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The Role of the TRIPS Agreement in the Global Health Policy

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Abstract

This note provides an overview of the role of the TRIPS Agreement as part of the global health policy. It examines how various policy considerations, in particular the need to balance the long-term social objective of providing incentives for future inventions and the short-term objective of allowing people to access and use existing inventions, are reflected in the provisions of the TRIPS Agreement relating to public health. It reviews the WTO's work on these matters over the past few years, including two legal instruments adopted by WTO Members. It also summarizes relevant jurisprudence under the WTO's dispute settlement mechanism. Finally, it looks at the broader picture with respect to access to medicines. This note is meant for informational purposes and does not take a particular position on any of the issues reviewed. Rather, it is hoped that it will contribute to an informed debate on the role of the TRIPS Agreement in public health matters.

I. INTRODUCTION

An effective response to the ever-changing challenges of global public health requires multi-sectoral and collective efforts by all stakeholders. The success of public health policy is thus closely dependent on other policy objectives, such as access to adequate and nutritious food, a clean environment, infrastructure, and economic development, all of which will need to be part of an effective response. A number of

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intergovernmental agencies contribute to this work within their field of competence. The primary role of the World Trade Organization (WTO) is to maintain and further develop the rules-based international trading regime, but this system intersects with many of the other policy areas. In particular, international trade indirectly supports public health policy by helping to generate the resources needed to improve public health. It can also make a more direct contribution by facilitating imports of health-related products and services.

The WTO has recognized the need of countries to safeguard the health of their populations in various trade agreements, going back to GATT 1947[1] and its jurisprudence.[2] For example, Article 8 of the Agreement on Trade-Related Aspects of Intellectual Property Rights (the TRIPS Agreement or TRIPS) recognizes that WTO Members may in formulating their laws and regulations adopt measures to protect public health and nutrition, provided those are TRIPS-consistent; and the subsequent Doha Declaration on the TRIPS Agreement and Public Health (the Doha Declaration) affirms that the Agreement can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health.[3]

The search for an optimal balance has continued to be central in the WTO's work on intellectual property (IP) matters since its establishment. The challenge from a policymaker's perspective is to strike a balance between two competing public interests, namely the long-term social objective of providing incentives for future inventions and creations, and the short-term objective of allowing people to access and use existing inventions and creations.

This problem is particularly acute in the area of patent protection for pharmaceutical products. On one hand, it is especially important from a social and public health perspective that new drugs and vaccines to treat and prevent diseases be generated. It is thus widely recognized that the incentives provided by the patent system play an important role in their development. On the other hand, precisely because of the social value of the drugs so generated, there is strong pressure for such drugs to be as accessible as quickly as possible. This inherent tension and the need for balance are explicitly

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[1] For example, the general exception clauses in art. XX(b) of the General Agreement on Tariffs and Trade 1994 [hereinafter GATT 1994] and art. XIV(b) of the General Agreement on Trade in Services [hereinafter GATS] allow, subject to certain conditions, WTO Members to take measures necessary to protect human life and health even if these measures would otherwise lead to restriction of trade. General Agreement on Tariffs and Trade 1994 art. XX(b), Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1A, 1867 U.N.T.S. 187 (1994); General Agreement on Trade in Services art. XIV(b), Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1B, 1869 U.N.T.S. 183 (1994). *See also* WTO Agreement on the Application of Sanitary and Phytosanitary Measures art. 2.1, Apr. 15, 1994, 1867 U.N.T.S. 493; Agreement on Technical Barriers to Trade art. 2.2, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1A, 1868 U.N.T.S. 120 (1994) (recognizing protection of human health as a legitimate objective of technical regulations).

[2] *See* Appellate Body Report, *European Communities–Measures Affecting Asbestos and Asbestos-Containing Products*, ¶ 168, WT/DS135/AB/R (Mar. 12, 2001) (noting that "it is undisputed that WTO Members have the right to determine the level of protection of health that they consider appropriate in a given situation"). This report and other WTO documents referred to in this note are available in the WTO Documents Online database at http://docsonline.wto.org.

[3] TRIPS Agreement and Public Health, Nov. 14, 2001, WT/MIN(01)/DEC/2; World Trade Organization, Ministerial Declaration of 14 November 2001, *Declaration on the TRIPS Agreement and Public Health*, WT/MIN(01)/DEC/1, 41 I.L.M. 746 (2002) [hereinafter Doha Declaration].

recognized in the Doha Declaration, and have subsequently been reiterated by several World Health Organization (WHO) resolutions.[4]

At the international level, the question of balance can also be approached from a somewhat different perspective, namely, on one hand, the need in an interdependent world for countries to accept some commitments to protect the intellectual property of right holders from other countries and, on the other, their concern to preserve sufficient policy space to optimize the IP system from their domestic perspective.[5] From an economic point of view, the question has also been framed in terms of how to distribute the common effort to fund research and development through the IP system among countries at different levels of development.

In the following, we will provide an overview of the TRIPS Agreement as an important component of the global health policy. We will first examine how the public policy considerations discussed above are reflected in the provisions of the TRIPS Agreement relating to public health. We will then discuss the WTO's work on these matters over the past few years, including two legal instruments adopted by WTO Members. This will be followed by a brief overview of the cases pertinent to public health brought to the WTO's dispute settlement mechanism. To complete the picture, we will also take a look at the broader picture with respect to access to medicines.

This overview is meant for informational purposes and does not take a particular position on any of the issues reviewed. Rather, it is hoped that it will contribute to an informed debate on the role of the TRIPS Agreement in public health matters.

II. TRIPS AND PUBLIC HEALTH

1. Certain TRIPS Provisions of Direct Relevance to Public Health

The TRIPS Agreement is based on a paradigm of minimum rights and non-discrimination that enables and promotes international trade in IP and the recognition of the rights of foreign right holders. This is coupled with flexibilities that allow countries to tailor their implementation of TRIPS to their particular economic and social needs, and in particular to pursue objectives in the area of public health. All provisions are to be interpreted in the light of the objectives and principles of the Agreement that, *inter alia*, emphasize the mutual advantage of producers and users of technological knowledge. The TRIPS Agreement thus attempts to strike a balance between competing public policy considerations. The following section will provide a brief overview of some of the key provisions relating to the interface between intellectual property rights (IPRs) and public health.

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[4] *See* World Health Association [WHA] Res. 61.21 (adoption of the Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property); WHA Res. 60.30 (Public Health Innovation and Intellectual Property); WHA Res. 59.24 (Public Health, Innovation, Essential Health Research and IPRs: Towards a Global Strategy and Plan of Action); WHA Res. 57.14 (Scaling Up Treatment and Care within a Coordinated and Comprehensive Response to HIV/AIDS); WHA Res. 56.30 (Global Health Sector Strategy for HIV/AIDS); WHA 56.27 (IPRs, Innovation and Public Health); and WHA Res. 55.14 (Ensuring Accessibility of Essential Medicines).

[5] *See* Adrian Otten, *The TRIPS Agreement – Has It Served Its Purpose Twelve Years On?*, 38 IIC INT'L REV. OF INTELL. PROP. & COMPETITION L. 6 (2007).

1.1. *Some General Principles*

The first part of the TRIPS Agreement contains certain important general provisions which are directly relevant to public health. Article 1.1 first clarifies that the Agreement, like pre-existing international IP conventions, only sets minimum standards but leaves Members free to provide more extensive protection. Members may do so for purely domestic reasons or because they conclude international agreements that go above the TRIPS standards-for example bilateral or regional free trade agreements. Secondly, it clarifies that Members are free to determine the appropriate method of implementing the provisions of the Agreement within their own legal system and practice. For example, while some Members provide for the protection of undisclosed information, including clinical test data generated for regulatory approval purposes, in their competition laws, others have included provisions on undisclosed information in their national health regulations or have opted for a *sui generis* law to protect such information.

The exhaustion of IPRs, another important general principle, is enshrined in Article 6. Exhaustion is addressed in a rather open-ended manner, the Article only requiring the respect of the non-discrimination obligations.[6] As confirmed by the Doha Declaration, this leaves WTO Members free to establish, without challenge, the exhaustion regime which best serves their domestic policy objectives. The term "exhaustion" refers to the generally accepted principle that a right holder's exclusive right to control the distribution of a protected product lapses after the first act of distribution. In case of "national exhaustion, the domestic law typically provides that once the product has been put on the domestic market by or with the consent of the right holder, the exclusive distribution right is considered exhausted and the right holder can no longer control further circulation of that product. Therefore, the right holder can use his IPRs to prevent "parallel importation" of protected products from third countries even if they have been put on the market there by him or with his consent. Under a domestic law that provides for "international exhaustion," the right holder would not be able to bar parallel importation since his IPRs would be held to have been exhausted by the earlier marketing in any country.[7]

It is generally understood that national exhaustion favours market segmentation, whereas international exhaustion facilitates parallel importation of the same product at lower prices from third countries. In the context of access to patented medicines, some argue that international exhaustion promotes competition by allowing developing countries to buy medicines from the cheapest sources in other countries. Others see national exhaustion as a means of promoting differential pricing based on the level of development of each country and potentially, a means of using the benefits obtained through higher prices in rich countries to cross-subsidize access for patients in low-income countries.

