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Patent Rights on Pharmaceutical Products and Affordable Drugs: Can TRIPS Provide a Solution?

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PATENT RIGHTS ON PHARMACEUTICAL PRODUCTS AND AFFORDABLE DRUGS: CAN TRIPS PROVIDE A SOLUTION?

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I.
INTRODUCTION

In the last few years, the debate over affordable life saving drugs for the poor and the nature of patent regime for the pharmaceutical industry has attracted more attention than any other issue within the World Trade Organization (WTO). The focus of the controversy is the requirement of an extensive, globally uniform patent protection regime for pharmaceutical products as described in 'The Agreement on Trade Related Aspects of Intellectual Property Rights' (TRIPS).[1] The Agreement marked the beginning of the global property epoch.[2] Before TRIPS came into force, many developing countries did not allow patents for pharmaceutical products,[3]only pharmaceutical processes could be patented.[4] Others simply excluded medicines from the ambit of patent laws.[5] This allowed local production of generic versions of the patented medicines,[6] and kept the prices of formulation at a much lower level then that in the developed world.[7] Article

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1 Agreement on Trade Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, LEGAL INSTRUMENTS- RESULTS OF THE URUGUAY ROUND vol. 31, 33 I.L.M. 81 (1994) [hereinafter TRIPS Agreement].

2 Peter Drahos, *Intellectual Property and Human Rights*, Intell. Prop. Q. No.3 349, 356 (1999) [hereinafter Drahos].

3 A product patent is different from a patent over a process. Patenting a process implies that only the process through which a product is made can be patented. The final product is not included under the right. A patent holder can restrict the other party from using the process, but he can make no claims on the product. Thus, another manufacturer can market the same product as long as she uses a different process.

4 *E.g.*, Argentina, India; *See* Theresa Beeby Lewis, *Patent Protection for the Pharmaceutical Industry: A Survey of the Patent Laws of Various Countries*, 30 INT'L LAW 835 (1996) [hereinafter Lewis].

5 *E.g.*, Brazil, Thailand, Korea.

6 The success of many Indian pharmaceutical companies, for example Cipla, is attributed to a weak patent regime.

7 For example, AZT (a drug for treatment of HIV) treatment was produced at a supply cost of $ 48 a month in India as compared with $239 in the United States; Lariam, a treatment for malaria, at a cost of $4 as compared with $37 in the U.S., according to a UN document published in 2000. *See* Audrey R. Chapman, *Approaching Intellectual Property*

27 of TRIPS provides, however, that there should be patent protection for inventions in all fields of technology without discrimination. According to this absolute command, there ought to be no distinction between (i) a process patent and a product patent, and (ii) between the industries. In contrast to this specific provision, there are general provisions such as Articles 7 and 8 (dealing with 'objectives' and 'principles' of the Agreement respectively). The language of these provisions is vague and does not provide guidelines for their implementation. Moreover, Article 6 (concerning 'exhaustion' of intellectual property rights), Article 30 (relating to 'exceptions to the [patent] rights conferred') and Article 31 (dealing with 'other use without authorization of the right holder') allow much scope for varying interpretations.

The ambiguity on fundamental issues has led to controversies in the past on the application of TRIPS. The developing countries affected most by the HIV/AIDS crisis began exploring options like compulsory licensing and parallel imports, partly to promote the generic industry and partly to keep drug prices down. This was met with opposition from big pharmaceutical companies and governments supporting a strong patent regime. The most notable dispute arose in South Africa where the pharmaceutical industry, along with the U.S. and the European Union opposed the government's efforts to provide cheap drugs.[8] A similar controversy erupted when the U.S. filed a complaint with the WTO over Brazil's patent legislation allowing local manufac-

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as a Human Right: Obligations Related to Article 15(1)(c), discussion paper submitted to the Committee on Economic, Social, and Cultural Rights, 24th Sess., at 22, U.N. Doc. E/C.12/2000/12 (2000).

[8] *See* Frank Wooldridge, *Analysis: Affordable Medicines - TRIPS and US Policies,* Intellectual Property Quarterly No. 1 (2000) 103; *see also* Toby Kasper , *South Africa's Victory for the Developing World*, Médecins Sans Frontières *available at* http://www.accessmed-msf.org/prod/publications.asp?scntid=3182001040389&contenttype=PARA& (last visited March 22, 2002) [hereinafter Kasper]; ('Pharmaceutical Manufacturers Association of South Africa' filed a case against the South African Government over the Medicine and Related Substances Control Amendment Act 90 of 1997. The legislation, among other things, authorized Minister of Health to 'prescribe conditions' for the supply of more affordable medicines so as to protect the health of public. In particular, under Section 15 C of the Act the Minister could grant compulsory licenses and allow measures such as parallel importing. The United States and the European Union demanded that South Africa should comply with US defined TRIPS plus requirements and complained that the section violated articles 27 and 28 of TRIPS and failed to take into account articles 6 and 31. Though United States and South African governments reached an agreement before WTO Seattle Ministerial Conference, the pharmaceutical industry did not withdraw the lawsuit. Interestingly, the association's principal objection to Section 15 C was not that it violated TRIPS, but that the provision was so broad that it authorized the Health Minister to abrogate all rights of pharmaceutical patent holders, and thus, it violated the South African Constitution. However, the South African Court could not announce a verdict. After a sustained campaign by NGOs and activists the lawsuit was dropped. But, as a result of a

turing of generic drugs. The United States, however withdrew its complaint against Brazil in June 2001.[9]

Granting a right to patent is akin to a grant of a monopoly[10] because it allows the patent holder to manipulate the market price of the product. Thus, if patent rights for pharmaceutical products result in higher prices, the issue is whether the existing patent regime, by treating pharmaceuticals at par with other fields of technology, conflicting with the right to health. In particular, do the provisions of TRIPS (written, interpreted, and applied), restrict WTO member countries implementing measures to protect and promote the health of their citizens? If they do, then there is a strong case, legally and morally, that TRIPS should be amended or repealed. The evidence on the value of patent rights to society, however, is mixed. It is not certain that we would be much better off without an intellectual property regime.[11] In this paper I avoid debating whether some other rights- or reward-based system would serve society better. I assume for the purposes of this paper that it is much better to be a part of the system, and there are advantages of working from within the international trade regime.[12] Thus, the need is to engage in a dialogue while at the same

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constant pressure from pharmaceutical industry, the implementation of the said Act was suspended and the implementing regulations were not in force even after a year).

[9] Kasper, *supra* note 8; *see generally* http://www.cptech.org/ip/health/c/brazil (last visited December 26 2003); (under the agreement, the parties decided to negotiate all disputes on the issue through a bilateral "Consultative Mechanism," and Brazil was required to notify the US government in advance in the event it finds it necessary to issue a compulsory license under its patent law).

[10] Robert Howse & Michael J. Trebilcock, THE REGULATION OF INTERNATIONAL TRADE at 309 (2nd ed. 1999).

[11] For an excellent critique of the legal theories for intellectual property rights, *see* Edwin C. Hettinger, *Justifying Intellectual Property*, 18 PHIL. & PUB. AFF. 31 (1989); *see also* EDITH T. PENROSE, THE ECONOMICS OF THE INTERNATIONAL PATENT SYSTEM, 20-41 (1951); *see also* PETER DRAHOS, A PHILOSOPHY OF INTELLECTUAL PROPERTY, 47-48 (1996); (scholars are also dissatisfied with the term of the protection granted by the intellectual property rights); *see* David Vaver, *Creating a Fair Intellectual Property System for the 21st Century*, 10 OTAGO L.REV. 1 (2001); *see generally* JAMES BOYLE, SHAMANS, SOFTWARE, AND SPLEEN: LAW AND THE CONSTRUCTION OF THE INFORMATION SOCIETY (1996) [hereinafter BOYLE]; *but see* Harvey E. Bale, Jr., *Patent Protection and Pharmaceutical Innovation*, 29 N.Y.U. J. INT'L L. & POL. 95 (1996) (for an opposing view, which supports the intellectual property rights in its current form); *see also* Henry Grabowski, *Patents, Innovation and Access to New Pharmaceuticals*, 5 J. INT'L ECON. L., 849 (2002); *see also* Edwin Mansfield, *Patents and Innovation: An Empirical Study*, 32 MGMT. SCI. 173 (1986); *see also* Shanker A. Singham, *Competition Policy and the Stimulation of Innovation: TRIPS and the Interface Between Competition and Patent Protection in the Pharmaceutical Industry*, 26 BROOK. J. INT'L L. 363 (2000).

