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Global Diseases, Global Patents and Differential Treatment in WTO Law: Criteria for Suspending Patent Obligations in Developing Countries

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"It is becoming ever more apparent that the patent system isn't working."
—*The Economist*, November 13, 2004, at 71.

I. INTRODUCTION[1]

Special and differential treatment of members is a controversial subject at the World Trade Organization ("WTO") and nowhere is the debate more pronounced than in the context of life-saving medicines and patent protection.[2] However, concerns have been raised in WTO negotiations

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[2] Numerous articles have been written on this topic in the past few years but they have not developed criteria for operationalizing special and differential treatment in TRIPS. *See, e.g.*, Alan. O. Sykes, *Public Health and International Law: TRIPS, Pharmaceuticals,*

regarding how to ensure that special and differential treatment targets developing countries' trade, financial and development needs, without prejudicing the rights of other WTO members.[3] In the fall of 2003, the WTO adopted a decision to amend the *Agreement on Trade-Related Aspects of Intellectual Property Rights* ("TRIPS") in order to enhance access to essential medicines in developing countries.[4] In the fall of 2004, the World Intellectual Property Organization ("WIPO") adopted an agenda to further the development of countries by considering different intellectual property regimes appropriate to the circumstances of a particular country or region.[5] The WTO and the WIPO are the two major entities working to develop international patent law, and one of the objectives of TRIPS is to establish a mutually supportive relationship between the two.[6] The application of TRIPS to developing countries has become even more important with the full entry into force of their patent obligations on January 1, 2005.

The current willingness to take individual circumstances into account is a significant development. However, while there is recognition of the

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Developing Countries, and the Doha "Solution," 3 CHI. J. INT'L L. 47 (2002); James Thuo Gathii, *The Legal Status of the Doha Declaration on Trips and Public Health Under the Vienna Convention on the Law of Treaties*, 15 HARV. J.L. & TECH. 291 (2002); 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 (2002); Laurence R. Helfer, *Regime Shifting: The TRIPs Agreement and New Dynamics of International Intellectual Property Lawmaking*, 29 YALE J. INT'L L.1 (2004); Gregory Shaffer, *Recognizing Public Goods in WTO Disputes Settlement: Who Participates? Who Decides? The Case of TRIPS and Pharmaceutical Patent Protection*, 7 J. INT'L ECON. L. 459 (2004); Bryan Mercurio, *TRIPs, Patents and Access to Life-Saving Drugs in the Developing World*, 8 MARQ. INTELL. PROP. L. REV. 211 (2004); Frederick M. Abbott, *The TRIPS Agreement, Access to Medicines and the WTO Doha Ministerial Conference*, (Florida State University College of Law, Public Law Working Paper No. 36, 2001) (Quaker U.N. Office, Occasional Paper No. 7, Oct. 2001), *at* http://papers.ssrn.com/sol3/papers.cfm?abstract_id=285934 (last visited Oct. 24, 2005).

[3] *See, e.g.*, WTO Comm. on Trade & Dev. (CTD), *Realizing Trade and Development Objectives Through Special and Differential Treatment: Submission by Canada*, ¶¶ 6, 23, TN/CTD/W/21 (Dec. 6, 2002); CTD, *The WTO Work Program on Special and Differential Treatment: Communication from the European Communities*, ¶¶ 5–6, TN/CTD/W/26 (Dec. 11, 2002) [hereinafter *Communication from the European Communities*]; CTD, *Remarks of the United States Delegation in the Committee on Trade and Developmental Special Session on Special and Differential Treatment,14 JUNE 2002*, ¶ 9, TN/CTD/W/9 (June 28, 2002).

[4] Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations, Annex 1C, LEGAL INSTRUMENTS – RESULTS OF THE URUGUAY ROUND, vol. 31, 33 I.L.M. 1197 (1994) [hereinafter TRIPS].

[5] Press Release, WIPO, Member States Agree to Further Examine Proposal on Development (Oct. 4, 2004), *available at* http://www.wipo.int/wilma/pressinfo-en/200410/msg00001.html.

[6] TRIPS pmbl.

need to adopt special and differential treatment to the individual circumstances of WTO members, the negotiations have not made much progress in determining the criteria that should be applied.[7] The rationale for introducing greater flexibility in the application of special and differential treatment is that differentiation amongst developing country members is necessary if special and differential treatment is to be made effective and targeted.[8] The issue of how to define developing countries has also been raised in this context, although there has been disagreement regarding whether this falls within the negotiating mandate.[9] Paragraph 44 of the Doha Ministerial Declaration established the mandate for negotiations on special and differential treatment for the Doha Round, in reaffirming that "provisions for special and differential treatment are an integral part of the WTO Agreements" and directing that "all special and differential treatment provisions shall be reviewed with a view to strengthening them and making them more precise, effective and operational."[10] In WTO negotiations in the Committee on Trade and

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[7] *See, e.g., Communication from the European Communities, supra* note 3, ¶ 6; CTD, *Approach to Facilitate Deliberation on the Agreement-specific S&D Proposals: Communication from the United States*, ¶ 5, TN/CTD/W/27 (Feb. 13, 2003); CTD, *Special Session on Special and Differential Treatment: Communication from Switzerland to the CTD in Special Session*, ¶ 6, TN/CTD/W/1 (Sept. 13, 2002); CTD, *Submission for the Committee on Trade and Development - Special Session on Special and Differential Treatment: Communication from the European Communities*, ¶ 14, TN/CTD/W/13 (Aug. 1, 2002).

[8] CTD, *Draft Report to the General Council*, ¶ 13, TN/CTD/W/25 (Dec. 6, 2002).

[9] *Id.*

[10] The *Draft Report* stated that:

> Ministers . . . endorsed the Work Programme on special and differential treatment set out in the Decision on Implementation-Related Issues and Concerns, and as per paragraph 12.1 of the Decision directed the Committee on Trade and Development (CTD):
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> (i) to identify those special and differential treatment provisions that are already mandatory in nature and those that are non-binding in character, to consider the legal and practical implications for developed and developing Members of converting special and differential treatment measures into mandatory provisions, to identify those that Members consider should be made mandatory, and to report to the General Council with clear recommendations for a decision by July 2002;
>
> (ii) to examine additional ways in which special and differential treatment provisions can be made more effective, to consider ways, including improved information flows, in which developing countries, in particular the least-developed countries, may be assisted to make best use of special and differential treatment provisions, and to report to the General Council with clear recommendations for a decision by July 2002; and
>
> (iii) to consider, in the context of the Work Program adopted at the Fourth Session of the Ministerial Conference, how special and differential treatment may be incorporated into the architecture of WTO rules.

Development, introducing the concept of "situational flexibility," or "member-specific flexibility," into special and differential treatment of developing countries has become a matter of debate.[11] In the context of TRIPS, the concept of situational flexibility is particularly relevant to the issue of extending transition periods[12] and striking the appropriate balance between the rights of producers and users of intellectual property.[13] Least-developed countries in particular want to strengthen special and differential treatment measures in TRIPS.[14]

In this article, several WTO mechanisms for implementing special and differential treatment in TRIPS with respect to pharmaceutical patents are analyzed. We challenge conventional economic views regarding the relationship between international intellectual property law and research incentives to invent medicines to treat global diseases in developing countries. In our analysis of the economics of pharmaceutical patents, we will distinguish between global diseases (which occur in both developed and developing countries) and neglected diseases (which occur overwhelmingly in developing countries, rather than in developed countries).[15] In other parts of our analysis, we will use the term "developing country diseases" to refer to both neglected and global diseases.

See id. ¶ 1. In pursuance of this mandate the Trade Negotiations Committee ("TNC"), in its meeting held from January 28 through February 1, 2002, agreed that "the review of all special and differential treatment provisions with a view to strengthening them and making them more precise, effective and operational provided for in paragraph 44 of the Ministerial Declaration shall be carried out by the Committee on Trade and Development in Special Sessions." *Id.*

[11] *See* CTD, 18th Sess., *Note on the Meeting of 7 December 2004*, ¶ 8, TN/CTD/M/18 (Jan. 27, 2005); CTD, 17th Sess., *Note on the Meeting of 28 October 2004*, ¶ 7, TN/CTD/M/17 (Dec. 7, 2004).

[12] *See* TRIPS arts. 65–66. It is important to note that Article 66.1 envisages extensions of the transition period for least-developed countries, whereas Article 65 does not envisage extensions for developing countries. The negotiating history of TRIPS appears to confirm that the intention of the parties was to restrict extensions to the least-developed countries. *See* Note by the Secretariat, *Negotiating Group on Trade-Related Aspects of Intellectual Property Rights, including Trade in Counterfeit Goods*, ¶ 34, MTN.GNG/NG11/21 (June 22, 1990) [hereinafter Note by the Secretariat]. In the Uruguay Round negotiations on TRIPS, a country-by-country or case-by-case approach to transition periods was rejected on the basis that such an approach would be difficult to negotiate. *Id.* ¶ 8.

[13] *See* TRIPS arts. 7–8. *See also* CTD, *Special and Differential Treatment Provisions: Joint Communication from the African Group in the WTO*, ¶¶ 18–19, TN/CTD/W/28 (Feb. 14, 2003).

[14] CTD, *Special and Differential Treatment Conditions: Joint Communication by the Least-Developed Countries*, ¶ 18, TN/CTD/W/4 (May 24, 2002).

[15] *See* Kevin Outterson, *Pharmaceutical Arbitrage: Balancing Access and Innovation in International Prescription Drug Markets*, 5 YALE J. HEALTH POL'Y L. & ETHICS 193 (2005) (noting the difference between global and neglected diseases).

We present a new analytical framework for determining differential treatment of developing and least-developed countries and apply this framework in the context of TRIPS.[16] We propose that the balance of legal rights between producers and users of patents be determined on a market-by-market basis, rather than on a global basis, and that criteria for doing so be developed.

In this article, an overview of key TRIPS obligations and exceptions relating to patents, as amended to date by the Doha Round negotiations is provided. Part III analyzes how WTO provisions on special and differential treatment of developing countries should be applied to TRIPS law and policy, taking into account the 2004 Appellate Body ruling in *European Communities – Tariff Preferences for Developing Countries*. Part IV analyzes the consistency of global patent rights with the economic and developmental objectives of the WTO and shows how strong patent rights in developing countries contradict these objectives. Part V then analyzes whether TRIPS is amenable to an interpretation that would achieve a more appropriate balance between the rights of producers and users of patented pharmaceuticals and shows that an amendment to TRIPS to facilitate the use of compulsory licensing in developing and least-developed countries is a solution. However, a better solution is to grant waivers for developing countries and extensions of the transition period for least-developed countries. This article proposes a set of measurable criteria to implement special and differential treatment of countries with respect to pharmaceutical patents on a market-by-market basis using these two mechanisms. Equal access to life-saving medicines requires equal access to legal rights that affect that access.

II. KEY TRIPS EXCEPTIONS RELATING TO PATENTS

TRIPS requires patents to provide patent owners with the exclusive right to prevent third parties from making, using, selling or importing a patented product without the owner's consent.[17] Articles 30 and 31 authorize exceptions to these rights. These two articles thus play a key role in balancing the rights of patent owners against the needs of consumers of patented products, whether they be pharmaceuticals or other patented products. The ability to manufacture drugs under compulsory license provides developing countries with bargaining power to extract price concessions for patented drugs or to issue compulsory licenses when negotiations fail. However, this bargaining power applies only to countries

[16] Our focus is on differential *treatment*, as opposed to differential *pricing*, of drugs. For a discussion of the latter issue in the context of TRIPS, see Peter J. Hammer, *Differential Pricing of Essential AIDS Drugs: Markets, Politics and Public Health*, 5 J. INT'L ECON. L. 883 (2002).

[17] TRIPS art. 28.1.

that have the capacity to produce generic drugs under compulsory licenses issued to government laboratories or private generic producers. Countries that lack domestic manufacturing capacity would need to be able to import generics manufactured under compulsory licenses in other countries in order to enjoy a comparable level of bargaining power. This section will discuss Article 30 first, followed by Article 31, and consider how effective these articles are in ensuring that governments can issue compulsory licenses to meet national needs, including with respect to public health problems.

