Global Diseases, Global Patents and Differential Treatment in WTO Law

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Abstract

As of January 1, 2005, all developing country members of the WTO are required to implement the WTO *Agreement on Trade Related Intellectual Property Rights* (TRIPS). We analyze the issue of access to patented medicine to treat global and neglected diseases in developing countries in the context of WTO law. We present legal and economic arguments that support balancing the rights of producers and users on a market-by-market basis and argue *against* taking a uniform approach globally. We conclude that global patent rights are not necessary to provide research incentives to pharmaceutical firms to invent treatments for global and neglected diseases. We develop an analytical framework for assessing special and differential treatment of developing countries in WTO law and apply this framework to TRIPS. We then propose a formula for assessing the correct balance between the rights of producers and users on a market-by-market basis.

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

"One of the strongest arguments against existing intellectual property law is that it encourages socially wasteful rent-seeking and regulative capture."
Michele Boldrin and David Levine, *Journal of Monetary Economics*, 51 (2004) at 129.

"Intellectual property is an integral part of sustainable development and its benefits must be equally shared."
Ambassador Bernard Kessedjian, Chairman, World Intellectual Property Organization General Assembly, Press Release 397, October 5, 2004.

I. Introduction

The debate over affordable access to essential medicines in poor countries has put the international law of patents in the spotlight. In the fall of 2003, the World Trade Organization (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.[1] In the fall of 2004, the World Intellectual Property Organization

[1] *Agreement on Trade-Related Aspects of Intellectual Property Rights*, April 15, 1994, Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations, LEGAL INSTRUMENTS – RESULTS OF THE URUGUAY ROUND, Annex 1C, vol. 31, 33 I.L.M. 1197 (1994) [hereinafter TRIPS]. Also see World Trade Organization, *Declaration on the TRIPS agreement and public health*, Adopted on 14 November 2001, WT/MIN(01)/DEC/2, 20 November 2001, available at http://www.wto.org; World Trade Organization, *Decision of the Council for TRIPS of 27 June 2002*, "Extension of the transition period under Article 66.1 of

(WIPO) adopted a development agenda to consider different intellectual property regimes appropriate to the circumstances of a particular country or region.[2] One of the objectives of TRIPS is to establish a mutually supportive relationship between the WTO and WIPO.[3] 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.

In this article, we examine the tension between access to patented medicine and the protection of patent rights in the context of TRIPS. We will challenge conventional legal wisdom regarding differential interpretation of international legal obligations and 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).

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the TRIPS Agreement for least-developed country members for certain obligations with respect to pharmaceutical products" (IP/C/25), available at http://www.wto.org; World Trade Organization, *Draft Waiver*, "Least-developed country members — obligations under article 70.9 of the trips agreement with respect to pharmaceutical products", submitted to the WTO General Council for approval on 8 July 2002, available at http://www.wto.org; and *Decision of 30 August 2003, Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and public health*, WTO Document IP/C/W/405, available at http://www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm.

[2] Press Release 396, Geneva, October 4, 2004, http://www.wipo.int/wilma/pressinfo-en/200410/msg00001.html at Nov. 20, 2004.

[3] TRIPS preamble.

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.[4] 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.

This article is organized as follows. First, we provide an overview of key TRIPS obligations and exceptions relating to patents, as amended by the Doha Round negotiations. Second, we analyze the legal effect of WTO provisions on special and differential treatment of developing countries on TRIPS law and policy, taking into account the 2004 Appellate Body ruling in *European Communities – Tariff Preferences for Developing Countries*. Third, we analyze the consistency of global patent rights with the economic and developmental objectives of the WTO. We conclude that strong patent rights in developing countries may contradict these objectives. We propose two alternative solutions. First, we propose interpreting exceptions to patent rights based on objective measures of economic and development needs. Second, we develop a formula for determine the circumstances in which the patent obligations of WTO members should be waived.

II. Overview of TRIPS Obligations and Exceptions

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.[5] Articles 30 and 31 authorize exceptions to these rights. Article 30

[4] 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. INTL ECON. L. 883 (2002).

[5] TRIPS Article 28.1.

permits "limited exceptions". 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".[6] 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.[7] However, the use of the patent must be "predominantly" to supply the domestic market[8] and the patent holder must be paid adequate remuneration, based on the economic value of the license.[9] The negotiation requirement may be waived in cases of national emergency, extreme urgency, or non-commercial public use.[10] Members are not obliged to comply with the negotiation requirement nor to predominantly serve the domestic market where the use is permitted to remedy anti-competitive practices.[11]

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

[6] TRIPS, footnote 7.

[7] TRIPS, Article 31(b).

[8] TRIPS, Article 31(f).

[9] TRIPS, Article 31(h).

[10] TRIPS, Article 31(b).