[12] Most of the countries are a part of the WTO. As of April 4, 2003, 146 countries were members of the organization, information *available at* http://www.wto.org/english/thewto_e/thewto_e.htm (last visited Dec. 26, 2003) (thus, by deciding to opt out of the system, an individual country is not only isolated, it is also deprived of benefits that may accrue from a multilateral trading system).

time remaining within the system. In this paper, I highlight the possible solutions within the TRIPS Agreement, and discuss the recent developments within the WTO framework. Part II of the paper evaluates TRIPS from a human rights perspective to see what extent the text of the TRIPS Agreement accommodates human rights concerns. Part III highlights the three possible options: compulsory licensing, parallel imports and the Article 30 exception. It concludes that the latter would provide the most feasible mechanism. Part IV discusses the Doha Declaration, the TRIPS Council's Decision on Paragraph 6 of the Doha Declaration, and notes that the WTO is favoring a solution that might fail to achieve the intended results. Finally, I conclude that the current controversy strengthens the calls for linking human rights, intellectual property rights, and trade so that the current system overcomes the technocratic notions that continue to bind it and make it blind towards the majority of the global population.

II.
TRIPS AND A HUMAN RIGHTS PERSPECTIVE

There is an implicit reference to human rights issues in TRIPS if the agreement is examined from a human rights perspective. At the same time, international human rights agreements also suggest a need for protecting intellectual property rights. The Universal Declaration of Human Rights (UDHR)[13] does not expressly refer to intellectual property rights, but Article 27.2 states that "[e]veryone has 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." Clause 1 to Article 27 also states, however, that everyone has "the right freely to participate in the cultural life of the community, to enjoy the arts and to share in scientific advancement and its benefits." Article 27, thus carries with it a tension familiar to intellectual property law – the tension between protection and participation. In other words, "tension between rules that protect the creators of information, and those that ensure the use and diffuse of information."[14] Similarly, Article 15 of The International Covenant on Economic Social and Cultural Rights (ICESCR)[15] identifies a need to balance the protection of both public and private interests in intellectual property. This article recognizes the right of everyone to take part in cultural life, and to enjoy the benefits of scientific progress and its applica-

[13] G.A. Res. 217A, U.N. GAOR, 3d Sess., Supp. No. 13, at 48, U.N. Doc. A/810 (1948).

[14] Drahos, *supra* note 2, at 358.

[15] G.A. Res. 2200A, U.N. GAOR, 21st Sess., Supp. No. 16, *at* 49, U.N. Doc. A/6316 (1966) [hereinafter ICESCR].

tions.[16] It also recognizes, however, 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 or she is the author.[17] The article binds States to design intellectual property systems that strike a balance between promoting general public interests by granting access to new knowledge easily, while at the same time protecting the interests of authors and inventors in such knowledge.

As far as TRIPS is concerned, the text is fairly explicit in regards to patent protection in all fields of technology on issues such as: the grant of rights, the duration of protection, and modes of enforcement. Potential links between human rights and TRIPS are indicated by the presence of provisions such as Articles 7, 8, 29 and 31. (A) Promoting technological innovation, transfer and dissemination of technology in a manner conducive to social and economic welfare;[18] (B) allowing the member states (i) to adopt measures necessary to protect public health and nutrition,[19] (ii) to promote the public interest in sectors of vital importance to their socio-economic and technological development,[20] (iii) to prevent the abuse of intellectual property rights,[21] (iv) to restrict practices which unreasonably restrain trade or adversely affect the international transfer of technology[22] and (v) to take action against anti-competitive practices;[23] (C) providing an exception for (i) the commercial exploitation to protect public order or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment[24] and (ii) diagnostic, therapeutic and surgical methods for the treatment of humans or animal[25] are measures that - at least in theory - are conducive to the promotion and protection of human rights and seek to maintain the balance sought under Article 27 of UDHR and Article 15 of ICESCR.

Therefore, a prima facie case can be made that intellectual property rights and human rights accommodate each other in international instruments, and there is very little conflict between the two. Nonetheless, there exist some fundamental differences which are summarized as follows: (a) the overall thrust of the TRIPS Agreement is the promotion of innovation through the provision of commercial incen-

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16 *Id.* art. 15(1)(a)-(b).
17 *Id.* art. 15(1)(c).
18 TRIPS, *supra* note 1, art. 7.
19 *Id.* art. 8(1).
20 *Id.*
21 *Id.* art. 8(2).
22 *Id.*
23 *Id.* art. 31(k).
24 *Id.* art. 27(2).
25 *Id.* art. 27(3)(a).

tives.[26] The various links with the subject matter of human rights (the promotion of public health, nutrition, environment, and development) are generally expressed in terms of exceptions to the rule, rather than as the guiding principles themselves, and are made subject to the provisions of the Agreement. (b) While the Agreement identifies the need to balance rights with obligations, it gives no guidance on how to achieve this balance. The Agreement only alludes to the responsibilities of patent holders that should balance those rights in accordance with its own objectives.[27] (c) Like any international treaty, TRIPS removes a degree of autonomy from the States. Prior to TRIPS, states could decide the level of protection they would allow to cover a technology they saw relevant to their development and public needs.[28] (d) The protection contained in the TRIPS Agreement focuses on the forms of protection that have developed in industrialized countries.[29] For example, in the case of patents, protection in the Agreement is most relevant to the protection of modern forms of technology (i.e. biotechnology), and most relevant to innovators situated in a select number of industrialized countries. This inference comes from World Bank figures relating to patent applications that show an overwhelming presence of technology holders and applications in developed nations.[30] Other factors for a human rights approach are efforts to extend patent life beyond the 20-year TRIPS minimum, to limit compulsory licensing in ways not required by TRIPS, and to limit exceptions that facilitate prompt introduction of generics. These measures have been referred to as – 'TRIPS plus'.[31]

Thus, there are doubts if the TRIPS Agreement satisfies the concerns raised from a human rights perspective. As noted in the High Commissioner's report, "a human rights approach requires that the public/private balance under Article 15 of ICESCR should be struck with the primary objective of promoting and protecting human rights. The balance should not work to the detriment of any other rights in the Covenant, and should also be consistent with the Vienna Declara-

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[26] *Report of the High Comm'r of the Human Rights Comm'n*, The Impact of the Agreement on Trade-Related Aspects of Intellectual Prop. Rights on Human Rights, ¶ 20-28, U.N. Doc. E/CN.4/Sub.2/2001/13 (2001) *available at* http://www.unhchr.ch/Huridocda/Huridoca.nsf/(Symbol)/E.CN.4.Sub.2.2001.13.En? [hereinafter U.N. CHR Report].

[27] *Id.* ¶ 23.

[28] *See generally* Lewis, *supra* note 4.

[29] U.N. CHR Report, *supra* note 26, ¶ 25.

[30] *Id.* (citing World Bank, *World Development Indicators 2000*, World Bank, Washington, D.C.: World Bank, Table 5.12).

