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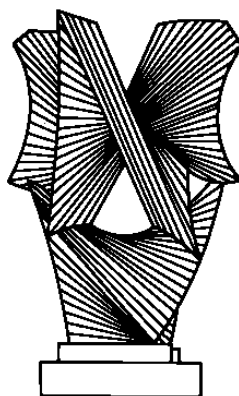
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**THE LAW SCHOOL
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TRIPs, Pharmaceuticals, Developing Countries and the Doha “Solution”

Alan O. Sykes*

Pharmaceutical prices in the developing world have been much in the news lately.¹ The bulk of the attention stems from the HIV/AIDS epidemic which affects many developing countries acutely,² and where much of the infected population is said to be unable to obtain effective therapies because of their prohibitive cost. The annual cost of advanced retroviral therapies in South Africa, where one in eight persons are thought to be infected, is said to be about (U.S.)\$12,000, far beyond the means of most South Africans.³ Only about 5% of the 1 million citizens of Thailand believed to be infected are able to afford the AIDS therapies prescribed to them.⁴

Much of the problem is attributed to the prices charged by pharmaceutical companies for their patented medications. A United Nations study reports, for example, that 150Mg of the HIV drug flucanazole costs \$55(U.S.) in India, where the drug does not enjoy patent protection, as compared to \$697 in the Philippines, \$703 in Indonesia and \$817 in the Philippines, where the drug is patented. Similarly, the HIV treatment known as AZT costs \$48 per month in India, as compared to \$239 in the United States where patent protection exists.⁵

Developing nations where patents are in place⁶ seek to reduce those prices with measures that the pharmaceutical manufacturers say would infringe their intellectual property rights. Some of these initiatives have already brought forth legal challenges. South Africa was the target of litigation initiated by a number of

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¹Academic commentaries also abound. See, e.g., Frederick M. Abbott, *The TRIPs-Legality of Measures Taken to Address Public Health Crises: A Synopsis*, 2001 *Widener L. Symposium J.* 71; Judy Rein, *International Governance Through Trade Agreements: Patent Protection for Essential Medicines*, 21 *NW. J. Int'l L. & Bus.* 379 (2001).

²See David Satcher, *The Global HIV/AIDS Epidemic*, 281 *J. Am. Med. Assn.* (April 28, 1999); UNAIDS-WHO, *Aids Epidemic Update, December 2000* (available at www.unaids.org/waq/2000/wad00/files/wad_epidemic_report.htm).

³Judy Rein, *supra* at 402.

⁴Sutin Wannabovorn, *Thais Protest U.S. Firms AIDS Drug Monopoly* (December 22, 1999), at biz.yahoo.com/rf/991222/bq/html.

⁵See United Nations Commission on Human Rights, *Report of the High Commissioner, The Impact of the Agreement on Trade-Related Aspects of Intellectual Property Rights on Human Rights ¶144, E/CN.4/Sub.2/2001/13* (June 2001) (hereafter “UNCHR Report”).

⁶Section I will address the legal reasons for the differences in patentability of pharmaceuticals across the developing world.

pharmaceutical manufacturers over South Africa's Medicines and Related Substances Control Act of 1997.⁷ The United States government also initiated action against Brazil within the World Trade Organization (WTO) over the compulsory licensing provisions in Brazil's Industrial Property Law.⁸

Developing nations subsequently united in an effort to relax (or at least "clarify") the scope of intellectual property protection required for pharmaceuticals under the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs).⁹ Certain developed nations, most prominently the United States and Switzerland, responded with a campaign to protect their interpretation of TRIPs against any developments that might undermine it.¹⁰ The eventual result was a ministerial interpretation of the TRIPs agreement in the form of a "Declaration on the TRIPs Agreement and Public Health," one of the few concrete legal developments during the recent WTO ministerial meetings in Doha, Qatar.¹¹ The declaration gave the developing nations many of the legal "clarifications" that they were seeking, although a number of issues remain unresolved.

The precise impact of the Doha declaration on the policies of developing nations remains to be seen, but it seems likely that the declaration will embolden them to enact measures that will reduce the returns to pharmaceutical patent holders, at least with respect to drugs that are used to treat certain diseases. Such measures will likely include the award of compulsory licenses for the production of patented medications (with minimal royalties payable to the patent holder), and the allowance of "parallel imports" of medications from nations where prices are lower. This essay will take a preliminary look at the merits of such policies from an economic perspective, and draw on this analysis to suggest some directions for the resolution of legal issues that remain on the table after Doha.