Articles 7 and 8 set out objectives for the protection and enforcement of IPRs and

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[6] Further provisions on exhaustion can be found in art. 28, n.6 of the TRIPS Agreement and in art. 6(5) of the Treaty on Intellectual Property in Respect of Integrated Circuits, 28 I.L.M. 1477 (1989), as incorporated into art. 35 of TRIPS.

[7] The European Union has opted for "regional exhaustion," where the right to control distribution is exhausted once the product has been put on the EU market by or with the consent of the right holder, but the right holder can still control importation from outside the EU.

delineate related principles that provide guidance for the interpretation of TRIPS provisions. Article 7 provides that protection and enforcement of IPRs 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 recognizes Members' right to adopt measures to protect public health and to promote the public interest or to prevent the abuse of IPRs, provided that those measures are consistent with TRIPS provisions. The panel opinion in *Canada – Pharmaceutical Patents* confirmed that the objectives and principles in Articles 7 and 8.1 are to be borne in mind when examining the specific meaning of TRIPS provisions.[8] Furthermore, the Doha Declaration emphasizes that TRIPS provisions are to be read in the light of the object and purpose of the Agreement as expressed, in particular, in its objectives and principles.[9]

1.2. *Patents*

The TRIPS Agreement requires WTO Members to make patents available for all inventions, whether products or processes, in all fields of technology without discrimination, subject to three criteria: novelty, inventiveness or non-obviousness, and industrial applicability or usefulness.[10] The definition of those elements is, however, left with national authorities, which constitutes an important flexibility. For example, India and the Philippines have recently adopted a narrow definition of what represents novelty and an inventive step, thus potentially limiting the number of patents to be granted in the pharmaceutical sector.[11] Furthermore, patents must be available and patent rights enjoyable without discrimination as to the place of invention or whether products are imported or locally produced (Article 27.1). With respect to permissible exclusions from patentability, Article 27.2 allows Members to exclude inventions the commercial exploitation of which would be contrary to *ordre public* or morality. It is unlikely to be applied to pharmaceutical inventions since normally their commercial exploitation is exactly what is desired in order to enable patients to access them. More relevant for the health sector is Article 27.3, which allows Members to exclude from patentability diagnostic, therapeutic and surgical methods for the treatment of humans or animals, as well as 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). The exclusions in the area of biotechnology are subject to an on-going review by the TRIPS Council.[12]

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[8] Panel Report, *Canada–Patent Protection of Pharmaceutical Products*, ¶¶ 7.23-7.26, WT/DS114/R (Mar. 17, 2000).

[9] Doha Decl., *supra* note 3, ¶ 5(a).

[10] *See* TRIPS, *supra* note 3, art. 27.1 n.5.

[11] *See* § 3(d) of the Indian Patents (Amendment) Act 2005, notified to the TRIPS Council in IP/N/1/IND/P/2 (Jun. 10, 2005); *see also* Philippine Republic Act No. 9502 (the "Universally Accessible Cheaper and Quality Medicines Act of 2008"), and Joint DOH-DTI-IPO-BFAD Administrative Order No. 2008-01 (Implementing Rules and Regulations of R.A. 9502), notified to the TRIPS Council in IP/N/1/PHL/I/10 (Apr. 1, 2009).

[12] For a summary of discussions, see WTO Secretariat, *Review of the Provisions of Article 27.3(b);* WTO Secretariat, *Summary of Issues Raised and Points Made*, IP/C/W/369/Rev.1 (Mar. 9. 2006).

TRIPS requires an applicant for a patent to disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art. Furthermore, Members 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 (Article 29.1). Applicants may also be required to disclose information about foreign applications and grants (Article 29.2). A pro-active implementation of the latter, optional requirement in domestic legislation could contribute to greater transparency with respect to existing patents in different countries. Once granted, a product patent confers the following exclusive rights on the right holder pursuant to Article 28: rights to make, use, offer for sale, sell, and import the patented product. Process patent protection must give exclusive rights not only over use of the process but also over products obtained directly by the process. Pursuant to Article 33, the term of protection is at least 20 years counted from the filing date.

Members may provide exceptions to the exclusive rights conferred by a patent, provided that the so-called "three-step test" under Article 30 is met. The three-step test requires that the exception be limited, that it does not unreasonably conflict with a normal exploitation of the patent, and that it does not unreasonably prejudice the legitimate interests of the patent owner, taking into account the legitimate interests of third parties. The panel in *Canada – Pharmaceutical Patents* gave valuable guidance on how this applies to pharmaceutical patents (*see* section 3.1, *infra*).

Furthermore, Article 31 allows compulsory licensing and government use without the authorization of the right holder, subject to a number of conditions. For example, such use may be permitted only after an unsuccessful attempt to obtain a voluntary license under reasonable commercial terms and conditions within a reasonable period of time. In addition, the right holder is to be compensated adequately according to the circumstances of each case, taking into account the economic value of the authorization. Decisions on compulsory licensing and government use are also subject to judicial or other independent review by a distinct higher authority. Another condition is that such use must be predominantly to supply the domestic market. Some of these conditions, namely the requirement to make prior efforts to obtain a voluntary license, are relaxed in cases of emergency or public non-commercial use, or when compulsory licenses are employed to remedy practices that have been established as anticompetitive by a legal process. The Doha Declaration confirmed the right of each WTO Member to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted.[13]

1.3. *Protection of Undisclosed Information*

For the first time in international public law, Article 39 explicitly requires that undisclosed information, *i.e.* trade secrets or know-how, benefit from protection. It also contains, in paragraph 3, provisions on undisclosed test data. Where countries require the submission of undisclosed test data or other data resulting from considerable efforts as a condition of approving the marketing of pharmaceutical or agricultural chemical products that use new chemical entities, WTO Members are obliged to protect such data against unfair commercial use. In addition, Members must protect it against disclosure, except

[13] Doha Decl., *supra* note 3, ¶ 5(b).

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

There are divergent views as to whether the "unfair commercial use" standard requires that a period of data exclusivity be given to the originators of the data. This interpretation would follow the practice of many developed countries and provisions in the IP chapters of a number of regional and bilateral trade agreements, which grant a period of exclusivity.[14] During the run-up to the Doha Ministerial Conference in 2001, some Members set forth views on the interpretation of Article 39.3 as part of the TRIPS Council's preparatory work on the Doha Declaration.[15] There is, however, no WTO jurisprudence or other authoritative guidance on this issue. The fact that the provision specifies two elements of protection, namely protection from disclosure and from "unfair commercial use," implies that protection against unfair commercial use involves more than merely keeping the test data secret. On this point, if a Member were not to provide a period of data exclusivity, it might need to demonstrate that it provides protection against unfair commercial use by some other means.

1.4. *Enforcement*

The TRIPS Agreement is the first multilateral treaty with detailed rules on domestic enforcement of IPRs. These rules require WTO Members to make available procedures permitting effective action against IPR infringement, including expeditious and deterrent remedies. The rules specify the civil and administrative procedures and remedies, including provisional measures, which must be available to redress any act of infringement of a covered intellectual property right. With respect to at least trademark counterfeiting and copyright piracy, additional procedures and remedies must also be provided, namely border measures and criminal procedures.

Given their increasing share in the global trade, falsified medicines and how to combat their distribution is currently being intensively debated in various international fora, including the WTO and the WHO. These discussions are guided by the common goal to keep such medicines out of the market, as they can have serious public health consequences. Concerns have, however, been expressed about an overly expansive interpretation of the term "counterfeit," which is sometimes used to designate falsified medicines. It is argued that the "loose use" of the term counterfeit potentially leads to confusion between falsified medicines and instances of ordinary patent and trademark infringement, confusion which may impede legitimate generic competition and access to medicines. In the TRIPS Agreement, the term "counterfeit" is used in connection with

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[14] Such agreements include the North American Free Trade Agreement (NAFTA, 1994); Colombia - Mexico (1995); EC - Mexico (2000); U.S. bilateral agreements with Chile (2004), Singapore (2004), Australia (2005), Bahrain (2006), Morocco (2006), Oman (2009) and Peru (2009); European Free Trade Association (EFTA) - Chile (2004); EFTA - Tunisia (2005); the Dominican Republic - Central America - United States Free Trade Agreement (CAFTA - DR, 2006); EFTA - Lebanon (2007); Japan - Thailand (2007); Canada - Peru (2009); and Japan - Switzerland (2009). (The years in parentheses indicate the year of entry into force.) These agreements can be accessed on the WTO regional trade agreements database at http://rtais.wto.org/UI/PublicMaintainRTAHome.aspx.