[11] TRIPS, Article 31(k).

and predominantly supply the domestic market. Since the term "adequate remuneration" is not defined, patent owners can not predict with certainty what compensation they will receive if a government abandons negotiations.[12] This gives the patent owners an incentive to determine the price through negotiation.

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 that have the capacity to produce generic drugs under compulsory licenses issued to government laboratories or private generic producers. 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 chip, the threat to issue a compulsory license to government or private pharmaceutical manufacturers must be

[12] 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]". Article 31(k) allows "the need to correct anti-competitive practices" to be taken into account in determining the amount of remuneration. Article 31(j) requires that "any decision relating to remuneration…shall be subject to judicial review or other independent review…in that Member". Article 1 provides that "Members shall be free to determine the appropriate method of implementing [TRIPS] within their own legal system and practice". 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.

credible. The TRIPS Declaration acknowledged this problem in Paragraph 6, which provides as follows:

> 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...[13]

In order to implement Paragraph 6, the WTO General Council agreed to amend Article 31(f) and 31(h).[14] The Paragraph 6 Decision waives the obligations of an exporter under Article 31(f) (to supply predominantly the domestic market) so that any country with manufacturing capacity can issue a compulsory license to produce generic drugs for export to countries that have insufficient or no manufacturing capacity, subject to several conditions.[15] The Article 31(h) requirement to compensate the patent holder for the economic value of the license is altered so that the exporting country must pay

[13] TRIPS Declaration, supra note 1, paragraph 6.

[14] See Decision of August 30, 2003, paragraph 11, which provides, "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".

[15] Decision of August 30, 2003, supra note 1, paragraph 2.

compensation, not the importing country.[16] The compensation is based on the economic value in the importing country alone.[17]

There is no formal restriction on the countries that are eligible to import.[18] However, the Paragraph 6 Decision creates four categories of importing members. Least-developed countries are eligible to import without formal notification to the WTO.[19] Two further categories consist of countries that have made a commitment to not use the system as importers[20] and countries that have committed to using the system as importers only in situations of national emergency or extreme urgency.[21] Countries making the latter

[16] *Ibid*, paragraph 3. Normally, the country issuing a compulsory license would do so to supply its own market.

[17] *Ibid*, paragraph 2. 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.

[18] *Ibid*, paragraph 1(b).

[19] 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 ibid*, note 2.

[20] Australia, Austria, Belgium, Canada, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Japan, Luxembourg, Netherlands, New Zealand, Norway, Portugal, Spain, Sweden, Switzerland, United Kingdom and United States of America. This list covers most, but not all, developed countries. See *ibid*, note 3.

[21] Until their accession to the European Union, Czech Republic, Cyprus, Estonia, Hungary, Latvia, Lithuania, Malta, Poland, Slovak Republic and Slovenia agreed that they would only use the system as importers in situations of national emergency or other circumstances of extreme urgency. These countries further agreed that upon their accession to the European Union, they will opt out of using the system as importers. Other Members that agreed that they would only use the system as importers in situations of national emergency or other circumstances of extreme urgency are Hong Kong China, Israel, Korea, Kuwait, Macao China, Mexico,

commitment have agreed, in effect, not to use the system for non-commercial public use; that is, not to use the system simply to lower the general cost of purchasing medicine for public health care systems, for example. These commitments resolve an issue that was of concern to the pharmaceutical industry—that countries that lacked manufacturing capacity, but that 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.

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.[22] 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

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Qatar, Singapore, Chinese Taipei, Turkey, United Arab Emirates. See *Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, Note from the Chairman*, WTO Doc JOB(03)/177, Council for TRIPS, August 27, 2003, available at http://www.wto.org/english/news_e/news03_e/trips_stat_28aug03_e.htm. The Note from the Chairman was carefully negotiated over several months.

[22] 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."

this system.[23] 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.[24] However, WTO members are free to determine whether to permit parallel imports without these laws being subject to WTO dispute settlement procedures.[25] Parallel imports involve products sold by the patent owner in one market that are then imported into another market without the patent owner's approval.

There is no restriction on the countries that are eligible to export. However, there is a series of procedural requirements and conditions that exporters are to follow, 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 product(s) and its export to an eligible importing Member(s)".[26] A further necessity test is introduced by requiring that the license restrict the authorization to "only the amount necessary to meet the needs of the eligible importing Member".[27]

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[23] Paragraph 6 Decision, supra note 1, paragraph 4.

[24] *Ibid*.

[25] TRIPS Article 6. Also see TRIPS Declaration, supra note 1, paragraph 5(d), which provides: "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.

[26] Paragraph 6 Decision, supra note 1, paragraph 2.

[27] Paragraph 6 Decision, supra note 1, paragraph 2(b)(i).