A. TRIPS Article 30

TRIPS Article 30 permits "limited exceptions" to patent rights. Academic opinions diverge over whether Article 30 can be interpreted to permit generic exports.[18] If one accepts the interpretation of Article 30 in *Canada – Patent Protection of Pharmaceutical Products*,[19] Article 30 does not permit such exports. However, if one rejects that interpretation, there is nothing in the wording of Article 30 to prevent such an interpretation.

Article 30 establishes three criteria, each of which must be satisfied in order to qualify for the exception: (1) the exception must be "limited"; (2) the exception must not "unreasonably conflict with the normal exploitation of the patent"; and (3) the exception must not "unreasonably prejudice the legitimate interests of the patent owner, taking into account the legitimate interests of third parties." The panel ruled that each of the three must be presumed to mean something different from the other two or else there would be redundancy.[20]

In *Canada – Patent Protection of Pharmaceutical Products*, the panel considered whether the Canadian Patent Act violated TRIPS by permitting

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[18] Several commentators have suggested that Article 30 be interpreted to allow generic exports to poor countries that lack manufacturing capacity. *See, e.g.*, Andrea M. Curti, *The WTO Dispute Settlement Understanding: An Unlikely Weapon in the Fight Against AIDS*, 27 AM. J.L. & MED. 469 (2001); Grace K. Avedissian, Comment, *Global Implications of a Potential U.S. Policy Shift Toward Compulsory Licensing of Medical Inventions in a New Era of "Super-Terrorism,"* 18 AM. U. INT'L L. REV. 237 (2002); 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 (2002).

[19] WTO Panel Report on E.C. Complaint Concerning Canada – Patent Protection of Pharmaceutical Products, WT/DS114/R (Mar. 17, 2000) [hereinafter *Canada – Patent Protection of Pharmaceutical Products*]. Amir Attaran argues that Article 30 does not provide the best means for implementing Paragraph 6 of the TRIPS Declaration, due to the interpretation given to this article by the panel in *Canada – Patent Protection of Pharmaceutical Products*. *See* Attaran, *supra* note 2, at 872. For an excellent critique of the panel's interpretation of Article 30, see Jonathan Michael Berger, *Tripping Over Patents: AIDS, Access to Treatment and the Manufacturing of Scarcity*, 17 CONN. J. INT'L L. 157 (2002).

[20] *See Canada – Patent Protection of Pharmaceutical Products*, *supra* note 19.

generic manufacturers to infringe patent rights (1) to develop submissions for regulatory approval in Canada or a foreign country (the regulatory review exception) and (2) to manufacture and stockpile a patented product during the final six months of the patent in preparation for sale after the patent expires (the stockpiling exception). The panel's decision thus examined the legality under TRIPS of two well-recognized exceptions to patent protection. The panel accepted the argument of the European Communities that both exceptions violated the "exclusionary" patent rights set out in TRIPS Article 28. Canada defended both exceptions under TRIPS Article 30. The panel ruled that the regulatory review exception passed the Article 30 test but the stockpiling exception did not.

In rejecting the stockpiling exception, the panel ruled that any exception that entirely removes the right to exclude making and using the patented product cannot be considered a "limited exception" under Article 30. In contrast, the regulatory review exception created a minimal reduction in the legal rights of the patentee and therefore qualified as a "limited exception." The regulatory review exception allowed a generic manufacturer to produce a limited quantity of patented drugs to submit to a national regulatory review process. The regulatory review exception was confined to conduct needed to comply with the requirements of the regulatory review process, and no commercial use was made of the products resulting from the production runs. Thus, the acts permitted would be small and narrowly bounded. The economic impact of this regulatory review exception could be considerable. Since it could take generic producers several years to develop the generic product and to obtain regulatory approval, permitting these activities during the course of the patent could significantly reduce the length of time that the patent owner would enjoy a monopoly in the market and thereby reduce profits. However, the panel reasoned that the first condition of Article 30 addresses the impact on legal rights, not economic impact.

The panel further reasoned that the regulatory review exception did not conflict with the normal exploitation of patents. The regulatory review process is an unintended consequence of the conjunction of patent laws with product laws, not a normal consequence of enforcing patent rights. Unlike many other kinds of patentable products, pharmaceuticals are subject to rigorous government scrutiny due to their potential to cause serious harm to human health through unintended side effects. Thus, patent owners cannot claim a "legitimate interest" in the economic benefits caused by the length of time required to get regulatory approval for generic drugs. While a number of governments had extended the patent term to compensate for the delays in obtaining approval, several others had not. Therefore, the interest claimed was neither so compelling nor so widely recognized that it could be regarded as a "legitimate interest." Moreover, the issue of regulatory review exceptions was well known before the TRIPS

negotiations, but was not addressed in the recorded agenda of the negotiations. Does this interpretation of the Article 30 exception stand in the way of issuing compulsory licenses on HIV/AIDS drugs exclusively for export or would that be too great an intrusion on patent rights to qualify as a limited exception? Such a license would not affect the economic interests of the patent holder in the market in which it is issued. Nor would it affect its legal rights or economic interests in the export market if that market is a least-developed country that will not provide patent protection until 2016. However, if one follows the reasoning of the panel, it would abrogate entirely the right to exclude making and using the patented product in protected markets and therefore fail the first test under Article 30 for the same reason as the stockpiling exception.

In addition to the panel interpretation, there are other reasons to conclude that Article 31, not Article 30, is the appropriate provision with respect to compulsory licenses to address public health problems. First, with the decision to amend Article 31 (discussed below), the WTO members have rejected the interpretation of Article 30 as a means to resolve the issue of compulsory licensing for countries that lack adequate manufacturing capacity.[21] Second, the negotiating history of TRIPS indicates that Article 31 was intended to govern compulsory licensing.[22] Finally, interpreting Article 30 to resolve compulsory licensing issues would be problematic. While it would provide greater certainty regarding the rights of WTO members, it would introduce a new element of uncertainty regarding the correct interpretation of Article 30 in other circumstances and the relationship between Articles 30 and 31.

B. TRIPS Article 31

Under Article 31, a government may issue a compulsory license authorizing the government or a third party to produce generic drugs without the authorization of the patent holder where negotiations fail to obtain authorization on reasonable commercial terms.[23] However, the use of the patent must be "predominantly" to supply the domestic market[24] and

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[21] The European Union had suggested that, in the absence of an agreement to amend Article 31(f), it would favor adopting an interpretation of Article 30 that would allow WTO members to permit the manufacture of generic drugs without the patent holder's permission for export to another country that is facing a serious public health problem. *See* WTO Council for Trade-Related Aspects of Intellectual Property Rights (TRIPS), *Concept Paper Relating to Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health: Communication from the European Communities and their Member States*, ¶¶ 23–24, IP/C/W/339 (Mar. 4, 2002).

[22] *See* Note by the Secretariat, *supra* note 12, ¶¶ 13, 21–22. The discussion regarding Article 27 of the U.S. proposal refers to a precursor of Article 31, not Article 30.

[23] TRIPS art. 31(b).

[24] *Id.* at art. 31(f).

the patent holder must be paid adequate remuneration, based on the economic value of the license.[25] The negotiation requirement may be waived in cases of national emergency, extreme urgency, or non-commercial public use.[26] Members are not obliged to comply with the negotiation requirement or to predominantly serve the domestic market where the use is permitted to remedy anti-competitive practices.[27]

The TRIPS provisions relating to compulsory licensing strengthen a government's position in price negotiations with patent holders by permitting the government to issue a compulsory license to manufacture drugs, rather than purchase them from the patent owner. For example, where a government provides drugs to patients through a public healthcare scheme, it meets the necessary conditions to halt price negotiations because generic versions manufactured under compulsory license would serve a non-commercial public use[28] and predominantly supply the domestic market. Since the term "adequate remuneration" is not defined, patent owners cannot predict with certainty what compensation they will receive if a government abandons negotiations.[29] This gives the patent owners an incentive to determine the price through negotiation.

Many developing countries do not have the capacity to manufacture generic drugs. This weakens their bargaining position substantially unless they can import generic drugs from another country that has issued a compulsory license on their behalf. To serve as an effective bargaining

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[25] *Id.* at art. 31(h).

[26] *Id.* at art. 31(b).

[27] *Id.* at art. 31(k).

[28] TRIPS Article 31(b) contemplates non-commercial public use by "the government or a contractor" and a patent "used by or for the government." *See id.* at art. 31(b). Thus, in the context of Article 31(b), a reasonable interpretation of the term "non-commercial public use" would include issuing a compulsory license on patented pharmaceuticals for their manufacture by the government, or by a contractor on behalf of the government, for public distribution through a government health-care system.

[29] Calculating compensation for compulsory licenses is likely to be an uncertain process in any legal system. Since TRIPS permits the process for calculating remuneration to differ from one WTO member to the next, uncertainty increases in the international context. TRIPS Article 31(h) requires that "the right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the [compulsory license]." TRIPS art. 31(h). Article 31(k) allows "the need to correct anti-competitive practices" to be taken into account in determining the amount of remuneration. *Id.* at art. 31(k). Article 31(j) requires that "any decision relating to remuneration . . . shall be subject to judicial review or other independent review . . . in that Member." *Id.* at art. 31(j). Article 1 provides that "[m]embers shall be free to determine the appropriate method of implementing [TRIPS] within their own legal system and practice." *Id.* at art. 1. The general nature of these compensation obligations, together with the flexibility permitted under Article 1, means that the specific manner in which compensation is determined may vary from one WTO member to the next, as may the principles that apply to judicial review or its equivalent in each legal system.

chip, the threat to issue a compulsory license to government or private pharmaceutical manufacturers must be credible. TRIPS Declaration Paragraph 6 acknowledged the difficulties countries with inadequate manufacturing capacity would face with respect to compulsory licensing:

> 6. We recognize that WTO members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement. We instruct the Council for TRIPS to find an expeditious solution to this problem . . ..[30]

C. The Paragraph 6 Decision

In order to implement Paragraph 6, the WTO General Council agreed to amend Articles 31(f) and 31(h) by means of a Decision that sets up a new set of rights and obligations, adding to the pre-existing rights and obligations set out in the TRIPS agreement.[31] We shall refer to this Decision of August 30, 2003 as the "Paragraph 6 Decision" and the new set of rights and obligations as the "Paragraph 6 System."

The Paragraph 6 Decision aims to increase the availability of pharmaceutical products needed to address public health problems in developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics.[32] Because the text of TRIPS Article 31(f) was clear, WTO members had to agree to an amendment in order to facilitate access to essential medicines in developing and least-developed countries that have inadequate manufacturing capacities. It was not possible to solve the problem through treaty interpretation.

The Paragraph 6 Decision waives an exporter's Article 31(f) obligation to supply predominantly to the domestic market, enabling any country with manufacturing capacity to issue a compulsory license to produce generic drugs for export to countries that have insufficient or no manufacturing capacity, subject to several conditions.[33] Article 31(h) requires the issuer of

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[30] WTO Ministerial Conference, *Declaration on the TRIPS Agreement and Public Health*, adopted on Nov. 14, 2001, ¶ 6, WT/MIN(01)/DEC/2 (Nov. 20, 2001) [hereinafter TRIPS Declaration].

[31] *See* WTO General Council, *Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health: Decision of 30 August 2003*, ¶ 11, WT/L/540 (Sept. 2, 2003), *available at* http://www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm ("This Decision, including the waivers granted in it, shall terminate for each Member on the date on which an amendment to the TRIPS Agreement replacing its provisions takes effect for that Member.") [hereinafter Paragraph 6 Decision].

[32] *Id.* ¶ 1(a); TRIPS Declaration, *supra* note 30, ¶ 1.

[33] Paragraph 6 Decision, *supra* note 31, ¶ 2.

a compulsory license to compensate the patent holder. The amendment clarifies that in the situation where the license is issued to serve an export market under the Paragraph 6 system (as opposed to serving the domestic market), the exporting country, not the importing country, must pay compensation.[34] The compensation takes into account the economic value in the importing country.[35] No formal restriction on the countries that are eligible to import exists under the Paragraph 6 system.[36] However, the Paragraph 6 Decision creates four categories of importing members. Least-developed countries are eligible to import without formal notification to the WTO.[37] Two further categories consist of countries that have made a commitment not to use the Paragraph 6 system as importers[38] and countries that have committed to using the system as importers only in situations of national emergency or extreme urgency.[39] Countries making the latter commitment have agreed, in effect, not to use the system for non-commercial public use. For example, they have agreed not to use the system simply to lower the general cost of purchasing medicine for public health care systems. These commitments resolve an issue of concern to the pharmaceutical industry—that countries that lacked manufacturing capacity, but could afford to pay the full price of patented medicine, would import cheaper generic versions instead. The fourth category consists of the members that do not fall into the first three categories.