[31] *Globalization, TRIPS and Access to Pharmaceuticals*, WHO POLICY PERSPECTIVES ON MEDICINES: WHO MEDICINES STRATEGY: 2000-2003, No. 3, March 2001, at 4.

tion that declares, "human rights are the first responsibility of Governments."[32]

III.
POLICY OPTIONS UNDER TRIPS

This part examines the rules of interpretation used when interpreting the TRIPS Agreement, and the three options under TRIPS: compulsory licensing, parallel imports, and 'limited exceptions' to patent rights under Article 3. The conclusion is that the correct interpretation of the TRIPS Agreement must be one that is consistent with States' obligations to respect, protect, and fulfil human rights and also the rights of a patent holder. First, however, it is important to indicate that historically TRIPS and its provisions relating to patent rights have been a highly politically sensitive issue,[33] and remain still today. Many commentators have examined recent controversies through a political lens.[34] The "Declaration on TRIPS and Public Health"[35] adopted at the Fourth WTO Ministerial Conference held in 2001 at Doha (Doha Declaration), and the recent decision by the Council for TRIPS for "Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health"[36] are significant developments in this regard. The next part will discuss how genuinely these two documents address the real issue.

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[32] U.N. CHR Report, *supra* note 26, ¶ 13.

[33] *See* DANIEL GERVAIS, THE TRIPS AGREEMENT: DRAFTING HISTORY AND ANALYSIS 11-25 (1998).

[34] An indication of that are the reports regarding anthrax controversy in the US and Canada in 2001, where both the countries threatened using the option of compulsory licenses to force Bayer to supply anthrax drug at a substantially reduced market price, *see* Editorial, 358 *The Lancet 9293*, 10 November 2001; *see also* Leo Lewis, *Anthrax drugs sparks outcry*, Independent on Sunday October 28, 2001, at 5; *see also* Sarah Bosley, *Drug Dealing,* The Guardian, October 24, 2001.

[35] Declaration on the TRIPS Agreement and Public Health, Nov. 20, 2001, WTO Res., 4th Sess., Ministerial Conference, WT/MIN(01)/DEC/2 [hereinafter Doha Declaration]. However, the content of the declaration was hotly debated with a typical north-south axis is play. Prior to and after the Doha Declaration papers submitted in WTO meetings on behalf of the US and the developing countries justify such a conclusion. Two contrasting drafts before the Doha Meeting are *available at* http://www.wto.org/english/tratop_e/trips_e/mindecdraft_w312_e.htm & http://www.wto.org/english/tratop_e/trips_e/mindecdraft_w313_e.htm (last visited April 1, 2002). For the post Doha developments, see http://www.wto.org/english/news_e/news02_e/trips_reg_020307_e.htm (last visited April 1, 2002); *see also* Ellen't Hoen, *Public Health and International Law: TRIPS, Pharmaceutical Patents, and Access to Essential Medicines: a Long Way from Seattle to Doha*, 3 CHI. J. INT'L L. 27 (2002). Many activists have trumpeted Doha Declaration to be a victory for the developing world.

[36] Doc. No. WT/L/540, *available at* http://www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm [hereinafter TRIPS Council Decision].

A. *Rules of Interpretation*

Well established in international law is that the Vienna Convention on the Law of the Treaties[37] is an authoritative statement, and a definite guide on treaty interpretation. According to Article 31 of the Vienna Convention, "[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 light of its object and purpose."[38] The Article further provides that in addition to the text, its article, and preambles, the context for the purpose of interpretation of a treaty shall comprise: (a) any agreement relating to the treaty made between all the parties in connection with the conclusion of the treaty; and (b) any instrument made by one or more parties in connection with the conclusion of the treaty, and accepted by the other parties as an instrument related to the treaty.[39] Together with the context, subsequent treaties and practice relating to the treaty and "any relevant rules of international law applicable in the relations between the parties" may also be used.[40] If the interpretation according to Article 31 leaves ambiguity, obscurity, or leads to a result which is manifestly absurd or unreasonable, there are supplementary means of interpretation. These include the preparatory work of the treaty, and the circumstances of its conclusion.[41]

The TRIPS Agreement is an annexure to the Marrakesh Agreement Establishing the WTO, and WTO law should guide its interpretation. Article 3.2 of the WTO's Dispute Settlement Understanding states that the existing rights and obligations of the member states must be clarified in accordance with customary interpretation rules of public international law.[42] WTO case law accepts that the Vienna Convention is a codification of customary international law, therefore binding all States,[43]and that Articles 31 and 32 of the Vienna Convention have attained the status of a rule of customary international law.[44] Thus, TRIPS should be interpreted first according to its text,

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[37] Vienna Convention of the Law of Treaties, opened for signature May 22, 1969, 8 I.L.M. 679 (entered into force Jan. 17, 1980) [hereinafter Vienna Convention].

[38] *Id.* art. 31(1).

[39] *Id.* art. 31(2).

[40] *Id.* art. 31(3).

[41] *Id.* art. 32.

[42] *General Agreement on Tariffs and Trade - Multilateral Trade Negotiations (The Uruguay Round): Understanding on Rules and Procedures Governing the Settlement of Disputes*, 33 I.L.M. 112, 134 (1994).

[43] *United States - Standards for Reformulated and Conventional Gasoline*, Report of the Appellate Body, WT/DS2/AB/R (April 29, 1996) at 17.

[44] *Japan - Taxes on Alcoholic* Beverages, Report of the Appellate Body, WT/DS8/AB/R, WT/DS10/AB/R, WT/DS11/AB/R (October 4, 1996) at 10 – 12.

including its preambles. It should then be interpreted according to prior decisions interpreting the treaties, customary international law, other relevant rules of international law, writings of the most "highly qualified publicists" related to TRIPS, and the preparatory work and circumstances of the Agreement of TRIPS, if a reasonable interpretation is not available through other means.[45] Additionally, paragraph 5(a) of the Doha Declaration states that "[i]n 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." The second part of the fourth paragraph of Doha Declaration also states ". . .we reaffirm the right of WTO Members to use, to the full, the provisions in the TRIPS Agreement, which provide flexibility for this purpose." However, the chapeau of the paragraph 5 of the Declaration clarifies that the members have flexibility but must "maintain [their] commitments in the TRIPS Agreement."[46]

There are numerous provisions in the TRIPS Agreement, in particular the Preamble and Articles 1, 7, 8, 27, 30 and 31 which indicate that provisions of the TRIPS can be interpreted to allow member countries flexibility in balancing their obligations to accord exclusive patent rights in fulfilment of their obligations to protect the right to health. For example Article 7 (Objectives) provides that intellectual property rights should contribute "to the promotion of technological innovation and to the transfer and dissemination of technology, to the

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[45] David Palmeter & Petros C. Mavroidis, *The WTO Legal System: Sources of Law*, 92 AM. J. INT'L L. 398, 399-413 (1998).

[46] The legal status of the declaration is disputed. It has been suggested that the Declaration constitutes a supplementary means of interpretation under Article 32 of Vienna Convention on the Law of Treaties, *see* Carmen Otero Garcia-Castrillon , *An approach to the WTO Ministerial Declaration on the Trips Agreement and Public Health*, 5 J. INTL. ECON. L. 212 (2002); *but see* Steve Charnovitz, *The Legal status of the Doha Declarations*, 5 J. INT'L ECON. L., 207 (2002) (according to another view, a Ministerial Conference pronouncement is not treaty language or a treaty interpretation, but, it might be a subsequent agreement between the parties regarding 'the application' of a treaty's provisions which is recognised by the Vienna Convention on the Law of Treaties, Article 31.3 (a), as a proper consideration in treaty interpretation); *but cf.* James T. Gathii, *The Legal Status of the Doha Declaration on Trips and Public Health Under the Vienna Convention on the Law of the Treaties*, 15 HARV. J. L.& TECH. 291 (2002) (yet, another view is that under customary international law the declaration constitutes an interpretative part of the interpretation of TRIPS). The declaration is significant because it constitutes an acknowledgement that provisions of TRIPS and by virtue of it, the present patent regime, has a major role to play in the accessibility of medicines to vast chunk of humanity. Post-Doha, there is little or almost no chance that for the time being complaints would be presented before the Dispute Settlement Body on these issues. The declaration can also play a big role in evolution of a more stable and a fair legal regime if the WTO members show understanding to each other's interests and need to address the health crisis and decide to follow the declaration as an interpretation of the TRIPS Agreement.

mutual advantage of producers and users of technological knowledge, and in a manner conducive to social and economic welfare and to the balance of rights and obligations." The Agreement resumes this theme in Article 8 (Principles) allowing WTO member countries to adopt measures necessary to protect public health and promote the public interest in sectors vital to their development, as well as to prevent the abuse of patent rights and practices that unreasonably restrain trade and the international transfer of technology. The earlier two articles amplify the recognition in the Preamble that 'developmental and technological objectives' should underlie 'public policy objectives of national systems for the protection of intellectual property'.