[15] *See* the minutes of the TRIPS Council meeting of Jun. 2001, IP/C/M/31; communication from the EC ¶¶ 15-16 IP/C/W/280; communication from Cuba 2 IP/C/W/299; submission by the African Group et al. ¶ 39, IP/C/W/296.

trademarks.[16] The relevant TRIPS provisions operate first and foremost to give the right holder a tool to protect his or her private IPRs. But their implementation by WTO Members and active use by right holders and, where appropriate, the competent authorities can also contribute to public health outcomes. In particular, this can help to ensure that trademarks function as reliable source identifiers of medicines, thus enabling patients and other purchasers of medicines to make informed choices, and, more broadly, to reduce the share of counterfeit medicines on the market.

1.5. *Transition Periods*

The TRIPS Agreement granted developing countries a five-year transition period until January 1, 2000. Moreover, they could avail themselves of an additional transition period until January 1, 2005 for product patent protection in respect of products that had not been previously subject to patent protection. The latter transition period is particularly relevant for the on-going debate on access to medicines since India, an important supplier of generic medicines for developing countries, only introduced product patents for medicines in 2005.[17] Notwithstanding the availability of exceptions to patent rights, there is a concern that because India has started granting pharmaceutical patents, the sources of generic versions of newer medicines may be progressively drying up.

Least developed countries (LDCs) currently enjoy a general extension of the transition period for the implementation of all TRIPS provisions until July 1, 2013.[18] Based on the instruction in the Doha Declaration, an earlier TRIPS Council Decision[19] already extended the LDC transition period until January 1, 2016 as regards the protection and enforcement of patents as well as undisclosed information in respect of pharmaceutical products. In conjunction, a General Council decision waived obligations regarding exclusive marketing rights under TRIPS Article 70.9 for LDCs for the same period.[20] Taking account of this extended transition period, some least developed countries, such as Bangladesh, Uganda or Tanzania, have invested in developing local manufacturing capacity or are actively exploring the potential to become producers of generic medicines.

2. Later Instruments Clarifying Existing Flexibilities and Adding New Flexibilities

2.1. *Doha Declaration on the TRIPS Agreement and Public Health*

In order to respond to the concerns that had been expressed about the possible implications of the TRIPS Agreement for access to medicines, the 2001 Doha Ministerial

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[16] *See* the definition of "counterfeit trademark goods" in TRIPS, *supra* note 3, art. 51 n.14.
[17] Indian Patents (Amendment) Act 2005, *supra* note 11 (notified by India under TRIPS Article 63.2).
[18] TRIPS Council Decision of Nov. 30, 2005, *Extension of the Transition Period Under Article 66.1 For Least-Developed Country Members*, IP/C/40 (Nov. 30, 2005).
[19] TRIPS Council Decision of Jun. 27, 2002, *Extension of the Transition Period under Article 66.1 of the TRIPS Agreement for Least-Developed Country Members for Certain Obligations with Respect to Pharmaceutical Products*, IP/C/25 (Jun. 27, 2002).
[20] TRIPS Council Decision of Jul. 8, 2002, *Least-Developed Country Members–Obligations Under Article 70.9 of the TRIPS Agreement with Respect to Pharmaceutical Products*, WT/L/478 (Jul. 8, 2002).

Conference adopted the Doha Declaration on the TRIPS Agreement and Public Health.[21] Although the Agreement allows countries to take various measures that may qualify or limit IPRs, including for public health purposes, some doubts had arisen before the adoption of the Declaration as to whether the Agreement provided sufficient space to pursue broader public health objectives. Those doubts resulted from divergent views on the nature and scope of those flexibilities, uncertainty about how such flexibilities would be interpreted, and questions regarding the preparedness of governments to make full use of them while facing the potential of political pressure from other trading partners.

Reflecting the two competing public policy considerations discussed above, the Declaration recognizes both the importance of IP protection for the development of new medicines and the concerns about the effects of IP protection on prices. It emphasizes that the Agreement does not and should not prevent countries from taking measures to protect public health and reaffirms the right of countries to use, in full, the provisions of the Agreement providing flexibility for this purpose. It affirms that the Agreement can and should be interpreted and implemented in a manner supportive of Members' right to protect public health and, in particular, to promote access to medicines for all. By doing so, the Declaration signals an acceptance by all WTO Members that they would not seek to prevent other Members from interpreting the Agreement in a pro-public health way. These statements provide guidance to individual Members and, in the event of disputes, to WTO dispute settlement bodies. Since these apply to the Agreement as a whole,[22] and not just to patent rights, they may be of potential relevance also for other provisions, such as those on test data.

The Declaration contains a number of important clarifications of some of the flexibilities contained in the Agreement. It states that each Member has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted. This addresses a common misunderstanding that compulsory licenses could only be granted in cases of national emergency or extreme urgency. Article 31(b) refers to such circumstances in connection with compulsory licenses, but merely to provide that the otherwise applicable condition that efforts must first be made to seek a voluntary license is waived in emergency situations. It also reaffirms Members' right to allow parallel imports (for discussion on exhaustion, *see* section 1.1, *supra*). Finally, as to the scope of the Declaration, the open language adopted in its paragraph 1—which emerged from heavy negotiations—makes it clear that it is not limited to the three diseases explicitly mentioned in it.

Another issue that arose in the preparatory work on the Declaration was the ability of countries with limited or no manufacturing capacities to make effective use of compulsory licensing. While the Agreement allows Members to issue compulsory licenses both for domestic production and importation, there was concern about whether sources of supply from generic producers in other countries would be available to meet the demand from countries seeking to import under a compulsory license. This was related to the requirement in Article 31(f) under which a potential supplying country could only grant compulsory licenses predominantly for purposes of supplying its

[21] Doha Decl., *supra* note 3.
[22] *See* Pascal Lamy, WTO Director-General, Address to 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.

domestic market. The Declaration recognized this problem in its paragraph 6 and called for an expeditious solution, discussed in section 2.2, *infra*.

Since its adoption, the Doha Declaration has served as a landmark and benchmark for all stakeholders, including international organizations, governments, the private sector and civil society. It has been referred to in numerous instruments, including many WHO resolutions.[23] It has also helped shape the framework for multilateral cooperation on IPRs and public health, including the trilateral cooperation between the WHO, WIPO and the WTO.[24] Moreover, it supports and gives guidance to governments who want to make use of TRIPS flexibilities at the domestic level. Finally, the Declaration has reinforced the understanding that the TRIPS Agreement supports a balanced and flexible framework for intellectual property that is responsive to the broader policy agenda. As a consequence, TRIPS flexibilities are largely recognized today.

2.2. *Paragraph 6 System*

As mentioned above, paragraph 6 of the Doha Declaration recognized the potential difficulties of WTO Members with inadequate domestic manufacturing capacities attempting to make effective use of compulsory licenses. One problem might arise when such Members need to import a pharmaceutical product that cannot be manufactured domestically and that is required to provide treatment to patients. To the extent that the medicine is patented in such a country, the act of importing in itself could be covered by a standard compulsory license, as it is permissible to grant of compulsory licenses for importation as well as for domestic production. No question of consistency with the TRIPS Agreement or domestic law would normally arise in this regard. However, the potential difficulty is located in the potential *exporting* country to the extent that the needed product is patented in it. The amount such a third country would be permitted export under a compulsory license is limited by Article 31(f), which provides that the production under such a license must be predominantly for the domestic market. This constraint raised questions as to whether sources of supply from generic producers in third countries would still be readily available to meet the needs of any importing country, taking into account the fact that some developing countries with important generic industries and export capacities came under an obligation to provide full patent protection for pharmaceutical products after the expiry of the special transition period in 2005.[25]

To respond to this problem, WTO Members agreed to establish the Paragraph 6 System ("the System"), named so after its origin in paragraph 6 of the Doha Declaration. In order to solve the potential legal difficulties in exporting countries so that public health problems in importing countries could be adequately addressed, the System provides for two derogations from TRIPS obligations under certain circumstances:

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[23] See *supra* note 4 for references to relevant WHA resolutions.

[24] *See*, *e.g.*, WHO, WIPO, and WTO Joint Technical Symposium, *Access to Medicines: Procurement and Pricing*, Geneva, Jul. 16, 2010, *background information available at* http://www.wto.org/english/news_e/news10_e/trip_16jul10_e.htm.

[25] *See* TRIPS, *supra* note 3, art. 65.4. For example, India complied with this obligation through adoption of the Patents (Amendment) Act 2005, *supra* note 11.