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[34] *Id.* ¶ 3. Normally, the country issuing a compulsory license would do so to supply its own market.

[35] *Id.* As we note above, calculating this compensation will be a difficult task. As we note below, the value of the market may be very little in the poorest countries, particularly where the patent holders were already selling the product at cost.

[36] *Id.* ¶ 1(b).

[37] All other members are required to notify the Council for TRIPS of its intention to use the system set out in the Paragraph 6 Decision; the notification is not subject to WTO approval. *See id.*

[38] This covers most, but not all, developed countries: 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 the United States. *See id.* at n.3; Note from the Chairman, Council for TRIPS, *Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health* (Aug. 27, 2003), *available at* http://www.ictsd.org/ministerial/cancun/docs/TRIPS_para6_16-12-02.pdf.

[39] The Czech Republic, Cyprus, Estonia, Hungary, Latvia, Lithuania, Malta, Poland, Slovak Republic and Slovenia all agreed to limit their use of the system as importers to emergencies until their accession to the European Union, when they will opt out as importers entirely. *See The General Council's Chairperson's statement*, WTO NEWS, (WTO, Geneva), Aug. 27, 2003, *at* http://www.wto.org/english/news_e/news03_e/ trips_stat_28aug03_e.htm (The Chairman's Note is carefully negotiated over several months). Other Members that have agreed to such limited use as importers are Hong Kong, China, Israel, Korea, Kuwait, Macao China, Mexico, Qatar, Singapore, Chinese Taipei, Turkey, and the United Arab Emirates. *Id.*

In order to ensure that imports occur only within the parameters set out in the Paragraph 6 Decision and that medicines supplied under this system do not make their way back to markets that have been carved out of the system under these commitments, members must have laws in place to prevent the diversion of medicine supplied under the system.[40] All importing countries, regardless of their development status, must also take "reasonable measures within their means, proportionate to their administrative capacities and to the risk of trade diversion" to prevent the re-export of the products they import under this system.[41] The types of measures that they must take are not specified. Where developing countries and least-developed countries experience difficulty implementing this provision, developed countries must provide technical and financial assistance to facilitate its implementation.[42] However, WTO members are free to determine whether to permit parallel imports without these laws being subject to WTO dispute settlement procedures.[43] Parallel imports involve products sold by the patent owner in one market and then imported into another market without the patent owner's approval.

No restrictions exist regarding the countries that are eligible to export. However, exporters are required to follow a series of procedural requirements and conditions, in addition to the compensation requirement noted above. Moreover, the obligations under Article 31(f) are waived only "to the extent necessary for the purposes of production of a pharmaceutical

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[40] Paragraph 5 provides as follows:

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

Paragraph 6 Decision, *supra* note 31, ¶ 5.

[41] *Id.* ¶ 4.

[42] *Id.*

[43] TRIPS art. 6; *see also* TRIPS Declaration, *supra* note 30, ¶ 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.") Under a system of international exhaustion of patents, the patent owner cannot prevent the importation of his own product from a foreign country once it has been sold there; that is, parallel imports. For example, if American drug company Merck sells AIDS drugs in Mexico for half the price it charges for the same drug in the United States, an American consumer might import the drug from Mexico rather than purchase it in the United States. This importation is known as a parallel import. TRIPS permits the United States (and other WTO members) to decide for itself whether to permit or prohibit American consumers from importing the drugs.

product(s) and its export to an eligible importing Member(s)."[44] A further necessity test requires that the license restrict the authorization to "only the amount necessary to meet the needs of the eligible importing Member(s)."[45]

Under the Paragraph 6 system, with the exception of least-developed countries, importing countries must specify the names and quantities of the products needed in their notification to the WTO.[46] They must also confirm that they have granted or intend to grant a compulsory license in accordance with TRIPS Article 31.[47] Finally, they must establish that they have insufficient or no manufacturing capacity in the pharmaceutical sector for the product in question in one of two ways. Either they have no manufacturing capacity in the pharmaceutical sector at all, or they have examined this capacity (excluding that owned or controlled by the patent holder) and found it to be insufficient to meet their needs.[48] The Paragraph 6 system will no longer apply once it is established that the capacity has become sufficient to meet its needs.[49]

The Paragraph 6 system does not apply to countries that have sufficient manufacturing capacity to issue compulsory licenses to meet the needs of their own populations. The question in a given case is whether the importing country has manufacturing capacity for the pharmaceutical product in question. For example, countries like China, India and Brazil could use the Paragraph 6 system to import drugs from generic manufacturers in other countries if they lack capacity for a particular medicine. However, where developing countries do have manufacturing capacity, they will have to determine whether and how to use compulsory licensing to reduce the cost of providing treatment by issuing licenses to their own generic manufacturers. When a country issues a compulsory license to its own generic drug manufacturers to serve its own market, the Paragraph 6 Decision will not apply. In order to strike the right balance between the rights of producers and users of patented drugs, the country must rely on TRIPS Article 31 exceptions, which continue to operate in this situation, unchanged by the Paragraph 6 Decision. Many of these exceptions are more ambiguous than paragraph 31(f), thus raising the issue of whether they need clarification or amendments to enhance access to essential medicine in these countries. The focus of the remainder of this article is on the application of TRIPS Article 31 to compulsory licenses issued in developing countries that have sufficient generic manufacturing capacity to meet their own needs without importing generic drugs under the

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[44] Paragraph 6 Decision, *supra* note 31, ¶ 2.
[45] *Id.* ¶ 2(b)(i).
[46] *Id.* ¶ 2(a)(i).
[47] *Id.* ¶ 2(a)(iii).
[48] *Id.* ¶ 2(a)(ii), Annex.
[49] *Id.* at Annex.

Paragraph 6 system.[50]

III. SPECIAL AND DIFFERENTIAL TREATMENT IN WTO LAW AND POLICY

Special and differential treatment of developing countries is a concept that finds expression throughout WTO law. This section proposes three tests to determine whether WTO law—and TRIPS patent provisions in particular—achieves its stated objective(s) with respect to developing countries. The first test is based on the development needs of WTO members. The second test is based on the economic impact of WTO provisions on developing countries. The third test asks whether the interpretation or design of the law is effective. Applying this analysis to TRIPS supports the view that the balance to be struck between producers and users of patented medicine should shift in favor of developing and least-developed countries when they are the users under consideration.

The conventional view of treaty interpretation is that legal rights and obligations must be interpreted in a uniform manner for all of the parties to the treaty. However, this view does not prevent taking the individual circumstances of member States into account where the text of the treaty supports such an interpretation. The Decision of November 28, 1979 on Differential and More Favorable Treatment, Reciprocity and Fuller Participation of Developing Countries (L/4903)[51] (the "Enabling Clause") introduced special and differential treatment as an "integral part of the GATT system."[52] The Uruguay Round of Multilateral Trade Negotiations

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[50] All developing countries were required to comply fully with TRIPS by January 1, 2005. TRIPS allowed least-developed countries and developing countries to delay providing patent protection for pharmaceuticals. Least-developed countries could delay intellectual property protection generally until 2006, while developing countries could do so until 2000. TRIPS arts. 66.1, 65.2. With respect to patents however, developing countries could delay protection until 2005 if they did not provide patent protection for a particular area of technology when TRIPS obligations came into effect in 1995. *Id.* at art. 65.4. Less than twenty developing countries fit this description, but they include Brazil and India. *See* WORLD HEALTH ORG. & WTO, WTO AGREEMENTS AND PUBLIC HEALTH n.13 (2002), *available at* http://www.who.int/media/homepage/en/who_wto_e.pdf. The transition period for least-developed countries under Article 66.1 was subsequently extended an additional ten years for pharmaceutical products. *See* WTO Council for TRIPS, *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: Decision of the Council for TRIPS of 27 June 2002*, IP/C/25 (July 1, 2002), *available at* http://www.wto.org/english/tratop_e/trips_e/art66_1_e.htm.

[51] GATT Secretariat, *Differential and More Favourable Treatment, Reciprocity and Fuller Participation of Developing Countries: Decision of 28 November 1979*, L/4903 (Dec. 4, 1979), *available at* http://www.wto.org/english/docs_e/legal_e/tokyo_enabling_e.pdf [hereinafter *Differential and More Favorable Treatment*]

[52] Director-General of GATT, GATT: THE TOKYO ROUND OF MULTILATERAL TRADE NEGOTIATIONS 99 (1979).

then incorporated several more provisions regarding special and differential treatment into WTO law. The legal effect of WTO provisions referring to special and differential treatment for developing countries varies with their wording and the context in which they appear. Nevertheless, special and differential treatment for developing countries is a concept that now finds expression throughout WTO law and supports the view that economic inequality can and should be taken into account in the design or interpretation of WTO rights.

In *European Communities – Conditions for the Granting of Tariff Preferences to Developing Countries* (the "Tariff Preferences case"), the WTO Appellate Body stated:

> [T]he Preamble to the WTO Agreement, which informs all the covered agreements including the GATT 1994 . . . explicitly recognizes the "need for positive efforts designed to ensure that developing countries, and especially the least developed among them, secure a share in the growth in international trade commensurate with the needs of their economic development." The word "commensurate" in this phrase appears to leave open the possibility that developing countries may have different needs according to their levels of development and particular circumstances. The Preamble to the WTO Agreement further recognizes that Members' "respective needs and concerns at different levels of economic development" may vary according to the different stages of development of different Members.
>
> [W]e read paragraph 3(c) [of the Enabling Clause] as authorizing preference-granting countries to "respond positively" to "needs" that are not necessarily common or shared by all developing countries. Responding to the "needs of developing countries" may thus entail treating different developing-country beneficiaries differently.
>
> [T]he existence of a "development, financial [or] trade need" must be assessed according to an objective standard. Broad-based recognition of a particular need, set out in the WTO Agreement or in multilateral instruments adopted by international organizations, could serve as such a standard.[53]

In the Tariff Preferences case, the Appellate Body recognized that the equal application of certain obligations, regardless of economic status,

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[53] WTO Appellate Body Report Concerning European Communities–Conditions for the Granting of Tariff Preferences to Developing Countries, ¶¶ 161–63, WT/DS246/AB/R (Apr. 7, 2004) [hereinafter *EC Tariff Preferences*]. Regarding the Preamble to the WTO Agreement, see Marrakesh Agreement Establishing the World Trade Organization, Apr. 15, 1994, 1867 U.N.T.S. 154, LEGAL INSTRUMENTS – RESULTS OF THE URUGUAY ROUND (1994), 33 I.L.M. 1144 (1994) [hereinafter WTO Agreement].

could run counter to the WTO objective of promoting economic development through trade:

> We thus understand that, between the entry into force of the GATT and the adoption of the Enabling Clause, the Contracting Parties determined that the MFN obligation failed to secure adequate market access for developing countries so as to stimulate their economic development. Overcoming this required recognition by the multilateral trading system that certain obligations, applied to all Contracting Parties, could impede rather than facilitate the objective of ensuring that developing countries secure a share in the growth of world trade.[54]

Switzerland has expressed a similar view in the Doha Round negotiations on special and differential treatment:

> The multilateral trading system is based upon the principle of non-discrimination. Yet, if common rules affect Members in substantially different ways, it might be necessary to modify the application of a rule or create a special rule in order not to discriminate against certain Members. Equal treatment of Members with fundamental differences of starting positions is not conducive to creating a competitive edge for and to fostering the trade interests of those—the poorest—who need it most.[55]

The *Vienna Convention on the Law of Treaties* requires contextual WTO rule interpretation.[56] Article 31 requires that the *ordinary meaning* be given to the terms of the treaty *in their context* and in the light of its *object and purpose*. The approach taken by the Appellate Body has been to first examine the context of the provision in which the language is expressed, then examine the context of the particular agreement in which the provision is found, and, lastly, examine the context of the *Uruguay Round Agreements* as a whole. Although it provides no binding right or obligation, the WTO preamble sets out the *object and purpose* of the trade agreements and provides an overall *context* in which to interpret trade obligations and exceptions, including those found in TRIPS. It thus directly affects interpretation as part of the single combined operation of Article 31. In *Japan—Taxes on Alcoholic Beverages*, the Appellate Body made the following general statement about the interpretation of WTO rules:

> WTO rules are not so rigid or so inflexible as not to leave room for

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[54] *Id.* ¶ 109.