With the exception of least-developed countries, importing countries must specify in their notification to the WTO the names and quantities of the products needed.[28] They must also confirm that they have granted or intend to grant a compulsory license in accordance with TRIPS Article 31.[29] Finally, they must establish that they have no or insufficient 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 that it is insufficient to meet their needs.[30] The Paragraph 6 system will no longer apply once it is established that the capacity has become sufficient to meet its needs.[31]

The aim of the Paragraph 6 Decision is to increase the availability of life-saving treatments for people with HIV/AIDS and other life-threatening diseases in the developing countries. 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 capacity. It was not possible to solve the problem through treaty interpretation.

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. Thus, for example, countries like China, India and Brazil will have to

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[28] Paragraph 6 Decision, supra note 1, paragraph 2(a)(i).

[29] Paragraph 6 Decision, supra note 1, paragraph 2(a)(iii).

[30] Paragraph 6 Decision, supra note 1, paragraph 2(a)(ii) and Annex, Assessment of Manufacturing Capacity in the Pharmaceutical Sector.

[31] Paragraph 6 Decision, supra note 1, Annex, Assessment of Manufacturing Capacity in the Pharmaceutical Sector.

determine whether and how to use compulsory licensing to reduce the cost of providing treatment. All developing countries are required to comply fully with TRIPS as of January 1, 2005.[32] These countries now must rely on TRIPS Article 31 exceptions – which continue to operate, unchanged by the Paragraph 6 Decision – in order to strike the right balance between the rights of producers and users of patented drugs. Many of these exceptions are more ambiguous than paragraph 31(f), thus raising the issue of whether conventional means of treaty interpretation can be applied to TRIPS to further enhance access to essential medicine these countries. These Article 31 exceptions are the focus of this article, rather than the Paragraph 6 system.

III. The Effect of Special and Differential Treatment in WTO Law and Policy

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 legal effect of provisions referring to preferential treatment for developing countries varies with their wording and

[32] 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 (TRIPS Article 66.1), while developing countries could do so until 2000 (TRIPS Article 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 (TRIPS Article 65.4). Less than twenty developing countries fit this description, but they include Brazil and India. See WHO/WTO, WTO AGREEMENTS AND PUBLIC HEALTH, August 22, 2002, p. 47, note 13, http://www.wto.org. The Decision of the Council for TRIPS of 27 June 2002, supra note 1, extended the transitions period for least-developed countries under Article 66.1 an additional ten years for pharmaceutical products.

the context in which they appear. Nevertheless, differential and preferential treatment for developing countries is a principle that finds expression throughout WTO law and supports the view that economic inequality can and should be taken into account in the interpretation of WTO rights.

In *European Communities – Conditions for the Granting of Tariff Preferences to Developing Countries* (the Tariff Preferences case), the 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 de veloping 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.
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> ...[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.[33]

The Enabling Clause introduced differential and more favorable treatment as an "integral part of the GATT system".[34] In the Tariff Preferences case, the Appellate Body recognized that the equal application of certain obligations, regardless of economic status, 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.[35]

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[33] European Communities – Conditions for the Granting of Tariff Preferences to Developing Countries, WTO Doc. WT/DS246/AB/R (2004) (Report of the Appellate Body), para 161-163 (footnotes omitted).

[34] Report by the Director-General of GATT, in GATT, The Tokyo Round of Multilateral Trade Negotiations (1979), Vol. I, p. 99.

[35] Tariff Preferences, WTO Doc. WT/DS246/AB/R (2004), supra note 33, para. 109.

The *Vienna Convention* requires that WTO rules be interpreted in their context.[36] Article 31 requires that the *ordinary meaning* to 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 proceed to examine the context of the particular agreement in which the provision is found, and lastly to 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 reasoned judgements 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.[37]

Despite conventional views of treaty interpretation that militate against differential interpretation of WTO rules, the asymmetries of economic development that exist among

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[36] Vienna Convention on the Law of Treaties, opened for signature 23 May 1969, 1155 UNTS 331 (entered into force 27 January 1980), Article 31.

[37] Japan—Taxes on Alcoholic Beverages, WTO Doc WT/DS8/10/11/AB/R (1996) (Report of the Appellate Body), 31.

the member States need to be addressed in order to ensure effective treaty interpretation 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'.[38] 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.[39] 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

[38] WTO Agreement preamble.

[39] *European Communities – Conditions for the Granting of Tariff Preferences to Developing Countries*, WTO Doc WT/DS246/AB/R (2004) (Report of the Appellate Body) para 161. For a useful discussion of this case, see S. Charnovitz, L. Bartels, R. Howse, J. Bradley, J. Pauwelyn and D. Regan, 'The Appellate Body's GSP Decision', 3 *World Trade Review* 239-265 (2004).

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.[40] Thus, the legal and economic effects of special and differential treatment provisions will vary with the legal and economic context of each agreement.

