretation of public international law."[36] Customary international law is normally unwritten, but some of the customary rules of treaty interpretation are codified in Art. 31, 32, and 33 of the Vienna Convention of the Law of Treaties (VCLT).[37] While the reference in Art. 3.2 of the DSU does not directly refer to these articles, the WTO's Appellate Body has ruled that they can serve as point for interpretation.[38]

b) History – What led to TRIPS?

The TRIPS Agreement was negotiated in the end of the Uruguay Round of the GATT in 1994.[39] Its inclusion was the result of intense lobbying by the United States, supported by Japan, the European Union and other developed countries. Pharmaceutical companies played an important role in the drafting of TRIPS.[40] In the early 1980s Pfizer mobilized corporations in the United States and made IP privileges an important part of the United States trade policy.[41] Prior to TRIPS, many countries had no IP protection, or if they had any, had excluded pharmaceutical inventions from their patent regimes.[42]

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member states' international trade policy; Philip Raworth & Linda C. Reif, The Law of the WTO: Final Text of the Gatt Uruguay Round Agreements, Summary & A Fully Searchable Diskette (1995) 15, 17.

[33] Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 2, Understanding on Rules and Procedures Governing the Settlement of Disputes, vol. 31, 33 I.L.M. 81 (1994) [hereinafter Understanding on Rules and Procedures Governing the Settlement of Disputes].

[34] Otten &Wager, *supra* fn 25, 411.

[35] Ibid.

[36] Understanding on Rules and Procedures Governing the Settlement of Disputes, *supra* fn 33, Art. 3.2.

[37] Vienna Convention on the Law of Treaties, May 23, 1969, Arts. 31, 32, 33, 1155 U.N.T.S. 331, [hereinafter VCLT] ("A treaty shall be interpreted in good faith in accordance with the ordinary meaning to be given to the terms of the treaty in their context and in the light of its object and purpose").

[38] WTO Panel Report, Canada-Patent Protection of Pharmaceutical Products, WT/DS114/R, P 7.13 (Mar. 17, 2000) ("rules that govern the interpretation of WTO agreements are the rules of treaty interpretation stated in Articles 31 and 32 of the Vienna Convention"). The Appellate Body of the WTO hears appeals issued by panels in disputes between WTO members.

[39] TRIPS, *supra* fn 13.

[40] Braithwaite and Drahos, Global Business Regulation, Cambridge University Press, 2000, Chapter 7.

[41] Ibid.

[42] World Health Organization and World Trade Organization Secretariat, WTO Agreements and public health: a joint study by the WHO and the WTO secretariat (2002) 42, available at http://www.wto.org/english/res_e/booksp_e/who_wto_e.pdf (22/05/2013); Jean O. Lanjouw, Intellectual Property and the Availability of Pharmaceuticals in Poor Countries, 3 Innovation Pol'Y & Economy (2003) 91, 96 (stating that several countries, that were not developing countries, only recently provided patent protection for pharmaceuticals: Japan (1976), Switzerland (1977), Sweden (1978)).

In fact, no regime prior to TRIPS had imposed the subject matter of patentability on all nations. Rather the issue was left to the countries as their sovereign political choices.[43]

c) TRIPS Implementation in Developing Countries

The TRIPS Agreement has been criticized to exert a negative influence on the implementation of domestic public health policies in developing countries by adversely affecting access to medicines.[44] It has been complained that developed countries are acting contrary to public health by establishing requirements that cannot easily be met by LDCs.[45] A 2005 World Health Organization (WHO) report found that many developing countries had not yet incorporated TRIPS flexibilities in their national legislations.[46] For the implementation of TRIPS developing countries were allowed a transitional period until 2005 to adjust their national laws to the requirements of TRIPS.[47] The transition period for LDCs was extended until 2013, and for pharmaceutical patents the Doha Declaration extended the deadline to apply provisions on pharmaceutical patents until January 1, 2016.[48] The transition period does not exempt LDCs from applying the TRIPS provisions. However, it gives them the freedom to choose whether or not to protect patents or other forms of IPRs. If they choose to protect them, they have to follow the TRIPS provisions of non-discrimination, national treatment and most-favoured nation (MFN) treatment in TRIPS Art. 3 and 4.[49]

d) Patentable Subject Matter of TRIPS

TRIPS Art. 27 limits the choices of sovereign states concerning the subject matter of patents. Under Art. 27(1), any invention in any field of technology is patentable, provided that it is new (novelty), involves an inventive step (non-obviousness) and is a capable of industrial application (usefulness).[50] With this provision the three typical requirements for patentability, prevalent in developed countries, were transferred into TRIPS.[51] Art. 27(1) makes clear that patents are available for both products and processes. Under Art. 27(2), a state may deny patentability on grounds of *ordre public,* morality or for the protection of human, animal or plant life and the environment. The *ordre public* exclusion with

[43] Kojo Yelpaala, Quo vadis WTO? The Threat of TRIPS and The Biodiversity Convention to Human Health and Food Security, Boston University International Journal (2012) 30, 114.
[44] Reichman, *supra* fn 15, 247; 248.
[45] Ibid.
[46] Musungu Sisule, Oh Cecilia, The use of flexibilities in TRIPS by developing countries: can they promote access to medicines? (2005) 1-123. The study had been commissioned by the CIPIH (Commission on Intellectual Property Rights, Innovation and Public Health) in August 2005, available at http://www.who.int/intellectualproperty/studies/TRIPSFLEXI.pdf (22/05/2013).
[47] World Trade Org., http://www.wto.org (22/05/2013). Poorest countries' extended intellectual property transition: time-limited or indefinite? World Trade Org., Transitional period http://www.wto.org/english/news_e/news13_e/trip_05mar13_e.htm (22/05/2013).
[48] Ibid.; Decision on Least-Developed Country Members-Obligations under Article 70.9 of the TRIPS Agreement with Respect to Pharmaceutical Products, adopted by the General Council on 8 July 2002.
[49] Ibid.
[50] Yelpaala, *supra* fn 43, 114.
[51] Ibid.

regards to patents refers only to inventions that induce riot or public disorder or lead to criminal or other offensive behavior.[52] Inventions harmful under these terms may be excluded from patentability. This exclusion, however, does not apply to harmless, inaccessibly priced inventions such as patented pharmaceutical products with the purpose of making them available on public health grounds.[53] Some authors nevertheless suggest that a state may successfully suspend patentability for pharmaceuticals under the *ordre public* doctrine[54], but the state has to consider first, if the goal could be achieved through less drastic measures like parallel importing or compulsory licensing.[55] Exclusion of patentability under the *ordre public* clause would mean that patentability was not denied because of the harmfulness of the invention, but rather because the invention was essential to humanity.[56]

e) Scope and Duration of Rights Conferred by TRIPS and the Problem Posed by Substantive Patent Provisions

Under TRIPS Art. 28(1), a patent confers to the right holder the usual exclusive and monopoly rights prevalent in the developed world.[57] These exclusive rights shall prevent others from making, using, offering for sale, selling, or importing a patented product or process without the patent holder's permission.[58] The monopoly right provided by the patent excludes others from making or using that particular invention, but does not prevent competition from other similar drugs, patented or not, that address the same medical conditions. According to TRIPS Art. 28(2), the patent holder has the exclusive power to assign or transfer patent rights or enter into a voluntary licensing contract. The licensee can legally use the formula encompassed in the patent. Art. 33 of the TRIPS Agreement grants a minimum of 20 years of patent protection. With the ability to exclude copies of the product for a certain number of years, the patent holder will earn monopoly profits and charge higher prices than would otherwise be the case.[59] It has been criticized that the monopoly rights together with the twenty-year patent regime rather prevent public health benefits of drugs.[60]

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[52] Ibid., 115; Kojo Yelpaala, Owning the Secrets of Life: Biotechnology and Property Rights Revisited, 32 McGeorge L.Rev. (2000) 200-210.
[53] Yelpaala, *supra* fn 43, 115; Judy Rein, International Governance Through Trade Agreements: Patent Protection for Essential Medicines, 21 Nw. J. Int'l L. & Bus. (2001) 379, 388.
[54] Robert Weissman, A Long, Strange TRIPS: The Pharmaceutical Industry Drive to Harmonize Global Intellectual Property Rules, and the Remaining WTO Legal Alternatives Available to Third World Countries, 17 U. Pa. J. Int'l Econ. L. (1996) 1069, 1099-1101, 1107; Carlos Correa, Public Health and Patent Legislation in Developing Countries, 3 Tul. J. Tech. Intell. Prop. (2001) 9 (noting that "there is no universally accepted notion of *ordre public*, leaving member countries some flexibility to define which situations are covered, depending upon their own social and cultural values.").
[55] Correa, ibid., 10.
[56] Yelpaala, *supra* fn 43, 116.
[57] Ibid., 118.
[58] TRIPS, *supra* fn 13, Art. 28(1).
[59] Haochen Sun, A wider Access to Patented Drugs Under the TRIPS Agreement, 21 B.U.Int'l L.J. (2003) 106.
[60] Richard T. Rapp & Richard P. Rozek, Benefits and Costs of Intellectual Property Protection in Developing Countries, 24 J. World Trade (1990) 75, 86.

TRIPS determines the subject matter of patent in Art. 27. The nature of the rights granted and the duration of the patent rights, however, are still governed by local laws, which must comply with the TRIPS Agreement.[61] Thus, the principle of territorial independence of patents was maintained under TRIPS.[62] Member states are free to set their national patent protection standards higher than the standards provided for in the TRIPS Agreement.[63] TRIPS, however, does not provide for states to demand higher national standards from other states. Since the rights conferred by TRIPS are considered minimum rights, IPRs can be expanded through bilateral agreements, referred to as TRIPS PLUS agreements.[64] TRIPS PLUS agreements are said to be often detrimental to public health needs of developing countries.[65] While TRIPS Art. 3 prohibits nationality-based discrimination, Art. 4 introduces most-favoured nation (MFN) treatment, used in international trade agreements, into IP protection agreements. Under the MFN provision developing countries, having entered into a TRIPS PLUS agreement, may not be entitled to deny third states the same rights.[66] Third states may benefit from TRIPS PLUS rights without having to bargain for trade and investment benefits.[67] Thus the patent provision of non-discrimination may be used to justify an extension of the patent system.[68] In effect, the guarantee of minimum rights under TRIPS and the MFN clause together expand IPRs at the expense of human health.[69] States with bargaining power can extend IPRs by negotiating TRIPS PLUS agreements with important developing countries.[70] With MFN and territorial independence of patents, they can use bilateral trade agreements to impose greater IP protection on weaker states for the benefit of other WTO member states.[71] The desire to restrict the possibility of compulsory licenses under TRIPS, has led to provisions in recent bilateral United States trade agreements.[72]

f) Exceptions to the Rights Conferred by TRIPS

Under TRIPS, member states can provide exceptions to the exclusive rights conferred "if such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not

[61] TRIPS, *supra* fn 13, Art. 1 (directing the nature and scope of obligations upon WTO Members under TRIPS); Yelpaala, *supra* fn 43, 119.
[62] TRIPS, *supra* fn 13, Art. 1.
[63] TRIPS, *supra* fn 13, Art. 1(1) ("Members may, but shall not be obliged to implement in their law more extensive protection than is required by this Agreement."); Otten & Wager, *supra* fn 25, 396.
[64] Yelpaala, *supra* fn 43, 121.
[65] See generally Grain, "TRIPS-plus" Through The Back Door (2001), available at http://www.grain.org/article/entries/5-trips-plus-through-the-back-door (22/05/2013); David Vivas-Eugui, Regional and Bilateral Agreements and a TRIPS-plus World: the Free Trade Area of the America (FTAA), TRIPS Issues Paper 1, 4 (2003), available at http://www.quno.org/geneva/pdf/economic/Issues/FTAs-TRIPS-plus-English.pdf (22/05/2013); Correa, *supra* fn 54, 69.
[66] Yelpaala, *supra* fn 43, 121.
[67] Ibid.
[68] Ibid.
[69] Ibid.
[70] Ibid.
[71] Ibid.
[72] Ibid.

unreasonably prejudice the legitimate interest of the patent owner."[73] Exceptions can take the form of special measures – parallel importing and compulsory licenses - to deal with public health problems.[74] Both exceptions are limited, they do not unreasonably conflict with the normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner. The first measure, compulsory license, is generally defined as a government's granting of a license without the patent holder's consent.[75] Prior to granting a compulsory license under TRIPS, the requesting party must attempt to obtain a voluntary license from the patent holder "on reasonable commercial terms".[76] If a voluntary license cannot be obtained, a compulsory license then can be issued.[77] In case of a "national emergency or other circumstances of extreme urgency" or in cases of "public non-commercial use" a compulsory license can be issued without first negotiating for a voluntary license.[78] The purpose of the waiver of the negotiation requirement is to save time.[79] TRIPS does not specify, what would qualify for a national emergency or other extreme urgent circumstances, which will be discussed below.

Under parallel importation products are sold into a parallel market at a cheaper price than they could have been sold by the patent owner.[80] This is beneficial for the party seeking pharmaceutical products on the parallel market, but the patent owner may lose profits.[81] Parallel importation is based on the principle of patent exhaustion.[82] A patent owner under the principle of patent exhaustion can no longer exercise the IPRs over a product, once the product protected by the IPR has been sold to the first party, regardless of whether the first party resells the goods or not.[83] Parallel importation is one method by which countries can gain access to life-saving treatments at lower prices.

4. Compulsory Licensing

a) Legal Status of Compulsory Licensing

Under TRIPS, a pharmaceutical patent confers exclusive rights to the patent owner to prevent third parties from "making, using, offering for sale, selling, or importing" the patented product without the

[73] TRIPS, *supra* fn 13, Art 30.
[74] Doha Declaration, *supra* fn 18, para. 5.
[75] Correa, *supra* fn 54, 43.
[76] TRIPS, *supra* fn 13, Art. 31(b); TRIPS and Public Health: Frequently Asked Questions, World Trade Org., http://www.wto.org/english/tratop_e/TRIPs_e/public_health_faq_e.htm (22/05/2013) [hereinafter TRIPS FAQ].
[77] TRIPS, *supra* fn 13, Art. 31(b).
[78] Ibid.
[79] TRIPS FAQ, *supra* fn 76.
[80] Yamaha Corp. of Am. v. United States, 961 F.2d 245, 248-49 (D.C. Cir. 1992).
[81] Ibid.
[82] International Exhaustion and Parallel Importation, World Intell. Prop. Org., available at http://www.wipo.int/sme/en/ip_business/export/international_exhaustion.htm (22/05/2013). Parallel importation occurs when goods are produced by the patent owner or with the patent owner's permission, through a license, and then subsequently imported into another country without permission of the patent owner.
[83] Ibid.

patent owner's consent.[84] In contrast to a voluntary license, a compulsory license grants a third party the right to use a patent without the patent holder's permission.[85] Compulsory licensing is a tool for reducing drug prices.[86] It reduces the adverse effects of patents on prices and availability of drugs and mitigates the effects of exclusive rights by seeking a balance between the right holder's interests and the public interest of innovation and affordability of drugs.[87] Compulsory licenses on pharmaceuticals promote drug competition and lower prices[88], as is essential to many developing countries.[89] Although Art. 31 of the TRIPS Agreement does not use the term "compulsory license", this article is generally accepted to provide a basis for authorizing the issuance of compulsory licenses.[90] Members, when drafting the TRIPS Agreement, realized that under certain circumstances exceptions to the patent holder's exclusive rights would be necessary.[91] Unlike compulsory licensing, which is specifically permitted under TRIPS, the treatment of parallel importation under TRIPS is left ambiguous. TRIPS Art. 6 provides that "nothing in this Agreement shall be used to address the issue of the exhaustion of intellectual property rights". It has been argued that this provision represents "an agreement to disagree" on the subject of parallel importing, leaving each member to adopt its own rules on exhaustion and parallel importing. [92]

b) Article 31 Analysis of the VCLT of TRIPS Article 31

According to the principles of interpretation contained in Art. 31 of the VCLT, the words of a treaty shall be given their ordinary meaning in their context and read in the light of the treaty's object and

[84] TRIPS, *supra* fn 13, Art. 28(a). Where the patented matter is a process, third parties are prohibited from using, offering for sale, selling, or importing the product obtained from the patented process. Ibid. Art. 28(1)(b).
[85] Correa, *supra* fn 54, 43; WTO, Doha Press Pack, Negotiations, Implementation and TRIPS Council Work, 24 (2001) [hereinafter Doha Press Pack] (stating that the Doha Conference intended to clarify ambiguities relating to Members' use of the flexibilities codified in TRIPS), available at http://www.wto.org/english/thewto_e/minist_e/min01_e/brief_e/doha_presspack_e.pdf (22/05/2013).
[86] Doha Press Pack, ibid., 43-44 (contrasting these advantages with the view held by the pharmaceutical industry that such licenses discourage investment, research, and development); Rein, *supra* fn 53, 389.
[87] Doha Press Pack, ibid.
[88] There is evidence from developed countries that prices fall quite steeply as soon as drugs go off patent, assuming there are generic competitors. The price fall seems to be greater the more generic competitors enter the market. See U.K. Commission on Intellectual Property Rights (CIPR), Final Report, Integrating Intellectual Property Rights and Development Policy (2002) 42, available at http://www.iprcommission.org/papers/pdfs/final_report/CIPRfullfinal.pdf (22/05/2013); Frederick M. Abbott, Compulsory Licensing for Public Health Needs: The TRIPS Agenda at the WTO After the Doha Declaration on Public Health 17 (Quaker United Nations Office (QUNO), Occasional Paper 9, 2002), available at http://www.cptech.org/ip/health/cl/quno-op9.pdf (22/05/2013).
[89] Ibid.
[90] Frederick M. Abbott, The TRIPS-Legality of Measures Taken to Address Public Health Crises: A Synopsis, 7 Widener L. Symp. J. (2001) 71-73 (noting that when Art. 31 of TRIPS is read in conjunction with Art. 2:1 of TRIPS and Art. 5.A.2 of the Paris Convention, TRIPS clearly provides authority for the issuance of compulsory licenses), ibid., 74.
[91] TRIPS, *supra* fn 13, Arts. 30, 31 (outlining exceptions to patent rights); Weissman, *supra* fn 54, 1099 (Arts. 30 and 31 are two important exceptions to the exclusive rights granted in TRIPs Art. 28).
[92] Abbott, *supra* fn 90, 71; 77.

purpose.[93] In interpreting the TRIPS Agreement, it is important to examine the text, the context, and the object and purpose of the treaty. When determining the object and purpose of a treaty, interpretation should be tied closely to the actual text. Selected material other than the text must be considered for providing context.[94]

Art. 7 and 8 of the TRIPS Agreement outline the objectives and principles of the TRIPS Agreement. According to Art. 7 (objectives), the protection and enforcement of IPRs shall contribute to the "promotion of technological innovation…to the mutual advantage of producers and users…and in a manner conducive to social and economic welfare, and to a balance of rights and obligations."[95] In accordance with the objectives, compulsory licensing can be viewed as a mechanism to ensure IPRs are protected and enforced in a manner conducive to social and economic welfare. TRIPS Art. 8 outlines the treaty's principles and explains that "Member States may adopt measures necessary to protect public health and nutrition…provided that such measures are consistent with the provisions of this Agreement."[96] Compulsory licensing in case of a public health crisis such as HIV also represents a measure that is necessary to protect public health. Art. 8(2) of the TRIPS Agreement emphasizes the need of appropriate measures in compliance with TRIPS "to prevent the abuse of intellectual property rights by right holders."[97] In case of a public health crisis such as the epidemic conditions of HIV in sub-Saharan Africa, patent right holders may be abusing their IPRs.[98] The limited supply of drugs and enormous high drug prices may represent an abuse of IPRs.[99] Compulsory licenses, considering them under these provisions of the TRIPS Agreement, may reflect the objectives and principles contained in Art. 7 and 8 of TRIPS, the balance of rights and obligations - promotion of technological innovation, and transfer and dissemination of technology, mutual advantage of producers and users of technological knowledge, and social and economic welfare.[100]

c) Compulsory Licensing under the Text of TRIPS

Art. 31 of the TIRPS Agreement sets forth the conditions to a state's issuance of a compulsory license.[101] Under normal conditions, a state must first engage the patent holder in negotiations before obtaining a compulsory license.[102] This requirement can be waived in case of a national emergency or other extremely urgent circumstances or for non-commercial public use.[103] In the wake of a national