[55] CTD, *Special Session on Special and Differential Treatment: Communication from Switzerland to the CTD in Special Session*, ¶ 6, TN/CTD/W/14 (Sept. 13, 2002).

[56] Vienna Convention on the Law of Treaties, Jan. 27, 1980, art. 31, 1155 U.N.T.S. 331, *available at* http://www.un.org/law/ilc/texts/treaties.htm.

> reasoned judgments in confronting the endless and ever-changing ebb and flow of real facts in real cases in the real world. They will serve the multilateral trading system best if they are interpreted with that in mind.[57]

The asymmetries of economic development that exist among the member States need to be addressed in order to ensure the effectiveness of special and differential treatment in WTO law. These need to be taken into account not only in the design of the rules but also with respect to their interpretation.

The preamble of the WTO Agreement indicates that the objective of special and differential treatment for developing countries is "to ensure that developing countries, especially the least developed among them, secure a share in the growth of international trade commensurate with the needs of their economic development."[58] According to the preamble, achieving this objective requires a consideration of their "respective needs and concerns at different levels of economic development." This objective applies to all of the covered agreements.[59] Therefore, the provisions in the WTO preamble inform the interpretation of TRIPS. The following analysis develops a framework for analyzing special and differential treatment provisions, including the references in the WTO preamble, before considering how the preamble should inform the interpretation of specific TRIPS provisions.

The Appellate Body's decision in *European Communities – Conditions for the Granting of Tariff Preferences to Developing Countries* recognizes that the references to the needs of developing countries in the WTO Agreement preamble support the view that they "may have different needs according to their levels of development and particular circumstances." However, variation in levels of development is only one factor to take into account in determining the legal and economic effects of special and differential treatment provisions. The needs of developing countries and the impact of special and differential treatment on their development both vary depending on the economic context of each WTO agreement. Likewise, variations in the interpretative context of special and differential treatment provisions must be taken into account in determining their legal effect in different agreements.[60] Thus, the legal and economic effects of special and differential treatment provisions will vary with the legal and economic context of each agreement.

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[57] WTO Appellate Body Report Concerning Japan – Taxes on Alcoholic Beverages, ¶ 6.35, WT/DS8/AB/R (Oct. 4, 1996).

[58] TRIPS pmbl.

[59] *EC Tariff Preferences*, *supra* note 53, ¶ 161; *see also* Steve Charnovitz et al., *The Appellate Body's GSP Decision*, 3 WORLD TRADE REV. 239, 239–65 (2004), *available at* http://journals.cambridge.org.

[60] Vienna Convention, *supra* note 56, at art. 31.

For example, the central thrust of GATT is to reduce tariffs and other barriers to trade (the legal context)[61] in order to stimulate economic growth through specialization in areas of comparative advantage (the economic context).[62] GATT seeks to remove barriers to competition. In contrast, TRIPS promotes intellectual property rights (the legal context)[63] in order to stimulate economic growth through innovation (the economic context).[64] TRIPS seeks to protect monopoly rights. In the context of GATT, economic development is based on market access for products in which developing countries enjoy a comparative advantage. In the context of TRIPS, economic development is based on access to technology. The nature of the rules and their underlying economic theories are different in these two agreements.

Since the legal and economic contexts of GATT and TRIPS are not the same and all developing countries are not the same, there cannot be special and differential treatment that is universally appropriate for all (1) covered agreements or (2) developing countries. Moreover, the context of special and differential treatment varies *within* each of the covered agreements. For example, both the legal and economic contexts in TRIPS will vary between different types of intellectual property rights (for example, patents versus geographical indications) and within categories of intellectual property right (for example, patents for medicine versus patents for computer technology).

This raises the issue of how to determine the appropriate level of special and differential treatment and the correct interpretation and application of special and differential treatment provisions from one agreement to the next. The basic purpose of special and differential treatment is to stimulate sustainable economic development in accordance with the needs of developing countries.[65] Thus, both the needs of developing countries and the economic impact of special and differential treatment on their development should be taken into account (1) when interpreting special and differential treatment provisions and (2) when

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[61] General Agreement on Tariffs and Trade, Oct. 30, 1947, pmbl., 61 Stat. A-11, T.I.A.S. 1700, 55 U.N.T.S. 194 [hereinafter GATT].

[62] *See, e.g.,* DAVID RICARDO, ON THE PRINCIPLES OF POLITICAL ECONOMY AND TAXATION (3d. ed. 1821); Eli Heckscher, *Utrikeshandelns verkan pa inkomstfordelningen [The Effect of Foreign Trade on the Distribution of Income]*, 21 EKONOMISK TIDSKRIFT 497 (1919).

[63] TRIPS pmbl.

[64] *See, e.g.,* JOSEPH SCHUMPETER, THE THEORY OF ECONOMIC DEVELOPMENT (Redvers Opie trans., 1934); ROBERT M. SOLOW, GROWTH THEORY: AN EXPOSITION (1988); Paul Romer, *Crazy Explanations for the Productivity Slowdown, in* NBER MACROECONOMICS ANNUAL 163 (1987).

[65] The WTO Agreement preamble refers to "sustainable development." WTO Agreement pmbl. A reasonable interpretation is that this refers to the concept developed in the Brundtland Report; while this ambiguous concept means different things to different people, sustainable economic development is generally accepted as constituting a core aspect of the term. *See* WORLD COMM'N. ON ENV'T. & DEV., *Our Common Future* (1987).

assessing the appropriateness of special and differential treatment as a policy. Applying the needs test and the economic impact test produce different results in different agreements and in different economic contexts.

Both the needs test and the economic impact test involve economic analysis.[66] For example, determining the needs of developing countries in the context of pharmaceutical patents requires an analysis of disease prevalence and purchasing power. Determining the economic impact of compulsory licenses for pharmaceuticals involves an assessment of the value of the market to the patent holder. Both tests also involve legal analysis. Both spring from the treaty text. How they play out will vary with the wording and the context of each provision that is analyzed. For example, paragraph 3(c) of the Enabling Clause specifies the developing country needs that are to be taken into account when developed countries design preferential schemes.[67] In order to determine the economic impact of a particular provision, its legal effect must be determined. Thus, the correct interpretation of a particular WTO provision will require a combination of legal and economic analysis.[68]

Special and differential treatment rules are not the only WTO provisions in which the needs of developing countries can be taken into account. A closely related issue is how the uniform application of other WTO rules may produce different results depending on the level of economic development enjoyed by a particular WTO member. Does the uniform application of WTO rules, irrespective of variations in development, give effect to the rules in a way that meets the needs of developing countries? Put another way, do variations in development levels need to be taken into account in order to ensure that WTO rules are

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[66] For a useful overview of the pros and cons of applying different kinds of economic analysis to different areas of international law, see Jeffrey L. Dunoff & Joel P. Trachtman, *Economic Analysis of International Law*, 24 YALE J. INT'L L. 1 (1999).

[67] *Differential and More Favorable Treatment*, *supra* note 51, ¶ 3(c) ("Any differential and more favorable treatment provided under this clause ... (c) shall in the case of such treatment accorded by developed contracting parties to developing countries be designed and, if necessary, modified, to respond positively to the development, financial and trade needs of developing countries.")

[68] Support for this proposition can also be found in the use of economic modeling to determine the level of retaliation permitted under the Understanding on Rules and Procedures Governing the Settlement of Disputes, art. 22.2, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 2, LEGAL INSTRUMENTS – RESULTS OF THE URUGUAY ROUND, 33 I.L.M. 112 (1994) [hereinafter DSU]. *See* WTO Decision by the Arbitrator Concerning United States – Continued Dumping and Subsidy Offset Act of 2000, WT/DS217/ARB/BRA (Brazil Compl.), WT/DS234/ARB/CAN (Canada Compl.), WT/DS217/ARB/CHL (Chile Compl.), WT/DS217/ARB/EEC (European Communities Compl.), WT/DS217/ARB/IND (India Compl.), WT/DS217/ARB/JAP (Japan Compl.), WT/DS217/ARB/KOR (Korea Compl.), WT/DS234/ARB/MEX (Mexico Compl.) (Aug. 31, 2004).

effective in achieving the objective(s) of a given rule (which may encompass more that just the objective of economic development in developing countries)? Must all WTO rules be effective for all WTO members?

Applying an effectiveness test, in addition to the needs test and the economic impact test, is consistent with the rules of treaty interpretation. The rule of effective treaty interpretation is a corollary of the general rule of treaty interpretation in *Vienna Convention* Article 31.[69] According to the rule of effective treaty interpretation, an interpreter is not free to adopt a reading that would result in reducing whole clauses or paragraphs of a treaty to redundancy or inutility.[70] Put another way, it is the duty of any treaty interpreter to "read all applicable provisions of a treaty in a way that gives meaning to all of them, harmoniously."[71] A treaty's interpretation must give effect to its provisions. A logical extension of this rule of interpretation is that the interpretation must give effect to the provision for not just some members, but for all of them. It is reasonable to conclude that the parties to a treaty intend its provisions to be effective for all. Thus, if the text supports an interpretation that makes a provision effective for all, then that interpretation should be preferred over one that does not.[72] Thus, testing the interpretation of an ambiguous provision for its effectiveness in achieving special and differential treatment objectives is "in accordance with customary rules of interpretation of public international law."[73]

Thus, there are three factors that should be taken into account in interpreting or designing special and differential treatment provisions to make them operational and effective. The first two factors reflect the objectives of the WTO Agreement preamble and TRIPS, while the third springs from a customary rule of interpretation of public international law:

(1) Development needs (TRIPS preamble and WTO Preamble);
(2) Economic impact (TRIPS Article 7 and WTO Preamble); and
(3) Effectiveness.

Taken together, these three factors or tests create an interdisciplinary

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[69] Vienna Convention, *supra* note 56, at art. 31.

[70] *See* WTO Appellate Body Report Concerning United States – Standards for Reformulated and Conventional Gasoline WT/DS2/AB/R, 35 I.L.M. 276 (Apr. 29, 1996).

[71] *See* WTO Appellate Body Report Concerning Korea – Definitive Safeguard Measure on Imports of Certain Dairy Products, at 81, WT/DS98/AB/R (Dec. 14, 1999).

[72] *See* Report of the International Law Commission on the Work of its Eighteenth Session, [1966] 2 Y.B. INT'L L. COMM'N 219 ("When a treaty is open to two interpretations one of which does and the other does not enable the treaty to have appropriate effects, good faith and the objects and purposes of the treaty demand that the former interpretation should be adopted.")

[73] DSU, *supra* note 68, at art. 3.2.

approach to the analysis of WTO law and policy. What these tests share in common is that they all seek to answer the same fundamental question—does the law, as interpreted or designed, achieve its stated objective(s) in both the legal and economic contexts?

The objectives of TRIPS must be understood in light of the overall objectives of the WTO Agreement relating to developing countries. The relationship between these two sets of objectives should be harmonious, in light of the principle of effective treaty interpretation and the presumption against conflicts in international law.

Two core objectives of TRIPS are to achieve a balance between the rights of producers and users of intellectual property and to promote development. There are a number of TRIPS provisions that support an approach to balancing TRIPS rights and obligations that differs with the level of development of the member in question. The objectives of TRIPS are to promote "technological innovation . . . to the mutual advantage of producers and users . . . in a manner conducive to social and economic welfare, and to a balance of rights and obligations."[74] Under TRIPS principles, WTO members may "adopt measures necessary to protect public health . . . provided that such measures are consistent with [TRIPS]."[75] The TRIPS preamble seeks "effective and adequate protection of intellectual property rights," while recognizing the developmental objectives of intellectual property protection and the special needs of least-developed countries for "maximum flexibility in the domestic implementation of laws."[76] These provisions reflect the concerns of developing countries in the Uruguay Round negotiations that earlier drafts of TRIPS did not adequately address, including the questions of the balance of the rights and obligations of rights holders, developmental concerns and public policy objectives. These concerns were reflected in the preamble so that they could be taken into account in the interpretation of the agreement.[77]

The WTO Agreement provides that: "The least-developed countries recognized as such by the United Nations will only be required to undertake commitments and concessions to the extent consistent with their individual development, financial and trade needs or their administrative and institutional capabilities."[78] The Decision on Measures in Favor of Least-

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[74] TRIPS art. VII.