B. Compulsory Licensing

The TRIPS Agreement does not mention the term 'compulsory license' in the text, but Article 31 is understood to allow compulsory licensing and government use. Compulsory licensing allows a third party to exploit a patent, whereas government use allows the government (through an authorised party if appropriate) to exploit the invention. Article 31 does not limit the grounds on which compulsory licensing is permissible, and there is a distinct balancing act to establish a government's right to issue compulsory licenses while attempting to safeguard the rights of the patent holder whenever possible.[47] The article does expressly refer to a number of circumstances, however, when compulsory licenses can be granted. These situations include: (a) situations of national emergency or extreme urgency,[48] (b) cases of public non-commercial use,[49] (c) cases where there is a need to 'correct anti-competitive practices,'[50] and (d) cases of dependent patents, where the exercise of one patent is dependent on the infringement of another.[51] In general, any potential user is required to have unsuccessfully undertaken prior negotiations with the patent owner but for the first two situations where there is no requirement to negotiate.

Compulsory license has long been recognized as the most important tool for addressing the adverse effects of the patent grant on pub-

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[47] Robert Weissman, *A Long Strange TRIPs: The Pharmaceutical Industry Drive to Harmonize Global Intellectual Property Rules, and the Remaining WTO Alternatives Available to Third World Countries*, 17 U. PA. J. INT.'L ECON. L. 1069, 1113 (1996) [hereinafter Weissman].

[48] TRIPS, *supra* note 1, art. 31(b).

[49] *Id.*

[50] *Id.* art. 31(k).

[51] *Id.* art. 31(l).

lic welfare.[52] A compulsory license can be used either by way of (a) actually granting it and exploiting the license or (b) threatening its use and forcing the patent holder to revise its own pricing and supply strategy. Developing countries, in particular have a compelling need to use compulsory licensing to improve access to medicines, vaccines, and other public health related inventions.

According to one view, the conditions of Article 31 are not a significant restriction to the introduction and efficient operation of compulsory licensing regime.[53] No developing country to date, however, has made use of compulsory licensing as a tool to address public health issues.[54] There are a number of economic and political reasons for this,[55] but there are also legal impediments as well. A number of conditions need to be satisfied before a country can legally grant compulsory license. There must be an effort to obtain authorization from the right holder "within a reasonable period of time" on "reasonable commercial terms."[56] The article further requires that the right holder shall be paid "adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization."[57] One of the most important restrictions is contained in Article 31(f) – the use of commercial license should be "predominantly for the supply of the domestic market." The term "predominantly" in Article

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[52] Frederick M. Abbott, *Compulsory Licensing for Public Health Needs: The TRIPS Agenda at the WTO after the Doha Declaration on Public Health*, Quaker United Nations Office, Occasional Paper No. 9 (2002), *available at* http://www.geneva.quno.info/main/search_publication.php?loop=0# (last visited December 26, 2003) [hereinafter Abbot]; *see* Carlos Correa, *Integrating Public Health Concerns into Patent Legislation in Developing Countries 93-94 at* http://www.southcentre.org/publications/publichealth/publichealth.org (for compulsory licensing provisions in various national legislations) [hereinafter Correa].

[53] Weissman, *supra* note 47, at 1113.

[54] F.M. Abbott, *The TRIPS Agreement, Access to Medicines and the WTO Doha Ministerial Conference* 11 (2002), *available at* http://www.geneva.quno.info/pdf/OP7Abbot1.pdf.

[55] The International Federation of Pharmaceutical Manufacturers Association (IFPMA) has on its website the following reasons against the issuance of compulsory licenses: (a) They may reduce incentive to innovate. If a country adopts compulsory license measures, then a natural consequence is for fewer research funds to be allocated either to that country or disease area due to the resulting disincentives for research. (b) Generic drugs manufactured under a compulsory license in developing countries will be parallel exported to developed countries. (c) Governments tend to use compulsory licensing measures as industrial policy instead of using it as a pro-consumer tool. (d) There are safety reasons: developing countries do not have the infrastructure or administrative systems in place to ensure and monitor the correct supply and delivery of medication; *see* IFPMA, TRIPs, PHARMACEUTICALS AND DEVELOPING COUNTRIES: IMPLICATIONS FOR HEALTH CARE ACCESS, DRUG QUALITY AND DRUG DEVELOPMENT (2002), *available at* http://www.ifpma.org/documents/NR86/TRIPS.pdf.

[56] TRIPS, *supra* note 1, art. 31(b).

[57] *Id.* art. 31(h).

31(f) implies that some exportation under compulsory license from the exporting nation could be allowed.

From a policy perspective, this is a virtual impediment. Less-developed nations that lack infrastructure and technical capabilities to build a reliable domestic industry able to supply modern pharmaceutical products are most likely to face serious problems due to this requirement. Even Canada, with a high per capita income, excellent universities, and a population during the 1970s of roughly 22 million, found it necessary to import most of the bulk pharmaceuticals ultimately supplied under compulsory licenses.[58] Thus, smaller less developed nations will have to issue their compulsory licenses mainly for importation rather than domestic production. This in turn requires that competitive global market supply sources exist.[59] On the other hand, countries that have the capacity to export compulsory licensed drugs are prevented from exploiting to the full scale of their economic position. Furthermore, a successful compulsory license requires expeditious licensing procedures. Article 31 also requires judicial or other independent review of the decisions taken by the licensing authority,[60] which might take too long if examined from a pharmaceutical company's perspective.[61] The Agreement does not provide any guideline for the exact interpretation of significant terms such as "reasonable period of time,"[62] "reasonable commercial terms,"[63] "national emergency,"[64] "predominantly for the supply of the domestic market" and "adequate remuneration."[65] Thus, the text of Article 31 does not fully develop the factors required for the issuing of compulsory licenses under legitimate circumstances.[66] Since no dispute has been referred to the WTO Dispute Settlement Mechanism on the issue of compul-

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[58] F.M. Scherer & Jayashree Watal, *Post-TRIPS Options for Access to Patented Medicines in Developing Countries* 29 (Comm'n on Macroeconomics & Health, Working Paper No. WG4:1, 2001) *available at* http://www.cmhealth.org/docs/wg4paper1.pdf (last visited January 28, 2004)[hereinafter Scherer & Watal].

[59] Abbott, *supra* note 52, at 29.

[60] Scherer & Watal, *supra* note 58, at 28-29.

[61] The longer the issuance of compulsory licenses is delayed after patented drugs enter the marketplace, the less time licensees have to recover their startup costs and the more difficult it is to achieve effective competition among multiple generic substitute suppliers.

[62] Alan O. Sykes, *TRIPS, Pharmaceuticals, Developing Countries, and the Doha "Solution"*, 3 CHI. J. INT'L L. 47, 52 (2002) [hereinafter Sykes].

[63] *Id.*

[64] *Id.* at 56.

[65] According to Weissman, this condition creates a critical obstacle to adopting a compulsory licensing program for a developing nation. Weissman, *supra* note 47, at 1114.

[66] Sara M. Ford, *Compulsory Licensing Provisions under the TRIPs Agreement: Balancing Pills and Patents*, 15 AM. U. INT'L L. REV. 941, 961 (2000)(citing Richard H. Marschall, *Patents, Antitrust and the WTO/GATT: Using TRIPs as a Vehicle for Antitrust Harmonization,* 28 LAW & POL'Y INT'L BUS. 1165, 1188-89 (1997)).

sory license, the precise scope of the provisions in the absence of any ruling from a panel/Appellate Body remains unclear.