For example, the central thrust of GATT is to reduce tariffs and other barriers to trade (the legal context)[41] in order to stimulate economic growth through specialization in areas of comparative advantage (the economic context).[42] GATT seeks to remove barriers to competition. In contrast, TRIPS promotes intellectual property rights (the legal context)[43] in order to stimulate economic growth through innovation (the economic context).[44] 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

[40] Vienna Convention Article 31.

[41] GATT preamble.

[42] See, inter alia, David Ricardo, *On The Principles of Political Economy and Taxation* (1821) and Eli Hecksher, 'Utrikeshandelns verkan pa inkomstfordelningen' (The Effect of Foreign Trade on the Distribution of Income) 21 *Ekonomisk Tidskrift* 497 (1919).

[43] TRIPS preamble.

[44] See, inter alia, Joseph Schumpeter, *The Theory of Economic Development* (1934), Robert Solow, *Growth Theory: An Exposition* (1970) and Paul Romer, 'Crazy Explanations for the Productivity Slowdown' in Stanley Fischer, ed, *NBER Macroeconomics Annual* (1987),163-201.

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 (1) for all covered agreements or (2) for all 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 right (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.[45] Thus, both the needs of developing countries and the 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 assessing the appropriateness of special and differential treatment as a policy.

[45] The WTO Agreement preamble refers to "sustainable development". A reasonable interpretation is that this refers to the concept that was 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 Commission on Environment and Development, OUR COMMON FUTURE, (1987).

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.[46] 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 and 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.[47] 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 may require a combination of legal and economic analysis.[48]

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[46] 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 and Joel P. Trachtman, *Economic Analysis of International Law*, 24 YALE J. INTL L. 1 (1999).

[47] Differential and More Favourable Treatment, Reciprocity and Fuller Participation of Developing Countries, Decision of 28 November 1979 (L/4903), paragraph 3(c) provides: "Any differential and more favourable 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."

[48] Support for this proposition can also be found in the use of economic modeling to determine the level of retaliation permitted under Dispute Settlement Understanding Article 22.2. See United States – Continued Dumping and Subsidy Offset Act, WT/DS217/ARB/BRA, WT/DS234/ARB/CAN, WT/DS217/ARB/CHL,

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 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. 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.[49] 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'.[50] A treaty's interpretation must give effect to its provisions. A logical

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WT/DS217/ARB/EEC, WT/DS/217/ARB/IND, WT/DS217/ARB/JAP, WT/DS217.ARB/KOR, WT/DS234/ARB/MEX (August 31, 2004) (Report of the Arbitrator).

[49] See, *United States – Standards for Reformulated and Conventional Gasoline*, WT/DS2/AB/R (1996) (Report of the Appellate Body), 23.

[50] See *Korea – Definitive Safeguard Measure on Imports of Certain Dairy Products*, WT/DS98/AB/R (2000) (Report of the Appellate Body), para 81.

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 does make a provision effective for all, then that interpretation should be preferred over one that does not.[51] 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".[52] (Of course, if the wording of a provision is unambiguous, there may not be more than one interpretation available.)

Thus, there are three tests that can be applied to interpret covered agreements (the doctrinal aspect) and to assess policy options (the normative aspect) in a way that addresses the needs of developing countries:

(1) A development needs test;

(2) An economic impact test; and

(3) An effectiveness test.

Taken together, these three tests create an interdisciplinary 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?

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[51] See *Yearbook of the International Law Commission*, Vol.. II (1966), 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.'

[52] DSU Article 3:2.

Before applying this analysis to TRIPS law and policy on patents, the specific objectives of TRIPS need to be determined. However, these objective 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 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".[53] Under TRIPS principles, WTO members may "adopt measures necessary to protect public health…provided that such measures are consistent with [TRIPS]".[54] The TRIPS preamble seeks "effective and adequate protection of intellectual property rights", while recognizing the developmental objectives of intellectual

[53] TRIPS Article 7.

[54] TRIPS Article 8. 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....". See *Canada - Term of Patent Protection*, AB-2000-7, WT/DS170/AB/R, at P101 (Sept. 18, 2000).

property protection and the special needs of least-developed countries for "maximum flexibility in the domestic implementation of laws."[55]

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."[56] The Decision on Measures in Favour of Least-Developed Countries leaves no doubt that this aspect of differential treatment applies to TRIPS: "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."[57] The WTO Agreement preamble also makes special reference to the needs of developing countries, "especially the least developed among them".[58] 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

[55] TRIPS Preamble.

[56] WTO Agreement, Article XI.

[57] *Decision on Measures in Favour of Least-Developed Countries*, Article 1.