[75] *Id.* at art. VIII. In *Canada – Term of Patent Protection*, the Appellate Body noted that its ruling did not in any way prejudge "the applicability of Article 7 or Article 8 of the TRIPS Agreement in possible future cases with respect to measures to promote the policy objectives of the WTO members that are set out in those Articles. Those Articles still await appropriate interpretation . . . ." WTO Appellate Body Report Concerning *Canada – Term of Patent Protection*, at 101, WT/DS170/AB/R (Sept. 18, 2000).

[76] TRIPS pmbl.

[77] *See* Note by the Secretariat, *supra* note 12, ¶ 14.

[78] WTO Agreement art. XI.

Developed Countries leaves no doubt that this aspect of differential treatment applies to TRIPS and repeats the language from above:

> if not already provided for in the instruments negotiated in the course of the Uruguay Round, notwithstanding their acceptance of these instruments, the least-developed countries . . . will only be required to undertake commitments and concessions to the extent consistent with their individual development, financial and trade needs or their administrative and institutional capabilities.[79]

The WTO Agreement preamble also makes special reference to the needs of developing countries, "especially the least developed among them."[80] The reference to sustainable development in the WTO Preamble provides further support for the view that TRIPS should be interpreted in a manner that supports the development needs of the developing and least-developed countries. While the term sustainable development has received a great deal of attention with respect to its role in balancing trade and environmental protection,[81] economic development is also an important aspect of sustainable development.

These provisions support the view that the balance to be struck between producers and users should shift in favor of developing and least-developed countries when they are the users under consideration. While the Uruguay Round negotiations on TRIPS rejected country-by-country transition periods, several members were of the view that the balance of rights between producers and users of intellectual property should take the needs of developing countries into account[82] and that transition periods alone were not enough to meet their needs.[83] Moreover, the promotion of innovation through the intellectual property regime was not an objective in and of itself but rather was a means of attaining other economic and social

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[79] Decision on Measures in Favor of Least-Developed Countries, art. 1, Apr. 14 1994, LEGAL INSTRUMENTS – URUGUAY ROUND MINISTERIAL DECISIONS AND DECLARATIONS (1994), 33 I.L.M. 136 (1994).

[80] WTO Agreement pmbl.

[81] The WTO Appellate Body noted the use of the term sustainable development in the WTO Preamble in its interpretation of GATT Article XX(g) to support the use of trade measures to achieve environmental protection. *See* WTO Appellate Body Report Concerning *United States – Import Prohibition of Certain Shrimp and Shrimp Products*, WT/DS58/AB/R (Oct. 12, 1998), 37 I.L.M. 834 (1998) (appealing Panel Report, WT/DS58/R (May 15, 1998)); WTO Appellate Body Report Concerning United States – Import Prohibition of Certain Shrimp and Shrimp Products: Recourse to Article 21.5 by Malaysia, WT/DS58/AB/RW (Oct. 22, 2001) (appealing Panel Report, WT/DS58/RW (June 15, 2001)).

[82] It is not specified which "several members" supported this view. *See* Note by the Secretariat, *supra* note 12, ¶ 13.

[83] *Id.* ¶ 37.

objectives. Existing international intellectual property conventions respected this and the fact that the relative costs and benefits of the protection on intellectual property rights varied from country to country depending on the level of economic development.[84] In order for special and differential treatment to be effective in meeting the needs of developing countries, the correct balance must differ from one market to the next, rather than be universally applicable without regard to the conditions existing in each market. The absence of internationally agreed criteria that determine the needs of each country at different levels of economic and technological development makes this difficult to achieve. However, the context of specific provisions and agreements provide guidance regarding the criteria that would be appropriate.

When read together, the objectives of TRIPS and the WTO Agreement integrate into TRIPS the twin themes of balancing intellectual property rights against development needs and providing differential treatment based on the level of development of WTO members. There is no inherent conflict between the objectives of the WTO Agreement and the specific objectives of TRIPS.

TRIPS permits flexibility in the manner in which its provisions are implemented in domestic legal systems. TRIPS Article 1 provides that "Members shall be free to determine the appropriate method of implementing [TRIPS] provisions within their own legal system and practice." The appropriateness of a particular legal system in a given market depends on the conditions prevailing in that market.[85] In the following section, we argue that patent laws, like legal systems in general, will be more effective in promoting innovation and economic development where their design, interpretation and implementation take into account prevailing conditions on a market-by-market basis.

IV. THE ECONOMIC IMPACT OF PATENTS AND THEIR EFFECT ON DEVELOPMENT NEEDS

In the context of drug patents, striking the right balance between the rights of producers and users requires an analysis of development needs and economic impact to determine whether patent rights (the rights of producers) or compulsory licensing rights (one of the rights of users) are more effective in promoting innovation that meets the needs of developing countries. This raises economic issues regarding the effect that patents have on innovation and economic development and whether drug patents are conducive to social and economic welfare.

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[84] *Id.* ¶ 15.

[85] Benito Arruñada & Veneta Andonova, *Market Institutions and Judicial Rulemaking*, *in* HANDBOOK OF NEW INSTITUTIONAL ECONOMICS 229–50 (C. Ménard & M. Shirley, eds., 2005).

The argument for patent rights in developing countries is based on several assumptions regarding the general economic impact of patents and the specific economic impact of patents in developing countries: (1) technological innovation promotes economic growth; (2) patent rights are necessary to provide research incentives to spur technological innovation; (3) patents in developing countries will provide research incentives to create technological innovations that serve the needs of developing countries; (4) patent rights in developing countries are necessary to promote the transfer of technological innovations from firms in developed countries and to promote technological innovation in developing countries; and (5) technology transfer to developing countries promotes economic growth in developing countries.

The theoretical foundation for drug patents lies in the economic argument that monopoly rights are necessary to spur innovation in the pharmaceutical field.[86] In essence, this argument states that, without patents, the invention of new pharmaceuticals would cease, making the issue of affordable access to medicine a moot point. This argument is normally used by pharmaceutical companies to make the case for *any* drug.[87] In particular, the argument has been put forward for HIV/AIDS drugs.[88]

However, the economic issues are different for global diseases (diseases that are prevalent in both developed and developing countries, such as HIV/AIDS) and neglected diseases (developing country diseases that are not prevalent in developed countries, such as malaria). This is because the markets for drugs that treat the diseases are different.

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[86] For example, paragraph 3 of the TRIPS Declaration makes reference to the effect of patent rights on research incentives as follows: "We recognize that intellectual property protection is important for the development of new medicines. We also recognize the concerns about its effects on prices." TRIPS Declaration ¶ 3.

[87] The thrust of the argument has been articulated in this document of the pharmaceutical industry:

> Innovators in all industries rely on patents to ensure that their inventions are protected and that they will be given an opportunity to recover their research investments. Strong intellectual property protection is essential for the preservation and growth of the research-based pharmaceutical industry – and thus for the continuing development of new and better medicines for patients. The reason is simple: no company would be able to invest the huge amount of time and money it takes to discover and develop a new medicine if the drug could be immediately copied and marketed at a greatly reduced cost by a competitor with no R&D expenses to recover.

PHARMACEUTICAL RESEARCH & MANUFACTURERS OF AMERICA, PHARMACEUTICAL INDUSTRY PROFILE 30 (2002), *available at* http://www.phrma.org/publications/publications/profile02/industryprofile2002.pdf [hereinafter PHRMA INDUSTRY PROFILE].

[88] *Id.*

In some cases, it may be difficult to determine whether a disease is global or neglected. For example, HIV/AIDS straddles both the developed world and the developing world, which suggests that it is best characterized as a global disease. However, the types of HIV infection found commonly in the developing and the developed worlds are not the same. There are many subtypes of HIV-1 (the most commonly occurring HIV infection in humans). The HIV-1 subtypes accounting for most infections in Africa are subtype C in southern Africa, subtypes A and D in eastern Africa, and a circulating recombinant form 02_AG (CRF02_AG) in west-central Africa.[89] On the other hand, the most commonly occurring form of HIV-1 in North America (and in Europe) is subtype B. The drugs developed are more effective against HIV-1 subtype B. Thus, the sub-types prevailing in developing countries can be characterized as neglected diseases. Moreover, HIV/AIDS drugs primarily serve the *developed* country markets. It is estimated that 98% of the revenue for drugs for combating HIV/AIDS come from the OECD countries.[90]

In the following sections, we consider various economic arguments for and against the use of patents to stimulate innovation in treatments for neglected and global diseases. The focus of our analysis in this section is on the issue of whether global pharmaceutical patents are necessary to create research incentives to treat neglected and global diseases in developing countries.[91]

A. Are global patents necessary to provide research incentives for neglected diseases?

One of the reasons proffered for having global patents is that a global patent system will provide research incentives for the development of drugs for neglected diseases.[92] According to this view, the reason these diseases

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[89] M. Peeters & P.M. Sharp, *Genetic Diversity of HIV-1:The Moving Target*, 14 A.I.D.S. S129, S129–30 (3d Supp. 2000).

[90] Jean O. Lanjouw, *A Patent Policy Proposal for Global Diseases* (The Brookings Institution, Working Paper No. 84, 2001), *available at* http://www.brook.edu/views/papers/lanjouw/20010611.htm (June 11, 2001).

[91] It is important to note that this issue is distinct from the issues of whether global patent rights lead to differential pricing (Ramsey pricing) and how regulatory capture affects research incentives; both issues that have been treated elsewhere in the literature. Regarding the former, see F.M. Scherer & Jayashree Watal, *Post-TRIPS Options for Access to Patented Medicines in Developing Countries*, 5 J. INT'L ECON. L. 913 (2002). Regarding the latter, see WILLIAM LANDES & RICHARD POSNER, THE POLITICAL ECONOMY OF INTELLECTUAL PROPERTY LAW (2004). For a recent extension of the Ramsey Pricing model, see also William Jack & Jean O. Lanjouw, *Financing Pharmaceutical Innovation: How Much Should Poor Countries Contribute?* (Cntr. for Global Dev., Working Paper No. 28, 2003), *available at* http://www.cgdev.org/content/publications/detail/2762.

[92] For example, the pharmaceutical industry argues that:

have been "neglected" by the pharmaceutical industry is due to the general absence of effective patent protection in developing countries prior to the implementation of TRIPS.

Another argument is that the risk of compulsory licensing makes developing countries unattractive for the pharmaceutical industry, even with global patent rights in place. The risk of losing their entire potential profits in developing countries makes it unattractive for the pharmaceutical companies to develop drugs for any disease – in particular for neglected diseases.[93] However, WTO rules—and national legislation in markets such as the United States—permit compulsory licensing. The risk of compulsory licensing in the United States has not deterred investment in the U.S. market. Moreover, WTO rules require compensation for the patent holder when compulsory licenses are issued.[94]

There are several arguments against global patents. Even with patent protection in developing countries, their markets lack the purchasing power needed to spur private investment in treatments for neglected diseases. Of the 1,393 new chemical entities marketed between 1975 and 1999, only sixteen were for tropical diseases and tuberculosis, i.e. diseases no longer found in developed countries.[95] Of the annual health-related research and development worldwide in 1999, only 0.2% was for pneumonia, diarrheal diseases and tuberculosis—yet these account for 18% of the global disease burden.[96] These statistics indicate that the advent of TRIPS has not created

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> Patent protection has become an important component of the World Trade Organization's trade rules. Strong intellectual property protection not only benefits patients, it also helps *developing nations* by improving the conditions for investment, encouraging the growth of local industry, and providing consumers with a wider selection of goods and services.

PHRMA INDUSTRY PROFILE, *supra* note 87, at 34 (emphasis added).

[93] The pharmaceutical industry argues that:

> Regardless of the stage of a country's economic development, compulsory licensing impedes the availability of new medications because, under the threat of a compulsory license, pharmaceutical companies are hesitant to invest R&D or other resources in such countries. For example when Canada implemented legislation in the 1970s that broadly permitted compulsory licensing with little compensation for patent holders, investment in pharmaceutical research and development declined sharply and fewer new products were introduced in Canada. Not until Canada restored full patent protection, and made compulsory licensing subject to the conditions in the TRIPS Agreement, did the research-based pharmaceutical industry begin to reinvest in Canada.