C. Parallel Imports

Parallel importing allows importation of a product from a country where a patent holder sells it at a lower price, essentially taking advantage of differential pricing. The underlying concept for allowing parallel imports is that since the inventor has been rewarded through the first sale or distribution of the product, they now have no right to control the use or resale of goods put on the market with their consent. In other words, the inventor's rights have been "exhausted". Parallel imports allow consumers to shop on the world market for the lowest price for a patented product. They are particularly important in the health sector, where the pharmaceutical industry sets prices differently throughout the world for the same medicine. Importation of a patented medicine from a country where it is sold at a lower price enables more patients in the importing country to gain access to the product, without preventing the patent owner from receiving the remuneration for the patented invention in the country where the product was first sold.

The availability of parallel importing depends on how the doctrine of exhaustion of rights is interpreted. The language of Article 6 of TRIPS excludes the patent rights exhaustion question from WTO's dispute resolution jurisdiction, unless there is discrimination based on the nationality of the rights holder.[67] It is interesting to note that an instrument supposed to be comprehensive on intellectual property matters overlooks this significant issue. General GATT principles seem to support the permissibility of parallel imports[68] and WHO also explicitly supported the use of parallel imports in order to advance the principle of 'preferential pricing in poor countries.'[69] Although it appears that member countries have a very broad leeway to implement parallel importation policies, the doctrine of international exhaustion as applied to patents remains controversial from both legal and economic aspects. There is an economic risk that the doctrine of exhaustion may discourage price discrimination, favoring the developing

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[67] Article 6 of the TRIPS states that: "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." 33 I.L.M. 1125, 1200 (1994).

[68] Correa, *supra* note 52, at 77.

[69] *Id.* at 77 (WHO has stated that "in cases where drug prices are higher in poor countries than in richer ones, recourse to parallel imports in low-income countries in order to reduce prices might be appropriate, while preventing parallel exports to industrialized countries")

countries. If parallel imports were to be admitted generally, then companies would tend to charge a single price worldwide, leading to an increase in the supposedly lower price that may otherwise be charged in low-income countries. Cross-market leaks concern the pharmaceutical industry because they could reduce its profit margins, and thereby its ability to recoup R&D investments. There are further questions concerning parallel importation from markets where pharmaceuticals prices are regulated. As Correa points out, overuse of the exhaustion doctrine could conflict with the exclusive right of importation conferred by article 28(a) of TRIPs, and with the thrust of article 27(1) of TRIPs, which forbids discrimination "as to . . . whether products are imported or locally produced."[70] A number of developing countries have been forced to remove parallel importing provisions from their patent legislation. For example, Thailand's patent law, which previously allowed parallel importation of generic medicines in some instances, now precludes it entirely.[71] Nevertheless, in the absence of any definite legal guidance, it is still an option for developing countries to allow international exhaustion, parallel importing, and to continue to be TRIPS compliant.

D. Article 30 Solution

Article 30 of TRIPS expressly authorizes Members to provide "limited exceptions" to patent rights under certain conditions.[72] The term "limited exceptions" in the Article allows for deviations from general rules within established boundaries. The exceptions should not unreasonably conflict with the normal exploitation of patents and should not unreasonably prejudice the legitimate interests of patent holders by taking into account the legitimate interests of third parties. One example of allowable exceptions could be the so called 'Bolar' exception. This exception allows generic manufacturers to start the approvals process from public health authorities for marketing generic versions of patented drugs before the patent expires to ensure that the generic drug is ready to market as soon as the patent expires. The Bolar exception is recognised in both developed and developing coun-

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[70] *Id.* at 76 ("Other authorities counter that article 28 is subject to article 6 and therefore cannot be subject to WTO dispute settlement procedures").

[71] *See generally* Rosemary Sweeney, *The U.S. Push for Worldwide Patent Protection for Drugs Meets the AIDS Crisis in Thailand: A Devastating Collision*, 9 PAC. RIM L. & POL'Y J. 445 (2000).

[72] TRIPS, *supra* note 1, art. 30 ("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").

tries.[73] This exception provides some relief from the artificial extension of patent rights beyond the normal life of the patent; but in order to gain full benefit from the exception, the capability to manufacture sufficient quantities of the generic drug to satisfy market demand must exist as soon as possible after the patent expires.

1. Exceptions under Article 30.

If Article 30 is read with Articles 7 and 8 of TRIPS, limited exceptions can be justified for public health crisis in developing countries. According to Abbott, criteria for authorizing exceptions under Article 30 may include: (a) whether the importing country is confronting an un-addressed health need; (b) whether the importing country has the financial resources to pay for patent drugs or other public health related inventions, whether locally produced or imported, to supply the needs of 'all' those in the need of treatment; and (c) whether the exporting country has the capacity to supply low-price pharmaceuticals or other public health inventions.[74] The decision to use Article 30 would be with the country that exports the drugs. It would have to consider whether allowing a generic competitor to manufacture and import a patented drug would unreasonably harm the interests of the patent holder. If the country considers such a move to be detrimental to its interests, it may refuse to authorize this exception, but it might also treat the social welfare benefits of access to medicines and balance appropriately the interests of the patent holder. As far as the importing country is concerned, it might have to issue compulsory licenses to overcome the objection from a local patent holder. But, in situations where the drug is not under patent or the local patent holder consents to importation, there would be no requirement of issuing a compulsory license and use of Article 30 would be enough.

Authorization of the export of public health related inventions without the consent of the patent holder would not be dependent on Article 31(f). There would be no need of a formal interpretation of Article 31 to allow compulsory licenses for imports to be used in connection with exports undertaken under Article 30. This exception would allow a country that has production facilities for drugs to manufacture and export without going through the laborious procedure of issuing a compulsory license. An interpretation of Article 30 that al-

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[73] Consumer Project on Technology, *Existing and Model Bolar Provisions* (showing the Bolar provisions of Argentina, Canada and the United States), *available at* http://www.cptech.org/ip/health/research/legislation.html (last visited Dec. 26, 2003).

[74] Abbott, *supra* note 52, at 33.

lows exports of health products without the consent of the patent holder would have the following advantages over Article 31 approach:

(a) It would provide the simplest and most direct solution to the problem for developing countries.
(b) It could be limited to health problems the Doha Declaration seeks to address by restricting its application to exports of health products.
(c) It could allow the decision for a compulsory license to remain in the country of consumption. It is neither logical nor desirable for an importing country to have to rely on an exporting country to issue a compulsory license on its behalf, which would be the case under an Article 31 solution.
(d) It would allow compensation to be paid to the patent holder in the country of consumption, if a patent exists. If a patent does not exist in the importing country, then logically no compensation should be paid. It does not make sense for compensation to be paid in the exporting country where the product is not consumed which would be the case under the Article 31 solution and hence may also result in double compensation.

2. *Canada Generics*

Article 30 is more operationally feasible as exporting countries would be more willing to use it by making a one-off amendment to their patent laws to implement this exception and it also safeguards the interests of all the stakeholders involved.[75] However, in the Canada Generics case, a WTO panel, on a complaint by the European Union, held that a Canadian regulation that permitted manufacture and storage of patented products before the expiration of the patent was not compliant with the TRIPS Agreement, though generic manufactures could test patented products before the required period of protection expired.[76]

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[75] Amir Attaran, *The Doha Declaration on the TRIPS Agreement and Public Health, Access to Pharmaceuticals, and Options under WTO Law*, 12 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 859, 870 (2002) [hereinafter Attaran] ("[f]rom the activist perspective, it is certainly more straightforward to use. From the industry perspective it avoids broaching amendments to TRIPS, which could lead to the undoing of TRIPS in more dangerous ways (e.g., tampering with Article 27.1 and WTO members' obligation to offer patent protection for pharmaceuticals). From all perspectives, it is likely to be more expeditious, which means less time and energy spent on conflict, and more rapid progress toward solving what could be a future barrier to pharmaceutical access").