[93] VCLT, *supra* fn 37 ("A treaty shall be interpreted in good faith in accordance with the ordinary meaning to be given to the terms of the treaty in their context and in the light of its object and purpose").
[94] Ibid., Art. 31(2), (3) (specifying the additional material outside of the treaty text that must be considered when conducting an ordinary meaning analysis).
[95] TRIPS, *supra* fn 13, Arts. 7, 8.
[96] Ibid.
[97] Ibid.
[98] Kara Bombach, Can South Africa Fight AIDS? Reconciling the South African Medicines and related Substances Act with the TRIPS Agreement, 19 B.U. Int' l L. J. (2001) 294.
[99] Ibid.
[100] TRIPS, *supra* fn 13, Art. 17.
[101] Ibid., Art. 31(a)-(l).
[102] Ibid., Art. 31(b); TRIPS FAQ, *supra* fn 76.
[103] TRIPS, ibid.

emergency, a state may engage in negotiations with the patent-holding pharmaceutical company, and if no agreement is reached, the state's government can declare a state of emergency and then apply TRIPS Art. 31 or apply Art. 31 in the absence of a declaration of a state of emergency, because it is not clear that Art. 31 requires a legal declaration of national emergency.[104] In any way, an epidemic condition like HIV, would also qualify for the broader condition of other circumstances of extreme urgency.[105] TRIPS neglects to define the term "national emergency" within the text.[106] This ambiguity in language led to different interpretations of the specific conditions under which a state may be issued a compulsory license.[107] Art. 31(f) of the TRIPS Agreement furthermore states that the patent holder shall be paid "adequate remuneration" in each case (compulsory licensing and parallel importing).[108] Remuneration shall take into account "the economic value of the authorization", which shall be independently reviewed by a "distinct higher authority".[109] The term adequate remuneration is neither detailed in TRIPS nor the Doha Declaration, possibly in order to pacify all member countries, especially developed countries.[110] Remuneration varies widely among countries.[111] In Remuneration Guidelines for Non-Voluntary Use of a Patent on Medical Technologies, it is pointed out that when countries set forth their guidelines for remuneration, those guidelines should not present "a barrier for access to medicines."[112] Remuneration in public health situations is typically low. When a compulsory license is issued for public health reason in low-income countries, the remuneration is usually between 0 and 6% of the generic price.[113] Although guidelines for remuneration have been published, it is unlikely that a consensus will be reached soon on the prevailing standards for adequate remuneration.[114]

5. The Doha Declaration on the TRIPS Agreement and Public Health

In part to clarify ambiguities such as the term "national emergency"[115], the Doha Declaration on the TRIPS Agreement and Public Health was adopted by the WTO Ministerial Conference in Doha, in

[104] Bombach, *supra* fn 98, 289; 290.
[105] Ibid.
[106] TRIPS, *supra* fn 13, Arts. 1-73 (lacking a definition of the term "national emergency").
[107] Sara M. Ford, Note, Compulsory Licensing Provisions Under the TRIPS Agreement: Balancing Pills and Patients, 15 Am. U. Int'l L. Rev. (2000) 963-67 (discussing the widely differing interpretations of Art. 31 language by developing and developed countries).
[108] TRIPS, *supra* fn 13, Art. 31(h).
[109] Ibid., Art. 31(h), (j).
[110] See generally TRIPS, *supra* fn 13; Doha Declaration, *supra* fn 18; Decision of the General Council, Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, WT/L/540 (Aug. 30, 2003) [hereinafter 2003 Decision].
[111] James Love, World Health Org., Remuneration Guidelines for Non-Voluntary Use of a Patent on Medical Technologies (2005) 5, available at http://www.who.int/hiv/amds/WHOTCM2005.1_OMS.pdf (22/05/2013).
[112] Ibid., 6 (noting two paramount issues: (1) "the system of setting royalties should not be overly complex or difficult to administer, given the capacity of the government managing the system," and (2) "the amount of the royalty should not present a barrier for access to medicines").
[113] Ibid. 5, 7, 8.
[114] Ibid., generally 1-110.

[115] Doha Press Pack, *supra* fn 85, 24 (stating that the objective of the ministerial declaration on TRIPS was to "clarify what governments can do under the TRIPS Agreement, and to reduce their uncertainties about using the

November 14, 2001.[116] The Doha Declaration recognizes the need to balance private property and public welfare interests in its para. 1 to 3 and contains its major conclusions in para. 4 to 6.[117] It is important to implement and interpret the TRIPS Agreement in a way supportive of public health[118] by both, promoting access to medicine[119] and creating new drugs.[120] It reaffirms a state's right to use the TRIPS flexibilities[121] and clarifies compulsory licensing.[122]

The first part of para. 4 emphasizes a member's right with regard to actions aimed at protecting public health.[123] The second part of para. 4 outlines that members should interpret TRIPS in a manner supportive of public health.[124] The most controversial para. 5 provides members with flexibilities in implementing TRIPS.[125] Para. 5(b) now explicitly emphasizes each member‘s right to grant compulsory licenses, and para. 5(c) states that members can determine by themselves what constitutes a national emergency or other extremely urgent conditions, thus clarifying Art. 31(b) of the TRIPS Agreement. The second part of para. 5(c) states that public health crises related to HIV/AIDS, malaria, tuberculosis or other epidemics can represent a national emergency or other extreme circumstances. Para. 6 of the Doha Declaration leaves the issue of compulsory licenses for members without pharmaceutical manufacturing capacities unresolved.[126]

The first three paragraphs of the Declaration are important for understanding the rest of the Declaration.[127] Para. 1 and the second sentence of para. 3 express the concern of developing countries about public health epidemics like HIV, tuberculosis or malaria in their countries and about high drug prices resulting from IP protection.[128] On the other hand, developed countries emphasize both, the

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flexibilities that are built into the agreement"), available at http://www.wto.org/english/thewto_e/minist_e/min01_e/brief_e/doha_presspack_e.pdf (22/05/2013); see *supra* fn 106, 107 and accompanying text (examples of ambiguities within TRIPS).

[116] Doha Declaration, *supra* fn 18.

[117] Ibid., para. 1-3, para. 4-6.

[118] Ibid., para. 4.

[119] Ibid.

[120] Ibid., para. 3.

[121] Ibid., para. 4.

[122] Ibid., para. 5(b).

[123] Ibid., para. 4 (stating that "we agree that the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health").

[124] Ibid. (stating that "the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all").

[125] Ibid., para. 5 (outlining the flexibilities contained in TRIPS, such as the power to grant compulsory licenses and the determination of a national emergency).

[126] Ibid., para. 6 (instructing the TRIPS Council to research a solution for those countries with inadequate pharmaceutical manufacturing capacities).

[127] Ibid., para. 1-3 (emphasizing both private and public interests as important considerations). The Declaration begins by recognizing that developing countries and LDCs are facing large public health problems. Ibid., para. 1. Para. 2 stresses that TRIPS should be "part of the wider national and international action." Ibid., para. 2. Finally, para. 3 highlights the importance of IP protection for the development of new medicines, but acknowledges concerns surrounding the higher prices. Ibid., para. 3.

[128] Ibid. para. 1, 3.

need of IPRs for the development of new drugs by stressing the importance of patent protection[129], and that public health epidemics necessitate a wider and more comprehensive effort.[130]

Para. 4 of the Doha Declaration now represents a valid basis for enacting exceptions of patent protection in national laws in order to promote access to medicines.[131] Although Art. 30 and 31 of the TRIPS Agreement already refer to flexibilities[132], they fail to provide any reference to TRIPS Art. 8 (principles) or the acceptable bases upon which members may exercise the TRIPS flexibilities[133]. According to the principles of treaty interpretation of Art. 31 of the VCLT[134], the text of Art. 30 and 31 of the TRIPS Agreement read in the light of Art. 7 and 8 of TRIPS may already permit countries to exercise TRIPS flexibilities to protect public health.[135] But the language of Art. 31 of the TRIPS Agreement is deliberately broad and does not explicitly use the term "compulsory license". Para. 4 of the Doha Declaration now specifically states that members have the right to use TRIPS flexibilities, thus avoiding the VCLT Art. 31 analysis.[136]

Para. 5(a) of the Doha Declaration, using the language of the VCLT[137], explicitly reminds members that "each provision of the TRIPS Agreement shall be read in the light of the object and purpose of the Agreement..., in particular, in its objectives and principles".[138] This analysis applies to the TRIPS flexibilities.[139]

The Doha Declaration goes beyond a mere reference to TRIPS flexibilities.[140] In contrast to Art. 31 of the TRIPS Agreement, para. 5(b) explicitly mentions a country's option to issue compulsory

[129] Ibid., para. 3.
[130] Ibid., para. 2.
[131] Ibid., para. 4; TRIPS, *supra* fn 13, Arts. 30-31 (failing to provide bases upon which a Member may exercise TRIPS flexibilities).
[132] TRIPS, ibid., Arts. 30-31 (containing the exceptions to the exclusive rights of patent holders). Art. 30 is titled "Exceptions to Rights Conferred." Art. 31 is titled "Other Use Without Authorization of the Right Holder."
[133] Ibid., Arts. 30-31 (TRIPS fails to provide bases upon which Members can obtain compulsory licenses). TRIPS Arts. 30 and 31 do not make any reference to the principles outlined in TRIPS Art. 8. The "national emergency" and "extreme urgency" clause of TRIPS Art. 31(b) is simply a basis for waiving licensing negotiations with the patent holder.
[134] VCLT, *supra* fn 37, Art. 31(1).
[135] TRIPS, *supra* fn 13, Arts. 30-31; 8 (members may enact measures that violate a patent holder's exclusive rights).
[136] Doha Declaration, *supra* fn 18, para. 4 (members may fully use the flexibilities in TRIPS for the "purpose" of protecting public health and promoting access to medicines).
[137] VCLT, *supra* fn 37, Art. 31.
[138] Doha Declaration, *supra* fn 18, para. 5(a) (providing guidance for interpreting international law and the TRIPS agreement).
[139] Ibid., para. 5.
[140] Ibid. (discussing compulsory licensing).

licenses.[141] Members should determine the grounds for issuing compulsory licenses to protect public health and promote access to medicines[142] in the light of para. 4.[143]

Para. 5(c) of the Doha Declaration clarifies the term "national emergency", left undefined in TRIPs Art. 31.[144] As the text of Art. 31 failed to provide interpretative guidance as to what constitutes a "national emergency"[145], both developed and developing countries sought to define the term. The Declaration explicitly leaves it to the members to determine what qualifies for a "national emergency"[146], at the same time stating that HIV/AIDS, malaria, and other epidemics will be considered as such national emergencies.[147]

a) Article 31 Analysis of the VCLT of Public Health

Developed countries may assume that developing countries use TRIPS flexibilities to address public health concerns that are not generally accepted as epidemics.[148] For instance, a developing country, experiencing a public health event, may decide to issue a compulsory license for a particular drug. The patent holder's country could state that the public health event is not the type of public health event under TRIPS that allows for compulsory licensing.

The Doha Declaration addresses "epidemics".[149] This term is narrower than the broad public health focus the developing countries had originally sought.[150] The intention of the Declaration was to clarify

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[141] Ibid., para. 5(b) ("Each Member has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted").
[142] Ibid., para. 4 (allowing Members to protect "public health" and "promote access to medicines").
[143] Ibid., para. 5 (first sentence stating "in the light of paragraph 4 above").
[144] Ibid., para. 5(c) ("Each Member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria, and other epidemics, can represent a national emergency or other circumstances of extreme urgency.").
[145] TRIPS, *supra* fn 13, Arts. 1-73 (failing to define the term "national emergency").
[146] Doha Declaration, *supra* fn 18, para. 5(c) (clarifying the circumstances that constitute a national emergency).
[147] Ibid., P 5(c) (specifying that "public health crises" would represent national emergencies; offering HIV/AIDS, tuberculosis, and malaria as representative examples of the epidemics included within the term "public health crises").
[148] Divya Murthy, Notes and Comment: The Future of Compulsory Licensing: Deciphering the Doha Declaration on the TRIPS Agreement and Public Health, 17 Am. U. Int'l L. Rev. (2002) 1326, comparing the Doha Declaration, para. 1, 5(c) (modifying public health with the clause "HIV/AIDS, tuberculosis, malaria, and other epidemics") with para. 4 (stating simply that Members should have the ability to enact measures that "protect public health" and "promote access to medicines"). Internal inconsistencies of the Declaration - the modification of the term "public health" in para. 1 and 5 of the Doha Declaration, and the absence of representative diseases and the phrase "other epidemics" in para. 4 of the Doha Declaration - may lead to varying interpretations and therefore, legal challenges.
[149] Doha Declaration, *supra* fn 18, para. 1, 5(c).
[150] Draft Ministerial Declaration, Proposal From a Group of Developing Countries, IP/C/W/312, WT/GC/W/450 (Oct. 4, 2001) (proposing a version of a declaration that contained the expectations and language of countries representing developing countries, suggesting a broad focus to include virtually every illness classified as a "disease"). The African Group, Bangladesh, Barbados, Bolivia, Brazil, Cuba, Dominican Republic, Ecuador, Haiti, Honduras, India, Indonesia, Jamaica, Pakistan, Paraguay, Philippines, Peru, Sri Lanka, Thailand, and Venezuela submitted this draft declaration, available at http://www.wto.org/english/tratop_e/trips_e/mindecdraft_w312_e.htm (22/05/2013).

ambiguous terms[151], but the text failed to achieve the goal to broaden the focus because of internal inconsistencies[152].

A WTO Panel confronted with a dispute between two countries concerning the type of public health event, the TRIPS flexibilities would apply to, would have to interpret the term "public health" in the context of TRIPS.[153] According to the VCLT, the first step is to look at the words of the treaty[154]. If the textual analysis is ambiguous, secondary materials have to be considered[155]. A WTO Panel must decide whether the Declaration is part of the treaty text or supplementary material.[156]

The legal status of the Doha Declaration is unclear[157]: It may be a subsequent agreement among the WTO member states; it gives evidence of the members' understanding of the TRIPS agreement and represents the beginning of subsequent practice; or it is a mere declaration of intent and commitment without enforceable legal obligation.[158] Both, subsequent agreement and practice are supplementary means for treaty interpretation.[159] It has been argued that, given the divergent interpretations of the TRIPS Agreement by developed and developing countries, the Doha Declaration is "an interpretive element in the interpretation of the TRIPS Agreement".[160] According to the WTO, WTO Panels may seek information from "any relevant source", therefore a WTO Panel will likely consider the Doha Declaration primary material and essential in providing context for the purpose of an ordinary meaning analysis under Art. 31 of the VCLT.[161]

Under the TRIPS Agreement, a public health event must constitute a national emergency to have a valid basis for issuing a compulsory license. Incorporating the Doha Declaration into the treaty interpretation does not resolve the difficulties.[162] Para. 1 and 5(c) of the Doha Declaration obviously define a public health event as an epidemic[163], para. 4 refers to public health concerns without

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[151] Doha Press Pack, *supra* fn, 85, 24.
[152] Murthy, *supra* fn 148, 1326 (highlighting internal inconsistencies).
[153] Ibid. (allowing interpretation disputes to be brought before a WTO Panel).
[154] VCLT, *supra* fn 37, Art. 31.
[155] Ibid., Art. 32.
[156] WTO Panel Report, Canada-Patent Protection of Pharmaceutical Products, *supra* fn 38.
[157] James Thuo Gathii, The Legal Status of the Doha Declaration on TRIPS and Public Health Under the Vienna Convention of the Law of Treaties, 15 Harv. J.L. & Tech. (2002) 299; Peng Jiang, Comment: Fighting the AIDS Epidemic: China's options under the WTO TRIPS Agreement, 13 Alb. L. J. Sci. & Tech. (2002) 237.
[158] Gathii, ibid.
[159] Ibid.
[160] Ibid. 292-93.
[161] Murthy, *supra* fn 148, 1328; Understanding on Rules and Procedures Governing the Settlement of Disputes, *supra* fn 33 (a panel has the right to seek information from any individual or body it deems appropriate).
[162] John H. Jackson et al., Legal Problems of International Economic Relations: Cases, Materials and Text (3d ed. 1995), 311-12 (concluding that this incorporation is valid despite the fact that a Declaration at a Ministerial Conference does not technically fall within the five official ways to modify or set new trade rules or policy, according to the WTO charter, including official "interpretations"). A reasonable treaty interpreter may regard the Declaration as an agreement within the meaning of Art. 31 of the Vienna Convention. Ibid.
[163] Murthy, *supra* fn 148, 1326 (discussing internal inconsistencies - the modification of the term "public health" in para. 1 and 5 of the Doha Declaration).

narrowing the focus[164]. Considering that the Declaration emphasizes the importance of IPRs[165], a WTO Panel may take a narrower view of "public health" and decide that the ordinary meaning of the term in its context and the light of object and purpose means epidemic.[166] According to the WHO, an epidemic is characterized by a temporary increase in prevalence in disease.[167] The public health event would therefore qualify as an epidemic if the citizens of a country suffer from a disease in dimensions not normally occurring.[168] The production of medicines under compulsory license to cope with the epidemic will accordingly be only temporary.[169]

b) Member Countries' Reaction and Utilization of the TRIPS Flexibilities

Developed countries by signing the TRIPS Agreement sought to secure the same or similar levels of IPRs in other countries which they afforded their own IP owners. This was done through setting up a framework in which countries can implement legislation and negotiate treaties. The main purpose of TRIPS was not to curb the HIV epidemic in developing countries.[170] Public health measures were a side issue and only came into focus after TRIPS had been established and drug prices remained high.[171] The problem with TRIPS flexibilities remains the constant conflict between the interests of developed countries on the one hand and developing countries and LDCs on the other. This became evident in the lawsuit filed by thirty-nine pharmaceutical companies – among them companies of the United States and European countries - to prevent South Africa pass the Medicines and Related Substances Bill (the Bill) in 1997.[172] This legislation would have empowered South Africa's Minister of Health to allow for parallel imports. After the lawsuit had been filed, South Africa's government

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[164] Ibid. (no representative diseases and the phrase "other epidemics" in para. 4 of the Doha Declaration).
[165] Compare TRIPS, *supra* fn 13, Art. 7 (commenting on the importance of the "protection and enforcement of intellectual property...in a manner conducive to social and economic welfare, and to a balance of rights and obligations"), and Art. 8 (stating that "Members may...adopt measures necessary to protect public health...provided that such measures are consistent with the provisions of this Agreement"), with the Doha Declaration, *supra* fn 18, para. 1, 3 (recognizing the "gravity of the public health problems, "but also recognizing that "intellectual property protection is important for the development of new medicines").
[166] Doha Declaration, ibid., para. 1, 5 (defining public health events with specific terms, including epidemic); Murthy *supra* fn 148, 1331.
[167] World Health Organization, Department of Communicable Disease Surveillance and Response, Hepatitis A, WHO/CDS/CSR/EDC/2000.7 (2000) 34 (defining an epidemic as "an outbreak of disease such that for a limited period a significantly greater number of persons in a community or region suffer from it than is normally the case"), available at http://www.who.int/csr/disease/hepatitis/HepatitisA_whocdscsredc2000_7.pdf (22/05/2013).
[168] Ibid., 34.
[169] TRIPS, *supra* note 13, Art. 31(b) (nations issue compulsory licenses for medicine in emergencies that require quick and temporary action); Murthy, *supra* fn 148, 1332.
[170] Scott Lucyk, Patents, Politics and Public Health: Access to Essential Medicines Under the TRIPS Agreement, 38 Ottawa K. Rev. (2006) 212.
[171] Ibid.
[172] Int'l Activity Report, South Africa: Big Pharma Backs Down, Doctors Without Borders (2001), available at http://www.doctorswithoutborders.org/publications/ar/report.cfm?id=1204 (22/05/2013); Anthony Stoppard, Health - South Africa: Drug Companies Drop Lawsuit Against Government, Inter Press Service (2001), available at http://www.ipsnews.net/2001/04/health-south-africa-drug-companies-drop-lawsuit-against-government/ (22/05/2013); Marla L. Mellino, The TRIPS Agreement: Helping or Hurting Least Developed Countries' Access to Essential Pharmaceuticals? 20 Fordham Intell. Prop. Media & Ent. L.J. (2010) 1368.

passed the South African Medicines and Medical Devices Regulated Authority Act (SAMMANDRA) repealing parts of the Medicines and Related Substances Bill.[173] The lawsuit was then stayed after the government had passed this Act. Additionally, parts of the Bill were criticized by South Africa's Constitutional Court and sent back for revision to the Health Department. Pharmaceutical companies argued that South Africa by passing the Bill would violate its obligations under the TRIPS Agreement, while South Africa insisted the Bill was in line with TRIPS.[174] During that time the United States exerted pressure on South Africa and put it on the Special 301 Report.[175] In 2001, at the time of the Doha Declaration, following media attention and extern pressure from non-governmental organizations like Médecins Sans Frontiéres, the lawsuit was dropped.[176] The United State then publicly expressed their support of public health measures by developing countries. Although the lawsuit was dropped, the legislation in South Africa has never implemented.