PHRMA INDUSTRY PROFILE, *supra* note 87, at 37.

[94] TRIPS art. 31(h).

[95] Patrice Trouiller, et al., *Drug Development for Neglected Diseases: A Deficient Market and a Public-Health Policy Failure*, 359 THE LANCET 2188 (2002).

[96] U.N. DEV. PROGRAMME, HUMAN DEVELOPMENT REPORT (1999), *available at*

adequate research incentives by itself. Only time will tell whether this trend will continue.

Nevertheless, there is another argument against the necessity of global patents. Patents do not provide an incentive for innovation even where there is adequate purchasing power in the market.[97] An "intellectual monopoly" approach to patent rights has the effect of stifling innovation because it provides an incentive to patent holders to invest in legal action to extend the life of their patents and to prevent others from developing new innovations. In economic terms, patents provide rights to the person first in the door of the patent office. This is an inefficient way of allocating economic resources. This has led many economists to believe that there is no inherent reason for patent protection.[98] Historical evidence favors this view.[99]

B. Are global patents necessary to provide research incentives for global diseases?

The argument in favor of global patents for global diseases is as follows. Developed country markets will be undermined through parallel imports unless patents are global, even if developed countries prohibit parallel imports. Prohibitions on illegal recreational drugs (such as cocaine or marijuana) are not effective in preventing their import and sale on black markets. The same would be true for pharmaceutical products.[100]

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http://hdr.undp.org/reports/global/1999/en/.

[97] Michele Boldrin & David Levine, *The Case Against Intellectual Property,* 92 AM. ECON. REV. 209, 210 (2002). *See also* THE DRUGS FOR NEGLECTED DISEASES WORKING GROUP, *A Survey of Private Sector Drug Research and Development, in* FATAL IMBALANCE: THE CRISIS IN RESEARCH AND DEVELOPMENT FOR DRUGS FOR NEGLECTED DISEASES 171 (2001); Robert A. Book, Public Research Funding and Private Innovation: The Case of the Pharmaceutical Industry (Dec. 10, 2003) (manuscript, on file with author); Danny Quah, 24/7 Competitive Innovation (May 2002) (unpublished manuscript, on file with author), *available at* http://econ.lse.ac.uk/staff/dquah/p/0204-247-2pp.pdf.

[98] For example, Suzanne Scotchmer notes that "[t]here is no economic rationale for protecting inventors per se." SUZANNE SCOTCHMER, THE POLITICAL ECONOMY OF INTELLECTUAL PROPERTY TREATIES 1 (Nat'l Bureau of Econ. Research, Working Paper No. 9114, 2003). We are indebted to Suzanne Scotchmer of the Department of Economics, University of California-Berkeley for providing us with this reference.

[99] For example, in the draft of Chapter 1 of "The Case Against Intellectual Monopoly," the authors forcefully put forward the case of how James Watt (of steam engine fame) managed to set back the clock of the industrial revolution by lobbying for and getting his monopoly extended. Boldrin & Levine, *supra* note 97, at ch.1. For a discussion of how the early American growth was fuelled by simply ignoring the European intellectual property laws, see B. ZORINA KHAN, THE DEMOCRATIZATION OF INVENTION: PATENTS AND COPYRIGHTS IN AMERICAN ECONOMIC DEVELOPMENT (2005).

[100] "There is widespread concern that reimportation schemes are inherently unsafe. Such plans would endanger public health; increase the supply of counterfeit, contaminated, and mislabeled drugs, and probably not even save money as intended." PHRMA INDUSTRY

However, drugs to treat potentially fatal diseases are not the same as recreational drugs. Fake recreational drugs (most often) do not harm the user's life. Fake drugs for HIV/AIDS (or other diseases) will. Most patients will not be willing to risk their lives buying pharmaceuticals on the black market that have potentially lethal consequences. We do not see drug dealers selling HIV/AIDS drug cocktails on the street corners of the United States, even though generic HIV/AIDS drug cocktails can be bought in developing countries for the tenth of the price that one has to pay in developed countries. Black markets for parallel imports of pharmaceuticals are unlikely.

An argument against global patents is that developed country markets provide sufficient incentives to invent drugs to treat global diseases, thus making developing country patents unnecessary. The case of treatments for HIV/AIDS supports this view. Global patents were not necessary to create research incentives to invent treatments, but global patents have impeded affordable access to treatment in developing countries. TRIPS permits WTO members to determine whether to allow parallel imports.[101] Therefore, patent laws in developing countries should focus on increasing affordable access to treatment, not research incentives. Global patents impede affordable access by reducing price competition.

Moreover, global patents have stifled innovation in HIV/AIDS treatment regimens. In markets served by patented drugs, the regimen requires a large number of pills taken three times a day. In contrast, in markets served by generic drugs, both the number of pills and the number of daily doses have been reduced. This innovation on the part of the generic manufacturers has simplified treatment for patients in countries where the patents are not in force, in addition to lowering the price of treatment considerably.[102] This provides further support for the argument against global patents, whether for neglected or global diseases.

We conclude that global patents are neither necessary for the development of drugs for global diseases nor for neglected diseases. The effect that patents have on innovation and economic development in developing countries is not conducive to their social and economic needs. Thus, uniform application of TRIPS obligations regarding drug patents is unlikely to be effective in promoting innovation that meets the needs of developing countries.

PROFILE, *supra* note 87, at 30.

[101] TRIPS art. 6.

[102] *See* Shankar Vedantam, *Foreign Drugs Approved For Anti-AIDS Program: Decision Means Treatment for More*, WASH. POST, Jan. 26, 2005, at A10.

V. MAKING TRIPS PATENT RULES EFFECTIVE IN ACHIEVING ECONOMIC AND DEVELOPMENT OBJECTIVES

Drug patents have neither a positive economic impact on developing countries nor meet their development needs. They have the opposite effect. The lack of affordable and effective access to medical treatment has a negative impact on development. Several measures of development are affected by HIV/AIDS, including GDP per capita, economic growth, education, life expectancy, and health. Indeed, Peter Piot, the executive director of the United Nations HIV/AIDS program, has stated that "[c]ountries like Botswana ... risk becoming what I would call 'undeveloping' because of HIV/AIDS."[103] Thus, if patents decrease access to life-saving medicines in developing countries, the impact on their development needs will be negative and defeat the objectives of the WTO.

The result is that TRIPS obligations regarding patent rights are not effective in meeting the objectives of the WTO Agreement and TRIPS. There are two possible solutions to this problem. A solution is to use the exceptions in TRIPS to achieve a better balance between the rights of users and producers until the patent obligations can be eliminated. This might be achieved through an interpretation of an amendment to Article 31. The first part of this section will examine specific Article 31 exceptions in that context. A better solution is to eliminate the obligation of developing countries to provide patent rights for pharmaceutical products, through waivers for developing countries (whose transition period has ended under TRIPS Article 65) and extending transition periods for least-developed countries (an option that is contemplated in TRIPS Article 66). This solution has been partly achieved for least-developed countries, whose obligations to protect pharmaceutical patents have been delayed until 2016. The second part of this section will propose an index that can be used to determine the circumstances in which patent obligations should be waived for developing countries whose obligations are already in force[104] or to

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[103] *No indication AIDS epidemic leveling off, UN says*, July 7, 2002, *at* http://www.globeandmail.com. Most studies estimate that AIDS epidemics in the worst hit countries have caused an annual loss of about 1% in per capita GDP. Clive Bell, Hans Gersbach and Shanta Devarajan challenge this view, arguing that the long-term impact on economic growth is much greater because of the impact on human capital of the disruption in the transmission of knowledge from one generation to the next and the impact on education. *See Epidemics and Economics*, THE ECONOMIST, Apr. 12, 2003, at 69.

[104] The procedure for waiving WTO obligations is set out in the WTO Agreement Article IX. In exceptional circumstances, the Ministerial Conference may decide to waive an obligation imposed on a member by the WTO Agreement or any of the Multilateral Trade Agreements. A request for a waiver concerning the Multilateral Trade Agreements must initially be submitted for consideration by the relevant Council, which then submits a report to the Ministerial Conference. In the interval between Ministerial Conferences, the WTO General Council may approve waivers.

extend transition periods further for least-developed countries.[105] Both are needed as part of the solution proposed in this article because TRIPS contemplates extending the transition period for least-developed countries, but not for developing countries. Moreover, the transition period for developing countries has ended, leaving waivers as the only mechanism to use to suspend their patent obligations.

Another option is to advocate an interpretation through the dispute settlement process of the WTO. However, this option is unappealing for three reasons. First, it would require waiting for a dispute to come before the dispute settlement body that raises the right issues. Second, even if this were to occur and the WTO Panel or Appellate Body were to adopt the advocated interpretation, the interpretation would be legally binding only for the parties to the dispute. Third, ambiguous treaty language should not be used to resolve a normative policy issue that is still a matter of unresolved political debate. Thus, other WTO decision-making mechanisms are preferable.

A. Solving the Problem through Interpretation or Amendment

Where TRIPS provisions are sufficiently ambiguous to be susceptible to an interpretation that resolves the issue of special and differential treatment, an official interpretation would be feasible.[106] However, where there is insufficient ambiguity, reforms are better addressed through the amendment process.[107] This section briefly considers the degree of ambiguity in Article 31 in this context, rather than engaging in a detailed

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[105] The WTO used a "decision" to extend the transition period for least-developed countries to 2016 for pharmaceutical patents. *See supra* note 50. As a general rule, the WTO is required to continue the GATT practice of "decision-making by consensus," which is defined as "no Member, present at the meeting when the decision is taken, formally object[ing] to the proposed decision." As a general rule, where a decision cannot be reached by consensus, the matter is decided by vote. A simple majority of WTO members may issue Decisions under the WTO Agreement. *See* WTO Agreement art. IX:1.

[106] WTO Agreement Article IX:2 gives the Ministerial Conference and the General Council "exclusive authority to adopt interpretations" of the WTO Agreement and Multilateral Trade Agreements. With respect to Annex 1 agreements (goods, services and intellectual property rights), interpretations must be based on a recommendation of the Council overseeing the particular agreement. The decision to adopt an interpretation must be taken by a three-fourths majority of the Members (though, as noted above, the preference is to take decisions by consensus). However, this mechanism cannot be used in place of the WTO amendment procedures. Thus, this procedure may only be used to clarify provisions that are otherwise ambiguous, not to create new obligations or exceptions.

[107] Under WTO Agreement Article X, decisions to amend provisions of the Multilateral Trade Agreements can be adopted through approval either by all members or by a two-thirds majority, depending on the nature of the provision concerned. Amendments only take effect for those WTO members who accept them. However, in order to maintain the consistency of WTO obligations, amendment decisions should be taken by consensus.

analysis. There is already a great deal of literature addressing how TRIPS Article 31 can be interpreted in ways favorable to developing countries. This section is limited to the point that interpretation is not the best route to follow in introducing objective criteria for applying situational flexibility to compulsory licensing exceptions.

In the context of patent provisions in TRIPS, the rights conferred on patent owners in Article 28(1) and 33 are expressed in unambiguous terms.[108] The lack of ambiguity in this treaty text makes it difficult to take special and differential treatment into account through interpretation. As noted earlier, Articles 30 and 31 authorize exceptions to TRIPS patent rights, and while Article 30 permits "limited exceptions," Article 31 is broader and provides a right to make other use of the subject matter of the patent without the authorization of the right holder.

Article 31 permits WTO members to allow "other use of the subject matter of the patent" and covers compulsory licensing of patents. The term "other use" means "use other than that allowed under Article 30."[109] The language in this provision is more ambiguous than the language in Articles 28 and 33. Thus, the rule of effective treaty interpretation might be applied to take the circumstances of the WTO member invoking Article 31 rights into account to ensure that the right is effective for that member in a specific case. Subsection (a) of Article 31 requires that a given authorization "be considered on its individual merits."

Subsection (b) provides that other use may only be permitted if "the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time." This provision contains sufficient ambiguity to be open to different interpretations. The needs of a developing country in a particular case might be taken into account to determine whether (1) the efforts are adequate, (2) whether the commercial terms and conditions are reasonable, and (3) what constitutes a reasonable period of time. Interpreting these three conditions in light of the objectives of the WTO Agreement and TRIPS means that the standard could vary with the level of economic development of the country invoking the right and the circumstances in which the right is invoked. For example, if the right is invoked to increase the affordability of medical treatment for a developing country disease (which could be a neglected disease or a global disease), the development needs of the country and the economic impact of expanding access to treatment should be taken into account to make access to the right effective. A similar analysis can be applied to the scope and duration of the use under subsection (c) and what constitutes adequate remuneration under subsection (h).