[58] WTO Agreement, Preamble.

with respect to its role in balancing trade and environmental protection[59], 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. That is, 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. When read together, the objectives of TRIPS and of 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." Arruñada and Andonova have shown that the appropriateness of a particular

[59] 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 *United States – Import Prohibition of Certain Shrimp and Shrimp Products*, WTO Doc WT/DS58, 15 May 1998 (Report of the Panel), WTO Doc WT/DS/AB/R, AB-1998-4, 12 October 1998 (Report of the Appellate Body adopted 6 November 1998) and *United States – Import Prohibition of Certain Shrimp and Shrimp Products, Recourse to Article 21.5 by Malaysia*, WTO Doc WT/DS58/RW, 15 June 2001 (Report of the Panel); WTO Doc WT/DS58/AB/RW, 22 October 2001, (Report of the Appellate Body adopted 21 November 2001).

legal system in a given market depends on the conditions prevailing in that market.[60] Thus, the proposition that some legal systems are more effective than others in promoting economic development is incorrect. In the following section, we argue that patents 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 under the development needs and economic impact tests to determine whether patents rights (the rights of producers) or compulsory licensing rights (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.

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

[60] Benito Arruñada and Veneta Andonova, *Market Institutions and Judicial Rulemaking*, in C. Ménard and M. Shirley, eds., HANDBOOK OF NEW INSTITUTIONAL ECONOMICS (2005), 229-250.

developing countries are necessary to promote the transfer of technological innovations from firms in developed countries and to promote technological innovation by 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.[61] 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 to make the case by pharmaceutical companies for *any* drug.[62] In particular, the argument has been put forward for HIV/AIDS drugs.[63]

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[61] 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."

[62] The thrust of the argument has been articulated in the document of the pharmaceutical industry entitled, THE PHRMA INDUSTRY PROFILE, available at (www.phrma.org/publications/publications/profile02/index.cfm accessed February 17, 2003) "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."
(www.phrma.org/publications/publications/profile02/chapter3.pdf, at 30 accessed February 17, 2003)

[63] *Ibid*.

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.

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 major HIV-1 subtypes accounting for most infections in Africa are subtype C in southern Africa, subtypes A and D in eastern Africa, and circulating recombinant form 02_AG (CRF02_AG) in west-central Africa.[64] On the other hand, the most commonly occurring form of HIV-1 in North America (and in Europe) is of subtype B. Thus, the subtypes 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.[65]

In the following sections, we consider various economic arguments for and against the use of patents to stimulate innovation in treatments for both types of disease. The focus of our analysis in this section is on the issue of whether global pharmaceutical patents are

[64] M. Peeters and P. M. Sharp, *Genetic diversity of HIV-1: the moving target*, AIDS 2000, Volume 14 (supplement 3) at S129 to S130.

[65] Jenny Lanjouw, *A Patent Policy Proposal for Global Diseases*, The Brookings Institution, available at http://www.brook.edu/views/papers/lanjouw/20010611.htm.

necessary to create research incentives to treat global and neglected diseases in developing countries.[66]

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

The argument in favor of global patents for neglected diseases is as follows. A global patent system will provide research incentives for the development of drugs for neglected diseases.[67] The reason these diseases 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

[66] 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, issues that have been treated elsewhere in the literature. Regarding the former, see Frederic M. Scherer and Jayashree Watal, *Post-TRIPS Options for Access to Patented Medicines in Developing Countries*, 5 J. INTL ECON. LAW 913 (2002). An extension of the Ramsay Pricing model has recently been provided by William Jack and Jean O. Lanjouw *Financing Pharmaceutical Innovation: How Much Should Poor Countries Contribute?* Center for Global Development Working Paper No. 28, July 28, 2003. Regarding the latter, see William Landes and Richard Posner, THE POLITICAL ECONOMY OF INTELLECTUAL PROPERTY LAW (2004).

[67] For example, the Pharmaceutical Industry's profile states "Patent protection has become an important component of the World Trade Organization's (WTO) 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." Pharmaceutical Industry Profile, 2002, Chapter 3, at 34.

place. The risk of losing the entire potential profits in developing countries makes it unattractive for the pharmaceutical companies to develop drugs for any disease – in particular in neglected diseases.[68] 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.[69]

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. Consider the following historical facts. Between 1975 and 1999, of 1393 new chemical entities marketed, only 16 were for tropical diseases and tuberculosis.[70] Of the annual health-related research and development

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[68] The Pharmaceutical Industry's profile states: "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." Pharmaceutical Industry Profile, 2002, Chapter 3, at 37.

[69] See supra, notes 6-12, and accompanying text.

[70] Patrice Trouiller, Piero Olliaro, Els Torreele, James Orbinski, Richard Laing, Nathan Ford, *Drug development for neglected diseases: a deficient market and a public-health policy failure*, THE LANCET, June 22, 2002 at 2188.

worldwide, only 0.2% goes for pneumonia, diarrhoeal diseases and tuberculosis—yet these account for 18% of the global disease burden.[71] These statistics indicate that the advent of TRIPS has not created 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.[72] Boldrin and Levine demonstrate that 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.[73] Historical evidence favors this view.[74]

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[71] UNDP, HUMAN DEVELOPMENT REPORT (1999), available at www.undp.org.