- First, derogation is permitted from the Article 31(f) obligation of any exporting Member that compulsory licenses be used predominantly to supply its domestic market. Under the System, "Paragraph 6-type" compulsory licenses may be granted for which the entirety of production under them is exported.

- Second, derogation is permitted from the Article 31(h) obligation of any importing Member to pay adequate remuneration to the right holder for the grant of a compulsory license. This would normally be required in instances where the needed product is patented in its originating territory. With a view to avoiding situations where double remuneration is paid to the right holder for the same product consignment where compulsory licenses are granted both in the importing and the exporting country, under the System, such compensation is only to be paid in the exporting country. In addition, calculation of the remuneration is to be based on the economic value of use of the needed product to the importing, and not the exporting Member.

In addition, there is a special derogation to Article 31(f) available for WTO Members who are parties to a regional trade agreement (RTA), provided that certain conditions are met, including that at least half of the RTA members are least developed countries as listed by the United Nations and that they share the public health problem in question. The purpose of this derogation is to allow a pharmaceutical product manufactured or imported under a compulsory license in one such RTA member country to be freely re-exported to the markets of other developing or LDC members of the RTA without being exposed to the constraints under Article 31(f). The derogation thus enables countries with smaller markets to better attract generic suppliers to engage in production, harness economies of scale for the purposes of enhancing purchasing power, and facilitate the setting up of local pharmaceutical production capacities.

As regards the System's scope of application, its paragraph 1(a) defines "pharmaceutical products" to mean "any patented product, or product manufactured through a patented process, of the pharmaceutical sector needed to address the public health problems as recognized in paragraph 1 of the Declaration," including active ingredients for their manufacture and diagnostic kits for their use.[26] LDC country Members automatically qualify as eligible importers under the System, whereas any other Member, when using it for the first time, has to notify the TRIPS Council of its intention to use the System.[27] Developed country Members have agreed to opt out from using the System as importers.[28] Eleven other Members have made a partial opt-out, indicating that they would use it as importers only in circumstances of extreme urgency.[29] All Members

[26] Although not explicitly mentioned, it is widely recognized that vaccines are also covered as they fall under the common definition of "pharmaceutical product."

[27] This is a one-time notification that can be made at any time, including in conjunction with the first more detailed notification regarding the Member's specific needs.

[28] For the list of countries concerned, see n.3 of the General Council Decision of Aug. 30, 2003, *Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health*, WT/L/540 and Corr.1 (Aug. 30, 2003); Protocol Amending the TRIPS Agreement, n.3, WT/L/641 (Dec. 8, 2005).

[29] For the list of countries concerned, see TRIPS General Council Chairperson Statement, ¶ 29, WT/GC/M/82 (Nov. 13, 2003); ¶ 30 WT/GC/M/100 (Mar. 27, 2006).

may act as exporting Members, but are not obliged to do so. This is because the System is an additional flexibility under TRIPS whose use is not mandatory.

The System is subject to a number of conditions to ensure transparency in its operation and safeguard against the risk that exports will be diverted to unintended markets. Importing and exporting Members are required to make certain notifications.[30] The notifications are for informational purposes only and do not require prior approval by any WTO body.[31] Each time use of the System is envisaged, the eligible importing Member must provide notice of the names and expected quantities of the product needed. Unless it is a least developed country,[32] the same Member also has to confirm that its manufacturing capacity in the pharmaceutical sector for the product needed is insufficient or not present at all, and provide information on how this has been established.[33] Finally, if the product in question is patent protected, the Member also has to confirm the grant or intention to grant a compulsory license for importation in accordance with Article 31.

It should be noted that the System explicitly provides for the possibility of joint notifications by regional organizations wishing to make use of the RTA derogation described above.[34] This is, however, not meant to be restrictive, as nothing prevents any other eligible importing Members from bundling their notifications under the System in order to make the envisaged production more attractive to generic suppliers from an economic standpoint.

Once the process under the System is initiated by the importing Member through notification, the exporting Member also has to notify the Council of the grant of the compulsory license and the conditions attached to it, the details of the license (name and address of the licensee, product(s) involved, quantity to be produced under the license, designated importing country or countries, duration of the license) and the website address where the licensee is required to post information on the quantities being supplied to each destination and the distinguishing features of the product(s) before shipment takes place.[35]

In addition to the preceding transparency provisions, some specific safeguards are built into the System to ensure that the products manufactured under it are used for public health purposes in the importing country instead of being diverted to other markets. In particular, certain conditions must be attached to the compulsory license in the exporting country. Those conditions must limit production to the quantity necessary to meet the needs of the importing Member, require that the entire production be exported to that Member, and, finally, make the application of distinguishing features by the supplier

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[30] In accordance with footnotes 5 and 9 of the August 2003 Decision and the Protocol Amending the TRIPS Agreement, those notifications are made publicly available through a dedicated webpage on the WTO website: http://www.wto.org/english/tratop_e/trips_e/public_health_e.htm.

[31] *See* n.2 of the General Council Decision of Aug. 30, 2003 and n.2 of the Protocol Amending the TRIPS Agreement, *supra* note 28.

[32] In order to facilitate use of the System by least developed country Members, LDCs are automatically exempted from this requirement, based on the assumption that they have insufficient or no manufacturing capacity.

[33] *See* General Council Decision of Aug. 30, 2003 and Protocol Amending the TRIPS Agreement, *supra* note 28, ¶ 2(a)(ii), as well as the Chairperson's statements in 2003 and 2005, *infra* note 38.

[34] *See* General Council Decision of Aug. 30, 2003 and Protocol Amending the TRIPS Agreement, *supra* note 28, n.4.

[35] For an example, see the website established by Apotex, which produced Apo-TriAvir under compulsory license in Canada for export to Rwanda, *available at* http://www.apotex.com/apotriavir/default.asp.

obligatory, provided those are feasible and without significant price impact, so that the products manufactured under the System can be clearly identified as such. Furthermore, importing Members must take measures to prevent the re-exportation of the products. In order to ensure that this would not become an overly burdensome requirement, several qualifiers apply to it: the measures must be reasonable, within the means of the Member concerned, and proportionate to its administrative capacities and to the risk of trade diversion. To avoid situations where medicines produced under the System are imported to or sold in their territories, all Members are required to make available to the right holder the legal means of recourse, consisting of standard enforcement procedures and remedies available under the Agreement that apply to medicines patented domestically.

The System was established in two stages by unanimous decisions by WTO Members at the General Council:

- First, in August 2003, in the form of a decision[36] granting the above waivers. Although waivers are by definition temporary measures, the advantage of the waiver decision was that it became effective as soon as it was adopted.

- Secondly, in December 2005, through an agreement to amend the TRIPS agreement to make those waivers a permanent part of the Agreement.[37] The latter will replace the provisions of the waiver decision once it enters into force, for which acceptance by two thirds of WTO Members is required. Procedures for acceptance are determined by the constitutional law of each WTO Member and its own practices in accepting international treaties. In order to deposit an instrument of acceptance to the WTO, only a few formal requirements need be met. These include: (i) a clear identification of the legal text which is accepted, i.e. the Protocol Amending the TRIPS Agreement done in Geneva on 6 December 2005 (the Protocol); (ii) a clear and unambiguous expression to the relevant Member's intention and consent to be bound by the Protocol; (iii) the issue and signature of the instrument either by the head of State or Government, by the Minister for Foreign Affairs, or by any other official with full powers; and (iv) the title of the signatory and the date and place where the instrument was issued.[38]

  Both instruments were adopted in the light of a Chairman's statement setting out

[36] General Council Decision of Aug. 30, 2003, *supra* note 28. The record of the discussion at the meeting provides further background on Members' positions. *See* General Council minutes, ¶¶ 10-89, WT/GC/M/82, Annex II. The Decision was made on the basis of a draft decision in document IP/C/W/405 that the TRIPS Council had agreed to forward to the General Council. References to the preparatory work by the TRIPS Council can be found in its annual reports for 2002 and 2003 in documents IP/C/27 and Add.1, and IP/C/30, respectively.

[37] Protocol Amending the TRIPS Agreement, *supra* note 28. *See also* World Trade Organization General Council, Minutes of Meeting of December 1, 2 and 6, 2005, ¶¶ 15-3, WT/GC/M/100 (Mar. 27, 2006). The Decision was adopted on the basis of a proposal for a decision in document IP/C/41 that the TRIPS Council had forwarded to the General Council. References to the preparatory work by the TRIPS Council can be found in its annual reports for 2003-2006 in documents IP/C/30, IP/C/32, IP/C/38 and Add.1, and IP/C/44, respectively.