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[108] *See* TRIPS arts. 28, 33.

[109] *Id.* at n.7.

Given the ambiguity of several subsections in Article 31 and the availability of arguments that support taking into account the needs of developing countries, an official interpretation might be used as the vehicle. However, given the need to negotiate criteria and the proviso that interpretations not be used to amend an agreement, it is a less satisfactory alternative than an amendment.

However, an amendment to Article 31 that would facilitate the use of compulsory licensing in developing and least-developed countries is another alternative. The aim of such an amendment would be to make Article 31 sufficiently flexible to vary the balance between the rights of producers and users of patented drugs on a market-by-market basis. This solution is problematic. It would be difficult to implement situational flexibility in a manner that would provide both certainty and flexibility, particularly with respect to the issue of what would constitute adequate compensation for the patent holder in specific cases. Moreover, the adequacy of compensation is a complex issue that is addressed in national courts, not the WTO.[110] Determining whether compensation is adequate through litigation is an uncertain and expensive process.[111] In contrast, eliminating patent obligations for drugs altogether through waivers or the extension of the transition period on a market-by-market basis provides legal certainty and is far easier to implement on a case-by-case basis. In the following section, we propose a set of criteria to be applied to determine the circumstances in which obligations should be suspended for pharmaceutical patents in a given market for a given medicine.

B. Eligibility for Exemption from Patent Obligations

Determining the correct balance between producers and users of patented products using the current breakdown of WTO members into the three categories of developed, developing and least-developed countries is

[110] TRIPS permits the process for calculating remuneration to differ from one WTO member to the next. *See supra* note 29. For example, in the United States, courts use a fifteen factor test to assess damages for reasonable royalties. *See, e.g.,* Gargoyles, Inc. v. United States, 113 F.3d 1572, 1580 (Fed. Cir. 1997); Ga.-Pac. Corp. v. U.S. Plywood Corp., 318 F. Supp. 1116, 1120 (S.D.N.Y. 1970), *modified & aff'd*, 446 F.2d 295, 302 (2d Cir. 1971).

[111] Under U.S. jurisprudence, the correct measure of compensation is "what the owner has lost, not what the taker has gained." Leesona Corp. v. United States, 599 F.2d 958, 969 (Ct. Cl. 1979) (cited with approval in *Gargoyles*, 113 F.3d at 1575); Hughes Aircraft Co. v. United States, 86 F.3d 1566, 1571–72, (Fed. Cir. 1996). However, it is not clear whether the same standard applies in Section 1498 cases, which involve the government. *See Gargoyles*, 113 F.3d at 1575; Tektronix, Inc. v. United States, 552 F.2d 343, 349 (Ct. Cl. 1977) ("[I]f lost profits are ever to be awarded under Section 1498, it should be only after the strictest proof that the patentee would actually have earned and retained those sums in its sales to the Government.") Since TRIPS permits the process for calculating remuneration to differ from one WTO member to the next, uncertainty increases in the international context.

overly simplistic and inappropriate in the context of pharmaceutical patents. This article proposes a more sophisticated categorization of the WTO membership in the form of an index that can be used to achieve a more equitable balance between the rights of producers and users on a market-by-market basis. This proposal is grounded on economic considerations and takes into account the need to apply a systematic standard to determine the particular needs of developing countries set out in the WTO Agreement or in multilateral instruments adopted by international organizations.[112] This section offers a step by step guide for permitting a country to waive or delay patent protection using a multidimensional approach. The method recognizes the needs of a country not just based on its level of poverty, but also on a threshold level of infection rate of a particular disease.

A difficult issue is how to determine the cut-off point with respect to economic development in the case of developing countries.[113] The WTO recognizes as least-developed countries those countries that have been designated as such by the United Nations.[114] A country like Brazil does not qualify as a least-developed country. Nevertheless, a country's level of development will affect the balance between research incentives and affordable access even in the case of a developing country like Brazil because the value of its market influences the evaluation of the impact of compulsory licenses on research incentives. For this reason, we propose a

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[112] *See EC Tariff Preferences*, *supra* note 53, ¶ 163.

[113] There are no WTO definitions of "developed" or "developing" countries. Members can announce for themselves whether they are developing countries. However, this does not automatically provide rights. Other members can challenge the announcement, which has happened in the area of intellectual property. This challenge can then lead to negotiations to clarify the position. For countries that joined the WTO after 1995, their status depends on the agreed terms from the accessions negotiations. *See* Guglielmo Verdirame, *The Definition of Developing Countries under GATT and Other International Law*, 39 GERMAN Y.B. OF INT'L. L. 164 (1996).

[114] Article XI:2 of the WTO Agreement recognizes as least-developed countries those designated as such by the United Nations. It provides that such countries "will only be required to undertake commitments and concessions to the extent consistent with their individual development, financial and trade needs or their administrative and institutional capabilities." There are currently fifty least-developed countries on the U.N. list; to date thirty-two have become WTO Members. These are: Angola, Bangladesh, Benin, Burkina Faso, Burundi, Cambodia, Central African Republic, Chad, Democratic Republic of the Congo, Djibouti, Gambia, Guinea, Guinea Bissau, Haiti, Lesotho, Madagascar, Malawi, Maldives, Mali, Mauritania, Mozambique, Myanmar, Nepal, Niger, Rwanda, Senegal, Sierra Leone, Solomon Islands, Tanzania, Togo, Uganda, and Zambia. Twelve additional least-developed countries are in the process of accession to the WTO. They are: Afganistan, Bhutan, Cape Verde, Equitorial Guinea, Ethiopia, Laos, Nepal, Samoa, São Tomé and Principe, Sudan, Vanuatu and Yemen. *See* UN Office of the High Representative for the Least Developed Countries, Landlocked Developing Countries and Small Island Developing States, *List of Least Developed Countries,* at http://www.un.org/special-rep/ohrlls/ldc/list.htm (Nov. 3, 2005) [hereinafter *LDC List*]; WTO, *Members and Observers, at* http://www.wto.org/ english/thewto_e/whatis_e/tif_e/org6_e.htm (Feb. 2005).

more sophisticated approach to balancing the rights of producers and users.

Least-developed countries are officially designated as such by the United Nations General Assembly on the basis of a number of criteria, including: low national income (per capita GDP) under $900 million for countries now joining the list); low levels of human development (a combined health, nutrition and education index); and economic vulnerability (a composite index based on indicators of instability, inadequate diversification and the handicap of small size). The population of countries that meet all the other criteria for admission to the category must not exceed 75 million inhabitants.[115]

This definition provides an inadequate measure for determining the correct balance between producers and users of patented drugs. Consider the case of HIV/AIDS. Using above criteria, a middle-income country with a high rate of HIV/AIDS infection, such as South Africa at 19.94%, would not qualify for the most favorable level of treatment.[116] Therefore, we propose that a different index be used (somewhat similar to the Human Development Index) to categorize countries and to determine the correct balance between TRIPS rights and obligations regarding pharmaceutical patents on a market-by-market basis.[117]

It is important to emphasize that we are not proposing that this index be used regarding other forms of intellectual property or other WTO agreements. Nor are we proposing that this index be used to justify the erosion of core non-discrimination obligations. Rather, we propose that this index be used for the narrow purpose of achieving equality among WTO

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[115] The formal definition is taken from Press Release, U.N., Third UN Conference on Least Developed Countries in Brussels: 14–20 May to Confront Economic Isolation of 'Poorest of the Poor,' (May 11, 2001), *available at* http://r0.unctad.org/conference/press/devbru1.htm (last visited Oct. 25, 2005).

[116] The fifty least-developed countries are as follows: Afghanistan, Angola, Bangladesh, Benin, Bhutan, Burkina Faso, Burundi, Cambodia, Cape Verde, Central African Republic, Chad, Comoros, Democratic Republic of the Congo, Djibouti, Equatorial Guinea, Eritrea, Ethiopia, Gambia, Guinea, Guinea Bissau, Haiti, Kiribati, Lao People's Democratic Republic, Lesotho, Liberia, Madagascar, Malawi, Maldives, Mali, Mauritania, Mozambique, Myanmar, Nepal, Niger, Rwanda, Samoa, Sao Tome and Principe, Senegal, Sierra Leone, Solomon Islands, Somalia, Sudan, Timor-Lesté, Togo, Tuvalu, Uganda, United Republic of Tanzania, Vanuatu, Yemen and Zambia. *See LDC List, supra* note 114.

[117] Of course, researchers do not agree that something more than per capita income is necessary to determine what should be done about a specific country. For example, Jean Lanjouw favors the use of per capita GDP only, noting: "It is arguable that a country with high income unequally distributed should not be given benefits in the form of low drug prices. Those countries have the resources to deal with poverty domestically." *See supra* note 90. In other words, if the income level is high, then the issue should be solved using some domestic mechanism, like tax-transfer. Email from Jean Lanjouw, to Bradly Condon & Tapen Sinha (Sept. 29, 2003) (on file with authors). The problem with this approach is that it is not at all clear how such a mechanism can be engineered before the country slides back into poverty due to a disease such as HIV/AIDS.

members with respect to access to medicine to address the HIV/AIDS pandemic and other public health problems. Finally, while the legal rights and obligations that flow from the concept of special and differential treatment for developing countries are far from clear, and the current means of defining developing and least-developed countries in international law are inadequate, we are by no means suggesting this index as the appropriate solution to these highly controversial issues.

There are three specific ingredients to the construction of the index: (1) disease prevalence; (2) per capita income; and (3) poverty rate.

1. Disease rate

First, a disease has to be above some threshold rate that will be determined by a world body. Once a country is above that threshold rate for the specific disease, it will qualify for a waiver (developing countries) or an extension of the transition period (least-developed countries) with respect to patent obligations for treatments for that disease. The reason developing countries would require a waiver is that the TRIPS Agreement does not contemplate an extension to the transition period for developing countries, which expired January 1, 2005.

Because this has to be done impartially on a global scale, we need to decide which world body should decide on the threshold. It seems logical that the World Health Assembly would be the right forum for making such a decision. After all, the World Health Assembly is authorized to adopt regulations on international health matters. But the reality of the World Health Assembly makes it the wrong forum for the following reason. In its entire history, it has only adopted two such regulations: (1) Unification of Statistical Classification of Morbidity and Mortality (in 1948 and subsequent revisions) and (2) International Sanitary Regulations (in 1951). Thus, it has not made much progress in setting standards for health-related matters in the past. Therefore, we could not rely on an international body that moves at glacial speed on matters that require urgent and speedy decisions. What about the World Health Organization ("WHO") itself? Eric Stein, the renowned legal scholar on international law, warns us about the decision-making by the WHO. He notes that "WHO activities have been carried out primarily by consensus through *nonbinding* and less formal procedures such as recommendations, resolutions, and promulgation of technical standards."[118] He also notes that the WHO has failed to set up a desperately needed legal settlement procedure.[119] In fact, the WHO has been very politicized. The decision-making processes at the WHO have

[118] *See* Eric Stein, *International Integration and Democracy: No Love at First Sight*, 95 AM. J. INT'L L. 489 (2001).

[119] *Id.* at 499.

been anything but transparent. Therefore, our recommendation is to have the TRIPS Council decide on the threshold. This raises the obvious objections that the WTO mandate is limited to trade-related matters and should not be expanded to include public health issues. However, this objection seems weak, given the relationship between patents, public health, and the work that has already been done in this area under the purview of TRIPS. Indeed, the issue of adopting criteria to implement special and differential treatment in WTO agreements is already the subject of negotiations in the Doha Round. Moreover, there is a precedent for the WTO to negotiate a threshold for addressing the special and differential treatment of developing countries in the context of a WTO Agreement.[120]

Suppose the disease rate in a country is denoted by r. Suppose, also one has agreed upon a threshold of the infection rate of the disease $t(r)$. The criterion used would be as follows. A country would qualify if the actual rate of infection prevailing in the country is larger than the agreed upon threshold value (in symbols, a country would qualify if $r > t(r)$ regardless of economic development or any other criterion). A high rate of infection would override every other criterion. The rationale for using this method is simple. It does not exclude countries that may not qualify because of otherwise mitigating factors such as a relatively high level of per capita income. How should the threshold be determined? This should depend on the disease in question. For infectious diseases, the threshold should be determined by a level such that with a higher rate, the disease would rapidly spread.[121]

2. Per capita income

Second, one needs to include a country if the income level is low. This requires a threshold value below which a country would qualify for a waiver. Once again, the threshold would be determined by a world body (in this case, the suitable organization would be the World Bank). If a country has a per capita income[122] below some threshold, it would automatically

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[120] *See* WTO Agreement Annex VII (establishing the threshold of GNP per capita of $1,000 for the application of Article 3.1(a) to the listed countries).