Despite the flexibility options under TRIPS and the Doha Declaration, there was first little movement on the part of developing countries and LDCs to use them. Prior to 2005, developing countries and LDCs purchased cheap HIV drugs from India, which until then had not adjusted its patent legislation to the TRIPS provisions.[177] In 2005, India implemented its patent protection on medicines in compliance with the TRIPS Agreement. Countries then were forced to follow the provisions of TRIPS to obtain compulsory licenses.[178] The process of utilizing compulsory licenses started off in 2006.[179] Thailand issued a compulsory license for the HIV drug Efavirenz made by Merck&Co in 2006[180] and for the HIV drug Kaletra made by Abbott Laboratories in 2007. [181] Brazil issued a compulsory license on Efavirenz after unsuccessful price negotiations with the pharmaceutical company Merck.[182] The Philippines enacted a law allowing for compulsory licensing and parallel imports.[183] When Thailand issued a compulsory license in 2007, the United States responded by placing Thailand on the Special

[173] Medicines and Related Substances Control Amendment Act, 1997, Bill 72B-97 (NA)/B30-97.
[174] Int'l Activity Report, *supra* fn 172; Mellino, *supra* fn 172, 1368.
[175] Lucyk, *supra* fn, 170, 191; 213; Office of the U.S. Trade Representative, Special 301 Report (2013), available at http://www.ustr.gov/sites/default/files/05012013%202013%20Special%20301%20Report.pdf (22/05/2013). The Office of the United States Trade Representative (the "USTR") created the Special 301 Report under section 301 of the U.S. Trade Act of 1974, placing on it countries that it believes enact or fail to enact laws or policies that violate American IPR holders. Countries that are found to have provided no adequate IP protection are subject to trade sanctions.
[176] Int'l Activity Report, *supra* fn 172; Mellino, *supra* fn 172, 1369.
[177] Sangeeta Shashikant, More Countries Use Compulsory License, But New Problems Emerge, Third World Network (2005), available at http://www.twnside.org.sg/title2/health.info/twninfohealth004.htm (22/05/2013).
[178] Ibid.
[179] Gail E. Evans, Strategic Patent Licensing for Public Research Organizations: Deploying Restriction and Reservation Clauses to Promote Medical R&D in Developing Countries, 34 Am. J.L. & Med. (2008) 175, 181-83.
[180] Examples of Health-Related Compulsory Licenses, Consumer Project on Tech., http://www.cptech.org/ip/health/cl/recent-examples.html (22/05/2013).
[181] Evans, *supra* fn 179, 184 (noting that U.S.-based Abbott Laboratories owned the patent on the antiretroviral drug licensed by Thailand).
[182] Ibid.
[183] Ibid.

301 Report[184] which allows the United States to pose trade sanctions.[185] Countries are therefore cautious to use the TRIPS flexibilities always having in mind the consequences their actions could have on direct foreign investments.

c) TRIPS Flexibilities and the Pharmaceutical Industry's Claims

The pharmaceutical industry argues that compulsory licenses greatly reduce the incentive for innovation and in the long run the access to innovative medicines.[186] A pharmaceutical patent, so the industry's view, is the reward for developing a new drug. The pharmaceutical patent grants an exclusive monopoly right to the market for a limited period. By removing patent protection, the reward is being removed.[187] Compulsory licensing is therefore a disincentive to innovation. The industry's view may be true for many pharmaceutical products, however, as far as HIV drugs are concerned, incentives for research and development of new drugs often come from funds and taxpayer money. The United States government funds the development of various AIDS drugs.[188] The funding goes to universities. Once a drug has been developed, the formula to produce the drug is licensed to a pharmaceutical company in a licensing contract. The pharmaceutical company then recoups the costs for production and also reaps large profits from the sales of the drug.[189] Furthermore, it is argued that while the pharmaceutical industry claims that the twenty-year patent term helps the company to recover research and development costs, pharmaceutical patents actually prevent public health benefits of the drug. The effective patent life is usually shorter, approximately ten to twelve years, due to the upcoming of new, more effective drugs or drugs with less side effects.[190] Marketability of a drug is therefore limited to only ten to twelve years. Opponents of pharmaceutical patents say that by maintaining the patent rights beyond that term of profitability, companies are simply preventing generic competition and public health benefit of the drugs.[191] Additionally, developing countries make up only a small portion of the pharmaceutical world market.[192] Due to the weak purchasing power of consumers, they do not represent a strong potential market.[193] Considering this, there will be no large impact on the pharmaceutical world market and on the industry's revenues, if developing countries start using compulsory licenses. The pharmaceutical industry's real concern seems to be that if

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[184] Ibid.
[185] Lucyk, *supra* fn 170, 212; Trade Act of 1974, § 301, 19 U.S.C. § 2411 (2006), *supra* fn 175.
[186] United States Constitution and United States case law pay homage to the incentive theory justification for intellectual property protection; U.S. Const. Art. I, 8, cl. 8 ("to Promote the Progress of Science and useful Arts."); Mazer v. Stein, 347 U.S. 201, 219 (1954).
[187] Ibid.
[188] Bombach, *supra* fn 98, 282; Pierre Chirac et al., AIDS: Patent Rights Versus Patient's Rights, 5 The Lancet (2000) 502 ("Public research institutes have funded antiretroviral drug development, including that for didanosine, abacavir, stavudine, zalcitabine").
[189] Bombach, *supra* fn 98, 284.
[190] Joseph A. DiMasi & Henry G. Grabowski, The Cost of Biopharmaceutical R&D: Is Biotech Different? 28 Managerial&Decision Econ. (2007) 853.
[191] Bombach, *supra* fn 98, 284.
[192] Ibid., 283.
[193] Lybecker, *supra* fn 1, 32.

developing countries start using compulsory licensing, wealthy countries will follow suit.[194] While compulsory licensing by poor countries has little impact on the world market, this may be different with wealthy countries. In case of parallel importation, a lack of price control by the pharmaceutical companies could increase pressure in the United States and Europe to lower drug prices elsewhere.[195] Through parallel importation, poor countries can purchase drugs where they are cheapest and thus limit the pharmaceutical company's price control monopoly. The pharmaceutical industry also claims that compulsory licenses or parallel importation will not reduce the drug prices enough for citizens in poor countries to afford the medicines.[196] Furthermore, given the possibility of poor-quality products finding their way to the local pharmaceutical markets in case of compulsory licenses or parallel imports, drug resistance problems are likely to emerge.[197]

6. The Problem for LDCs and the Decision of the General Council of August 2003

LDCs facing an epidemic have difficulties to use compulsory licensing: First, the TRIPS Agreement requires negotiations prior to the issuance of a compulsory license and efforts to obtain a voluntary license on reasonable commercial terms.[198] Due to the lack of resources, LDCs may be unable to offer commercially reasonable terms to the patent owner. To circumvent the negotiation requirement, LDCs would have to declare a state of national emergency to request a compulsory license. The compulsory license would then enable the LDC to use the patented formula or technology of the patent. The LDC would nevertheless have to follow the other provisions of Art. 31 of the TRIPS Agreement. Art. 31(h) requires that when granting a compulsory license, the right holder shall receive adequate remuneration "taking into account the economic value of the authorization."[199] Adequate remuneration in public health situations, as stated earlier, is naturally low.[200] However, the requirement of offering adequate remuneration may nevertheless place an obstacle to LDCs. Second, LDCs probably have no manufacturing capacity to produce the drugs themselves if a compulsory license is issued and the LDC is allowed to use the formula in the patent. Is the LDC entitled to issue a compulsory license to a foreign drug manufacturer?

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[194] Bombach, *supra* fn 98, 287.
[195] Ibid.
[196] Ben Sihanya, Managing the Challenges of WTO Participation: Case Study 19, Patents, Parallel Importation and Compulsory Licensing of HIV/AIDS Drugs: The Experience of Kenya (stating that "AIDS drugs are expensive partly because of royalties that must be paid to patent holders under the TRIPS Agreement and Kenya's Industrial Property Act, 2001"), available at http://www.wto.org/english/res_e/booksp_e/casestudies_e/case19_e.htm (22/05/2013).
[197] Ibid. (Patients might start with a treatment and then lack the resources to continue the treatment. Even if a treatment is affordable, a rural patient might abandon the treatment after it has begun, because it is too difficult and expensive to travel to the medical facility. If a patient takes drugs irregularly or low-quality drugs, this may result in drug resistance).
[198] TRIPS, *supra* fn 13, Art. 31(b).
[199] Ibid., Art. 31(h).
[200] Love, *supra* fn 111, 5-8.

The interpretation of the term "third party" in Art. 31 of the TRIPS Agreement according to Art. 31 of the VCLT, does not necessarily exclude foreign manufacturers.[201] A foreign manufacturer may therefore be permitted to supply another country with needed pharmaceuticals. However, this would not comply with Art. 31(f) of the TRIPS Agreement[202] and constitute a violation of the principle of territoriality.[203] According to the principle of territoriality, every country has sovereign powers within its borders and must not interfere with the rights of the patent holder in another country.[204] Under the framework of TRIPS, members retained their sovereign powers in the intellectual property field.[205] A government in compliance with the principle of territoriality is not allowed to issue a compulsory license to a manufacturer in a foreign country,[206] because this would interfere with the inventor's rights in the other country. In effect, the principle of territoriality excludes non-domestic manufacturers from inclusion within the term "third party" of Art. 31 of the TRIPS Agreement.[207] Art. 31(f) of the TRIPS Agreement furthermore demands that compulsory licensing shall be granted „predominantly for the supply of the domestic market of the Member".[208] With this provision, the production of patented pharmaceuticals under compulsory license is restricted. It shall be used for the predominant supply of the domestic market of the WTO member that issued the compulsory license. The term "predominantly" in Art. 31(f) requires that more or less all the pharmaceuticals manufactured are distributed and sold by the member who authorized the issuance of the compulsory license. Art. 31(f) does not allow the licensee to sell the goods to other markets or go beyond the purpose that the license had been issued for.[209] The purpose of this provision is to prevent misuse.[210] It would be inconsistent with Art. 31(f) if a country granted a compulsory license to its manufacturers to produce the drug solely for export to a non-producing LDC affected by a public health crisis. Hence, a compulsory license would only benefit a country with manufacturing capacity which can make use of

[201] TRIPS, *supra* fn 13, Art. 31 (lacking a definition of the term "third parties" that specifically excludes foreign entities); Murthy, *supra* fn 148, 1336.
[202] TRIPS, ibid., Art. 31(f) (which requires that patented products manufactured pursuant to Art. 31 are directed "predominantly").
[203] Draft Communication from the European Communities and its Member States to the TRIPS Council: Concept Paper relating to paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health (2002) [hereinafter Communication from EU], 3 (II.1.6/7) available at http://trade.ec.europa.eu/doclib/docs/2003/june/tradoc_113126.pdf (22/05/2013) (impermissibility of a Member granting a compulsory license to a foreign entity).
[204] Abbott, *supra* fn 26, 83-92 ("the sovereignty of each national government within its own territory is the paramount principle by which the international legal and political order was constituted"). The principle of territoriality also requires an inventor to seek a patent in each country in which he wishes patent protection. Ibid.
[205] TRIPS, *supra* fn 13, Art. 1 (directing the nature and scope of obligations upon WTO Members under TRIPS).
[206] Communication from EU, *supra* fn 203, 3 (the patent covering the product in the other country is independent from the patent in the former country, therefore a member cannot grant a compulsory license to a foreign manufacturer).
[207] Ibid.
[208] TIRPS, *supra* fn 13, Art. 31(f).
[209] TRIPS, *supra* fn 13, Art. 31(c) (the scope of the other use shall be limited to the purpose for which it was authorized) read together with Art. 31(f) (the purpose in granting a compulsory license must be to primarily provide the domestic market of the authorizing member such use).
[210] Ibid., Art. 31 (setting forth various restrictions on "other use").

the formula or technology included in the patent.[211] Countries lacking their own manufacturing capacity to utilize the formula or technology face difficulties.[212] LDCs naturally rely on imports from foreign suppliers due to the lack of production capacities.[213] If they want to import medicines from another country, where a patent exists on the drug and a compulsory license is therefore needed for the production of the drug, TRIPS poses a barrier to the import.[214] Art. 31(f) of the TRIPS Agreement would need to be suspended if a country wanted to issue a compulsory license for the purpose of export of pharmaceuticals to another country.[215]

The Doha Declaration was adopted in part to deal with this issue, but in the end did not resolve the problem.[216] Instead it called on the Council for TRIPS to address the issue and find a solution to the problem by the end of 2002 (para. 6 of the Doha Declaration).[217] With this provision, the TRIPS Council was delegated the power to grant waivers.[218] According to the WTO Agreement, only the Ministerial Conference is allowed to make a decision granting waivers.[219] The TRIPS Council only submits reports to the Ministerial Conference with details on waiver application, but normally cannot make a decision itself.[220]

The instruction in para. 6 of the Doha Declaration to address the problem and find a solution for WTO members with no or insufficient manufacturing capacities was fulfilled by a decision of the Council for TRIPS in August 30, 2003.[221] The 2003 decision loosened the domestic market requirement set forth in TRIPs Art. 31(f) by creating a system known as the Paragraph 6 System.[222] The Paragraph 6 System allows WTO members with no or insufficient manufacturing capacity in the pharmaceutical field to issue a compulsory license on export of generic versions of a patented drug.[223] On December 6, 2005, the WTO members agreed on an amendment to the TRIPS Agreement to make permanent the temporary waiver of the 2003 decision.[224] It was the first amendment ever to the TRIPS Agreement.

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[211] Communication from EU, *supra* fn 207, 3 (compulsory licenses for export would not be workable because of the limitation under 31(f) of the TRIPS Agreement, which demands that a predominant part of the production under a compulsory license must remain on the domestic market of the member granting the license).
[212] WTO Illustrative guide to notifying under the Paragraph 6 system, available at http://www.wto.org/english/tratop_e/trips_e/par6_modelnotifs_e.htm (22/05/2013).
[213] Ibid.
[214] Ibid.
[215] Communication from EU, *supra* fn 203, 5; 6 (III.1.17/18) (suggesting an exception clause to TRIPS Art. 31(f)).
[216] Doha Declaration, *supra* fn 18.
[217] Ibid., para. 6 (instructing the Council for TRIPS to find a solution to this problem before the end of 2002).
[218] WTO Agreement, *supra* fn 28, Art. IX:3(b).
[219] Ibid.
[220] Ibid.
[221] 2003 Decision, *supra* fn 110.
[222] Ibid.; Doha Development Agenda, Press/350/Rev.1 (2003) Decision removes final patent obstacle to cheap drug imports, available at http://www.wto.org/english/news_e/pres03_e/pr350_e.htm (22/05/2013).
[223] 2003 Decision, *supra* fn 110, para. 2(a)(iii) (stating that the importing country must grant a compulsory license, where the product is patented on its territory).
[224] Decision of the General Council, Amendment of the TRIPS Agreement, WT/L/641 (Dec. 6, 2005) [hereinafter 2005 Protocol]; Press Release, World Trade Org., Members OK Amendment to Make Health

With the 2005 protocol, the TRIPS Agreement was amended by inserting Art. 31bis after TRIPs Art. 31 and by inserting the Annex to the TRIPS Agreement after Art. 73.[225] Thus, the 2003 decision was formally accepted as an amendment of the TRIPS Agreement, however, to make the decision legally binding, two-thirds of the WTO members must adopt and ratify the agreement.[226] A deadline for accepting the TRIPS amendment was set until December 1, 2007, which was extended in 2008 until December, 31, 2009, and again by the General Council until December, 31, 2013.[227]

a) Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health

The 2003 decision sets forth the framework ("Paragraph 6 System") under which a developing country may export to other countries with a national health problem.[228] Paragraph 6 refers to the provision of the Doha Declaration which is implemented by the 2003 decision and 2005 protocol.[229] Within the framework, each WTO member country decides for itself how it will implement the decision domestically through its legislation. The Paragraph 6 System creates a new form of compulsory license specifically for the export of drugs. The use of this compulsory license requires formal notification to the TRIPS Council by the member that wishes to make use of the Paragraph 6 System.[230] There are three types of notifications under the system: (1) an importing country's one-off notification to make use of the Paragraph 6 System, which LDCs do not require; (2) an importing country's specific notification of the details of the drug needed and other details required under the system, whenever it makes use of the system; and (3) an exporting country's notification of the granting of a compulsory license for export and the conditions as required under the system. [231] Notifications are made for transparency reasons and do not require approval by the WTO.[232]

Countries that want to import under the system have to notify to the WTO in two steps.[233] First, they have to announce once that they intend to make use of the system as importers.[234] Second, they have to supply information each time they use the system. The two requirements are set forth in para. 1(b) and para. 2(a) of the 2003 decision and are repeated in the Annex to the TRIPS Agreement provided for in the 2005 protocol amending the agreement.[235] Notifications are made public by the WTO Secretariat

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Flexibility Permanent (Dec. 6, 2005), available at http://www.wto.org/english/news_e/pres05_e/pr426_e.htm (22/05/2013).
[225] Ibid., Attachment 1. The new Article 31bis and annex of the TRIPS Agreement are attached to the protocol of amendment.
[226] Ibid., para. 3; WTO Agreement, *supra* fn 28, Art. X, para. 3.
[227] Press Release, *supra* fn 224.
[228] 2003 Decision, *supra* fn 110.
[229] 2005 Protocol, *supra* fn, 224.
[230] WTO Illustrative guide to notifying under the Paragraph 6 System, *supra* fn 212.
[231] Ibid.
[232] Ibid.
[233] Ibid.
[234] Ibid.
[235] Ibid.

on the WTO website.[236] No para. 1(b) notification has been made so far.[237] Some members, however, have agreed not to use the system as importers[238], and some have stated that they will use the system only in national emergencies or other extremely urgent circumstances.[239] Since the 2003 decision, only one country has used of the Paragraph 6 System - Canada provided HIV drugs to Rwanda under the system. In 2007 Rwanda's notification under para. 2(a) was received by the Council for TRIPS.[240]

The principal definition of "eligible importing members" under the Paragraph 6 System is found in para. 1(b) and 2(a)(ii) of the 2003 decision. Eligible importing members are LDCs. LDCs (for instance Rwanda) are deemed to have insufficient or no manufacturing capacities in the pharmaceutical field and do not have to notify to the TRIPS Council under para. 1(b) to make use of the system.[241] Other members can become importing members as long as they meet the guidelines[242]: They must notify once to the Council of TRIPS that they intend to make use of the system.[243] They can use the system in whole or limited to a national emergency or other circumstance of extreme urgency or in cases of public non-commercial use[244] - this language is consistent with the language of TRIPS and the Doha Declaration[245]. Details for both, LDCs and other eligible countries, to notify each time, a member uses the system, are laid out in para. 2 of the 2003 decision. Importing members must specify the names and expected quantities of the needed products to the Council for TRIPS and grant a compulsory license if the pharmaceutical product is patented in their territories.[246] According to para. 2(a)(ii) and the Annex of the 2003 decision the eligible importing country (other than a LDC) must have established that it has no manufacturing capacity in the pharmaceutical field or that its manufacturing capacity is currently insufficient to meet its needs, in which case the system applies for the duration of the insufficient supply.