The ultimate wisdom of measures that relax intellectual property protection for pharmaceuticals in developing countries turns on complex

⁷See Duane Nash, South Africa's Medicines and Related Substances Control Amendment Act of 1997, 15 Berkeley Tech. L. J. 495 (2000).

⁸See International Centre for Trade and Sustainable Development, U.S. Drops TRIPs Dispute Against Brazil's Patent Law, Bridges Between Trade and Sustainable Development, Year 5, No. 5, p.5 (June 2001).

⁹See Developing Countries Push for TRIPs to Allow Cheaper Medicines, Inside U.S. Trade, vol. 19, no. 25, p. 7 (June 22, 2001); International Centre for Trade and Sustainable Development, "TRIPs Council Battles with Access to Drugs," Bridges Between Trade and Sustainable Development, Year 5, No. 6, p.6 (July-August 2001).

¹⁰See WTO Ministers Likely to Face Difficult Choice on TRIPs, Public Health, Inside U.S. Trade Special Report, p. 1 (October 30, 2001).

¹¹WTO, Declaration on the TRIPs Agreement and Public Health, WT/MIN(01)/W/2, November 14, 2001 (available at www.wto.org) (hereafter "Doha Declaration").

matters, including empirical issues about which one can only hazard an educated guess. It is conceivable that patent rights in the developing world have negligible impact on research incentives -- they may simply raise prices on patented drugs, transferring rents to foreign pharmaceutical patentholders and creating deadweight losses by pricing consumers out of the market who are willing to pay the marginal cost of medicines but not the monopoly markup charged by the patentholder.

But there is another possibility, one which in my view better accords with what we know about the importance of patents to pharmaceutical research, and with the extraordinary value to consumers of medicines that successfully treat serious conditions. Developing nations have long had little intellectual property protection for pharmaceuticals, and we have concurrently witnessed an apparent dearth of research into the diseases of particular importance to them such as malaria and drug-resistant tuberculosis. The lack of patent protection may have resulted at least in part from an acute collective action problem—developing nations reap the full benefits from lower prices when they do not create pharmaceutical patents, yet the costs in terms of diminished research incentives are largely externalized to the rest of the developing world. The WTO TRIPs agreement held out some promise of overcoming part of this problem. Yet, just as the obligations of developing nations under TRIPs were beginning to take hold, the Doha ministerial declaration casts great doubt on the future credibility of patent rights for pharmaceuticals in the developing nations. The result may be quite unfortunate for research incentives, especially those relating to particular diseases.

Section I provides an overview of the legal issues under TRIPs and the history of the tensions that they have created. Section II lays out the basic economic issues, while Section III offers some legal and policy discussion.

I. The Legal Landscape

Prior to the creation of the WTO, which replaced the General Agreement on Tariffs and Trade (GATT) in 1995, national intellectual property laws were largely unregulated within the GATT system. Certain aspects of intellectual property law were affected by other multilateral covenants, most importantly the Berne Convention on copyright, but the details of patent protection in particular were largely left to national discretion.¹²

Developed nations, with greater stocks of human capital and higher levels of educational attainment on average, tend to generate the bulk of new inventions in the world and have historically maintained the greatest degree of

¹²See John H. Jackson, *The World Trading System* 310-13 (2d ed. 1997).

patent protection under national law. Developing nations with much less inventive activity within their borders typically lack a strong domestic political constituency for patent protection, and indeed may benefit from the opportunity to use technology developed and patented elsewhere without the need to pay royalties. Consequently, patent protection in developing countries has been lax historically by comparison to the developed world.

This “North-South” divide on the scope of intellectual property rights was the source of many heated disputes in years past, with developed nations regularly accusing the developing world of “piracy.” The United States, for example, unilaterally declared that the failure of foreign governments to protect U.S. intellectual property rights was an unfair trade practice, and could be the subject of retaliatory sanctions under Section 301 of the Trade Act of 1974, even though no international agreement had been violated.¹³ Pursuant to this authority, the United States initiated a number of unfair trade cases against developing countries for “inadequate” intellectual property protection, extracting concessions in some instances.¹⁴

The North American Free Trade Agreement (NAFTA), signed in late 1992, began a trend toward the integration of intellectual property rules into trade agreements. NAFTA effectively replaced the U.S.-Canada Free Trade Agreement, which had little to say about intellectual property rights. But when the arrangement was expanded to encompass Mexico with the creation of NAFTA, Mexico was required to commit itself to provide intellectual property rights comparable to those in place to its North.¹⁵ NAFTA Chapter 17 thus sets out elaborate provisions on what each member State must do to protect intellectual property, including requirements for patent protection in Article 1709.¹⁶

The Uruguay Round of negotiations under the auspices of GATT (which ultimately led to the creation of the WTO) were already underway when NAFTA was signed. The developed members of GATT built on the NAFTA model and labored to ensure that intellectual property protection would be included in the

¹³See 19 U.S.C. §2411(d); 19 U.S.C. §2242. The history of these statutory provisions is discussed briefly in John H. Jackson, William J. Davey & Alan O. Sykes, *International Economic Relations* 818-20, 832-35 (3d ed: West 1995) (hereafter Jackson, Davey & Sykes).