[72] Michele Boldrin and David Levine, *The case against intellectual property*, 92 AMERICAN ECONOMIC REVIEW at 210 (May 2002). Also see Danny Quah, *24/7 Competitive innovation* (2002) at 6, paper available at econ.lse.ac.uk/staff/dquah/p/0204-247-2pp.pdf (accessed April 4, 2003), *A Survey of Private Sector Drug Research and Development*, footnote 6, available at www.neglecteddiseases.org/4-1.pdf (accessed April 13, 2003), and Robert Book, PUBLIC RESEARCH FUNDING AND PRIVATE INNOVATION: THE CASE OF THE PHARMACEUTICAL INDUSTRY (2002) at 5. Available at home.uchicago.edu/~rbook/Book_PharmInnov.pdf (accessed April 1, 2003).

[73] For example, Suzanne Scotchmer notes "There is no economic rationale for protecting inventors *per se*." Scotchmer, *Political economy of intellectual property rights*, Working Paper, National Bureau of Economic Research, January 2003, at 1. We are indebted to Suzanne Scotchmer of the Department of Economics, University of California-Berkeley for providing us with the reference.]

Thus, we conclude that global patents do not provide enough incentives for the pharmaceutical companies to develop drugs for neglected diseases, whether due to the stifling effects of patents on innovation or the lack of purchasing power in the affected markets.

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.[75] 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.[76]

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 will. Most patients will not be willing to risk their lives buying pharmaceuticals

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[74] For example, in the draft of Chapter 1 of THE CASE AGAINST INTELLECTUAL MONOPOLY, by Michele Boldrin and David Levine, the authors forcefully put the case of how James Watt (of the steam engine fame) managed to set back the clock of the industrial revolution by lobbying for and getting his monopoly extended. How the early American growth was fuelled by simply ignoring the European intellectual property laws is illustrated by B. Zorina Khan, THE FUEL OF INTEREST: PATENTS AND COPYRIGHTS IN AMERICAN ECONOMIC DEVELOPMENT, Cambridge University Press (forthcoming in 2004).

[75] See note 25, supra, and accompanying text.

[76] "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." Pharmaceutical Industry Profile, 2002, Chapter 3, at 37.

on the black market that have potentially lethal consequences. We do not see drug dealers selling in 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.[77] 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.[78] Therefore, patent laws in developing countries should focus on increasing affordable access to treatment, not research incentives.

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.[79] This provides further

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[77] See note 66, supra, and accompanying text.

[78] See note 25, supra, and accompanying text.

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

support for the Boldrine and Levine 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.

V. How to make 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, executive director of the UN HIV/AIDS program, has stated, "Countries like Botswana…risk becoming what I would call 'undeveloping' because of HIV/AIDS."[80] Thus, if patents decrease access to

[80] *No indication AIDS epidemic leveling off, UN says*, www.globeandmail.com, July 7, 2002. Most studies estimate that AIDS epidemics in the worst hit countries have caused an annual loss of about 1 percent 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, April 12, 2003, at 69.

medical treatment 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 patents rights are not effective in meeting the objectives of the WTO Agreement and TRIPS. There are two possible solutions to this problem. The second-best 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. Part III, above, laid out the legal basis for differential application of exceptions that use ambiguous language. The first part of this section will will examine specific exceptions in that context. The best solution is to eliminate the obligation of developing countries to provide patent rights for pharmaceutical products. 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 and index that can be used to determine the circumstances in which patent obligations should be waived.[81]

A. Solving the Problem through Treaty Interpretation

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. The lack of ambiguity in this treaty text makes it difficult to take special and differential treatment into account in its interpretation. However, Article 31 provides a right to make other use of the subject matter of the patent without the authorization of the right holder. The language in this provision is more ambiguous. Thus, the rule of effective treaty interpretation can be applied to take the

[81] The procedure for waiving WTO obligations is set out in WTO Agreement Article IX.

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. Paragraph 31(a) requires that a given authorization "be considered on its individual merits".

Paragraph 31(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 interpreted and applied differently, taking into account variations in circumstances. In this provision, the needs of a developing country in a particular case can 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. Applying special and differential treatment to the interpretation of these three conditions means that the standard will 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, the development needs of the country and the economic impact of expanding access to treatment will have to 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 paragraph 31(c) and what constitutes adequate remuneration under paragraph 31(h).