Exporting member countries must also meet certain requirements under the Paragraph 6 System.[247] They can only manufacture the amount necessary to meet the needs of the importing member, whose needs have been specified to the Council for TRIPS before, and the entire amount of that production

[236] Ibid.
[237] Ibid.
[238] WTO, General Council Chairperson's statement (2003), WT/GC/M/82, at http://www.wto.org/english/tratop_e/trips_e/gc_stat_30aug03_e.htm (22/05/2013); members having agreed to opt out of the system as importers include Australia, Belgium, Austria, Germany, Japan, Sweden, Switzerland, the United Kingdom and the United States.
[239] Ibid. Members having agreed that they will only use the system as importers in cases of national emergency or other extremely urgent circumstances include Israel, Korea, Turkey, China, Mexico, and the United Arab Emirates.
[240] Notification under paragraph 2a of the decision of 30 August 2003 on the implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, IP/N/9/RWA/1 (July 2007).
[241] WTO Illustrative guide to notifying under the Paragraph 6 System, *supra* fn 212; Annex of 2003 Decision, *supra* fn 110.
[242] 2003 Decision, *supra* fn 110, para. 1(b); 2(a).
[243] Ibid., para. 1(b).
[244] Ibid.
[245] TRIPS, *supra* fn 13, Art 31; Doha Declaration, *supra* fn 18, para. 1, 5 (c).
[246] 2003 Decision, *supra* fn 110, para. 2(a)(i), (iii).
[247] WTO Illustrative guide to notifying under the Paragraph 6 System, *supra* fn 212.

must be exported to the requesting importing member[248]. The products must be specifically identified as being produced under the Paragraph 6 System.[249] Prior to the shipment, the exporting member must post information on a website including the quantities being supplied to the destination and the distinguishing features of the product.[250] The exporting country must also provide adequate remuneration pursuant to Art. 31(h) of the TRIPS Agreement "taking into account the economic value to the importing Member of the use that has been authorized in the exporting Member", whereas this requirement is waived for the importing country. [251] Exporting countries must provide information on the conditions attached to the compulsory license.[252] Eligible importing members shall take "reasonable measures within their means" to ensure that the products under the Paragraph 6 System are used for public health purposes and to prevent re-exportation of the products.[253]

The 2003 decision additionally opens another possibility to bring pharmaceuticals to developing countries and LDCs.[254] According to para. 6 of the 2003 decision, an importing developing or least-developed country which has produced or imported a pharmaceutical product may export the product to another developing or least developed country that is party to the same regional trade agreement and shares the same health problem.[255] It is understood that "this will not prejudice the territorial nature of the patent rights in question".[256] With this provision, the 2003 decision, in effect, is condoning parallel importation to the extent that similarly suffering developing or least developed countries can export pharmaceuticals to each other consistent with TRIPS if they are in need of treatment for the same health problems.[257]

b) Assessing the Paragraph 6 System

The Paragraph 6 System aims to restore to countries without manufacturing capacities the ability to make use of compulsory licensing in the same way as countries with manufacturing capacity can do.[258] Certain developing countries like Brazil or India possess manufacturing capabilities, but many LDCs like those in sub-Saharan Africa do not.[259] The pharmaceutical industry claims that compulsory licenses for export under the Paragraph 6 System will reduce the revenues of the pharmaceutical

[248] 2003 Decision, *supra* fn 110, para. 2(b)(i).
[249] Ibid., para. (b)(ii).
[250] Ibid., para. (b)(iii).
[251] Ibid., para. 3.
[252] Ibid., para. 2(c), specified in the 2005 Protocol, *supra* fn 224 (the name and address of the licensee, the products and quantity to be produced under the license, the importing member, and the duration of the license).
[253] Ibid., para. 4.
[254] Ibid., para. 6(i).
[255] Ibid.
[256] Ibid., para. 6(ii).
[257] Mellino, *supra* fn. 172, 1364-65.
[258] Amir Attaran, Symposium: The Nexus Symposium: An interdisciplinary forum on the impact of international patent&trade agreements in the fight against HIV&AIDS: Article: Assessing and Answering paragraph 6 of the Doha Declaration on the TRIPS Agreement and public health: The case for greater flexibility and an non-justiciability solution, 17 Emory int'l L. Rev. (2003), 753.
[259] Mellino, *supra* fn 172, 1358.

companies.[260] This fear appears to be exaggerated because there are no economically relevant markets that lack manufacturing capacity. All developed countries and emerging markets possess manufacturing capacity including Brazil, China, Mexico, South Africa and Thailand.[261] They can use compulsory licensing without being affected by the Paragraph 6 System. Only the poorest countries, the LDCs, lack production capacity. If LDCs start using the Paragraph 6 System, the impact on the pharmaceutical world market will be negligible.[262] Also the use of the Paragraph 6 System, as seen in the example of Rwanda, will likely remain the exception.[263] The fear of trade retaliation persists similar to when a developing country outside the Paragraph 6 System issues a compulsory license.[264] Compulsory licensing on pharmaceuticals alone or within the Paragraph 6 System is generally uncommon.[265] Many legislations contain compulsory licensing laws – the United States regularly practices compulsory licensing for non-pharmaceuticals[266] –, but for diplomatic and political reasons and in order not to render the patent system useless, it belongs to the custom of countries aspiring to the polite society not to compulsorily license medicines.[267] If governments hesitate to issue a compulsory license for the domestic market supply, they are all the more unlikely to do so for export to help foreigners.[268] An exceptional use of the Paragraph 6 System will hardly reduce revenues of the pharmaceutical industry.

The United States and the European Union insist that the Paragraph 6 System be limited to HIV, malaria, tuberculosis, and certain other infectious diseases, whereas developing countries insist the system is not limited to specific diseases.[269] Para. 6 of the Doha Declaration, and the 2003 Decision do not explicitly limit the scope of diseases the system applies to[270], and regarding the purpose of para. 6, to achieve equality among countries with and without manufacturing capacity, such limitation was certainly not intended[271]: Countries with manufacturing capacity are entitled to issue compulsory licenses under Art. 31 of the TRIPS Agreement for any disease and any drug[272]; the same must account for countries without manufacturing capacity under the Paragraph 6 System.[273]

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[260] Attaran, *supra* fn 258, 743.
[261] Ibid., 746.
[262] Bombach, *supra* fn 98, 283 (stating that "there will be a negligible discrepancy between the drug company's profits before and after compulsory licensing").
[263] Notification of Rwanda to the TRIPS Council, *supra* fn 240.
[264] Dutfield, *supra* fn 1, 123.
[265] Attaran, *supra* fn 258, 747.
[266] Bombach, *supra* fn 98, 294.
[267] Attaran, *supra* fn 266, 750.
[268] Ibid., 748.
[269] Ibid., 751-52, 754; Bebe Loff, No Agreement Reached in Talks on Access to Cheap Drugs, 360 Lancet (2002) 1950.
[270] See generally 2003 Decision, *supra* fn 110.
[271] Attaran, *supra* fn 258, 754.
[272] TRIPS, *supra* fn 13, Art. 31 (no word of any limitation as to the scope of diseases or medicines).
[273] Attaran, *supra* fn 258, 754.

Other countries than LDCs are eligible to become importing countries by notifying to the TRIPS Council.[274] With this provision, other diseased, but lower-middle income countries like Kenya are included in the system.[275] Their inclusion is fair and will unlikely harm the pharmaceutical industry because, as stated earlier, all economically important countries possess manufacturing capacity.[276] A country facing an acute public health emergency can use the Paragraph 6 System, even if it is no LDC and possesses manufacturing capacity, if this capacity is currently overwhelmed by the public health emergency and found insufficient.[277] The country can use the system to import pharmaceuticals produced under compulsory license elsewhere and shall be entitled to do so for the duration of the crisis.[278]

c) Utilization of the Paragraph 6 System

To date, only one country without manufacturing capacity, Rwanda, has used the Paragraph 6 System to obtain drugs from Canada.[279] Canada changed its patent legislation with the Jean Chretien Pledge to Africa (the Jean Chretien Act) in 2004, creating the framework for Canada's Access to Medicines Regime (CAMR).[280] CAMR sets forth the requirements for importing countries and companies that wish to participate in the system.[281] Canada used the system in September 2007 to ship HIV drugs to Rwanda.[282] The drug maker Apotex had been authorized by GlaxoSmithKline and the Canadian subsidiaries of Shire and Boehringer Ingelheim to manufacture a triple combination of antiretroviral medicine for Rwanda and has shipped two freights of HIV drugs to Rwanda.[283] Under CAMR, the importing country is required to identify a drug from a list of eligible medicines, deliver the required notification to the WTO, and find a pharmaceutical company for export.[284] The exporting pharmaceutical company is required to enter into an agreement with the importing country for a certain quantity of a certain drug, and then to obtain allowance for export from Canada's Commissioner of Patents.[285] The products used for export must meet the same safety requirements

[274] 2003 Decision, *supra* fn 110, para. 1(b), 2(a).
[275] Attaran, *supra* fn 226, 759.
[276] Ibid.
[277] Ibid., 764; 2003 Decision, *supra* fn 110, Annex (ii).
[278] 2003 Decision, ibid., Annex (ii).
[279] Notification of Rwanda to the TRIPS Council, *supra* fn 240.
[280] Background, Can.'s Access to Meds. Regime, Background, available at http://www.camr-rcam.gc.ca/intro/context-eng.php (22/05/2013) [hereinafter Background, CAMR]; Mellino, *supra* fn 172, 1372.
[281] Ibid.
[282] Big Pharmaceutical Firms Agree to Generic Drugs for Rwanda, Africa Good News (2009) http://africagoodnews.com/content/big-pharmaceutical-firms-agree-to-generic-drugs-for-rwanda (22/05/2013) [hereinafter Generic Drugs for Rwanda]; Mellino, *supra* fn 172, 1373.
[283] Ibid.
[284] Requirements for Importing Countries, Can.'s Access to Meds. Regime, http://www.camr-rcam.gc.ca/countr-pays/import/index-eng.php (22/05/2013).

[285] Requirements for Companies, Can.'s Access to Meds. Regime, http://www.camr-rcam.gc.ca/compan-entrepris/req-exig/index-eng.php (22/05/2013).

than those for national use.[286] They must be distinguished by colouring or labelling from products reserved for national use.[287]

CAMR has received criticism for a number of reasons. Critics including Apotex have found the legislation to be too complicated and the process too complex.[288] There are over nineteen sections and one hundred clauses and sub-clauses under CAMR, and their study and analysis require legal expertise[289] which LDCs lack due to limited resources. Under CAMR, there is only a limited list of medicines available.[290] The requesting country can only choose from this particular list of eligible medicines. If a drug is not available on the list, it cannot be exported. Drugs and technologies available in developed countries, however, are not always directed to the needs in developing countries and LDCs, because LDCs need many drugs that are not listed.[291] CAMR limits the quantity of the license to the amount requested by the country. If Rwanda wanted to use the Paragraph 6 System again, it would have to restart the CAMR process.[292] CAMR requires obtaining a voluntary license prior to obtaining a compulsory license which is time-consuming and costly.[293] Parties have to engage in negotiations before they can issue compulsory licenses. Apotex already threatened to retreat from the project, because the process was too costly.[294] The negotiation requirement under CAMR is not compulsory under the Paragraph 6 System, and exporting and importing countries would be better off without it. [295] As common with compulsory licensing, there remains the steady fear of retaliation.[296] LDCs may hesitate to seek products from an exporting country under the Paragraph 6 System in fear of trade retaliation.[297] A country like the United States may pose trade sanctions on another country taking part in trade activities under CAMR that affect markets in the United States.[298] The United

[286] Ibid.
[287] Anti-Diversionary Measures - Companies, Can.'s Access to Meds. Regime, http://www.camr-rcam.gc.ca/compan-entrepris/req-exig/anti-eng.php (22/05/2013).
[288] Press Release, Apotex Inc., Second Shipment of Life-Saving Aids Drug Leaving for Africa (Sept. 18, 2009), available at http://www.apotex.com/global/about/press/20090918.asp (22/05/2013).
[289] Marilyn McHarg, Médecins Sans Frontiéres Can., Review of the Canadian Access to Medicines Regime: Submission to the Government of Canada (2007) 2, available at http://www.camr-rcam.gc.ca/review-reviser/camr_rcam_msf_11-eng.pdf (22/05/2013); Mellino, *supra* fn 172, 1374-75.
[290] Ibid.
[291] Aaron S. Kesselheim, Think Globally, Prescribe Locally: How Rational Pharmaceutical Policy in the U.S. Can Improve Global Access to Essential Medicines, 34 Am. J.L. & Med. (2008) 125; Pharmaceutical companies currently have little incentive to spend money on specific treatments for poor nations due to their low purchasing power and the low return on investment, ibid.; Dufield, *supra* fn 1, 112-13; see U.K. Commission on Intellectual Property Rights (CIPR), *supra* fn 88, 30-34.
[292] See generally Jillian C. Cohen-Kohler, Laura C. Esmail & Andrea Perez Cosio, Canada's Implementation of the Paragraph 6 Decision: Is It Sustainable Public Policy? Globalization & Health (2007), available at http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2180169/ (22/05/2013); Mellino, *supra* fn 172, 1374.
[293] McHarg, *supra* fn 289, 1; Preparing to Submit an Application, Can.'s Access to Meds. Regime, available at http://www.camr-rcam.gc.ca/compan-entrepris/applic-demande/prepar-eng.php (22/05/2013) ("At least 30 days before submitting the application, the company must try to obtain from the patent holder a voluntary license to make and export the patented product.").
[294] Generic Drugs for Rwanda, *supra* fn 282.
[295] McHarg, *supra* fn 289, 2; Mellino, *supra* fn 265, 1384.
[296] Dutfield, *supra* fn 1, 123; Mellino, ibid., 1376.
[297] Mellino, ibid.
[298] Evans, *supra* fn 179, 184; Lucyk, *supra* fn 170, 212.

States responded to the implementation of TRIPS flexibilities through several countries by placing them on the Special 301 Report.[299] Keeping this in mind, countries are careful on the trade actions they take. Unless a deterrent mechanism is included in TRIPS to prevent countries from engaging in trade retaliation, fear of retaliation may persist.[300] Despite the criticism, CAMR can serve as an example and case study for other countries which intend to implement a version of the Paragraph 6 System within their legislation.

7. Analysis of the three TRIPS Options

The current three public health measures of the TRIPS Agreement – compulsory licenses, the Paragraph 6 System and parallel importation – can help developing countries and LDCs to obtain medicines in urgent public health situations. They do not, however, provide long-term solutions due to their steady interference with IPRs.[301] A compulsory license, even though the patent monopoly will be still recognized in the market where companies make the most profits, interferes with the interests of the patent holder. The patent holder gets little remuneration for a compulsory license. Within the Paragraph 6 System the patent holder also dedicates production capacity and capital to produce and export the drugs – resources that could otherwise generate profits. Yet, compulsory licenses alone or within the Paragraph 6 System can provide LDCs with drugs to treat epidemics like HIV, but they should not be used in the long run. [302] The Paragraph 6 System allows LDCs to import pharmaceuticals, but LDCs by using the system will never learn to sustain themselves with medicines without the help of developed countries.[303] The drawback of the Paragraph 6 System is the lack of sustainability. The ultimate goal for LDCs would be to have full manufacturing and distribution capacities in place as well as IP regimes in place to protect and enforce IPRs. [304]

8. The Pharmaceutical Industry's Options

The pharmaceutical industry could donate drugs to ease the access problem. But it will unlikely offer an unlimited supply for unlimited time.[305] Often a combination with another drug is needed that is not provided for free, thus, standing alone, the drug is virtually useless.[306] Costs may also be transferred to other drugs making other critical drugs less accessible.[307] Price negotiations with multilateral pharmaceutical companies are usually conducted for each country and each drug.[308] They appear to be non-efficient to sustainably reduce prices to affordable levels. The threat of issuing a compulsory

[299] Office of the U.S. Trade Representative, Special 301 Report (2013), *supra* fn 175.
[300] Mellino, *supra* fn 172, 1377.
[301] Ibid., 1377-78, 81-82.
[302] Ibid.
[303] Ibid., 1381.
[304] Ibid., 1386.
[305] Bombach, *supra* fn 98, 299; 303.
[306] Ibid.
[307] Ibid.
[308] Ibid.

license may strengthen the bargaining power of countries with manufacturing capacity to obtain lower prices[309], but the problem with negotiations is always finding an affordable price.[310] Also a government will not accept an agreement under the condition to give up its right to seek cheaper drugs elsewhere.[311] Pharmaceutical companies could issue voluntary licenses.[312] In contrast to price reductions, voluntary licenses are a sustainable method for countries to supply their citizens with drugs according to their demand.[313]

9. Conclusion

The TRIPS Agreement is characterized by the opposite views of developed and developing countries. As common with legal provisions in international agreements, substantive TRIPS provisions lack clarity because they represent compromise formulations resulting from multilateral negotiations. The Doha Declaration and the TRIPS amendment aim to clarify the ambiguities of the TRIPS Agreement, but do not resolve the underlying problem. Pharmaceutical patents continue to represent an obstacle for access to medicines in developing countries, while at the same time they seem to be essential for pharmaceutical companies to develop innovative drugs. The TRIPS flexibilities can help developing countries purchase cheaper drugs than if bought directly from the pharmaceutical firms. Developing countries can either produce medicines themselves by using a compulsory license. LDCs can use the Paragraph 6 System to gain cheaper drugs elsewhere. However, for political reasons and the steady fear of trade retaliation, the use of compulsory licenses is limited and the use of the Paragraph 6 System exceptional. To my mind, developing countries should be encouraged to use flexibility mechanisms under TRIPS more often, e.g. by offering them legal advice on how to do so and most importantly by including a deterrent mechanism in the TRIPS Agreeement to prevent countries from partaking in trade reatliations after a compulsory license is issued. Unless the TRIPS Agreement is amended in this way, countries will hesitate to use the TRIPS flexibilities in fear of trade retaliations. However, even if the TRIPS flexibilities were used more often, they would not represent a sustainable solution to the current access problem. Compulsory licenses, parallel importing and the Paragraph 6 System are useful in public health emergency situations, but do not represent long-term solutions.[314] They constantly interfere with the interests of the patent holder in protecting IPRs. Particularly LDCs, by using the Paragraph 6 System, will never learn to procude the drugs they need themselves. The Paragraph 6 System under CAMR (Canada's Access to Medicines Regime) has received criticism. Nevertheless, CAMR can serve other countries as example to revise their legislation and make changes to ensure more use of the system.[315] This could be achieved by removing the negotiation

[309] Lucyk, *supra* fn 170, 193.
[310] Bombach, *supra* fn 98, 303.
[311] Ibid., 298-99.
[312] Ibid., 303.
[313] Ibid.
[314] Mellino, *supra* fn, 172, 1377.
[315] Ibid., 1376.

requirement under CAMR, eliminating unnecessary rules to simplify the system, and extending the number of drugs available for export.[316] The Council for TRIPS should study the process and product exchange for possible needed changes of the Paragraph 6 System.[317] Finally, pharmaceutical companies ought to do more to work with national governments and non-governmental organizations to loosen price control and increase access to medicines.[318]

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[316] Ibid., 1383.
[317] Ibid., 1376.
[318] Bombach, *supra* fn 98, 304.