[38] Detailed background information on the procedure and content requirements regarding acceptance of the Protocol was provided by the WTO Secretariat during the 2010 annual review, IP/C/57 and Corr.1, and is also available at http://www.wto.org/english/tratop_e/trips_e/accept_e.htm.

several key shared understandings of Members on how the System would be interpreted and implemented.[39] The statements were designed to respond to concerns that the System would be too open-ended and could therefore be abused for industrial or commercial purposes. Consequently, the statements particularly recognize that the System should be used in good faith to protect public health. Moreover, the statements are the only documentation of the list of partial opt-out countries, i.e. those Members that have agreed to use the System only in circumstances of extreme urgency. Agreement on them was a prerequisite that paved the way for the agreement on the System itself and are therefore closely linked to it.[40]

By April 2011, 34 WTO Members, counting the European Union as one, had notified their acceptance of the Protocol Amending the TRIPS Agreement.[41] By doing so, those Members have expressed their consent to be bound by the Protocol, or, in other words, their consent that all WTO Members are entitled to make use of additional flexibilities in the TRIPS Agreement in form of the System. The Protocol is currently open for acceptance until 31 December 2011[42]; if necessary, this period may be extended once more through a decision by the General Council.

It should be emphasized that the acceptance of the Protocol and the adoption of domestic implementing legislation are two distinct processes that can be dealt with separately at the national level. For example, the United States was the first Member to accept the Protocol back in December 2005, but it has not yet implemented the System into domestic law. In contrast, Canada was among the first Members to implement the System in its domestic legislation in 2005, but notified its acceptance of the Protocol only in 2009.

A number of Members have notified the Council of steps taken to implement the System into their respective national legislation. Such implementing legislations are based on the System, but do not follow a uniform model; this explains certain variances in the way the System has been incorporated into national law. There appears to be three main approaches to implementation. First, a number of WTO Members have created a legal basis for their domestic manufacturers to produce exclusively for export under a compulsory license. This category includes Albania, Canada, Croatia, the European Union, India, Norway, and Switzerland. Secondly, Singapore has provided a basis to act solely as an importing Member. Finally, China, Hong Kong, Korea and the Philippines have notified the Council of laws that allow them to act both as importers and exporters under the System.[43]

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[39] *See* World Trade Organization General Council, *Minutes of Meeting of Aug. 25, 26, and 30, 2003*, ¶¶ 29-31, WT/GC/M/82 (Nov. 13, 2003); *Minutes of Meeting of Dec. 1, 2, and 6, 2005*, *supra* note 37, ¶¶ 28-32.

[40] On the legal status of the Chairman's statement, see the discussions in the TRIPS Council prior to the adoption of the Protocol Amending the TRIPS Agreement: Agenda Item H, IP/C/M/43 (meeting of Mar. 8, 2004); Agenda Item H, IP/C/M/44 (meeting of Jun. 16, 2004); Agenda Item H, IP/C/M/47 (meeting of Mar. 8, 9 and 31, 2005); Agenda Item G, IP/C/M/49 (meeting of Oct. 25, 26 and 28, Nov. 29, and Dec. 6, 2005).

[41] *See* IP/C/W/490/Rev.8; *Members Accepting Amendment of the TRIPS Agreement* (dedicated WTO website with regularly updated information), *available at* http://www.wto.org/english/tratop_e/trips_e/amendment_e.htm.

[42] General Council Decision of Dec. 17, 2009, *Second Extension of the Period for the Acceptance by Members of the Protocol Amending the TRIPS Agreement*, WT/L/785 (Dec. 17, 2009).

[43] In accordance with their statements at the time of adoption of the System (*see supra* note 29), Singapore, Hong Kong, and Korea have limited their legal basis to act as importers to situations of national emergency or other circumstances of extreme urgency, thus duly taking into account those countries' status as partial

With respect to the System's operation so far, one instance of use has been reported to the TRIPS Council. In response to a notification from Rwanda,[44] Canada[45] issued a compulsory license under its Access to Medicines Regime (CAMR) to a domestic pharmaceutical manufacturer in October 2007, authorizing the manufacture of a fixed-dose combination medicine for the treatment of HIV infection for export to Rwanda under the System. Shipments of the medicine in question took place in September 2008 and 2009.[46]

Commenting on the System in December 2008, the WTO Director-General noted that:

> WTO members did not raise concerns during the last annual review of the operation of the System and instead, led by the African Group, reaffirmed the system two years after its adoption. This may be linked to the fact that the use of the Paragraph 6 System is confined to specific and well-defined circumstances, thus keeping the burden on potential users with fewer administrative resources to a minimum. In fact this system constitutes an additional flexibility to the many that are already in the TRIPS Agreement, including as recognized and clarified in the Doha Declaration on the TRIPS Agreement and Public Health. In any event, the system is far from being the sole solution to problems encountered in the public health sector. But this does not mean that we should have a blind faith in its success. Just like any WTO agreement, the Paragraph 6 System should be periodically reviewed and lessons drawn from these evaluations so that the WTO can continue its effort to make it work as a contribution among others to enhancing access to medicines.[47]

Pursuant to paragraph 8 of the August 2003 Decision, the Council for TRIPS has annually reviewed the functioning of the System since 2004.[48] More thorough discussions took place at the two most recent reviews in 2009[49] and, in particular, in 2010, when the Council set aside the second day of its October meeting for the review.[50] This provided an opportunity for a robust and comprehensive debate on the System's functioning. Follow-up discussions took also place at the Council's meetings in March and June 2010,

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opt-out Members. A summary of the implementing legislation formally notified in October 2010 by eleven WTO Members can be found in the report on the 2010 review of the System, circulated in IP/C/57 and Corr.1. Regularly updated information can also be found on the dedicated webpage, *Members' Laws Implementing the Paragraph 6 System*, http://www.wto.org/english/tratop_e/trips_e/par6laws_e.htm.

[44] IP/N/9/RWA/1 (Jul. 19, 2007).

[45] IP/N/10/CAN/1 (Oct. 5, 2007).

[46] More information on the use of the System by Canada and Rwanda can be found in the annual reviews 2007-2010, ¶¶4-5, IP/C/46; ¶ 6, IP/C/49; ¶ 6, IP/C/53; and ¶ 6, IP/C/57. Details were also provided by Canada in its Communication, IP/C/W/526, and in the discussions in March and October 2010 at the Council for TRIPS. *See* Council Minutes, ¶¶185-195, IP/C/M/62 and ¶¶74-82, ¶¶105-121, IP/C/M/64.

[47] See *supra* note 3.

[48] For reports on the reviews carried out during the period 2004 to 2008, see IP/C/33, IP/C/37, IP/C/42, IP/C/46 and IP/C/49 and Corr.1.

[49] *See* Report to the General Council for TRIPS, Annual Review of the Decision on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, IP/C/53 (Dec, 4, 2009).

[50] For the report from the 2010 annual review, see IP/C/57 and IP/C/W/57/Corr.1.

as well as in March 2011.[51] The latter was based on a list of issues Members had identified at the 2010 annual review as requiring further discussion or information, and prepared by the Secretariat on the basis of the record of the annual review.

These recent discussions covered both specific questions on the functioning of the System as well as broader issues related to access to medicines. At the 2010 annual review, Members shared their experiences on the use of the System and its domestic implementation, and discussed the process of acceptance of the Protocol, capacity building on the System and related TRIPS flexibilities, and any alternatives to the use of the System to achieve the objectives of improving access to medicines and procurement policies, among others.

At the 2010 annual review, some developing country Members raised concerns about the System's operation, questioning whether it is too complex and bureaucratic. According to them, the System does not represent the expected effective and expeditious solution to the public health problems of developing countries. In their view, this is evidenced by the System's limited use in only one case so far, as well as by the as yet relatively small number of acceptances of the Protocol Amending the TRIPS Agreement. Some other Members argued in response that the shipments of medicines from Canada to Rwanda demonstrated that the System can operate effectively. The success of the System should not be measured in terms of the number of compulsory licenses granted, but whether it has contributed to better access to affordable medicines. In their view, there may have been less need to use the System due to other measures enhancing access to medicines, including improved international procurement, increased donations of free medicines, and lower prices often provided by right holders.

Furthermore, the WHO noted that patent protection is in many cases not an issue since medicines are available off patent; an isolated discussion of the System would therefore be misleading as it applies to very specific situations only, whereas access to medicines is determined by a variety of factors. Others also pointed out that the need to use the System may increase in the future, given the fact that India, the major source of generic medicines, had implemented patent protection for pharmaceutical products in 2005, and the transition period for LDCs was due to expire soon. Discussions also touched on related issues, such as the proper functioning of government procurement policies and the efficacy and safety of medicines procured under the system.

3. Dispute Settlement, the TRIPS Agreement and Public Health

Another important contribution of the TRIPS Agreement is that it has brought IP disputes within the ambit of the WTO dispute settlement system. Under this system, WTO Members have agreed to use WTO procedures when they seek to take action against a violation of a TRIPS obligation, rather than making a unilateral determination to the effect that a violation has occurred.[52] To date, 29 complaints have been lodged in the

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[51] *See* the respective Council Minutes in ¶¶168-211, IP/C/M/62; ¶¶184-247, IP/C/M/63; item F, IP/C/M/65.