The evaluation of the TRIPS consistency of measures taken by countries in the context of the HIV/AIDS pandemic involves balancing the need for the development of new medicine against the need for affordable access to existing treatments. This requires an inquiry into the impact of measures on incentives for patent holders to invest in research on the one hand, and the affordability of medicines in a particular country on the other. With

respect to the latter, the balance should favor affordability in cases involving developing countries, especially least-developed countries. As long as developed country markets are secure, the pharmaceutical industry has sufficient incentives to continue research in this field. Thus, in this context, the application of the rules of interpretation of customary international law to TRIPS should favor affordable access in both developing and least-developed countries.

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 overly simplistic and inappropriate in the context of pharmaceutical patents. We propose 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. Our proposal is grounded on economic considerations and takes into account the need to apply an objective standard to determine the particular needs of developing countries set out in the WTO Agreement or in multilateral instruments adopted by international organizations.[82]

This section offers a step by step guide for permitting a country to waive 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.

[82] See Tariff Preferences, WTO Doc. WT/DS246/AB/R (2004), supra note 33, para. 163.

A difficult issue is how to determine the cut-off point with respect to economic development in the case of developing countries.[83] The WTO recognizes as least-developed countries those countries that have been designated as such by the United Nations.[84] 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 more sophisticated approach to balancing the rights of producers and users.

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[83] There are no WTO definitions of "developed" and "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, and this has sometimes 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 terms agreed in the accessions negotiations. See WTO, *Who are the developing countries*, available on the web at www.wto.org/english/tratop_e/devel_e/d1who_e.htm. Also see Guglielmo Verdirame, *The Definition of Developing Countries under GATT and Other International Law*, 39 GERMAN YEARBOOK OF INTERNATIONAL LAW 164 (1996).

[84] The WTO recognizes as least-developed countries those designated as such by the United Nations. There are currently 48 least-developed countries on the UN list, 29 of which to date have become WTO Members. These are: Angola, Bangladesh, Benin, Burkina Faso, Burundi, Central African Republic, Chad, Congo, Democratic Republic of the, Djibouti, Gambia, Guinea, Guinea Bissau, Haiti, Lesotho, Madagascar, Malawi, Maldives, Mali, Mauritania, Mozambique, Myanmar, Niger, Rwanda, Sierra Leone, Solomon Islands, Tanzania, Togo, Uganda, Zambia. Seven additional least-developed countries are in the process of accession to the WTO. They are: Cambodia, Cape Verde, Laos, Nepal, Samoa, Sudan and Vanuatu. See WTO, *Who are the developing countries*, available on the web at www.wto.org/english/tratop_e/devel_e/d1who_e.htm.

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 gross domestic product (GDP) under $900 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.[85]

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%,[86] would not qualify for the most favorable level of treatment.[87] 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.[88]

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[85] The formal definition is taken from r0.unctad.org/conference/press/devbru1.htm (accessed 14 April 2003).

[86] See note 36, supra.

[87] The 49 LDCs 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, Togo, Tuvalu, Uganda, United Republic of Tanzania, Vanuatu, Yemen and Zambia.

[88] Of course, all researchers do not agree that anything 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

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 members with respect to access to medicine to address the HIV/AIDS pandemic and other public health crises. Finally, while the legal rights and obligations that flow from the concept of 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. We will discuss each in turn.

1. Disease rate

First, a disease has to be above some threshold rate that will be determined by a world body (such as the World Health Assembly). Leaving it to the discretion of the World Health Assembly to determine the threshold for this criterion is necessary because the appropriate threshold may vary from one disease to the next and because this is a global

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only. She notes the following. "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." In other words, if the income level is high, then it should be solved using some domestic mechanism like tax-transfer [Her view was expressed in a private email correspondence with the 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 to poverty due to a disease like HIV/AIDS.

body that has the necessary expertise to make such a decision. Once a country is above that threshold rate for the specific disease, it will qualify for a waiver of patent obligations with respect to the treatments for that disease.

Suppose the disease rate in a country is denoted by r. Suppose, we also have also 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 of qualify if $r > t(r)$ regardless of the economic development or any other criterion). Thus, 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. [89]

[89] A paper by Romualdo Pastor-Satorras and Alessandro Vespignani, *Epidemic dynamics in finite size scale-free networks*, arXiv:cond-mat/0202298 v1 18 Feb 2002 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. These two groups have been instrumental in the spread of the disease in many parts of the world. There is an intense debate whether these groups should be viewed as the *causes* of acting as the conduits. For example, in desperately poor economies, many women do not have any way to eke out a living other than selling sex (often for food for subsistence). If they would like to have their clients use condoms, asymmetry of economic power between them and their clients forces them not to use condoms. It matters little who gets the blame. The consequence is literally deadly for them and their clients.

2. Per capita income

Second, we need to include a country if the income level is low. We will require 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). Thus, if a country has a per capita income[90] below some threshold, it would automatically qualify. Let us denote the per capita income by pci and the corresponding threshold per capita income by t(pci). Expressing in symbols, we will write the criterion 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. The average income does not do the job because it papers over the inequality in income among the population.[91]

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[90] 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 in local currencies (which are not comparable across countries) into some fixed currency (usually in US dollars) on the basis of the exchange rate on a given day. However, current exchange rate does not necessarily reflect the purchasing power of certain income in a given country. One way of adjusting for it 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 US dollars.