[121] A paper by Romualdo Pastor-Satorras and Alessandro Vespignan gives us clues as to how to determine the threshold. Roughly speaking, the threshold is determined by the number of "nodes" that allow the spread of the disease. If there are many nodes, the spread speeds up. In the case of HIV/AIDS, the identifiable nodes are commercial sex workers and truck drivers. Romualdo Pastor-Satorras and Alessandro Vespignan, *Epidemic Dynamics in Finite Size Scale-Free Networks* (Feb. 18, 2002), *available at* http://arxiv.org/abs/cond-mat/0202298 (last visited Oct. 25, 2005).

[122] Here we have left the exact method of determining the value of per capita income open. Usually, to get comparable per capita income across countries, we convert per capita income from local currencies (which are not comparable across countries) into some fixed currency (usually U.S. dollars) on the basis of the exchange rate on a given day. However,

qualify. The per capita income is denoted by *pci* and the corresponding threshold per capita income by *t(pci)*. Expressing in symbols, the criterion is written as follows: If the per capita income $pci < t(pci)$, then the country automatically qualifies.

3. Poverty rate

Third, we need to have a mechanism to take into account the poverty level in the country. One possible candidate could be the average level of income in the country. Unfortunately, the average income does not do the job because it papers over the inequality in income among the population.[123]

There are different measures of inequality that are potential candidates. One commonly-used measure is the Gini coefficient.[124] However, the Gini coefficient is not affected by a multiplicative factor: If everyone's income increases by ten-fold, the Gini coefficient is not affected.[125] To take a concrete example, Uganda and the United States have approximately the same Gini coefficient of income distribution.[126] Thus, the Gini coefficient would be meaningless as a measure of inequality that can be compared across countries at a given point in time.

A more appropriate measure of inequality is to include people who are

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the current exchange rate does not necessarily reflect the purchasing power of a certain income in a given country. One way of adjusting for purchasing power is the so-called Purchasing Power Parity ("PPP") method. The idea for the PPP adjustment is to create an index by calculating how much a fixed basket of goods and services would cost in different countries (in local currency) and then adjusting the "value" of one unit of that currency in terms of U.S. dollars. We are recommending a purchasing power adjustment for per capita income but not for determining the poverty level threshold. The reason is the following: The general wellbeing of the population in a given country is determined by how much money can buy in the country. The use of the poverty level index is meant to capture the affordability of medicine in the international market, as it is likely that medicines have to be imported. If the average PPP adjusted income is high, such as in South Africa or in Brazil, the people who need medicine but cannot afford it will be captured by the threshold measure of poverty — $1 a day in income.

[123] There is an ancient joke that says if you put your head in the oven and your feet in the freezer, you are comfortable on the average.

[124] The most common geometric definition of the Gini coefficient is based on the Lorenz (or concentration) curve. It represents cumulative income share as a function of cumulative population share. If a population share is always exactly equal to a share in overall income, then there is a situation of perfect equality.

[125] Technically, the Gini coefficient is a *relative* measure of inequality.

[126] Both are around 38%. The lower the number, the more equal the income. Conversely, the higher the number, the higher the inequality. Thus, a zero percent Gini coefficient means everybody in the economy has the same income. On the other hand, 100% value of the Gini coefficient implies that one person has all the income in the country and everyone else has zero income. Of course, in real life, neither extreme is observable. In real life, it ranges from around 25% (for countries such as Belgium, Finland and the Czech Republic) to over 60% (for countries such as Brazil or Sierra Leone).

poor in the country in absolute terms. One possibility would be to consider a threshold of some proportion of people who are below some absolute measure of poverty level. The rationale is simple. If there are many people below some absolute poverty level, they cannot afford treatment. A simple measure (available for most countries around the world) is the proportion of people in the country who live on $1 or less a day. So, the criterion would be the following: If the proportion of population (p) with $1 income exceeds some threshold $t(p)$, then the country would automatically qualify. In symbols, if $p > t(p)$, then a country automatically qualifies for a waiver.

Thus, there are three possible indices that could be used for determining the countries that qualify. The three are combined to arrive at a single criterion. In plain English, if a country qualifies using any of the above threshold criteria, it should qualify. The following criterion that includes all three measures using a compact notation can be used: If maximum $\{r - t(r), t(pci) - pci, p - t(p)\} > 0$, the country qualifies. This criterion ensures that: If (1) the disease rate (r) is *above* the pre-determined threshold ($t(r)$), then the country qualifies; (2) if the per capita income (pci) is below the predetermined threshold ($t(pci)$), then the country qualifies; and (3) if the proportion of population (p) is above the threshold ($t(p)$), then the country qualifies.

Although the measure above is useful, it is not entirely satisfactory. Suppose a country has all the above problems but it fails each threshold criterion by some amount and therefore fails to qualify. Clearly, we will need a method of "adding" each "score" to come up with an aggregate value that reflects the issue in all three dimensions. There are two ways of achieving this, which are discussed below.

Let $max(r)$ be the country with the maximum infection rate. Let $min(pci)$ be the country with minimum per capita income. Let $max(p)$ be the country with the maximum proportion of people below $1 per day per capita income. We construct the following absolute index (Absolute Component Summed Index or Absolute CSI):

$$\text{Absolute CSI for a country} = [r/max(r) + min(pci)/pci + p/max(p)]/3$$

The rationale for the formula is as follows. If a country hits the maximum infection rate, minimum income level and maximum number of poor people in the pool of all countries, the CSI will hit a maximum of 1. We can set a predetermined value of the Absolute CSI such that any country with the value of the index above that level would qualify for a waiver.

Since this measure will never hit zero, some people might consider this measure unsatisfactory. We can adjust that by considering a modified version that measures different dimensions in relative terms. Thus, we construct the Relative Component Summed Index:

Relative CSI for a country = $[I(r) + I(pci) + I(p)]/3$

where, $I(r) = [r - min(r)]/[max(r) - min(r)]$, $I(pci) = [max(pci) - pci]/[max(pci) - min(pci)]$ and $I(p) = [p - min(p)]/[max(p) - min(p)]$.

To see why we take such ratios, consider the first one: $I(r)$. If, for a given country, the infection rate r is the highest among all countries, then the index $I(r) = 1$. On the other hand, if the infection rate r is the lowest among all countries, $I(r) = 0$. Similarly, if the per capita income (pci) is the lowest among all countries, then the index $I(pci) = 1$. On the other hand if the per capita income pci is the highest among all countries, then the index $I(pci) = 0$. If the $1 a day population p is the highest among all the countries in question, then $I(p) = 1$, whereas if it is the lowest, then $I(p) = 0$. Thus, the relative CSI is a measure bounded by 0 and 1 as two extremes. By construction, the relative CSI could touch the limits for the best case scenario (it would approach 0) and the worst case scenario (it would approach 1).[127]

With the Relative CSI (RCSI), the criterion should specify a threshold (t): if the RCSI > t, the country should qualify under the composite measure for the most favorable level of treatment available. To incorporate this measure in our overall criterion, we propose the following:

If maximum $\{r - t(r), t(pci) - pci, p - t(p)$, RCSI - $t\} > 0$, then a country should qualify for the most favorable level of treatment.

This measure for determining "economic needs" is quite consistent with the long run interest of the pharmaceutical companies. Consider the case of Botswana. It was called the "miracle country" of Africa until the early 1990s. The real GDP of Botswana grew at a rate of 8–9% per year for more than a decade. However, with the devastating effects of HIV/AIDS, the country is slowly sinking. The life expectancy at birth has fallen by 10 years. HIV/AIDS is reversing much of the economic gains of the past decades. If the pharmaceutical industry insists on protection of their drug patents, it will generate very little profit now. Worse, they will have to forego all the future growth in profits they might have generated in the future. Botswana will recede into the backwaters of economic development.

The use of our index allows these types of countries to return to

[127] It should be noted that the country with the worst outcome in terms of Absolute CS Index ("ACSI") may not be the country with the worst outcome in terms of the Relative CS Index ("RCSI"). Thus, it is quite probable that in the list of all countries we will never observe the extreme value 1 for the RCSI. Similarly the country with the best outcome in RCSI measure may not be the country with the best outcome in ACSI measure. Thus, we might not observe the extreme value 0 in a sample of countries.

economic growth. That process should eventually push them over the threshold value of the index so that they no longer qualify for the waiver. Without such measures, these countries will be caught in a vicious circle and, therefore, will never generate the level of purchasing power needed to create a market for the pharmaceutical industry.

The index allows us to redress this balance of incentives through a mechanism that is implemented, using objective standards recognized by international bodies that represent all interested parties. The index serves to promote affordable access to medicine using criteria that are tailored to address the specific circumstances surrounding global or neglected diseases, which is more appropriate than the U.N. measure of least developed or developing countries.

VI. CONCLUSION

The HIV/AIDS epidemic has sparked a broader debate over the right balance to strike between the rights of patent holders and the needs of developing countries. Pharmaceutical companies are concerned about the precedent that may be set for intellectual property rights as a result of the measures taken to address HIV/AIDS. However, we conclude that their concerns are largely unfounded.[128]

TRIPS established uniform minimum standards for the protection of intellectual property rights. At the same time, however, both the WTO Agreement and TRIPS recognized that vastly different levels of economic development warranted differential treatment of WTO members, based on their level of development. The TRIPS Declaration represents a partial acknowledgement that the differential treatment that was initially set out in TRIPS was inadequate, by extending the transition period for least-developed countries and recognizing that WTO members did not enjoy equal access to patent exceptions due to the lack of manufacturing capacity in the pharmaceutical sector. The Paragraph 6 Decision further refines how differential treatment is to operate in practice with respect to compulsory licensing for export. However, it conditions access to legal rights on the level of economic development in a manner that does not resolve the fundamental issue of equal access to legal rights and the access to medicine that these imply.

Conditioning special and differential treatment in TRIPS based on the categorization of countries as developed, developing and least-developed, determining membership in the latter category based on the U.N. method, is inappropriate when it comes to patents for medicines. This article has

[128] For a contrasting view, see Sykes, *supra* note 2 (arguing that the course charted by the TRIPS Declaration will encourage developing countries to engage in compulsory licensing and parallel importation of pharmaceuticals and thus may reduce both pharmaceutical innovation and access to affordable drugs).

proposed two alternative methods for rectifying this problem: the first based on an amendment and the second based on the adoption of objective criteria to make decisions regarding waivers and extensions of transition periods. In the context of global and neglected diseases, uniformity of TRIPS obligations relating to patented medicine impose unnecessarily high costs on users and poor distribution of costs and benefits among producers and users of intellectual property. Uniform rules can have disparate effects that worsen inequalities rather than correct them. To achieve the correct balance between the rights of producers and users of patented medicine, a broader range of factors must be taken into account than are currently used in the WTO and U.N. contexts.

This article has questioned the underlying premise of TRIPS, that strong global patent rights are necessary to ensure innovation. Even if one accepts the premise that patents rights are necessary for *every* WTO member, regardless of the member's level of development, the proposed index shows that the U.N. classification of countries is an inappropriate basis for achieving an equitable balance between the rights of patent owners and users. The U.N. classification, based solely on per capita income, was developed for giving economic aid. It was not meant for handling a complex issue such as HIV/AIDS, which encompasses epidemiological issues (such as incidence of infection in the population). The proposals set out in this article take into account the objectives of the WTO Agreement and TRIPS, and provide a systematic basis for incorporating member-specific flexibility into TRIPS. It is hoped that these proposals will move the current WTO negotiations forward in the area of special and differential treatment for developing countries and dispel the notion that member-specific flexibility is unworkable in practice.