[76] Report of the Panel. *Canada-Patent Protection of Pharmaceutical P*roducts, WT/DS114/R at 146, ¶ 7.7 (Nov. 17, 2000) (the disputed sections of the Canadian Patent Act, which created exceptions to the exclusive rights of patent owners read as follows: Section 55.2(1): "It is not an infringement of a patent for any person to make, construct, use or sell

It was stated that for a measure to satisfy the requirements of Article 30, it should satisfy the following three requirements: (a) it should be limited; (b) it should not unreasonably conflict with a normal exploitation of the patent; and (c) it should not unreasonably prejudice the legitimate interests of the rights holder, taking into account the legitimate interests of third parties.[77] These conditions need to be interpreted in relation to each other and a separate meaning should be given to each of the three to avoid redundancy.[78] By taking a skewed approach the panel held that "limited exception" means a "narrow exception – one which makes only a small diminution of the rights in question."[79] "Normal exploitation" includes a "more or less brief period of market exclusivity after the patent has expired" by precluding the generic competitors from building an inventory during the patent period,[80] and when considering "legitimate interests", the legitimacy and weight of the patent owner's legitimate interests get priority over the third party interests.[81] Therefore, it could be argued that if the panel did not allow stockpiling of a patented product, it seems impossible to authorize the manufacture for export and sale of a product when a patent is in force.[82] Thus, either an exception needs to be created for the current situation or the law needs to be repealed thereby causing legal uncertainty[83] and it remains doubtful if the Bolar exception would provide any real benefit for the majority of the developing countries.

One of the first things to note is that the case was dealing with substantially different context and it is difficult to predict how the case would be applied in the present circumstances. The panel's interpretation is not an authoritative interpretation on legitimacy of all types of regulatory review exceptions or other relevant aspects of national patent systems. Furthermore, the interpretation adopted in Canada

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the patented invention solely for uses reasonably related to the development and submission of information required under any law of Canada, a province or a country other than Canada that regulates the manufacture, construction, use or sale of any product." (Regulatory Review Exception).

Section 55.2 (2): "It is not an infringement of a patent for any person who makes, constructs, uses or sells a patented invention in accordance with subsection (1) to make, construct, or use the invention, during the applicable period provided for by the regulations, for the manufacture and storage of articles intended for sale after the date on which the term of the patent expires." (The Stockpiling Exception)).

77 *Id.* ¶ 7.20.

78 *Id.* ¶ 7.21.

79 *Id.* ¶ 7.30.

80 *Id.* ¶ 7.56.

81 *See id.* ¶ 7.60.

82 Attaran, *supra* note 75, at 872.

83 *Id.*

Generics was twisted and in violation of the rule of interpretation of international treaties. In deciding on "limited exception" and "legitimate interests", the panel skipped to the negotiating history of the TRIPS Agreement as a source of treaty interpretation. It did not apply the interpretative sources under Article 31 of the Vienna Convention, according to which Article 30 of TRIPS should have been interpreted in light of the context, purpose and object of the TRIPS Agreement.[84] The narrow reading of the term "limited exception" was also repugnant to the Appellate Body's decision in EC-Hormones where it was held that ". . .merely characterizing a treaty provision as an exception does not by itself justify a stricter or narrower interpretation of that provision than would be warranted by examination of the ordinary meaning of the actual treaty words, viewed in context and in the light of the treaty's object and purpose. . ."[85] or, in other words, by applying the normal rules of treaty interpretation. According to Howse, the correct approach would have been to interpret "limited" by not only taking into account the restriction on the right holders' interests but also public health and the interests of consumers generally.[86] On the issue of normal exploitation of the patents, before construing the term "normal exploitation", it needs to be considered if a measure which aims to prevent or stop the abuse of a patent because of local non-working or insufficient working or higher prices of the patent product or a measure for national emergency or to deal with anti-competitive actions of the patent holder could affect the normal exploitation of the patent by the patent holder. For example, an action of a patent holder to intentionally increase the price of the product by not supplying it in enough quantities to the market cannot be justified as "normal exploitation" of the patent. Only where a government measure does not aim to curtail practices analogous to those above mentioned should the enquiry move to the interpretation of the phrase "normal exploitation." In Canada Generics, while dealing with that phrase, the panel was guided purely by economic considerations and reflected a bias to protect the rights of the patent holder.[87] The distinction drawn by the panel between the testing exception and stockpiling provision was artificial and cannot be supported by the

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[84] Robert L. Howse, The Canadian Generic Medicines Panel: A Dangerous Precedent in Dangerous Times, 3 J. WORLD. INTELL. PROP. 493, 496 (2000) [hereinafter Howse].

[85] EC Measures Concerning Meat and Meat Products (Hormones) (Report of the Appellate Body of the World Trade Organization, WT/DS26/AB/R, WT/DS48/AB/R) Jan. 16, 1998, *at* ¶ 104 (relied upon by Howse, *supra* note 82).

[86] Howse, *supra* note 84, at 497-98.

[87] *Id.* at 499.

text of the article.[88] Similarly, merely because the Article mentions the phrase "legitimate interests of the patent owner" before "legitimate interests of third parties", it does not automatically lead to a conclusion that the patent owners' interests are more important. The provision is primarily to balance the interests of the patent holder and the third parties.[89] The interpretation adopted by the panel silenced the "competing social and economic interests entirely by starting off with defining the rights holder's interests as so weighty or fundamental that other legitimate interests cannot possibly outweigh the prejudice to the right holder's interests."[90] Moreover, the composition of the clause and the presence of a comma before the last clause of the article lead to an inference that the legitimate interests of third parties are to be taken into account with all other clauses of Article 30; such as normal exploitation and the legitimate interests of the patent holder.

Canada Generics also discussed whether the treatment of patent holders in the field of pharmaceutical invention as less favourable than other inventions violated the anti-discrimination provision in Article 27.1 of TRIPS. The panel found that the exceptions under Article 30 cannot include exceptions to the non-discrimination provisions in Article 27.1 of the TRIPS Agreement. Thus, if a state measure is designed in such a way that it is applicable only in the field of pharmaceutical products without being applicable to other sectors, according to Canada Generics, the measure would be illegal.[91] However, there are adequate grounds to state that this construction is not justified. The non-discriminatory provision in Article 27.1 is different from those found in other WTO Agreements.[92] Article 30 is a broad exception and it can be assumed that exception is explicitly applicable to the subject matter, i.e. patent rights. It is not conditional on some other provision of the TRIPS unlike other provisions which have been qualified by using the phrase "subject to" to that other provision.[93] Moreover, even if it is assumed that Article 30 is subject to Article 27.1, it can still be directed only to the pharmaceuticals as all Article 27.1 provides is that patent rights shall be enjoyable "without discrimination", which implies that unfair or unjustifiably adverse treatment is not allowed.[94] If special regulation of the pharmaceutical industry is

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88 *Id.* at 500.

89 *Id.* at 501.

90 *Id.*

91 Attaran, *supra* note 75, at 871.

92 Howse, *supra* note 84, at 505.

93 *Id.* at 506 (listing arts. 6, 27.1, 36 and 65.1 as examples).

94 Abbot, *supra* note 52, at 38.

specifically required to address important public interests, it cannot be termed as discriminatory. On the other hand, it is recognition of legitimate public interests. "To read Article 30 consistently with world health policy would mean giving clear priority to the legitimate health interests in question over many competing interests of the rights holder; if the reference to public health in Article 8.1 of TRIPS is to have any significance at all, it must surely be that the specific provisions of the TRIPS Agreement should be read in a manner consistent with what is required for the protection of public health, as defined by world health policy."[95]

IV.
DOHA DECLARATION AND THE DECISION OF THE TRIPS COUNCIL

In the above discussion I have indicated that the best possible solution to deal with the current global health crisis would be an article 30 approach. It is an easier, quicker and the least complicated way to take measures to address health crisis in any region of the world. Unfortunately, the discussions in the WTO have failed to move in a direction that prefers an Article 30 approach. In this section I discuss the dialogue within the WTO system to reform the intellectual property regime to provide for affordable medicines, with specific reference to the Doha Declaration and the latest decision of the TRIPS Council.