[91] 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.

There are different measures of inequality that are potential candidates. One commonly used measure is the Gini coefficient.[92] However, Gini coefficient is not affected by a multiplicative factor. Thus, if everyone's income increases by ten-fold, the Gini coefficient is not affected.[93] To take a concrete example, Uganda and the United States have approximately the same Gini coefficient of income distribution.[94] 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 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 relatively 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

[92] The most common geometric definition of 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.

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

[94] 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% (such as Brazil or Sierra Leone).

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. We combine the three to arrive at a single criterion. In plain English, if a country qualifies using *any* of the above threshold criteria, it should qualify. We can use the following criterion that include all three measures using a compact notation:

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* certain 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 reflect the issue in all three dimensions. There are two ways of achieving this. We discuss them 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 Compassion Sentiment Index or Absolute CSI):

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 Compassion Sentiment 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 (in that case, it will touch 0) and the worst (in that case, it will touch 1) case scenarios.[95]

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.

Our 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 up until the early 1990s. The real GDP of Botswana grew at a rate of 8-9% per year over 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 a decade. 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 economic growth. That process should eventually push them over the threshold value of the index so that they

[95] It should be noted that the worst outcome country in one measure may not be the worst outcome country in terms of another measure. Thus, it is quite probable that in the list of all countries we will never observe the extreme value 1. Similarly the best outcome country in one measure may not be the best outcome country in another. Thus, we might not observe the extreme value 0 in a sample of countries.

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 recongnized 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 UN measure.

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. [96]

Countries with manufacturing capacity have the power they need to reach the optimal price in negotiations with patent owners. If the cost of manufacturing generic

[96] For a contrasting view, see Alan O. Sykes, *TRIPs, Pharmaceuticals, Developing Countries, and the Doha "Solution"*, John M. Olin Law and Economics Working Paper No. 140, 2002 and Alan O. Sykes, *Public Health and International Law: TRIPS, Pharmaceuticals, Developing Countries, and the Doha "Solution"*, 3 CHI. J. INT'L L. 47 (2002) (17 Am. U. Int'l L. Rev. 1097 (2002) (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).

versions under compulsory license (or of importing from generic producers in other countries) is lower than the cost of buying from the patent owner, the country will do the former. This price competition ensures that the drug in question is supplied at the lowest possible cost. Thus, the level of bargaining power a country enjoys ultimately affects the price it pays for medicine and the affordability of treatment for global and neglected diseases. This has a direct impact on the number of patients that get access to treatment. To put least-developed countries and developing countries that lack manufacturing capacity on a similar footing, they need to have equal access to generic products. To achieve equality of bargaining power, countries with generic manufacturing capacity need to use the threat of compulsory licensing on behalf of those who lack the capacity, to strengthen the hand of the latter in price negotiations.

Since the introduction of the Paragraph 6 system, all WTO members have the right to issue compulsory licenses in order to produce or import generic drugs. Developing countries that had not yet implemented TRIPS could produce and export generic drugs that were patented before 1995 without a compulsory license, until 2005. As of January 1 2005, exporters that do not qualify as least-developed countries will have to comply with the Paragraph 6 Decision system. In practice, this means that countries lacking manufacturing capacity will have to use the Paragraph 6 Decision system in order to make effective use of compulsory licensing as of 2005. This system imposes procedural requirements that those with manufacturing capacity do not have to face. WTO members that have manufacturing capacity will be able to use the Article 31 exceptions to issue compulsory licenses to serve their domestic markets.

TRIPS established uniform minimum standards for the protection of intellectual property rights, imposing uniform obligations and exceptions upon WTO members. 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. However, the differential treatment that was originally set out in TRIPS applied with clarity only with respect to the transition periods members enjoyed. The TRIPS Declaration represents a partial acknowledgement that the differential treatment that was initially set out in TRIPS was inadequate, 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.

We have argued that conditioning the application of TRIPS obligations and exceptions based on the categorization of countries as developed, developing and least-developed, determining membership in the latter category based on the UN method, is inappropriate when it comes to patents for medicines. We have proposed two alternative methods of rectifying this problem, one based on treaty interpretation and the other based on objective criteria. In the context of global and neglected diseases, uniformity of TRIPS obligations and exceptions 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 UN contexts.

We have questioned the underlying premise of TRIPS that strong global patent rights are necessary to ensure innovation. Even if we accept the premise that patents rights are necessary in *every* WTO member, regardless of the member's level of development, our proposed index shows that the UN classification of countries is an inappropriate basis for achieving an equitable balance between the rights of patent owners and users.