[52] *See* Understanding on Rules and Procedures Governing the Settlement of Disputes, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 2, art. 23.1, 23.2(a), 1869 U.N.T.S. 401 (1994) [hereinafter Dispute Settlement Understanding or DSU]. *See* also Panel Report, *United States–Sections 301–310 of the Trade Act of 1974*, WT/DS152/R (Dec. 22, 1999), *adopted by* the Dispute Settlement Body on Jan. 27, 2000 (confirming that it is for the WTO through the dispute settlement

area of TRIPS, relating to 23 different matters, with panel and/or Appellate Body reports adopted in ten cases.[53] These reports have helped to clarify certain key provisions of the TRIPS Agreement. The following briefly reviews the cases most relevant to public health.

3.1. *Canada – Patent Protection of Pharmaceutical Products*

Arguably the most important panel report examining the intersection between TRIPS and public health is *Canada – Pharmaceutical Patents,*[54] which sheds light on the scope of permitted exceptions under Article 30. The EC complaint concerned two exceptions to exclusive patent rights available under Canada's former Patent Act. The first was the so-called "regulatory review exception" in Section 55.2(1) (this type of exception is also known as the "Bolar exemption"), exempting from patent infringement any acts to generate information with a view to obtaining marketing approval for regulated products. This is of particular importance in the pharmaceutical sector, as it allows a generic competitor to produce samples of a patent-protected medicine and to complete the lengthy marketing approval process before expiration of the patent term. In anticipation of marketing approval, the generic manufacturer could thus start producing and selling its medicines immediately upon patent expiry. The second one was the so-called stockpiling exception, which permitted the manufacturing and stockpiling of patented products six months prior to patent expiry as long as the sale took place after the expiry of the patent. This enabled generic manufacturers to enter the market on day one after patent expiry.

The EC argued that those provisions violated TRIPS Articles 27.1 and 28.1. While there was no dispute among the Parties that the measures at issue violated the exclusive rights available under Article 28.1, Canada defended them as permissible exceptions under Article 30. To support its view, Canada referred to Articles 7 and 8 as relevant to the object and purpose of Article 30. It argued that those provisions taken together would "call for a liberal interpretation of the three conditions stated in Article 30 of the Agreement, so that governments would have the necessary flexibility to adjust patent rights to maintain the desired balance with other important national policies."[55] The panel noted that "the exact scope of Article 30's authority will depend on the specific meaning given to its limiting conditions," and that both the goals and limitations stated in Articles 7 and 8.1, as well as other TRIPS provisions indicating its object and purposes, must be borne in mind when examining those conditions.[56]

Article 30 contains the so-called three step test. It is similar to, but not identical with, the three step test applying to copyright[57] and also resembles the exceptions clause

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process, and not an individual WTO Member, to determine that a measure is inconsistent with WTO obligations).

[53] Fourteen cases have been subject to amicable settlement without reaching the panel, two cases are in the stage of active consultations, and three cases have become inactive. Cases relating to the TRIPS Agreement therefore represent about 7% out of the total of 424 complaints under the DSU.

[54] Panel Report, *Canada–Patent Protection of Pharmaceutical Products*, *supra* note 8.

[55] *Id.* at ¶ 7.24.

[56] *Id.* at ¶ 7.26.

[57] Panel Report, *US–Section 110(5) of the U.S. Copyright Act*, WT/DS160/R (Jun. 15, 2000) (interpreting TRIPS art. 13).

applicable to trademarks.[58] The three steps under Article 30 are: (i) an exception must be limited, (ii) there must be no unreasonable conflict with the normal exploitation of the patent, and (iii) there must be no unreasonable prejudice to the legitimate interests of the patent owner, taking into account third parties' legitimate interests. In examining Canada's exceptions, the panel decided that the three criteria apply cumulatively and that, therefore, an exception has to pass each of them to qualify under it.

As regards the first step, the panel held that a limited exception is to be understood as a "narrow exception, which makes only a small diminution of the rights in question."[59] Moreover, it was to be measured by the extent to which the patent owner's exclusive legal rights had been curtailed, and not by the size or extent of the economic impact.

The panel decided that the stockpiling exception constituted a substantial curtailment of the patent owner's exclusive rights. It was not limited, as there were no limitations on the quantity of production; furthermore, allowing a third party to stockpile the protected invention during the lifetime of the patent eliminated the benefit of a short period of extended market exclusivity after patent expiry, which was inherent to the patent right. Since it failed to pass the first test under Article 30, the panel found that Canada's stockpiling exception was inconsistent with Article 28.1.

As regards the regulatory review exception, the panel decided that the impact of the permitted acts was small and narrowly bounded so that they would fall within the scope of a limited exception under Article 30.[60] The patent owner's rights were not impaired, as long as the unauthorized acts were solely for regulatory purposes and no commercial use was made of the end products. According to the panel, this was equally valid for activities seeking product approvals under foreign regulatory procedures. While recognizing that the economic impact of the regulatory review exception could be considerable, the panel found that the effects of such curtailment of the patent owner's rights were addressed by the other two criteria.

As the regulatory review exception was found to constitute a limited exception, the panel continued its examination by looking into the second criterion, i.e. whether there was an unreasonable conflict with the normal exploitation of the patent. The term "exploitation" was understood to refer to the commercial activity by which patent owners employ their exclusive patent rights to extract economic value from their patents.[61] The panel was persuaded by Canada's argument that the additional period of de facto market exclusivity created by using patent rights to preclude submissions for regulatory authorization was not to be considered part of the "normal exploitation," since it constituted an unintended consequence resulting from the conjunction of patent and regulatory approval laws.[62]

The panel concluded its examination by looking into the third criterion. It considered that "legitimate interests" did not merely refer to the patent owner's legal rights, but rather to a broader normative concept relating to interests that are justifiable in

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[58] Panel Report, *EC–Protection of Trademarks and Geographical Indications for Agricultural Products and Foodstuffs*, WT/DS290/R (Mar. 15, 2005) (interpreting TRIPS art. 17).
[59] Panel Report, *Canada–Patent Protection of Pharmaceutical Products*, *supra* note 8, ¶ 7.30.
[60] *Id.* at ¶ 7.45.
[61] *Id.* at ¶ 7.54.
[62] *Id.* at ¶ 7.57.

the sense that they are supported by relevant public policies or other social norms.[63] It accepted Canada's argument that the private economic advantage to be gained from a de facto extension of the term of protection beyond the normal lifetime of a patent due to the health regulatory system would not constitute part of the patent owner's legitimate interests within the meaning of Article 30.[64] In this context, the panel refrained from pronouncing on the appropriateness of compensatory patent term extensions adopted by a number of governments[65]—in particular in the pharmaceutical sector—to remedy lengthy approval procedures for the originator product, as this was a matter of ongoing political debate and governments had no unanimous view regarding the merits of such measure. The concept of "legitimate interests" in Article 30 should thus not serve to decide a normative policy issue.[66] The panel therefore concluded that Canada's regulatory review exception met the three step test and was not inconsistent with Article 28.1 TRIPS.

Finally, the panel examined the EC's claim that the regulatory review exception resulted in a *de jure* and *de facto* discrimination against a particular field of technology, as it only applied to the pharmaceutical sector, and thus violated Article 27.1. To start with, the panel acknowledged the applicability of the non-discrimination requirement to exceptions under Article 30.[67] However, the measure at issue did not constitute a *de jure* discrimination as the EC had not produced sufficient evidence to overcome the open-ended wording of the regulatory review exception and assurances provided by Canada that its meaning was not limited to the pharmaceutical sector. Furthermore, the panel rejected the EC's argument of a *de facto* discrimination against the pharmaceutical sector. The EC failed to provide evidence that the regulatory review exception had a discriminatory impact on pharmaceutical products or that its purpose was to discriminate against such products. Consequently, the regulatory review exception was considered by the panel as not infringing Canada's obligations under Article 27.1 TRIPS.