A. The Doha Declaration

Doha Declaration was significant because for the first time within the WTO it was openly acknowledged that the public health problems in many countries were in part a result of the intellectual property regime under the TRIPS Agreement. The declaration came in the backdrop of an increased mutual sensitivity between the developed and the developing countries in the wake of the terrorist attacks and the anthrax controversy in the U.S. The Declaration was intended to dispel the notion that the organization is not sympathetic to human rights issue and solely concentrates on a trade motivated agenda.

The Declaration proposes a balancing approach to interpretation of TRIPS Agreement.[96] The first four paragraphs of the Declaration

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[95] Howse, *supra* note 84, at 505.

[96] Doha Declaration, *supra* note 35, ¶ 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

are more in the form of a preamble to a statute and lack any substantive rule. In these initial paragraphs, the Ministerial Conference agreed that the TRIPS Agreement had to be a part of wider national and international action to address the grave public health problems afflicting many developing and least developed countries, especially the problems resulting from HIV/AIDS, tuberculosis, malaria, and other epidemics.[97] In paragraphs 3 and 4, the WTO members tried a balancing act. On the one hand the Declaration states that the intellectual property protection is important for the development of new medicines and reiterates the commitment to TRIPS. On the other hand it also acknowledges the effect of IP protection on drug prices and agrees that TRIPS should not prevent Members from taking measures to protect public health. Thus, it affirms the "right of WTO members to use, to the full, the provisions in the TRIPS Agreement, which provides flexibility for [protecting public health]."

The seven paragraph long Declaration leaves open all the possibilities that already existed under the TRIPS Agreement, without providing clear guidance as to which one of the options would be the best to achieve the desired results alluded to in the opening paragraphs. The all important paragraph 5 recognizes the flexibilities available to a member country. Paragraph 5(a) is very broad and could be interpreted along with paragraph 4 to allow resort to the Article 30 exception.[98] It also appears from the Declaration that countries are free to decide what provisions they will have in national laws relating to parallel importing.[99] Member nations are only required to apply most-favored nation and national treatment systematically.

However, the emphasis seems to be on the use of the compulsory licensing option. As far as the compulsory license is concerned, the Declaration states: "each member has the right to grant compulsory licences and the freedom to determine the grounds upon which such licences are granted."[100] The issue, however, is not whether compul-

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WTO Members' right to protect public health and, in particular, to promote access to medicines for all").

97 *Id.* ¶ ¶ 1 & 2.

98 Paragraph 5(a) reads as follows: "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."

99 Doha Declaration, *supra* note 35, ¶ 5(d) ("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").

100 *Id.* ¶ 5(b) (the paragraph provides as follows: "Each member has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted").

sory licensing is permitted under TRIPS but under what circumstances can it be done. The Declaration, except for allowing the use of compulsory license, does not throw any light on how to interpret terms like "reasonable commercial terms," "predominantly for the supply of the domestic market" and "adequate remuneration." Thus, many of the questions remain unanswered. For example, it is unclear if a patent holder would have to acquiesce to the compensation decided by the government or it merely creates a presumption that the compensation given would be considered adequate and fair? Would the adequate compensation involve R&D costs for the drug in question and also the unsuccessful research aimed at the same medical problem?[101] Furthermore, if a member country could be allowed to grant compulsory licenses in favour of non-domestic manufacturers is not obvious.[102]

The only concession the Member states were given was a right to determine what constitutes a "national emergency." Without defining any parameters to be considered nor giving a hint as to the factors to be taken into account before declaring a national emergency, it was provided that "public health crisis, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics can represent a national emergency or other circumstances of extreme urgency."[103]

Doha Declaration in paragraph 6 recognized the difficulties that countries with insufficient or no manufacturing capacities in the pharmaceutical sector may encounter in making effective use of compulsory licenses under TRIPS. Thus, it left to the TRIPS Council to find "expeditious solution to this problem and to report to the General Council before the end of 2002". In subsequent meetings of the TRIPS Council, however, it was quite clear that the U.S., advocating the cause of its pharmaceutical industry, was in no mood for concessions. By December 2002, the talks reached a stalemate primarily over the scope of diseases to be covered. The group of African, Caribbean and Pacific countries wanted the solution under Paragraph 6 to have reference to the first paragraph of the Doha Declaration, i.e., a specific reference to the public health problems afflicting many developing and least developing countries, especially resulting from HIV/AIDS, tuberculosis and malaria. However, the U.S. wanted any solution to be limited to the diseases mentioned above or other infectious epidemics of comparable gravity and scale. This was opposed by the

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101 Sykes, *supra* note 62, at 151.

102 Divya Murthy, *The Future of Compulsory Licensing: Deciphering the Doha Declaration on the TRIPS Agreement and Public Health*, 17 AM. U. INT'L L. REV. 1299, 1332-1336 (2002) (arguing that term 'third party' should not be limited to domestic manufacturers).

103 Doha Declaration, *supra* note 35, ¶ 5(c).

majority of the WTO members as an attempt to limit the scope of diseases already agreed to at Doha. Even as late as June 2003, no consensus seemed to be emerging. As the developing countries backed by many international organizations were in no mood to back down, and a fear of possible backlash at Cancun loomed large, the U.S. did bow to the pressure. Just few days before the 2003 Cancun Ministerial Conference, the Council for TRIPS arrived at a decision on the "Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and public health."[104]

B. Decision of the TRIPS Council

The decision aims to provide waivers from the obligations set out in paragraphs (f) and (h) of Article 31 if certain exceptional circumstances exist. The decision lays down several conditions to be met both by the importing and the exporting country for a compulsory license to be granted under the Decision, and the general responsibility of all WTO members.

An importing member country has to fulfill the following conditions: (A) to qualify as an eligible importing member, the country should either be a least developed country or any other member that notifies the Council for TRIPS of its intention to use the waiver only in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use.[105] Some member countries have already declared that they will not use the system or have limited the situations where they can use the system.[106] (B) The notification from the importing country should:[107] (i) specify the names and expected quantities of the product; (ii) confirm that the member has established that it has insufficient or no manufacturing capacities in the pharmaceutical sector for that product;[108] and, (iii) also confirm that in case the imported product is already under a patent, a compulsory license has already been granted. (C) The importing country has to take reasonable measures to prevent re-exportation of

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104 TRIPS Council Decision, *supra* note 36.

105 TRIPS Council Decision, *supra* note 36, ¶ 1(b) (note 2 of the Decision also clarifies that the notification does not have to be approved by a WTO body in order to use this system set out in the Decision).

106 TRIPS Council Decision, *supra* note 36, note 3 (the list of countries are: Australia, Austria, Belgium, Canada, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Japan, Luxembourg, Netherlands, New Zealand, Norway, Portugal, Spain, Sweden, Switzerland, United Kingdom and United States of America).

107 TRIPS Council Decision, *supra* note 36, ¶ 2(a).

108 This condition is not required for a least developing country. The Annex to the Decision provides two ways by which Assessment of Manufacturing Capacities in the Pharmaceutical Sector is to be done.

the products that have actually been imported into their territory. They have to ensure that the imported products are used for public health purposes only.[109] (D) The importing country is not obliged to pay "adequate remuneration" as set out in Article 31 (h) of TRIPS if the exporting country has already done so with respect to the product imported.