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11. ANNEX

AGREEMENT ON TRADE-RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS

PART I GENERAL PROVISIONS AND BASIC PRINCIPLES

AGREEMENT ON TRADE-RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS

Members,

Desiring to reduce distortions and impediments to international trade, and taking into account the need to promote effective and adequate protection of intellectual property rights, and to ensure that measures and procedures to enforce intellectual property rights do not themselves become barriers to legitimate trade;

Recognizing, to this end, the need for new rules and disciplines concerning:

(a) the applicability of the basic principles of GATT 1994 and of relevant international intellectual property agreements or conventions;

(b) the provision of adequate standards and principles concerning the availability, scope and use of trade-related intellectual property rights;

(c) the provision of effective and appropriate means for the enforcement of trade-related intellectual property rights, taking into account differences in national legal systems;

(d) the provision of effective and expeditious procedures for the multilateral prevention and settlement of disputes between governments; and

(e) transitional arrangements aiming at the fullest participation in the results of the negotiations;

Recognizing the need for a multilateral framework of principles, rules and disciplines dealing with international trade in counterfeit goods;

Recognizing that intellectual property rights are private rights;

Recognizing the underlying public policy objectives of national systems for the protection of intellectual property, including developmental and technological objectives;

Recognizing also the special needs of the least-developed country Members in respect of maximum flexibility in the domestic implementation of laws and regulations in order to enable them to create a sound and viable technological base;

Emphasizing the importance of reducing tensions by reaching strengthened commitments to resolve disputes on trade-related intellectual property issues through multilateral procedures;

Desiring to establish a mutually supportive relationship between the WTO and the World Intellectual Property Organization (referred to in this Agreement as "WIPO") as well as other relevant international organizations;

Hereby agree as follows:

PART I

GENERAL PROVISIONS AND BASIC PRINCIPLES

Article 1

Nature and Scope of Obligations

1. Members shall give effect to the provisions of this Agreement. Members may, but shall not be obliged to, implement in their law more extensive protection than is required by this Agreement, provided that such protection does not contravene the provisions of this Agreement. Members shall be free to determine the appropriate method of implementing the provisions of this Agreement within their own legal system and practice.

2. For the purposes of this Agreement, the term "intellectual property" refers to all categories of intellectual property that are the subject of Sections 1 through 7 of Part II.

3. Members shall accord the treatment provided for in this Agreement to the nationals of other Members.[319] In respect of the relevant intellectual property right, the nationals of other Members shall be understood as those natural or legal persons that would meet the criteria for eligibility for protection provided for in the Paris Convention (1967), the Berne Convention (1971), the Rome Convention and the Treaty on Intellectual Property in Respect of Integrated Circuits, were all Members of the WTO members of those conventions.[320] Any Member availing itself of the possibilities provided in

[319] When "nationals" are referred to in this Agreement, they shall be deemed, in the case of a separate customs territory Member of the WTO, to mean persons, natural or legal, who are domiciled or who have a real and effective industrial or commercial establishment in that customs territory.

[320] In this Agreement, "Paris Convention" refers to the Paris Convention for the Protection of Industrial Property; "Paris Convention (1967)" refers to the Stockholm Act of this Convention of 14 July 1967. "Berne Convention" refers to the Berne Convention for the Protection of Literary and Artistic Works; "Berne Convention (1971)" refers to the Paris Act of this Convention of 24 July 1971. "Rome Convention" refers to the International

paragraph 3 of Article 5 or paragraph 2 of Article 6 of the Rome Convention shall make a notification as foreseen in those provisions to the Council for Trade-Related Aspects of Intellectual Property Rights (the "Council for TRIPS").

Article 2

Intellectual Property Conventions

1. In respect of Parts II, III and IV of this Agreement, Members shall comply with Articles 1 through 12, and Article 19, of the Paris Convention (1967).

2. Nothing in Parts I to IV of this Agreement shall derogate from existing obligations that Members may have to each other under the Paris Convention, the Berne Convention, the Rome Convention and the Treaty on Intellectual Property in Respect of Integrated Circuits.

Article 3

National Treatment

1. Each Member shall accord to the nationals of other Members treatment no less favourable than that it accords to its own nationals with regard to the protection[321] of intellectual property, subject to the exceptions already provided in, respectively, the Paris Convention (1967), the Berne Convention (1971), the Rome Convention or the Treaty on Intellectual Property in Respect of Integrated Circuits. In respect of performers, producers of phonograms and broadcasting organizations, this obligation only applies in respect of the rights provided under this Agreement. Any Member availing itself of the possibilities provided in Article 6 of the Berne Convention (1971) or paragraph 1(b) of Article 16 of the Rome Convention shall make a notification as foreseen in those provisions to the Council for TRIPS.

2. Members may avail themselves of the exceptions permitted under paragraph 1 in relation to judicial and administrative procedures, including the designation of an address for service or the appointment of an agent within the jurisdiction of a Member, only where such exceptions are necessary to secure compliance with laws and regulations which are not inconsistent with the provisions of this Agreement and where such practices are not applied in a manner which would constitute a disguised restriction on trade.

Article 4

Most-Favoured-Nation Treatment

With regard to the protection of intellectual property, any advantage, favour, privilege or immunity granted by a Member to the nationals of any other country shall be accorded immediately and unconditionally to the nationals of all other Members. Exempted from this obligation are any advantage, favour, privilege or immunity accorded by a Member:

(a) deriving from international agreements on judicial assistance or law enforcement of a general nature and not particularly confined to the protection of intellectual property;

Convention for the Protection of Performers, Producers of Phonograms and Broadcasting Organizations, adopted at Rome on 26 October 1961. "Treaty on Intellectual Property in Respect of Integrated Circuits" (IPIC Treaty) refers to the Treaty on Intellectual Property in Respect of Integrated Circuits, adopted at Washington on 26 May 1989. "WTO Agreement" refers to the Agreement Establishing the WTO.

[321] For the purposes of Articles 3 and 4, "protection" shall include matters affecting the availability, acquisition, scope, maintenance and enforcement of intellectual property rights as well as those matters affecting the use of intellectual property rights specifically addressed in this Agreement.

(b) granted in accordance with the provisions of the Berne Convention (1971) or the Rome Convention authorizing that the treatment accorded be a function not of national treatment but of the treatment accorded in another country;

(c) in respect of the rights of performers, producers of phonograms and broadcasting organizations not provided under this Agreement;

(d) deriving from international agreements related to the protection of intellectual property which entered into force prior to the entry into force of the WTO Agreement, provided that such agreements are notified to the Council for TRIPS and do not constitute an arbitrary or unjustifiable discrimination against nationals of other Members.

Article 5

Multilateral Agreements on Acquisition or Maintenance of Protection

The obligations under Articles 3 and 4 do not apply to procedures provided in multilateral agreements concluded under the auspices of WIPO relating to the acquisition or maintenance of intellectual property rights.

Article 6

Exhaustion

For the purposes of dispute settlement under this Agreement, subject to the provisions of Articles 3 and 4 nothing in this Agreement shall be used to address the issue of the exhaustion of intellectual property rights.

Article 7

Objectives

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

Article 8

Principles

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

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

PART II

STANDARDS CONCERNING THE AVAILABILITY, SCOPE AND USE OF INTELLECTUAL PROPERTY RIGHTS

SECTION 1: COPYRIGHT AND RELATED RIGHTS

Article 9

Relation to the Berne Convention

1. Members shall comply with Articles 1 through 21 of the Berne Convention (1971) and the Appendix thereto. However, Members shall not have rights or obligations under this Agreement in respect of the rights conferred under Article 6*bis* of that Convention or of the rights derived therefrom.

2. Copyright protection shall extend to expressions and not to ideas, procedures, methods of operation or mathematical concepts as such.

Article 10

Computer Programs and Compilations of Data

1. Computer programs, whether in source or object code, shall be protected as literary works under the Berne Convention (1971).

2. Compilations of data or other material, whether in machine readable or other form, which by reason of the selection or arrangement of their contents constitute intellectual creations shall be protected as such. Such protection, which shall not extend to the data or material itself, shall be without prejudice to any copyright subsisting in the data or material itself.

Article 11

Rental Rights

In respect of at least computer programs and cinematographic works, a Member shall provide authors and their successors in title the right to authorize or to prohibit the commercial rental to the public of originals or copies of their copyright works. A Member shall be excepted from this obligation in respect of cinematographic works unless such rental has led to widespread copying of such works which is materially impairing the exclusive right of reproduction conferred in that Member on authors and their successors in title. In respect of computer programs, this obligation does not apply to rentals where the program itself is not the essential object of the rental.

Article 12

Term of Protection

Whenever the term of protection of a work, other than a photographic work or a work of applied art, is calculated on a basis other than the life of a natural person, such term shall be no less than 50 years from the end of the calendar year of authorized publication, or, failing such authorized publication within 50 years from the making of the work, 50 years from the end of the calendar year of making.

Article 13

Limitations and Exceptions

Members shall confine limitations or exceptions to exclusive rights to certain special cases which do not conflict with a normal exploitation of the work and do not unreasonably prejudice the legitimate interests of the right holder.

Article 14

Protection of Performers, Producers of Phonograms (Sound Recordings) and Broadcasting Organizations

1. In respect of a fixation of their performance on a phonogram, performers shall have the possibility of preventing the following acts when undertaken without their authorization: the fixation of their unfixed performance and the reproduction of such fixation. Performers shall also have the possibility of preventing the following acts when undertaken without their authorization: the broadcasting by wireless means and the communication to the public of their live performance.

2. Producers of phonograms shall enjoy the right to authorize or prohibit the direct or indirect reproduction of their phonograms.

3. Broadcasting organizations shall have the right to prohibit the following acts when undertaken without their authorization: the fixation, the reproduction of fixations, and the rebroadcasting by wireless means of broadcasts, as well as the communication to the public of television broadcasts of the same. Where Members do not grant such rights to broadcasting organizations, they shall provide owners of copyright in the subject matter of broadcasts with the possibility of preventing the above acts, subject to the provisions of the Berne Convention (1971).

4. The provisions of Article 11 in respect of computer programs shall apply *mutatis mutandis* to producers of phonograms and any other right holders in phonograms as determined in a Member's law. If on 15 April 1994 a Member has in force a system of equitable remuneration of right holders in respect of the rental of phonograms, it may maintain such system provided that the commercial rental of phonograms is not giving rise to the material impairment of the exclusive rights of reproduction of right holders.

5. The term of the protection available under this Agreement to performers and producers of phonograms shall last at least until the end of a period of 50 years computed from the end of the calendar year in which the fixation was made or the performance took place. The term of protection granted pursuant to paragraph 3 shall last for at least 20 years from the end of the calendar year in which the broadcast took place.

6. Any Member may, in relation to the rights conferred under paragraphs 1, 2 and 3, provide for conditions, limitations, exceptions and reservations to the extent permitted by the Rome Convention. However, the provisions of Article 18 of the Berne Convention (1971) shall also apply, *mutatis mutandis*, to the rights of performers and producers of phonograms in phonograms.

SECTION 2: TRADEMARKS

Article 15

Protectable Subject Matter

1. Any sign, or any combination of signs, capable of distinguishing the goods or services of one undertaking from those of other undertakings, shall be capable of constituting a trademark. Such signs, in particular words including personal names, letters, numerals, figurative elements and combinations of colours as well as any combination of such signs, shall be eligible for registration as trademarks. Where signs are not inherently capable of distinguishing the relevant goods or services, Members may make registrability depend on distinctiveness acquired through use. Members may require, as a condition of registration, that signs be visually perceptible.

2. Paragraph 1 shall not be understood to prevent a Member from denying registration of a trademark on other grounds, provided that they do not derogate from the provisions of the Paris Convention (1967).

3. Members may make registrability depend on use. However, actual use of a trademark shall not be a condition for filing an application for registration. An application shall not be refused solely on the ground that intended use has not taken place before the expiry of a period of three years from the date of application.

4. The nature of the goods or services to which a trademark is to be applied shall in no case form an obstacle to registration of the trademark.

5. Members shall publish each trademark either before it is registered or promptly after it is registered and shall afford a reasonable opportunity for petitions to cancel the registration. In addition, Members may afford an opportunity for the registration of a trademark to be opposed.

Article 16

Rights Conferred

1. The owner of a registered trademark shall have the exclusive right to prevent all third parties not having the owner's consent from using in the course of trade identical or similar signs for goods or services which are identical or similar to those in respect of which the trademark is registered where such use would result in a likelihood of confusion. In case of the use of an identical sign for identical goods or services, a likelihood of confusion shall be presumed. The rights described above shall not prejudice any existing prior rights, nor shall they affect the possibility of Members making rights available on the basis of use.

2. Article 6*bis* of the Paris Convention (1967) shall apply, *mutatis mutandis*, to services. In determining whether a trademark is well-known, Members shall take account of the knowledge of the trademark in the relevant sector of the public, including knowledge in the Member concerned which has been obtained as a result of the promotion of the trademark.

3. Article 6*bis* of the Paris Convention (1967) shall apply, *mutatis mutandis*, to goods or services which are not similar to those in respect of which a trademark is registered, provided that use of that trademark in relation to those goods or services would indicate a connection between those goods or services and the owner of the registered trademark and provided that the interests of the owner of the registered trademark are likely to be damaged by such use.

Article 17

Exceptions

Members may provide limited exceptions to the rights conferred by a trademark, such as fair use of descriptive terms, provided that such exceptions take account of the legitimate interests of the owner of the trademark and of third parties.

Article 18

Term of Protection

Initial registration, and each renewal of registration, of a trademark shall be for a term of no less than seven years. The registration of a trademark shall be renewable indefinitely.

Article 19

Requirement of Use

1. If use is required to maintain a registration, the registration may be cancelled only after an uninterrupted period of at least three years of non-use, unless valid reasons based on the existence of obstacles to such use are shown by the trademark owner. Circumstances arising independently of the will of the owner of the trademark which constitute an obstacle to the use of the trademark, such as import restrictions on or other government requirements for goods or services protected by the trademark, shall be recognized as valid reasons for non-use.

2. When subject to the control of its owner, use of a trademark by another person shall be recognized as use of the trademark for the purpose of maintaining the registration.

Article 20

Other Requirements

The use of a trademark in the course of trade shall not be unjustifiably encumbered by special requirements, such as use with another trademark, use in a special form or use in a manner detrimental to its capability to distinguish the goods or services of one undertaking from those of other undertakings. This will not preclude a requirement prescribing the use of the trademark identifying the undertaking producing the goods or services along with, but without linking it to, the trademark distinguishing the specific goods or services in question of that undertaking.

Article 21

Licensing and Assignment

Members may determine conditions on the licensing and assignment of trademarks, it being understood that the compulsory licensing of trademarks shall not be permitted and that the owner of a registered trademark shall have the right to assign the trademark with or without the transfer of the business to which the trademark belongs.

SECTION 3: GEOGRAPHICAL INDICATIONS

Article 22

Protection of Geographical Indications

1. Geographical indications are, for the purposes of this Agreement, indications which identify a good as originating in the territory of a Member, or a region or locality in that territory, where a given quality, reputation or other characteristic of the good is essentially attributable to its geographical origin.

2. In respect of geographical indications, Members shall provide the legal means for interested parties to prevent:

(a) the use of any means in the designation or presentation of a good that indicates or suggests that the good in question originates in a geographical area other than the true place of origin in a manner which misleads the public as to the geographical origin of the good;

(b) any use which constitutes an act of unfair competition within the meaning of Article 10*bis* of the Paris Convention (1967).

3. A Member shall, *ex officio* if its legislation so permits or at the request of an interested party, refuse or invalidate the registration of a trademark which contains or consists of a geographical indication with respect to goods not originating in the territory indicated, if use of the indication in the trademark for such goods in that Member is of such a nature as to mislead the public as to the true place of origin.

4. The protection under paragraphs 1, 2 and 3 shall be applicable against a geographical indication which, although literally true as to the territory, region or locality in which the goods originate, falsely represents to the public that the goods originate in another territory.

Article 23

Additional Protection for Geographical Indications for Wines and Spirits

1. Each Member shall provide the legal means for interested parties to prevent use of a geographical indication identifying wines for wines not originating in the place indicated by the geographical indication in question or identifying spirits for spirits not originating in the place indicated by the geographical indication in question, even where the true origin of the goods is indicated or the geographical indication is used in translation or accompanied by expressions such as "kind", "type", "style", "imitation" or the like.[322]

2. The registration of a trademark for wines which contains or consists of a geographical indication identifying wines or for spirits which contains or consists of a geographical indication identifying spirits shall be refused or invalidated, *ex officio* if a Member's legislation so permits or at the request of an interested party, with respect to such wines or spirits not having this origin.

3. In the case of homonymous geographical indications for wines, protection shall be accorded to each indication, subject to the provisions of paragraph 4 of Article 22. Each Member shall determine the practical conditions under which the homonymous indications in question will be differentiated from each other, taking into account the need to ensure equitable treatment of the producers concerned and that consumers are not misled.

4. In order to facilitate the protection of geographical indications for wines, negotiations shall be undertaken in the Council for TRIPS concerning the establishment of a multilateral system of notification and registration of geographical indications for wines eligible for protection in those Members participating in the system.

[322] Notwithstanding the first sentence of Article 42, Members may, with respect to these obligations, instead provide for enforcement by administrative action.

Article 24

International Negotiations; Exceptions

1. Members agree to enter into negotiations aimed at increasing the protection of individual geographical indications under Article 23. The provisions of paragraphs 4 through 8 below shall not be used by a Member to refuse to conduct negotiations or to conclude bilateral or multilateral agreements. In the context of such negotiations, Members shall be willing to consider the continued applicability of these provisions to individual geographical indications whose use was the subject of such negotiations.

2. The Council for TRIPS shall keep under review the application of the provisions of this Section; the first such review shall take place within two years of the entry into force of the WTO Agreement. Any matter affecting the compliance with the obligations under these provisions may be drawn to the attention of the Council, which, at the request of a Member, shall consult with any Member or Members in respect of such matter in respect of which it has not been possible to find a satisfactory solution through bilateral or plurilateral consultations between the Members concerned. The Council shall take such action as may be agreed to facilitate the operation and further the objectives of this Section.