3.2. *Other Relevant Cases*

Some of the early cases relating to the pharmaceutical sector addressed transitional arrangements. *India–Patents I*[68] concerned a complaint by the U.S. shortly after the entry into force of the TRIPS Agreement in late 1996 and covered the issue of mailbox applications and exclusive marketing rights in Articles 70.8 and 70.9 of TRIPS and whether these provisions were consistent with India's patent regime during the transition period. The panel found that India's patent regime at the time was inconsistent with both TRIPS provisions, because it failed to create a mailbox system for the filing of patent applications for pharmaceutical and agricultural chemical products and did not provide for the grant of exclusive marketing products for such products. Those findings were upheld by the Appellate Body. A similar complaint against India was initiated by

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[63] *Id.* at ¶ 7.69.
[64] *Id.* at ¶ 7.82.
[65] *See*, *e.g.*, Commission Regulation 469/2009, of the European Parliament and of the Council of 6 May 2009 Concerning the Supplementary Protection Certificate for Medicinal Products, 2009 O.J. (L152) 1.
[66] *Id.* at ¶ 7.82.
[67] *Id.* at ¶ 7.93.
[68] Panel Report, *India–Patent Protection for Pharmaceutical and Agricultural Chemical Products*, WT/DS50/R (Sept. 5, 1997); Appellate Body Report, *India–Patent Protection for Pharmaceutical and Agricultural Chemical Products*, WT/DS50/AB/R (Dec. 19, 1997).

the EC.[69] Another similar complaint by the U.S. concerning Pakistan's transitional arrangements was settled.[70]

In 1999, the U.S. challenged the term of patent protection under Canada's former Patent Act, which was limited to 17 years from the date of issuance of patents filed before October 1989, for its inconsistency with TRIPS Articles 33 and 70. The panel found that the requirement to grant 20 years of patent protection in Article 33 applied to inventions patented in Canada prior to the date of entry into force of the TRIPS Agreement, i.e. January 1, 1996. As such, Canada's Patent Act did not provide for a term of protection of at least 20 years to certain patented subject matters and was therefore inconsistent with the TRIPS Agreement. Those findings were upheld by the Appellate Body.[71]

Three settled cases are worth mentioning. In 1999, the U.S. alleged the absence of exclusive marketing rights under Article 70.9 TRIPS during Argentina's transition period, and challenged the consistency of changes to Argentina's regime for the protection of undisclosed test data with the transitional provisions in Article 65.5. In 2000, the U.S. requested additional consultations with Argentina regarding a number of measures also affecting public health, including test data protection. In 2002, the parties notified the WTO of a mutually agreed solution covering both complaints.[72] In 2000, the U.S. initiated consultations with Brazil concerning the "local working" requirement in Article 68 of Brazil's Industrial Property Law. Under a mutually agreed solution, Brazil agreed to hold prior talks under a bilateral consultative mechanism, should it ever consider granting a compulsory license on patents held by U.S. companies.[73] There is no indication that Brazil has considered the grant of a compulsory license on such grounds, or that such bilateral talks have been held since then.

Finally, at the time of writing this paper, consultations initiated by India and Brazil in 2010 concerning *European Union and a Member State – Seizure of Generic Drugs in Transit* were pending. The reasons for the consultations, including the identification of the measures at issue and the legal basis for the complaints, are given in the documents containing the requests for consultations submitted by India and Brazil.[74] Before requesting consultations under the DSU, Brazil and India had raised concerns in

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[69] Panel Report, *India–Patent Protection for Pharmaceutical and Agricultural Chemical Products*, complaint by the European Communities and their member States, WT/DS79/R (Aug. 24, 1998) [hereinafter *India–Patents II*].

[70] Notification of a Mutually-Agreed Solution, *Pakistan–Patent Protection for Pharmaceutical and Agricultural Chemical Products*, WT/DS36/4 (Mar. 7, 1997). For a review of these and other early cases, see Matthijs Geuze and Hannu Wager, *WTO Dispute Settlement Practice Relating to the TRIPS Agreement*, 2 J. OF INT'L ECON. L. 347.

[71] Panel Report, *Canada–Term of Patent Protection*, WT/DS170/R (May 5, 2000); Appellate Body Report, *Canada–Patent Term*, WT/DS170/AB/R (Sept. 18, 2000).

[72] Notification of a Mutually-Agreed Solution According to the Conditions Set Forth in the Agreement, *Argentina–Patent Protection for Pharmaceuticals and Test Data Protection for Agricultural Chemicals*, WT/DS171/3 (May 31, 2002); Notification of a Mutually-Agreed Solution According to the Conditions Set Forth in the Agreement, *Argentina–Certain Measures on the Protection of Patents and Test Data*, WT/DS196/4 (May 31, 2002).

[73] Notification of Mutually-Agreed Solution, *Brazil–Measures Affecting Patent Protection*, WT/DS199/4 (Jul. 19, 2001).

[74] *See* Request for Consultations by India, WT/DS408/1 (May 19, 2010); Request for Consultations by Brazil, WT/DS409/1 (May 19, 2010).

various fora about the customs treatment of medicines in transit through EU ports, produced in India and destined for developing countries. The measure at issue, the suspension of release by certain EU member States' customs authorities, was based on grounds of alleged infringement of intellectual property rights in the transit country, which is provided for under Council Regulation (EC) No.1383/2003[75] and the national law of the member States concerned. The records of these earlier discussions provide further background information on the relevant measures and the views held by both sides.[76]

III. ACCESS TO MEDICINES: THE BROADER PICTURE

While emphasizing the scope of flexibilities in the TRIPS Agreement available for Members to tailor their domestic implementation with the view of promoting access to medicines, the Doha Declaration stresses the need for the Agreement to be "part of the wider national and international action to address these problems." It is generally accepted that there is a need for a broad-based approach to access to medicines, which should include dimensions such as innovation, access, and funding.

Other policies affecting access to medicines that have regularly been referred to in recent discussions[77] include:

- Applying transparent, competitive, and non-discriminatory procurement procedures and practices, as those could result in lower prices and more effective use of limited financial resources. Such procurement practices should be supported by better information on existing patents in the relevant jurisdictions, applied prices and the broader framework, including tariffs, taxes and health regulations;

- Applying effective competition policies to lower prices, supported by transparent and readily available information on prices applied;

- Establishing a sound regulatory system and competent national authorities to ensure the quality, safety and efficacy of medicines, so that high quality and safe medicines reach patients and falsified medicines are kept out of the market;

- Lowering or eliminating tariffs and taxes, where still applied to imported medicines and active ingredients, to avoid any negative impact on prices for medicines; and

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[75] O.J. 2003 (L196) 7.

[76] The issue was first raised at the 124th Executive Board meeting of the WHO in January 2009. In the WTO, Brazil and India raised the issue under "Other Business" at the General Council meeting of February 3, 2009, as well as at subsequent TRIPS Council meetings. *See* World Trade Organization General Council, Minutes, ¶¶72-98, WT/GC/M/118; ¶¶122-191, IP/C/M/59; ¶¶125-167, IP/C/M/60; ¶¶254-294, IP/C/M/61; ¶¶213-232, IP/C/M/62.

[77] These issues also came up in the TRIPS Council's Annual Review in 2010, in particular under the heading "Any alternatives to the use of the Paragraph 6 System to achieve the objective of access to medicines, procurement policies, and other related aspects affecting access to medicines." The record of the discussion is available in the report on the annual review of the System in ¶¶174-221, IP/C/57, Annex.

- Improving the health care infrastructure with respect to availability of health care professionals, hospitals and delivery systems, so that adequate delivery and administration of medicines can be ensured.

It has also been emphasized that alternative funding mechanisms, donations, partnership programmes and licensing agreements, as well as the increased application of tiered pricing schemes by pharmaceutical companies have contributed to positive changes regarding access to medicines.[78] Several WTO Members have referred to their funding commitments, in particular to support for the activities of the Global Fund to Fight AIDS, Tuberculosis and Malaria.

Another dimension of coherence is the relationship between the WTO trade regime and human rights, in particular the right to health. It is important to note that the trading system contributes to the realization of economic, social and cultural rights by stimulating economic growth and thereby helping to generate the resources that are needed for the fulfillment of such rights. As regards intellectual property in particular, it should be noted that the International Covenant on Economic, Social and Cultural Rights[79] recognizes both "the right of everyone to the enjoyment of the highest attainable standard of physical and mental health" (Article 12) and "the right to the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he is the author" (Article 15.1(c)). The General Comment on the latter right underlines the need to strike an adequate balance between the various rights guaranteed in the Covenant.[80] The tensions that are inherent between various interdependent human rights are similar to those that underlie the consideration of the appropriate balance in IP systems discussed in this paper. Irrespective of whether one lays emphasis on human rights or utilitarian rationale, such as those reflected in Article 7 of the TRIPS

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[78] The importance of differential pricing and financing of access to essential medicines was already the subject of an intensive debate among experts at a workshop jointly organized by the WHO, the WTO, Norway's Foreign Ministry, and the Global Health Council in April 2001. The workshop examined, among other topics, the economic and political feasibility of differential pricing as well as the mechanisms needed to carry forward the concept. WHO/WTO Workshop on Differential Pricing and Financing of Essential Drugs, Høsbjør, Norway, Apr. 8-11, 2001, *final report and other materials available at* http://www.wto.org/english/tratop_e/trips_e/tn_hosbjor_e.htm#finalreports. According to recent reports by the pharmaceutical industry, differential pricing schemes have led to significantly lower prices and an increasing number of beneficiary countries. For example, not-for-profit pricing of the ARV medicine Combivir in all the LDCs and the countries of sub-Saharan Africa reportedly lowered the price from USD 730 per patient per year in 2001 to USD 197 in 2010. Another example is offering human insulin to LDCs at prices not exceeding 20% of the average price in Europe, Japan and the US; in 2009, 36 LDCs used this pricing scheme to buy insulin at or below this price, compared to 32 in 2008. For further details regarding preferential pricing initiatives, see International Federation of Pharmaceutical Manufacturers & Associations, DEVELOPING WORLD HEALTH PARTNERSHIPS DIRECTORY, *available at* http://www.ifpma.org/fileadmin/content/Publication/IFPMA_Partnerships_Directory_Summary_2010.pdf.