Among the conditions to be fulfilled by an exporting country, the following are required: (A) the compulsory license granted by exporting member has to meet the following requirements:[110] (i) no more than the amount required by the importing country may be manufactured and the entire production has to be sent to the importing country; (ii) the product to be exported under compulsory license should be clearly identified through specific labeling or marking. Such identification could be through special packaging or special coloring or shaping of the products, provided it does not impact the price significantly; (iii) the information related to the compulsory license and the product shall be publicly available on a website and the Council for TRIPS shall be notified about the compulsory license and conditions attached to it. (B) The exporting country should pay adequate remuneration to the patent holder taking into account the economic value to the importing country.[111]

Apart from the obligations cast on the importing and the exporting country, the Decision also mentions the general responsibility of all member countries: (A) All members have to ensure effective legal means to prevent importation and sale of the products using the waiver.[112] (B) A general obligation is cast upon all the members to promote transfer of technology and capacity building in pharmaceutical sector to overcome the problem identified in paragraph 6 of the Doha Declaration.[113]

Reading the Decision along with the Doha Declaration it is quite clear that of the three options discussed earlier in this paper, the WTO considers compulsory license as the most feasible option to address the health crisis. However, as already identified, any approach that seeks to use compulsory license as an option for the present crisis has numerous legal, economic, and political shortcomings. Though the decision throws some light on legally troublesome terms like "adequate remuneration" and "predominantly for the supply of the domestic market", there is no doubting the fact that the process of obtaining

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109 TRIPS Council Decision, *supra* note 36, ¶ 4.
110 *Id.* ¶ 2(b).
111 *Id.* ¶ 3.
112 *Id.* ¶ 5.
113 *Id.* ¶ 7.

compulsory license as such is legally cumbersome. Clearly, the developed countries and its pharmaceutical manufacturers are apprehensive over the possibility where the generic manufacturers exploit the waiver to divert drugs into the E.U. or the U.S., thereby making a dent in the profits of the companies. Under the new mechanism, two compulsory licenses would have to be issued in most of the circumstances, and the Decision gives the W.T.O. a new authority to second guess the granting of individual compulsory licenses to generic companies. The decision fails to clarify if "economic efficiency" can be a ground for determining the lack of manufacturing capacity in the importing country. It is still to be seen how this system would work and if it would provide a sound legal framework under which life saving drugs at affordable prices could be provided to the poor. One thing, that clearly emerges is that the decision adds many constraints on the business practice of the generic companies.

Thus, the earlier criticism of the IPR regime under the WTO – that it prohibits the countries from taking effective steps to address the public health crisis – still remains valid. The Doha Declaration and the TRIPS Council Decision purport to address the problem, but they fail to do so effectively and can, at the most, be seen as a public relations exercise by the WTO. However, the current decision is a temporary waiver and a permanent amendment to the TRIPS is scheduled for 2004. It is thus imperative that the developing countries put up a united front, in the same manner as was done at Cancun, and push for an amendment that simplifies and clarifies the procedures under the TRIPS and removes unnecessary obstacles to address the public health problems.

V.
CONCLUSION

Patents on pharmaceuticals may be required for providing incentives to the industry and to encourage research and development in new drugs and vaccines, but the effectiveness of the current system needs a thorough evaluation. Patent protection has to be attuned to a level that provides incentives but at the same time does not harm public interests. Interpretation and implementation of TRIPS would have life or death consequences for the citizens of the less developed world and the consequences would be felt globally. A balanced approach may go a long way in ameliorating the suffering of those fighting for their life against diseases. It is important to interpret TRIPS keeping in mind its social ramifications, taking into consideration the interests of those who at first sight do not seem to be a part of the global trad-

ing system. It is, thus, necessary to make optimum use of the "windows" provided in the Agreement – "windows" that allow the governments to look beyond the interests of the patent holder while framing their policies and interpreting this highly technical instrument. Furthermore, the need is to identify the interest that is being harmed but hardly highlighted: 'right to health'. This human right may be ill defined and may have been traditionally considered weak,[114] yet only by using the language of human rights would it be possible to argue for carving out exceptions to the patent rights.[115] Right to health is an appropriate value that can balance the patent rights under TRIPS. An argument based on this right would not only call for availability of medicines at lower price but it would also stress upon the states to provide funds for research and development on drugs for diseases that affect a major chunk of population. Right to health can work as a double edged sword. Private pharmaceutical sector also stands to gain from the above mentioned proposition through increased funding from the government.

However, within this debate lie larger issues. The current intellectual property regime needs to live up to its objective of promoting social good. It needs to dispel the notion that social welfare is being overlooked in favour of private interests. Intellectual property needs to provide a conceptual apparatus which mediates the tension prevailing in the society.[116] It must have a convincing explanation that granting of property rights motivates the innovators and benefits the society.[117] It must explain why the "one shoe fits all" approach is followed and why the trade off between innovation and motivation should be the same for all kinds of industries and all types of technol-

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[114] *See* BRIGIT C.A. TOEBES, THE RIGHT TO HEALTH AS A HUMAN RIGHT IN INTERNATIONAL LAW (1999); *see also* Philip Alston, *U.S. Ratification of the Covenant on Economic, Social and Cultural Rights: the Need for an Entirely New Strategy*, 84 AM. J. INT'L L. 365 (1990); *see also* JACK DONNELLY, UNIVERSAL HUMAN RIGHTS IN THEORY AND PRACTICE, 28-31 (1989); *see also* Audrey R. Chapman, *A New Approach to Monitoring the International Covenant on Economic, Social and Cultural Rights*, 55 REV. INT'L COMM. JURISTS 23 (1995); *see also* David P. Fidler, *International Law And Global Public Health*, 48 U. KAN. L. REV. 1 (1999); *see also* Eleanor D. Kinney, *The International Human Right To Health: What Does This Mean For Our Nation And World?*, 34 IND. L. REV. 1457 (2001); *see also* Virginia A. Leary, *The Right to Health in International Human Rights Law*, 1 HEALTH AND HUMAN RIGHTS 25 (1994).

[115] *See generally* RONALD DWORKIN, TAKING RIGHTS SERIOUSLY (1977); *see also* Alan Gewirth, *The Epistemology of Human Rights*, 1 SOC. PHIL. & POL'Y 1 (1984); *see also* JOEL FEINBERG, RIGHTS, JUSTICE, AND THE BOUNDS OF LIBERTY: ESSAYS IN SOCIAL PHILOSOPHY 150 (1980); *see also* ASBJORN EIDE, UNIVERSALIZATION OF HUMAN RIGHTS VERSUS GLOBALIZATION OF ECONOMIC POWER, IN RENDERING JUSTICE TO THE VULNERABLE, LIBER AMICORUM IN HONOUR OF THEO VAN BOVEN 99 (Fons Coomans *et al.* ed., 2000).

[116] BOYLE, *supra* note 11, at 49-50.

[117] *Id.*

ogy. It must also move away from being 'inventor centric' so as not to ignore the other interests. Moreover, as exemplified by Canada Generics it is easy to get influenced by the technocratic notions of the system while neglecting other dimensions to the problem. According to Drahos this is the reason why the institution of intellectual property has evolved and globalized without some set of shared understandings concerning the role it has to play in social issues including health of citizens around the world.[118] "Linking intellectual property to human rights discourse is a crucial step in the project of articulating theories and policies that will provide guidance in the adjustment of existing intellectual property rights and the creation of new ones. Human rights in its present state of development offers at least a common vocabulary with which to begin this project, even if, for the time being, not a common language."[119] Human rights organizations and practitioners need to take a cue from the point made by Drahos. "A human rights approach offers an alternative vision of the purpose and requirements of intellectual property as well as a set of obligations that places intellectual property in a wider context."[120] Such an approach would demand that the intellectual property system exhibits greater coherence and persuasiveness to gain and keep public respect for its survival. The present controversy raises genuine doubts on the way the intellectual property law has been enforced. International community has to respond to contemporary demands of society through interactions among all the stakeholders and there is a need to depart from the traditional thinking – both as regards to patent rights and the right to health.

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[118] Drahos, *supra* note 2, at 368.

[119] *Id.* at 368-69.

[120] Audrey Chapman, *The Human Rights Implications of Intellectual Property Protection*, 5 J. INT'L ECON. L., 861, 879 (2002).