3. In implementing this Section, a Member shall not diminish the protection of geographical indications that existed in that Member immediately prior to the date of entry into force of the WTO Agreement.

4. Nothing in this Section shall require a Member to prevent continued and similar use of a particular geographical indication of another Member identifying wines or spirits in connection with goods or services by any of its nationals or domiciliaries who have used that geographical indication in a continuous manner with regard to the same or related goods or services in the territory of that Member either (*a*) for at least 10 years preceding 15 April 1994 or (*b*) in good faith preceding that date.

5. Where a trademark has been applied for or registered in good faith, or where rights to a trademark have been acquired through use in good faith either:

(a) before the date of application of these provisions in that Member as defined in Part VI; or

(b) before the geographical indication is protected in its country of origin;

measures adopted to implement this Section shall not prejudice eligibility for or the validity of the registration of a trademark, or the right to use a trademark, on the basis that such a trademark is identical with, or similar to, a geographical indication.

6. Nothing in this Section shall require a Member to apply its provisions in respect of a geographical indication of any other Member with respect to goods or services for which the relevant indication is identical with the term customary in common language as the common name for such goods or services in the territory of that Member. Nothing in this Section shall require a Member to apply its provisions in respect of a geographical indication of any other Member with respect to products of the vine for which the relevant indication is identical with the customary name of a grape variety existing in the territory of that Member as of the date of entry into force of the WTO Agreement.

7. A Member may provide that any request made under this Section in connection with the use or registration of a trademark must be presented within five years after the adverse use of the protected indication has become generally known in that Member or after the date of registration of the

trademark in that Member provided that the trademark has been published by that date, if such date is earlier than the date on which the adverse use became generally known in that Member, provided that the geographical indication is not used or registered in bad faith.

8. The provisions of this Section shall in no way prejudice the right of any person to use, in the course of trade, that person's name or the name of that person's predecessor in business, except where such name is used in such a manner as to mislead the public.

9. There shall be no obligation under this Agreement to protect geographical indications which are not or cease to be protected in their country of origin, or which have fallen into disuse in that country.

SECTION 4: INDUSTRIAL DESIGNS

Article 25

Requirements for Protection

1. Members shall provide for the protection of independently created industrial designs that are new or original. Members may provide that designs are not new or original if they do not significantly differ from known designs or combinations of known design features. Members may provide that such protection shall not extend to designs dictated essentially by technical or functional considerations.

2. Each Member shall ensure that requirements for securing protection for textile designs, in particular in regard to any cost, examination or publication, do not unreasonably impair the opportunity to seek and obtain such protection. Members shall be free to meet this obligation through industrial design law or through copyright law.

Article 26

Protection

1. The owner of a protected industrial design shall have the right to prevent third parties not having the owner's consent from making, selling or importing articles bearing or embodying a design which is a copy, or substantially a copy, of the protected design, when such acts are undertaken for commercial purposes.

2. Members may provide limited exceptions to the protection of industrial designs, provided that such exceptions do not unreasonably conflict with the normal exploitation of protected industrial designs and do not unreasonably prejudice the legitimate interests of the owner of the protected design, taking account of the legitimate interests of third parties.

3. The duration of protection available shall amount to at least 10 years.

SECTION 5: PATENTS

Article 27

Patentable Subject Matter

1. Subject to the provisions of paragraphs 2 and 3, patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an

inventive step and are capable of industrial application.[323] Subject to paragraph 4 of Article 65, paragraph 8 of Article 70 and paragraph 3 of this Article, patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.

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

3. Members may also exclude from patentability:

(a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals;

(b) plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof. The provisions of this subparagraph shall be reviewed four years after the date of entry into force of the WTO Agreement.

Article 28

Rights Conferred

1. A patent shall confer on its owner the following exclusive rights:

(a) where the subject matter of a patent is a product, to prevent third parties not having the owner's consent from the acts of: making, using, offering for sale, selling, or importing[324] for these purposes that product;

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

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

Article 29

Conditions on Patent Applicants

1. Members shall require that an applicant for a patent shall disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art and may require the applicant to indicate the best mode for carrying out the invention known to the inventor at the filing date or, where priority is claimed, at the priority date of the application.

2. Members may require an applicant for a patent to provide information concerning the applicant's corresponding foreign applications and grants.

[323] For the purposes of this Article, the terms "inventive step" and "capable of industrial application" may be deemed by a Member to be synonymous with the terms "non-obvious" and "useful" respectively.
[324] This right, like all other rights conferred under this Agreement in respect of the use, sale, importation or other distribution of goods, is subject to the provisions of Article 6.

Article 30

Exceptions to Rights Conferred

Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.

Article 31

Other Use Without Authorization of the Right Holder

Where the law of a Member allows for other use[325] of the subject matter of a patent without the authorization of the right holder, including use by the government or third parties authorized by the government, the following provisions shall be respected:

(a) authorization of such use shall be considered on its individual merits;

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

(c) the scope and duration of such use shall be limited to the purpose for which it was authorized, and in the case of semi-conductor technology shall only be for public non-commercial use or to remedy a practice determined after judicial or administrative process to be anti-competitive;

(d) such use shall be non-exclusive;

(e) such use shall be non-assignable, except with that part of the enterprise or goodwill which enjoys such use;

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

(g) authorization for such use shall be liable, subject to adequate protection of the legitimate interests of the persons so authorized, to be terminated if and when the circumstances which led to it cease to exist and are unlikely to recur. The competent authority shall have the authority to review, upon motivated request, the continued existence of these circumstances;

(h) the right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization;

[325] "Other use" refers to use other than that allowed under Article 30.

(i) the legal validity of any decision relating to the authorization of such use shall be subject to judicial review or other independent review by a distinct higher authority in that Member;

(j) any decision relating to the remuneration provided in respect of such use shall be subject to judicial review or other independent review by a distinct higher authority in that Member;

(k) Members are not obliged to apply the conditions set forth in subparagraphs (b) and (f) where such use is permitted to remedy a practice determined after judicial or administrative process to be anti-competitive. The need to correct anti-competitive practices may be taken into account in determining the amount of remuneration in such cases. Competent authorities shall have the authority to refuse termination of authorization if and when the conditions which led to such authorization are likely to recur;

(l) where such use is authorized to permit the exploitation of a patent ("the second patent") which cannot be exploited without infringing another patent ("the first patent"), the following additional conditions shall apply:

(i) the invention claimed in the second patent shall involve an important technical advance of considerable economic significance in relation to the invention claimed in the first patent;

(ii) the owner of the first patent shall be entitled to a cross-licence on reasonable terms to use the invention claimed in the second patent; and

(iii) the use authorized in respect of the first patent shall be non-assignable except with the assignment of the second patent.

Article 32

Revocation/Forfeiture

An opportunity for judicial review of any decision to revoke or forfeit a patent shall be available.

Article 33

Term of Protection

The term of protection available shall not end before the expiration of a period of twenty years counted from the filing date.[326]

Article 34

Process Patents: Burden of Proof

1. For the purposes of civil proceedings in respect of the infringement of the rights of the owner referred to in paragraph 1(b) of Article 28, if the subject matter of a patent is a process for obtaining a

[326] It is understood that those Members which do not have a system of original grant may provide that the term of protection shall be computed from the filing date in the system of original grant.

product, the judicial authorities shall have the authority to order the defendant to prove that the process to obtain an identical product is different from the patented process. Therefore, Members shall provide, in at least one of the following circumstances, that any identical product when produced without the consent of the patent owner shall, in the absence of proof to the contrary, be deemed to have been obtained by the patented process:

(a) if the product obtained by the patented process is new;

(b) if there is a substantial likelihood that the identical product was made by the process and the owner of the patent has been unable through reasonable efforts to determine the process actually used.

2. Any Member shall be free to provide that the burden of proof indicated in paragraph 1 shall be on the alleged infringer only if the condition referred to in subparagraph (a) is fulfilled or only if the condition referred to in subparagraph (b) is fulfilled.

3. In the adduction of proof to the contrary, the legitimate interests of defendants in protecting their manufacturing and business secrets shall be taken into account.

SECTION 6: LAYOUT-DESIGNS (TOPOGRAPHIES) OF INTEGRATED CIRCUITS

Article 35

Relation to the IPIC Treaty

Members agree to provide protection to the layout-designs (topographies) of integrated circuits (referred to in this Agreement as "layout-designs") in accordance with Articles 2 through 7 (other than paragraph 3 of Article 6), Article 12 and paragraph 3 of Article 16 of the Treaty on Intellectual Property in Respect of Integrated Circuits and, in addition, to comply with the following provisions.

Article 36

Scope of the Protection

Subject to the provisions of paragraph 1 of Article 37, Members shall consider unlawful the following acts if performed without the authorization of the right holder:[327] importing, selling, or otherwise distributing for commercial purposes a protected layout-design, an integrated circuit in which a protected layout-design is incorporated, or an article incorporating such an integrated circuit only in so far as it continues to contain an unlawfully reproduced layout-design.

Article 37

Acts Not Requiring the Authorization of the Right Holder

1. Notwithstanding Article 36, no Member shall consider unlawful the performance of any of the acts referred to in that Article in respect of an integrated circuit incorporating an unlawfully reproduced layout-design or any article incorporating such an integrated circuit where the person performing or ordering such acts did not know and had no reasonable ground to know, when acquiring the integrated circuit or article incorporating such an integrated circuit, that it incorporated an unlawfully reproduced layout-design. Members shall provide that, after the time that such person has received sufficient notice that the layout-design was unlawfully reproduced, that person may perform

[327] The term "right holder" in this Section shall be understood as having the same meaning as the term "holder of the right" in the IPIC Treaty.

any of the acts with respect to the stock on hand or ordered before such time, but shall be liable to pay to the right holder a sum equivalent to a reasonable royalty such as would be payable under a freely negotiated licence in respect of such a layout-design.

2. The conditions set out in subparagraphs (a) through (k) of Article 31 shall apply *mutatis mutandis* in the event of any non-voluntary licensing of a layout-design or of its use by or for the government without the authorization of the right holder.

Article 38

Term of Protection

1. In Members requiring registration as a condition of protection, the term of protection of layout-designs shall not end before the expiration of a period of 10 years counted from the date of filing an application for registration or from the first commercial exploitation wherever in the world it occurs.

2. In Members not requiring registration as a condition for protection, layout-designs shall be protected for a term of no less than 10 years from the date of the first commercial exploitation wherever in the world it occurs.

3. Notwithstanding paragraphs 1 and 2, a Member may provide that protection shall lapse 15 years after the creation of the layout-design.

SECTION 7: PROTECTION OF UNDISCLOSED INFORMATION

Article 39

1. In the course of ensuring effective protection against unfair competition as provided in Article 10*bis* of the Paris Convention (1967), Members shall protect undisclosed information in accordance with paragraph 2 and data submitted to governments or governmental agencies in accordance with paragraph 3.

2. Natural and legal persons shall have the possibility of preventing information lawfully within their control from being disclosed to, acquired by, or used by others without their consent in a manner contrary to honest commercial practices[328] so long as such information:

(a) is secret in the sense that it is not, as a body or in the precise configuration and assembly of its components, generally known among or readily accessible to persons within the circles that normally deal with the kind of information in question;

(b) has commercial value because it is secret; and

(c) has been subject to reasonable steps under the circumstances, by the person lawfully in control of the information, to keep it secret.

3. Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilize new chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use. In addition, Members shall protect such data against disclosure, except where

[328] For the purpose of this provision, "a manner contrary to honest commercial practices" shall mean at least practices such as breach of contract, breach of confidence and inducement to breach, and includes the acquisition of undisclosed information by third parties who knew, or were grossly negligent in failing to know, that such practices were involved in the acquisition.

necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use.

SECTION 8: CONTROL OF ANTI-COMPETITIVE PRACTICES IN CONTRACTUAL LICENCES

Article 40

1. Members agree that some licensing practices or conditions pertaining to intellectual property rights which restrain competition may have adverse effects on trade and may impede the transfer and dissemination of technology.

2. Nothing in this Agreement shall prevent Members from specifying in their legislation licensing practices or conditions that may in particular cases constitute an abuse of intellectual property rights having an adverse effect on competition in the relevant market. As provided above, a Member may adopt, consistently with the other provisions of this Agreement, appropriate measures to prevent or control such practices, which may include for example exclusive grantback conditions, conditions preventing challenges to validity and coercive package licensing, in the light of the relevant laws and regulations of that Member.

3. Each Member shall enter, upon request, into consultations with any other Member which has cause to believe that an intellectual property right owner that is a national or domiciliary of the Member to which the request for consultations has been addressed is undertaking practices in violation of the requesting Member's laws and regulations on the subject matter of this Section, and which wishes to secure compliance with such legislation, without prejudice to any action under the law and to the full freedom of an ultimate decision of either Member. The Member addressed shall accord full and sympathetic consideration to, and shall afford adequate opportunity for, consultations with the requesting Member, and shall cooperate through supply of publicly available non-confidential information of relevance to the matter in question and of other information available to the Member, subject to domestic law and to the conclusion of mutually satisfactory agreements concerning the safeguarding of its confidentiality by the requesting Member.

4. A Member whose nationals or domiciliaries are subject to proceedings in another Member concerning alleged violation of that other Member's laws and regulations on the subject matter of this Section shall, upon request, be granted an opportunity for consultations by the other Member under the same conditions as those foreseen in paragraph 3.

PART III

ENFORCEMENT OF INTELLECTUAL PROPERTY RIGHTS

SECTION 1: GENERAL OBLIGATIONS

Article 41

1. Members shall ensure that enforcement procedures as specified in this Part are available under their law so as to permit effective action against any act of infringement of intellectual property rights covered by this Agreement, including expeditious remedies to prevent infringements and remedies which constitute a deterrent to further infringements. These procedures shall be applied in such a manner as to avoid the creation of barriers to legitimate trade and to provide for safeguards against their abuse.

2. Procedures concerning the enforcement of intellectual property rights shall be fair and equitable. They shall not be unnecessarily complicated or costly, or entail unreasonable time-limits or unwarranted delays.

3. Decisions on the merits of a case shall preferably be in writing and reasoned. They shall be made available at least to the parties to the proceeding without undue delay. Decisions on the merits of a case shall be based only on evidence in respect of which parties were offered the opportunity to be heard.

4. Parties to a proceeding shall have an opportunity for review by a judicial authority of final administrative decisions and, subject to jurisdictional provisions in a Member's law concerning the importance of a case, of at least the legal aspects of initial judicial decisions on the merits of a case. However, there shall be no obligation to provide an opportunity for review of acquittals in criminal cases.

5. It is understood that this Part does not create any obligation to put in place a judicial system for the enforcement of intellectual property rights distinct from that for the enforcement of law in general, nor does it affect the capacity of Members to enforce their law in general. Nothing in this Part creates any obligation with respect to the distribution of resources as between enforcement of intellectual property rights and the enforcement of law in general.

SECTION 2: CIVIL AND ADMINISTRATIVE PROCEDURES AND REMEDIES

Article 42

Fair and Equitable Procedures

Members shall make available to right holders[329] civil judicial procedures concerning the enforcement of any intellectual property right covered by this Agreement. Defendants shall have the right to written notice which is timely and contains sufficient detail, including the basis of the claims. Parties shall be allowed to be represented by independent legal counsel, and procedures shall not impose overly burdensome requirements concerning mandatory personal appearances. All parties to such procedures shall be duly entitled to substantiate their claims and to present all relevant evidence. The procedure shall provide a means to identify and protect confidential information, unless this would be contrary to existing constitutional requirements.

Article 43

Evidence

1. The judicial authorities shall have the authority, where a party has presented reasonably available evidence sufficient to support its claims and has specified evidence relevant to substantiation of its claims which lies in the control of the opposing party, to order that this evidence be produced by the opposing party, subject in appropriate cases to conditions which ensure the protection of confidential information.

2. In cases in which a party to a proceeding voluntarily and without good reason refuses access to, or otherwise does not provide necessary information within a reasonable period, or significantly impedes a procedure relating to an enforcement action, a Member may accord judicial authorities the authority to make preliminary and final determinations, affirmative or negative, on the basis of the information presented to them, including the complaint or the allegation presented by the party adversely affected by the denial of access to information, subject to providing the parties an opportunity to be heard on the allegations or evidence.

Article 44

[329] For the purpose of this Part, the term "right holder" includes federations and associations having legal standing to assert such rights.

Injunctions

1. The judicial authorities shall have the authority to order a party to desist from an infringement, *inter alia* to prevent the entry into the channels of commerce in their jurisdiction of imported goods that involve the infringement of an intellectual property right, immediately after customs clearance of such goods. Members are not obliged to accord such authority in respect of protected subject matter acquired or ordered by a person prior to knowing or having reasonable grounds to know that dealing in such subject matter would entail the infringement of an intellectual property right.

2. Notwithstanding the other provisions of this Part and provided that the provisions of Part II specifically addressing use by governments, or by third parties authorized by a government, without the authorization of the right holder are complied with, Members may limit the remedies available against such use to payment of remuneration in accordance with subparagraph (h) of Article 31. In other cases, the remedies under this Part shall apply or, where these remedies are inconsistent with a Member's law, declaratory judgments and adequate compensation shall be available.

Article 45

Damages

1. The judicial authorities shall have the authority to order the infringer to pay the right holder damages adequate to compensate for the injury the right holder has suffered because of an infringement of that person’s intellectual property right by an infringer who knowingly, or with reasonable grounds to know, engaged in infringing activity.

2. The judicial authorities shall also have the authority to order the infringer to pay the right holder expenses, which may include appropriate attorney's fees. In appropriate cases, Members may authorize the judicial authorities to order recovery of profits and/or payment of pre-established damages even where the infringer did not knowingly, or with reasonable grounds to know, engage in infringing activity.

Article 46

Other Remedies

In order to create an effective deterrent to infringement, the judicial authorities shall have the authority to order that goods that they have found to be infringing be, without compensation of any sort, disposed of outside the channels of commerce in such a manner as to avoid any harm caused to the right holder, or, unless this would be contrary to existing constitutional requirements, destroyed. The judicial authorities shall also have the authority to order that materials and implements the predominant use of which has been in the creation of the infringing goods be, without compensation of any sort, disposed of outside the channels of commerce in such a manner as to minimize the risks of further infringements. In considering such requests, the need for proportionality between the seriousness of the infringement and the remedies ordered as well as the interests of third parties shall be taken into account. In regard to counterfeit trademark goods, the simple removal of the trademark unlawfully affixed shall not be sufficient, other than in exceptional cases, to permit release of the goods into the channels of commerce.

Article 47

Right of Information

Members may provide that the judicial authorities shall have the authority, unless this would be out of proportion to the seriousness of the infringement, to order the infringer to inform the right

holder of the identity of third persons involved in the production and distribution of the infringing goods or services and of their channels of distribution.

Article 48

Indemnification of the Defendant

1. The judicial authorities shall have the authority to order a party at whose request measures were taken and who has abused enforcement procedures to provide to a party wrongfully enjoined or restrained adequate compensation for the injury suffered because of such abuse. The judicial authorities shall also have the authority to order the applicant to pay the defendant expenses, which may include appropriate attorney's fees.

2. In respect of the administration of any law pertaining to the protection or enforcement of intellectual property rights, Members shall only exempt both public authorities and officials from liability to appropriate remedial measures where actions are taken or intended in good faith in the course of the administration of that law.

Article 49

Administrative Procedures

To the extent that any civil remedy can be ordered as a result of administrative procedures on the merits of a case, such procedures shall conform to principles equivalent in substance to those set forth in this Section.