[79] International Covenant on Economic, Social and Cultural Rights, Dec. 16, 1966, 993 U.N.T.S. 3; S. Exec. Doc. D, 95-2 (1978); S. Treaty Doc. No. 95-19, 6 I.L.M. 360, *available at* http://www.ohchr.org/english/law/cescr.htm.

[80] UN Committee on Economic, Social and Cultural Rights, General Comment No. 17, *The Right of Everyone to Benefit from the Protection of the Moral and Material Interests Resulting from any Scientific, Literary, or Artistic Production of Which He Is The Author* (International Covenant on Economic, Social and Cultural Rights, *supra* note 79 art. 15 ¶ 1(c)), ¶ 35, E/C.12/GC/17 (Nov. 21, 2005).

Agreement, there is a need for careful social and economic analysis and empirical evidence when designing appropriate policy responses to best achieve the stated objectives.[81]

The issue of access to medicines is heavily influenced by a number of key players intervening at different levels, ranging from discussions, norm-setting, and jurisprudence at the international level all the way down to concrete decisions adopted by the research-based and generic pharmaceutical industries. Coherence, cooperation, and dialogue are indispensable at all levels in order to make effective responses to the challenges posed for public health, set a meaningful agenda for global health policy, and ensure that the IPR regime is balanced, fair and effective.

The broad issues discussed above have fostered cooperation between the three intergovernmental organizations with key responsibilities in this area, namely the WHO, WIPO, and the WTO. It was initially framed by the Doha Declaration and has now led to an intensified process of trilateral cooperation, which also includes the implementation of the WHO's Global Strategy and Plan of Action. For example, in July 2010, the three organizations held a Joint Technical Symposium on "Access to Medicines: Pricing and Procurement Policies." The event was designed to promote a better understanding of experiences in the pricing and procurement of medicines as an important determinant of access. It focused on the review of available sources of information with respect to prices, availability, and quality of medicines and patents and the scope of patent coverage, as well as a range of other IPR and trade issues. This partnership between the three organizations builds on the complementary roles of each organization and takes into account the different nature of their respective mandates and priorities. At the above-mentioned event, the WTO Director-General noted that

> [G]lobal public health is a complex puzzle; getting it right is a teasing challenge, involving effective use of the full set of applicable policy tools…. The pooled perspective needs to cover the international trade dimension but also consider domestic policies and practices, and above all the evolving state of the actual global disease burden, a priority setting for front-line treatments and patents for the production and dissemination of medicines.[82]

On 18 February 2011, a second Joint Technical Symposium on "Access to Medicines, Patent Information and Freedom to Operate" addressed one of the issues identified at the earlier event, namely the growing importance of access to reliable patent information for public health.[83] In particular, such information is at the basis of decisions by procurement agencies regarding the sources of legal supply of medical products; it also helps determining public and private sector strategies regarding medical research, development and production and supports analysing innovation activities. The

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[81] For a discussion on trade and human rights, see Robert D. Anderson and Hannu Wager, *Human Rights, Development, and the WTO, the Cases of Intellectual Property and Competition Policy*, 9 J. OF INT'L ECON. L. 707, 707-747.

[82] *See* Pascal Lamy, WTO Director-General, Opening Remarks, WHO-WIPO-WTO Joint Technical Symposium, *supra* note 24, Jul. 16, 2010, available *at* http://www.wto.org/english/tratop_e/trips_e/techsymp_july10_e/techsymp_july10_e.htm#dg.

[83] *See Symposium Tackles How to Know Whether a Medicine is Patented*, WTO NEWS ITEM, Feb. 18, 2001, *available at* http://www.wto.org/english/news_e/news11_e/trip_18feb11_e.htm.

Symposium aimed to demonstrate how patent information can be used to determine the freedom to operate in improving access to medicines, explore what kind of patent information is required and to what extent this information is available and accessible, and identify gaps. Among the key issues raised was the difficulty of obtaining reliable domestic patent information in many countries and the difficulty of assessing the status of patents related to medical products.

The WTO in particular can serve as a useful and productive forum for discussions. For example, Members have often taken up issues related to public health at meetings of the TRIPS Council, and they are regularly addressed in the annual review of the System. The Council's discussions have led to the adoption of new instruments, including the Doha Declaration in 2001 and the waiver decision in 2003, as well as the first ever proposed amendment to a WTO agreement in the form of the Protocol adopted in 2005. Another core function is the WTO dispute settlement mechanism, which in resolving disputes has provided some important clarifications of the relevant rules. Moreover, the WTO Secretariat provides a number of technical assistance activities each year which are either dedicated to the TRIPS Agreement and public health or which include at least a comprehensive session on this topic.[84] Those activities are designed to facilitate enhanced participation and informed decision-making in developing countries through, among other methods, awareness raising and capacity building, as well as the provision of factual and technical information. The WTO Secretariat also contributes to the work carried out by other international organizations in the field of public health.

Aside from multilateral institutions, governments have a major role to play in promoting access to medicines, both in respect of their IP policy and how it interfaces with other relevant policy areas. It is within their responsibility to carefully define domestic policy objectives and adopt an appropriate legal framework to implement them. This includes the consideration of the use of flexibilities available under the TRIPS Agreement. For example, where neglected diseases are to be addressed, implementing an innovation policy to create incentives to invest in research and development of medicines to treat such diseases is indispensable. Governments also determine their international commitments both at the multilateral, regional, and bilateral levels and such commitments influence the space which they have to pursue their domestic health policies.

Last, but not least, civil society, philanthropic organizations, and industry have made important contributions to shaping the global health policy agenda. Civil society, for example, has helped to move IPR-related issues to the centre of the political agenda, thus making sure that the necessary attention is given to the interface between IPRs and public health in all relevant fora. Philanthropic organizations not only play a key role in the funding of medicine purchases, but they also provide an important contribution to the design of IP management models and the increase of transparency regarding prices paid for medicines. Finally, the pharmaceutical industry contributes at different levels to this agenda. This includes investment in research and development of new medicines, partnerships to facilitate drug development, management of IPR portfolios of individual projects, and application of tiered pricing schemes.

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[84] For more information on the WTO's activities, see WTO Secretariat, *Technical Cooperation in the TRIPS Area*, IP/C/W/553 (2010).

IV. CONCLUSION

Issues relating to access to medicines have been central to the WTO's work on trade matters in general and, in particular, in the area of intellectual property over the past several years and will continue to be so. Important steps have been taken in the WTO and elsewhere since the adoption of the 2001 Doha Declaration to improve access while also maintaining the necessary incentives for the development of new drugs. The challenge in the development of an adequate IPR policy is to find an optimal system that is both effective and fair, ensuring continued innovation as well as access to the results of such innovation by society at large.

As part of the ongoing reflection on how to best reconcile the inherent tension between these objectives, a number of key elements must be taken into account. Those include the consideration, at the domestic level, of optimal implementation and use of both rights and flexibilities available under the TRIPS Agreement with a view to enhancing access to medicines. A country may need to implement into its domestic law flexibilities available under the Agreement in order to make use of them, since merely having them recognized under an international agreement may not be enough. It is also necessary to ensure that cooperation at all levels delivers tangible results that respond to the concerns and practical needs of WTO Member countries and their populations. Finally, it should be borne in mind that, while international IP rules can make an important contribution to improved access to medicines, they form only one component of a larger network of efforts required, both at the national and international levels, to address the grave public health problems afflicting many developing and least developed countries and to enhance access to medicines for their populations.

In terms of the current state of play, there are good reasons to make a cautiously optimistic assessment of the situation today as compared to ten years ago. Access to medicines has been improved through price reductions, partnerships, enhanced international funding, and a greater recognition of the need to find a balance within the IPR system, as well as the use of some of the flexibilities by certain WTO Members. It is also encouraging that the international community, industry, and civil society are now constantly seized with the problem and have recognized the need to increase funding, develop social and health infrastructure, and increase R&D for neglected diseases that mainly afflict the developing world. This being said, a continuous and constructive engagement of all relevant players is and will be required to make more progress.