SECTION 3: PROVISIONAL MEASURES

Article 50

1. The judicial authorities shall have the authority to order prompt and effective provisional measures:

(a) to prevent an infringement of any intellectual property right from occurring, and in particular to prevent the entry into the channels of commerce in their jurisdiction of goods, including imported goods immediately after customs clearance;

(b) to preserve relevant evidence in regard to the alleged infringement.

2. The judicial authorities shall have the authority to adopt provisional measures *inaudita altera parte* where appropriate, in particular where any delay is likely to cause irreparable harm to the right holder, or where there is a demonstrable risk of evidence being destroyed.

3. The judicial authorities shall have the authority to require the applicant to provide any reasonably available evidence in order to satisfy themselves with a sufficient degree of certainty that the applicant is the right holder and that the applicant’s right is being infringed or that such infringement is imminent, and to order the applicant to provide a security or equivalent assurance sufficient to protect the defendant and to prevent abuse.

4. Where provisional measures have been adopted *inaudita altera parte*, the parties affected shall be given notice, without delay after the execution of the measures at the latest. A review, including a right to be heard, shall take place upon request of the defendant with a view to deciding, within a reasonable period after the notification of the measures, whether these measures shall be modified, revoked or confirmed.

5. The applicant may be required to supply other information necessary for the identification of the goods concerned by the authority that will execute the provisional measures.

6. Without prejudice to paragraph 4, provisional measures taken on the basis of paragraphs 1 and 2 shall, upon request by the defendant, be revoked or otherwise cease to have effect, if proceedings leading to a decision on the merits of the case are not initiated within a reasonable period, to be determined by the judicial authority ordering the measures where a Member's law so permits or, in the absence of such a determination, not to exceed 20 working days or 31 calendar days, whichever is the longer.

7. Where the provisional measures are revoked or where they lapse due to any act or omission by the applicant, or where it is subsequently found that there has been no infringement or threat of infringement of an intellectual property right, the judicial authorities shall have the authority to order the applicant, upon request of the defendant, to provide the defendant appropriate compensation for any injury caused by these measures.

8. To the extent that any provisional measure can be ordered as a result of administrative procedures, such procedures shall conform to principles equivalent in substance to those set forth in this Section.

SECTION 4: SPECIAL REQUIREMENTS RELATED TO BORDER MEASURES[330]

Article 51

Suspension of Release by Customs Authorities

Members shall, in conformity with the provisions set out below, adopt procedures[331] to enable a right holder, who has valid grounds for suspecting that the importation of counterfeit trademark or pirated copyright goods[332] may take place, to lodge an application in writing with competent authorities, administrative or judicial, for the suspension by the customs authorities of the release into free circulation of such goods. Members may enable such an application to be made in respect of goods which involve other infringements of intellectual property rights, provided that the requirements of this Section are met. Members may also provide for corresponding procedures concerning the suspension by the customs authorities of the release of infringing goods destined for exportation from their territories.

Article 52

Application

Any right holder initiating the procedures under Article 51 shall be required to provide adequate evidence to satisfy the competent authorities that, under the laws of the country of

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[330] Where a Member has dismantled substantially all controls over movement of goods across its border with another Member with which it forms part of a customs union, it shall not be required to apply the provisions of this Section at that border.

[331] It is understood that there shall be no obligation to apply such procedures to imports of goods put on the market in another country by or with the consent of the right holder, or to goods in transit.

[332] For the purposes of this Agreement:

(a) "counterfeit trademark goods" shall mean any goods, including packaging, bearing without authorization a trademark which is identical to the trademark validly registered in respect of such goods, or which cannot be distinguished in its essential aspects from such a trademark, and which thereby infringes the rights of the owner of the trademark in question under the law of the country of importation;

(b) "pirated copyright goods" shall mean any goods which are copies made without the consent of the right holder or person duly authorized by the right holder in the country of production and which are made directly or indirectly from an article where the making of that copy would have constituted an infringement of a copyright or a related right under the law of the country of importation.

importation, there is *prima facie* an infringement of the right holder's intellectual property right and to supply a sufficiently detailed description of the goods to make them readily recognizable by the customs authorities. The competent authorities shall inform the applicant within a reasonable period whether they have accepted the application and, where determined by the competent authorities, the period for which the customs authorities will take action.

Article 53

Security or Equivalent Assurance

1. The competent authorities shall have the authority to require an applicant to provide a security or equivalent assurance sufficient to protect the defendant and the competent authorities and to prevent abuse. Such security or equivalent assurance shall not unreasonably deter recourse to these procedures.

2. Where pursuant to an application under this Section the release of goods involving industrial designs, patents, layout-designs or undisclosed information into free circulation has been suspended by customs authorities on the basis of a decision other than by a judicial or other independent authority, and the period provided for in Article 55 has expired without the granting of provisional relief by the duly empowered authority, and provided that all other conditions for importation have been complied with, the owner, importer, or consignee of such goods shall be entitled to their release on the posting of a security in an amount sufficient to protect the right holder for any infringement. Payment of such security shall not prejudice any other remedy available to the right holder, it being understood that the security shall be released if the right holder fails to pursue the right of action within a reasonable period of time.

Article 54

Notice of Suspension

The importer and the applicant shall be promptly notified of the suspension of the release of goods according to Article 51.

Article 55

Duration of Suspension

If, within a period not exceeding 10 working days after the applicant has been served notice of the suspension, the customs authorities have not been informed that proceedings leading to a decision on the merits of the case have been initiated by a party other than the defendant, or that the duly empowered authority has taken provisional measures prolonging the suspension of the release of the goods, the goods shall be released, provided that all other conditions for importation or exportation have been complied with; in appropriate cases, this time-limit may be extended by another 10 working days. If proceedings leading to a decision on the merits of the case have been initiated, a review, including a right to be heard, shall take place upon request of the defendant with a view to deciding, within a reasonable period, whether these measures shall be modified, revoked or confirmed. Notwithstanding the above, where the suspension of the release of goods is carried out or continued in accordance with a provisional judicial measure, the provisions of paragraph 6 of Article 50 shall apply.

Article 56

Indemnification of the Importer and of the Owner of the Goods

Relevant authorities shall have the authority to order the applicant to pay the importer, the consignee and the owner of the goods appropriate compensation for any injury caused to them through the wrongful detention of goods or through the detention of goods released pursuant to Article 55.

Article 57

Right of Inspection and Information

Without prejudice to the protection of confidential information, Members shall provide the competent authorities the authority to give the right holder sufficient opportunity to have any goods detained by the customs authorities inspected in order to substantiate the right holder's claims. The competent authorities shall also have authority to give the importer an equivalent opportunity to have any such goods inspected. Where a positive determination has been made on the merits of a case, Members may provide the competent authorities the authority to inform the right holder of the names and addresses of the consignor, the importer and the consignee and of the quantity of the goods in question.

Article 58

Ex Officio Action

Where Members require competent authorities to act upon their own initiative and to suspend the release of goods in respect of which they have acquired *prima facie* evidence that an intellectual property right is being infringed:

(a) the competent authorities may at any time seek from the right holder any information that may assist them to exercise these powers;

(b) the importer and the right holder shall be promptly notified of the suspension. Where the importer has lodged an appeal against the suspension with the competent authorities, the suspension shall be subject to the conditions, *mutatis mutandis*, set out at Article 55;

(c) Members shall only exempt both public authorities and officials from liability to appropriate remedial measures where actions are taken or intended in good faith.

Article 59

Remedies

Without prejudice to other rights of action open to the right holder and subject to the right of the defendant to seek review by a judicial authority, competent authorities shall have the authority to order the destruction or disposal of infringing goods in accordance with the principles set out in Article 46. In regard to counterfeit trademark goods, the authorities shall not allow the re-exportation of the infringing goods in an unaltered state or subject them to a different customs procedure, other than in exceptional circumstances.

Article 60

De Minimis Imports

Members may exclude from the application of the above provisions small quantities of goods of a non-commercial nature contained in travellers' personal luggage or sent in small consignments.

SECTION 5: CRIMINAL PROCEDURES

Article 61

Members shall provide for criminal procedures and penalties to be applied at least in cases of wilful trademark counterfeiting or copyright piracy on a commercial scale. Remedies available shall include imprisonment and/or monetary fines sufficient to provide a deterrent, consistently with the level of penalties applied for crimes of a corresponding gravity. In appropriate cases, remedies available shall also include the seizure, forfeiture and destruction of the infringing goods and of any materials and implements the predominant use of which has been in the commission of the offence. Members may provide for criminal procedures and penalties to be applied in other cases of infringement of intellectual property rights, in particular where they are committed wilfully and on a commercial scale.

PART IV

ACQUISITION AND MAINTENANCE OF INTELLECTUAL PROPERTY RIGHTS AND RELATED *INTER-PARTES* PROCEDURES

Article 62

1. Members may require, as a condition of the acquisition or maintenance of the intellectual property rights provided for under Sections 2 through 6 of Part II, compliance with reasonable procedures and formalities. Such procedures and formalities shall be consistent with the provisions of this Agreement.

2. Where the acquisition of an intellectual property right is subject to the right being granted or registered, Members shall ensure that the procedures for grant or registration, subject to compliance with the substantive conditions for acquisition of the right, permit the granting or registration of the right within a reasonable period of time so as to avoid unwarranted curtailment of the period of protection.

3. Article 4 of the Paris Convention (1967) shall apply *mutatis mutandis* to service marks.

4. Procedures concerning the acquisition or maintenance of intellectual property rights and, where a Member's law provides for such procedures, administrative revocation and *inter partes* procedures such as opposition, revocation and cancellation, shall be governed by the general principles set out in paragraphs 2 and 3 of Article 41.

5. Final administrative decisions in any of the procedures referred to under paragraph 4 shall be subject to review by a judicial or quasi-judicial authority. However, there shall be no obligation to provide an opportunity for such review of decisions in cases of unsuccessful opposition or administrative revocation, provided that the grounds for such procedures can be the subject of invalidation procedures.

PART V

DISPUTE PREVENTION AND SETTLEMENT

Article 63

Transparency

1. Laws and regulations, and final judicial decisions and administrative rulings of general application, made effective by a Member pertaining to the subject matter of this Agreement (the availability, scope, acquisition, enforcement and prevention of the abuse of intellectual property rights)

shall be published, or where such publication is not practicable made publicly available, in a national language, in such a manner as to enable governments and right holders to become acquainted with them. Agreements concerning the subject matter of this Agreement which are in force between the government or a governmental agency of a Member and the government or a governmental agency of another Member shall also be published.

2. Members shall notify the laws and regulations referred to in paragraph 1 to the Council for TRIPS in order to assist that Council in its review of the operation of this Agreement. The Council shall attempt to minimize the burden on Members in carrying out this obligation and may decide to waive the obligation to notify such laws and regulations directly to the Council if consultations with WIPO on the establishment of a common register containing these laws and regulations are successful. The Council shall also consider in this connection any action required regarding notifications pursuant to the obligations under this Agreement stemming from the provisions of Article 6*ter* of the Paris Convention (1967).

3. Each Member shall be prepared to supply, in response to a written request from another Member, information of the sort referred to in paragraph 1. A Member, having reason to believe that a specific judicial decision or administrative ruling or bilateral agreement in the area of intellectual property rights affects its rights under this Agreement, may also request in writing to be given access to or be informed in sufficient detail of such specific judicial decisions or administrative rulings or bilateral agreements.

4. Nothing in paragraphs 1, 2 and 3 shall require Members to disclose confidential information which would impede law enforcement or otherwise be contrary to the public interest or would prejudice the legitimate commercial interests of particular enterprises, public or private.

Article 64

Dispute Settlement

1. The provisions of Articles XXII and XXIII of GATT 1994 as elaborated and applied by the Dispute Settlement Understanding shall apply to consultations and the settlement of disputes under this Agreement except as otherwise specifically provided herein.

2. Subparagraphs 1(b) and 1(c) of Article XXIII of GATT 1994 shall not apply to the settlement of disputes under this Agreement for a period of five years from the date of entry into force of the WTO Agreement.

3. During the time period referred to in paragraph 2, the Council for TRIPS shall examine the scope and modalities for complaints of the type provided for under subparagraphs 1(b) and 1(c) of Article XXIII of GATT 1994 made pursuant to this Agreement, and submit its recommendations to the Ministerial Conference for approval. Any decision of the Ministerial Conference to approve such recommendations or to extend the period in paragraph 2 shall be made only by consensus, and approved recommendations shall be effective for all Members without further formal acceptance process.

PART VI

TRANSITIONAL ARRANGEMENTS

Article 65

Transitional Arrangements

1. Subject to the provisions of paragraphs 2, 3 and 4, no Member shall be obliged to apply the provisions of this Agreement before the expiry of a general period of one year following the date of entry into force of the WTO Agreement.

2. A developing country Member is entitled to delay for a further period of four years the date of application, as defined in paragraph 1, of the provisions of this Agreement other than Articles 3, 4 and 5.

3. Any other Member which is in the process of transformation from a centrally-planned into a market, free-enterprise economy and which is undertaking structural reform of its intellectual property system and facing special problems in the preparation and implementation of intellectual property laws and regulations, may also benefit from a period of delay as foreseen in paragraph 2.

4. To the extent that a developing country Member is obliged by this Agreement to extend product patent protection to areas of technology not so protectable in its territory on the general date of application of this Agreement for that Member, as defined in paragraph 2, it may delay the application of the provisions on product patents of Section 5 of Part II to such areas of technology for an additional period of five years.

5. A Member availing itself of a transitional period under paragraphs 1, 2, 3 or 4 shall ensure that any changes in its laws, regulations and practice made during that period do not result in a lesser degree of consistency with the provisions of this Agreement.

Article 66

Least-Developed Country Members

1. In view of the special needs and requirements of least-developed country Members, their economic, financial and administrative constraints, and their need for flexibility to create a viable technological base, such Members shall not be required to apply the provisions of this Agreement, other than Articles 3, 4 and 5, for a period of 10 years from the date of application as defined under paragraph 1 of Article 65. The Council for TRIPS shall, upon duly motivated request by a least-developed country Member, accord extensions of this period.

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

Article 67

Technical Cooperation

In order to facilitate the implementation of this Agreement, developed country Members shall provide, on request and on mutually agreed terms and conditions, technical and financial cooperation in favour of developing and least-developed country Members. Such cooperation shall include assistance in the preparation of laws and regulations on the protection and enforcement of intellectual property rights as well as on the prevention of their abuse, and shall include support regarding the establishment or reinforcement of domestic offices and agencies relevant to these matters, including the training of personnel.

PART VII

INSTITUTIONAL ARRANGEMENTS; FINAL PROVISIONS

Article 68

Council for Trade-Related Aspects of Intellectual Property Rights

The Council for TRIPS shall monitor the operation of this Agreement and, in particular, Members' compliance with their obligations hereunder, and shall afford Members the opportunity of consulting on matters relating to the trade-related aspects of intellectual property rights. It shall carry out such other responsibilities as assigned to it by the Members, and it shall, in particular, provide any assistance requested by them in the context of dispute settlement procedures. In carrying out its functions, the Council for TRIPS may consult with and seek information from any source it deems appropriate. In consultation with WIPO, the Council shall seek to establish, within one year of its first meeting, appropriate arrangements for cooperation with bodies of that Organization.

Article 69

International Cooperation

Members agree to cooperate with each other with a view to eliminating international trade in goods infringing intellectual property rights. For this purpose, they shall establish and notify contact points in their administrations and be ready to exchange information on trade in infringing goods. They shall, in particular, promote the exchange of information and cooperation between customs authorities with regard to trade in counterfeit trademark goods and pirated copyright goods.

Article 70

Protection of Existing Subject Matter

1. This Agreement does not give rise to obligations in respect of acts which occurred before the date of application of the Agreement for the Member in question.

2. Except as otherwise provided for in this Agreement, this Agreement gives rise to obligations in respect of all subject matter existing at the date of application of this Agreement for the Member in question, and which is protected in that Member on the said date, or which meets or comes subsequently to meet the criteria for protection under the terms of this Agreement. In respect of this paragraph and paragraphs 3 and 4, copyright obligations with respect to existing works shall be solely determined under Article 18 of the Berne Convention (1971), and obligations with respect to the rights of producers of phonograms and performers in existing phonograms shall be determined solely under Article 18 of the Berne Convention (1971) as made applicable under paragraph 6 of Article 14 of this Agreement.

3. There shall be no obligation to restore protection to subject matter which on the date of application of this Agreement for the Member in question has fallen into the public domain.

4. In respect of any acts in respect of specific objects embodying protected subject matter which become infringing under the terms of legislation in conformity with this Agreement, and which were commenced, or in respect of which a significant investment was made, before the date of acceptance of the WTO Agreement by that Member, any Member may provide for a limitation of the remedies available to the right holder as to the continued performance of such acts after the date of application of this Agreement for that Member. In such cases the Member shall, however, at least provide for the payment of equitable remuneration.

5. A Member is not obliged to apply the provisions of Article 11 and of paragraph 4 of Article 14 with respect to originals or copies purchased prior to the date of application of this Agreement for that Member.

6. Members shall not be required to apply Article 31, or the requirement in paragraph 1 of Article 27 that patent rights shall be enjoyable without discrimination as to the field of technology, to

use without the authorization of the right holder where authorization for such use was granted by the government before the date this Agreement became known.

7. In the case of intellectual property rights for which protection is conditional upon registration, applications for protection which are pending on the date of application of this Agreement for the Member in question shall be permitted to be amended to claim any enhanced protection provided under the provisions of this Agreement. Such amendments shall not include new matter.

8. Where a Member does not make available as of the date of entry into force of the WTO Agreement patent protection for pharmaceutical and agricultural chemical products commensurate with its obligations under Article 27, that Member shall:

(a) notwithstanding the provisions of Part VI, provide as from the date of entry into force of the WTO Agreement a means by which applications for patents for such inventions can be filed;

(b) apply to these applications, as of the date of application of this Agreement, the criteria for patentability as laid down in this Agreement as if those criteria were being applied on the date of filing in that Member or, where priority is available and claimed, the priority date of the application; and

(c) provide patent protection in accordance with this Agreement as from the grant of the patent and for the remainder of the patent term, counted from the filing date in accordance with Article 33 of this Agreement, for those of these applications that meet the criteria for protection referred to in subparagraph (b).

9. Where a product is the subject of a patent application in a Member in accordance with paragraph 8(a), exclusive marketing rights shall be granted, notwithstanding the provisions of Part VI, for a period of five years after obtaining marketing approval in that Member or until a product patent is granted or rejected in that Member, whichever period is shorter, provided that, subsequent to the entry into force of the WTO Agreement, a patent application has been filed and a patent granted for that product in another Member and marketing approval obtained in such other Member.

Article 71

Review and Amendment

1. The Council for TRIPS shall review the implementation of this Agreement after the expiration of the transitional period referred to in paragraph 2 of Article 65. The Council shall, having regard to the experience gained in its implementation, review it two years after that date, and at identical intervals thereafter. The Council may also undertake reviews in the light of any relevant new developments which might warrant modification or amendment of this Agreement.

2. Amendments merely serving the purpose of adjusting to higher levels of protection of intellectual property rights achieved, and in force, in other multilateral agreements and accepted under those agreements by all Members of the WTO may be referred to the Ministerial Conference for action in accordance with paragraph 6 of Article X of the WTO Agreement on the basis of a consensus proposal from the Council for TRIPS.

Article 72

Reservations

Reservations may not be entered in respect of any of the provisions of this Agreement without the consent of the other Members.

Article 73

Security Exceptions

Nothing in this Agreement shall be construed:

(a) to require a Member to furnish any information the disclosure of which it considers contrary to its essential security interests; or

(b) to prevent a Member from taking any action which it considers necessary for the protection of its essential security interests;

(i) relating to fissionable materials or the materials from which they are derived;

(ii) relating to the traffic in arms, ammunition and implements of war and to such traffic in other goods and materials as is carried on directly or indirectly for the purpose of supplying a military establishment;

(iii) taken in time of war or other emergency in international relations; or

(c) to prevent a Member from taking any action in pursuance of its obligations under the United Nations Charter for the maintenance of international peace and security.

WORLD TRADE ORGANIZATION

WT/MIN(01)/DEC/2
20 November 2001

(01-5860)

MINISTERIAL CONFERENCE
Fourth Session
Doha, 9 - 14 November 2001

DECLARATION ON THE TRIPS AGREEMENT AND PUBLIC HEALTH

Adopted on 14 November 2001

1. We 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.

2. We stress the need for the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) to be part of the wider national and international action to address these problems.

3. We recognize that intellectual property protection is important for the development of new medicines. We also recognize the concerns about its effects on prices.

4. We agree that the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPS Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all.

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

5. Accordingly and in the light of paragraph 4 above, while maintaining our commitments in the TRIPS Agreement, we recognize that these flexibilities include:

1. 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 particular, in its objectives and principles.

2. Each Member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted.

3. Each Member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency.

4. The effect of the provisions in the TRIPS Agreement that are relevant to the exhaustion of intellectual property rights is to leave each Member free to establish its own regime for such exhaustion without challenge, subject to the MFN and national treatment provisions of Articles 3 and 4.

6. We recognize that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement. We instruct the Council for TRIPS to find an expeditious solution to this problem and to report to the General Council before the end of 2002.

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

GENERAL COUNCIL

WT/L/540 and Corr.1
1 September 2003

Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and public

health

Decision of the General Council of 30 August 2003 *

The General Council,

Having regard to paragraphs 1, 3 and 4 of Article IX of the Marrakesh Agreement Establishing the World Trade Organization ("the WTO Agreement");

Conducting the functions of the Ministerial Conference in the interval between meetings pursuant to paragraph 2 of Article IV of the WTO Agreement;

Noting the Declaration on the TRIPS Agreement and Public Health (WT/MIN(01)/DEC/2) (the "Declaration") and, in particular, the instruction of the Ministerial Conference to the Council for TRIPS contained in paragraph 6 of the Declaration to find an expeditious solution to the problem of the difficulties that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face in making effective use of compulsory licensing under the TRIPS Agreement and to report to the General Council before the end of 2002;

Recognizing, where eligible importing Members seek to obtain supplies under the system set out in this Decision, the importance of a rapid response to those needs consistent with the provisions of this Decision;

Noting that, in the light of the foregoing, exceptional circumstances exist justifying waivers from the obligations set out in paragraphs (f) and (h) of Article 31 of the TRIPS Agreement with respect to pharmaceutical products;

Decides as follows:

1. For the purposes of this Decision:

(a) "pharmaceutical product" means 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 Declaration. It is understood that active ingredients necessary for its manufacture and diagnostic kits needed for its use would be included; (1)
(b) "eligible importing Member" means any least-developed country Member, and any other Member that has made a notification (2) to the Council for TRIPS of its intention to use the system as an importer, it being understood that a Member may notify at any time that it will use the system in whole or in a limited way, for example only in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use. It is noted that some Members will not use the system set out in this Decision as importing Members (3) and that some other Members have stated that, if they use the system, it would be in no more than situations of national emergency or other circumstances

of extreme urgency;

(c) "exporting Member" means a Member using the system set out in this Decision to produce pharmaceutical products for, and export them to, an eligible importing Member.

2. The obligations of an exporting Member under Article 31(f) of the TRIPS Agreement shall be waived with respect to the grant by it of a compulsory licence to the extent necessary for the purposes of production of a pharmaceutical product(s) and its export to an eligible importing Member(s) in accordance with the terms set out below in this paragraph:

(a) the eligible importing Member(s) (4) has made a notification (2) to the Council for TRIPS, that:

(i) specifies the names and expected quantities of the product(s) needed (5);

(ii) confirms that the eligible importing Member in question, other than a least developed country Member, has established that it has insufficient or no manufacturing capacities in the pharmaceutical sector for the product(s) in question in one of the ways set out in the Annex to this Decision; and

(iii) confirms that, where a pharmaceutical product is patented in its territory, it has granted or intends to grant a compulsory licence in accordance with Article 31 of the TRIPS Agreement and the provisions of this Decision (6);

(b) the compulsory licence issued by the exporting Member under this Decision shall contain the following conditions:

(i) only the amount necessary to meet the needs of the eligible importing Member(s) may be manufactured under the licence and the entirety of this production shall be exported to the Member(s) which has notified its needs to the Council for TRIPS;

(ii) products produced under the licence shall be clearly identified as being produced under the system set out in this Decision through specific labelling or marking. Suppliers should distinguish such products through special packaging and/or special colouring/shaping of the products themselves, provided that such distinction is feasible and does not have a significant impact on price; and

(iii) before shipment begins, the licensee shall post on a website (7) the following information:

- the quantities being supplied to each destination as referred to in indent (i) above; and
- the distinguishing features of the product(s) referred to in indent (ii) above;

(c) the exporting Member shall notify (8) the Council for TRIPS of the grant of the licence, including the conditions attached to it (9). The information provided shall include the name and address of the licensee, the product(s) for which the licence has been granted, the quantity(ies) for which it has been granted, the country(ies) to which the product(s) is (are) to be supplied and the duration of the licence. The notification shall also indicate the address of the website referred to in subparagraph (b)(iii) above.

3. Where a compulsory licence is granted by an exporting Member under the system set out in this Decision, adequate remuneration pursuant to Article 31(h) of the TRIPS Agreement shall be paid in that Member taking into account the economic value to the importing Member of the use that has been authorized in the exporting Member. Where a compulsory licence is granted for the same products in the eligible importing Member, the obligation of that Member under Article 31(h) shall be waived in respect of those products for which

remuneration in accordance with the first sentence of this paragraph is paid in the exporting Member.

4. In order to ensure that the products imported under the system set out in this Decision are used for the public health purposes underlying their importation, eligible importing Members shall take reasonable measures within their means, proportionate to their administrative capacities and to the risk of trade diversion to prevent re-exportation of the products that have actually been imported into their territories under the system. In the event that an eligible importing Member that is a developing country Member or a least-developed country Member experiences difficulty in implementing this provision, developed country Members shall provide, on request and on mutually agreed terms and conditions, technical and financial cooperation in order to facilitate its implementation.

5. Members shall ensure the availability of effective legal means to prevent the importation into, and sale in, their territories of products produced under the system set out in this Decision and diverted to their markets inconsistently with its provisions, using the means already required to be available under the TRIPS Agreement. If any Member considers that such measures are proving insufficient for this purpose, the matter may be reviewed in the Council for TRIPS at the request of that Member.

6. With a view to harnessing economies of scale for the purposes of enhancing purchasing power for, and facilitating the local production of, pharmaceutical products:

(i) where a developing or least-developed country WTO Member is a party to a regional trade agreement within the meaning of Article XXIV of the GATT 1994 and the Decision of 28 November 1979 on Differential and More Favourable Treatment Reciprocity and Fuller Participation of Developing Countries (L/4903), at least half of the current membership of which is made up of countries presently on the United Nations list of least developed countries, the obligation of that Member under Article 31(f) of the TRIPS Agreement shall be waived to the extent necessary to enable a pharmaceutical product produced or imported under a compulsory licence in that Member to be exported to the markets of those other developing or least developed country parties to the regional trade agreement that share the health problem in question. It is understood that this will not prejudice the territorial nature of the patent rights in question;

(ii) it is recognized that the development of systems providing for the grant of regional patents to be applicable in the above Members should be promoted. To this end, developed country Members undertake to provide technical cooperation in accordance with Article 67 of the TRIPS Agreement, including in conjunction with other relevant intergovernmental organizations.

7. Members recognize the desirability of promoting the transfer of technology and capacity building in the pharmaceutical sector in order to overcome the problem identified in paragraph 6 of the Declaration. To this end, eligible importing Members and exporting Members are encouraged to use the system set out in this Decision in a way which would promote this objective. Members undertake to cooperate in paying special attention to the transfer of technology and capacity building in the pharmaceutical sector in the work to be undertaken pursuant to Article 66.2 of the TRIPS Agreement, paragraph 7 of the Declaration and any other relevant work of the Council for TRIPS.

8. The Council for TRIPS shall review annually the functioning of the system set out in this Decision with a view to ensuring its effective

operation and shall annually report on its operation to the General Council. This review shall be deemed to fulfil the review requirements of Article IX:4 of the WTO Agreement.

9. This Decision is without prejudice to the rights, obligations and flexibilities that Members have under the provisions of the TRIPS Agreement other than paragraphs (f) and (h) of Article 31, including those reaffirmed by the Declaration, and to their interpretation. It is also without prejudice to the extent to which pharmaceutical products produced under a compulsory licence can be exported under the present provisions of Article 31(f) of the TRIPS Agreement.

10. Members shall not challenge any measures taken in conformity with the provisions of the waivers contained in this Decision under subparagraphs 1(b) and 1(c) of Article XXIII of GATT 1994.

11. This Decision, including the waivers granted in it, shall terminate for each Member on the date on which an amendment to the TRIPS Agreement replacing its provisions takes effect for that Member. The TRIPS Council shall initiate by the end of 2003 work on the preparation of such an amendment with a view to its adoption within six months, on the understanding that the amendment will be based, where appropriate, on this Decision and on the further understanding that it will not be part of the negotiations referred to in paragraph 45 of the Doha Ministerial Declaration (WT/MIN(01)/DEC/1).

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Assessment of Manufacturing Capacities in the Pharmaceutical Sector

Least-developed country Members are deemed to have insufficient or no manufacturing capacities in the pharmaceutical sector.

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.

Amendment of the TRIPS Agreement

Decision of 6 December 2005

See also:
> Press release: Members OK amendment to make health flexibility permanent

The General Council;

Having regard to paragraph 1 of Article X of the Marrakesh Agreement Establishing the World Trade Organization ("the WTO Agreement");

Conducting the functions of the Ministerial Conference in the interval between meetings pursuant to paragraph 2 of Article IV of the WTO Agreement;

Noting the Declaration on the TRIPS Agreement and Public Health (WT/MIN(01)/DEC/2) and, in particular, the instruction of the Ministerial Conference to the Council for TRIPS contained in paragraph 6 of the Declaration to find an expeditious solution to the problem of the difficulties that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face in making effective use of compulsory licensing under the TRIPS Agreement;

Recognizing, where eligible importing Members seek to obtain supplies under the system set out in the proposed amendment of the TRIPS Agreement, the importance of a rapid response to those needs consistent with the provisions of the proposed amendment of the TRIPS Agreement;

Recalling paragraph 11 of the General Council Decision of 30 August 2003 on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health;

Having considered the proposal to amend the TRIPS Agreement submitted by the Council for TRIPS (IP/C/41);

Noting the consensus to submit this proposed amendment to the Members for acceptance;

Decides as follows:

1. The Protocol amending the TRIPS Agreement attached to this Decision is hereby adopted and submitted to the Members for acceptance.

2. The Protocol shall be open for acceptance by Members until 1 December 2007 or such later date as may be decided by the Ministerial Conference.

3. The Protocol shall take effect in accordance with the provisions of paragraph 3 of Article X of the WTO Agreement.

ATTACHMENT back to top

PROTOCOL AMENDING THE TRIPS AGREEMENT

Members of the World Trade Organization;

Having regard to the Decision of the General Council in document WT/L/641, adopted pursuant to paragraph 1 of Article X of the Marrakesh Agreement Establishing the World Trade Organization ("the WTO Agreement");

Hereby agree as follows:

1. The Agreement on Trade-Related Aspects of Intellectual Property Rights (the "TRIPS Agreement") shall, upon the entry into force of the Protocol pursuant to paragraph 4, be amended as set out in the Annex to this Protocol, by inserting Article 31bis after Article 31 and by inserting the Annex to the TRIPS Agreement after Article 73.

2. Reservations may not be entered in respect of any of the provisions of this Protocol without the consent of the other Members.

3. This Protocol shall be open for acceptance by Members until 1 December 2007 or such later date as may be decided by the Ministerial Conference.

4. This Protocol shall enter into force in accordance with paragraph 3 of Article X of the WTO Agreement.

5. This Protocol shall be deposited with the Director-General of the World Trade Organization who shall promptly furnish to each Member a certified copy thereof and a notification of each acceptance thereof pursuant to paragraph 3.

6. This Protocol shall be registered in accordance with the provisions of Article 102 of the Charter of the United Nations.

Done at Geneva this sixth day of December two thousand and five, in a single copy in the English, French and Spanish languages, each text being authentic.

ANNEX TO THE PROTOCOL AMENDING THE TRIPS AGREEMENT back to top

Article 31bis

1. The obligations of an exporting Member under Article 31(f) shall not apply with respect to the grant by it of a compulsory licence to the extent necessary for the purposes of production of a pharmaceutical product(s) and its export to an eligible importing Member(s) in accordance with the terms set out in paragraph 2 of the Annex to this Agreement.

2. Where a compulsory licence is granted by an exporting Member under the system set out in this Article and the Annex to this Agreement, adequate remuneration pursuant to Article 31(h) shall be paid in that Member taking into account the economic value to the importing Member of the use that has been authorized in the exporting

Member. Where a compulsory licence is granted for the same products in the eligible importing Member, the obligation of that Member under Article 31(h) shall not apply in respect of those products for which remuneration in accordance with the first sentence of this paragraph is paid in the exporting Member.

3. With a view to harnessing economies of scale for the purposes of enhancing purchasing power for, and facilitating the local production of, pharmaceutical products: where a developing or least developed country WTO Member is a party to a regional trade agreement within the meaning of Article XXIV of the GATT 1994 and the Decision of 28 November 1979 on Differential and More Favourable Treatment Reciprocity and Fuller Participation of Developing Countries (L/4903), at least half of the current membership of which is made up of countries presently on the United Nations list of least developed countries, the obligation of that Member under Article 31(f) shall not apply to the extent necessary to enable a pharmaceutical product produced or imported under a compulsory licence in that Member to be exported to the markets of those other developing or least developed country parties to the regional trade agreement that share the health problem in question. It is understood that this will not prejudice the territorial nature of the patent rights in question.

4. Members shall not challenge any measures taken in conformity with the provisions of this Article and the Annex to this Agreement under subparagraphs 1(b) and 1(c) of Article XXIII of GATT 1994.

5. This Article and the Annex to this Agreement are without prejudice to the rights, obligations and flexibilities that Members have under the provisions of this Agreement other than paragraphs (f) and (h) of Article 31, including those reaffirmed by the Declaration on the TRIPS Agreement and Public Health (WT/MIN(01)/DEC/2), and to their interpretation. They are also without prejudice to the extent to which pharmaceutical products produced under a compulsory licence can be exported under the provisions of Article 31(f).

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1. For the purposes of Article 31bis and this Annex:

(a) “pharmaceutical product” means 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 Declaration on the TRIPS Agreement and Public Health (WT/MIN(01)/DEC/2). It is understood that active ingredients necessary for its manufacture and diagnostic kits needed for its use would be included [1];
(b) “eligible importing Member” means any least-developed country Member, and any other Member that has made a notification[2] to the Council for TRIPS of its intention to use the system set out in Article 31bis and this Annex (“system”) as an importer, it being understood that a Member may notify at any time that it will use the system in whole or in a limited way, for example only in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use. It is noted that some Members will not use the system as importing Members[3] and that some other Members have stated that, if they use the system, it would be in no more than situations of national emergency or other

circumstances of extreme urgency;
(c) "exporting Member" means a Member using the system to produce pharmaceutical products for, and export them to, an eligible importing Member.

2. The terms referred to in paragraph 1 of Article 31bis are that:

(a) the eligible importing Member(s)[4] has made a notification[2] to the Council for TRIPS, that:
(i) specifies the names and expected quantities of the product(s) needed[5];
(ii) confirms that the eligible importing Member in question, other than a least developed country Member, has established that it has insufficient or no manufacturing capacities in the pharmaceutical sector for the product(s) in question in one of the ways set out in the Appendix to this Annex; and
(iii) confirms that, where a pharmaceutical product is patented in its territory, it has granted or intends to grant a compulsory licence in accordance with Articles 31 and 31bis of this Agreement and the provisions of this Annex[6];
(b) the compulsory licence issued by the exporting Member under the system shall contain the following conditions:
(i) only the amount necessary to meet the needs of the eligible importing Member(s) may be manufactured under the licence and the entirety of this production shall be exported to the Member(s) which has notified its needs to the Council for TRIPS;
(ii) products produced under the licence shall be clearly identified as being produced under the system through specific labelling or marking. Suppliers should distinguish such products through special packaging and/or special colouring/shaping of the products themselves, provided that such distinction is feasible and does not have a significant impact on price; and
(iii) before shipment begins, the licensee shall post on a website[7] the following information:
— the quantities being supplied to each destination as referred to in indent (i) above; and
— the distinguishing features of the product(s) referred to in indent (ii) above;
(c) the exporting Member shall notify[8] the Council for TRIPS of the grant of the licence, including the conditions attached to it.[9] The information provided shall include the name and address of the licensee, the product(s) for which the licence has been granted, the quantity(ies) for which it has been granted, the country(ies) to which the product(s) is (are) to be supplied and the duration of the licence. The notification shall also indicate the address of the website referred to in subparagraph (b)(iii) above.

3. In order to ensure that the products imported under the system are used for the public health purposes underlying their importation, eligible importing Members shall take reasonable measures within their means, proportionate to their administrative capacities and to the risk of trade diversion to prevent re-exportation of the products that have actually been imported into their territories under the system. In the event that an eligible importing Member that is a developing country Member or a least-developed country Member experiences difficulty in implementing this provision, developed country Members shall provide, on request and on mutually agreed terms and conditions, technical and financial cooperation in order to facilitate its implementation.

4. Members shall ensure the availability of effective legal means to prevent the importation into, and sale in, their territories of products produced under the system and diverted to their markets inconsistently with its provisions, using the means already required to be available under this Agreement. If any Member considers that such measures are proving insufficient for this purpose, the matter may be reviewed in the Council for TRIPS at the request of that Member.

5. With a view to harnessing economies of scale for the purposes of enhancing purchasing power for, and facilitating the local production of, pharmaceutical products, it is recognized that the development of systems providing for the grant of regional patents to be applicable in the Members described in paragraph 3 of Article 31bis should be promoted. To this end, developed country Members undertake to provide technical cooperation in accordance with Article 67 of this Agreement, including in conjunction with other relevant intergovernmental organizations.

6. Members recognize the desirability of promoting the transfer of technology and capacity building in the pharmaceutical sector in order to overcome the problem faced by Members with insufficient or no manufacturing capacities in the pharmaceutical sector. To this end, eligible importing Members and exporting Members are encouraged to use the system in a way which would promote this objective. Members undertake to cooperate in paying special attention to the transfer of technology and capacity building in the pharmaceutical sector in the work to be undertaken pursuant to Article 66.2 of this Agreement, paragraph 7 of the Declaration on the TRIPS Agreement and Public Health and any other relevant work of the Council for TRIPS.

7. The Council for TRIPS shall review annually the functioning of the system with a view to ensuring its effective operation and shall annually report on its operation to the General Council.

APPENDIX TO THE ANNEX TO THE TRIPS AGREEMENT back to top

Assessment of Manufacturing Capacities in the Pharmaceutical Sector

Least-developed country Members are deemed to have insufficient or no manufacturing capacities in the pharmaceutical sector.

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.