¹⁴Targets of U.S. action included Brazil, Argentina, India, Thailand, the People’s Republic of China, and the Republic of China (Taiwan). For a history of these disputes and their outcomes, see Alan O. Sykes, *Constructive Unilateral Threats in International Commercial Relations: The Limited Case for Section 301*, 23 L. & Pol. Int’l Bus. 263 (1992) (a table of disputes is set out in the Appendix).

¹⁵See Jackson, Davey & Sykes at 491.

¹⁶The text of NAFTA may be found in many places, among which is John H. Jackson, William J. Davey & Alan O. Sykes, *Documents Supplement to International Economic Relations* (3d ed: West 1995) (NAFTA Chapter 17 is at pages 647-66) (hereafter “Documents Supplement”).

results of Uruguay Round. Resistance from developing countries was intense, but ultimately they acceded to the inclusion of what is now known as the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights, or TRIPs.¹⁷

A. Pertinent Provisions of TRIPs

The patent requirements of TRIPs are contained in Articles 27–34.¹⁸ Patents must be made available for all “inventions, whether products or processes,”¹⁹ and must last for at least twenty years from the date of the filing of a patent application.²⁰ The clear inclusion of process patents within the required scope of coverage was of particular interest to the pharmaceutical industry.²¹ Article 28 provides that the patent holder must be given the exclusive right to make, use, offer for sale, or sell the patented product (in the case of a product patent) or the product made from the patented process (in the case of a process patent). Patent holders also have a “qualified” exclusive right to import, as discussed below.

Pursuant to various transition provisions, these rules did not have immediate effect in the developing world. In general, developing nations were permitted to delay the application of most provisions of the TRIPs agreement for five years after its entry into force (until January 1, 2000).²² Least developed countries have until January 1, 2006 to comply with most TRIPs obligations.²³ Finally, developing nations that did not provide patent protection for a particular

¹⁷The text of TRIPs may be found in Documents Supplement, at 335–65.

¹⁸See *id.* pp. 346–49.

¹⁹TRIPs Article 27.1.

²⁰TRIPs Article 33.

²¹New drugs can be covered by patents on their chemical composition (so-called “composition of matter” patents), or by patents on the process used to make the drug. It is not uncommon for synthesis of a new pharmaceutical compound to precede its commercial use (or the capacity of a manufacturer to produce it cheaply) by many years. Accordingly, the patent on an economical commercial process for making the drug will often remain in force considerably longer than the initial composition of matter patent.

A nice example is the general anesthetic ultane (brand name Sevoflurane), which is now the market leader among inhalation anesthetics in the United States. The composition of matter patent on the product expired in 1989, well before its commercial success occurred. But it remains protected by a process patent (for a few more years) and has been a tremendously successful proprietary product for Abbott Laboratories over the past decade. [find nonconfidential cites from *sevo* litigation].

The failure of many developing countries to protect process patents, and its effect on the pharmaceuticals industry, was a particular concern of the United States entering the Uruguay Round. Several of the unfair trade cases initiated under Section 301 of the Trade Act of 1974 addressed this issue (cite background material on Brazil and Argentina cases).

²²TRIPs Article 65.2–3.

²³TRIPs Article 66.1.

area of technology (such as pharmaceuticals) prior to the entry into force of TRIPs are given until January 1, 2005 to enforce patent rights in that area²⁴—this transition rule explains the present lack of patent protection for pharmaceuticals in India noted in the introduction to this essay. These transitional exemptions have run out or soon will run out, however, and so developing nations must turn to generally applicable exceptions to the patent rules of TRIPs if they are to avoid full patent protection for pharmaceuticals in the future without violating WTO law.

One candidate for an exception in this regard is TRIPs Article 27.2, which provides: “Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect *ordre public* ...including to protect human...health...provided that such exclusion is not made merely because the exploitation is prohibited by their law.” This confusingly worded exception might be read to create a general “public health” exception to the requirement of patentability, but is not so interpreted. Rather, it is understood to refer to inventions that are themselves harmful to the *ordre public*, and that cannot be exploited under national law²⁵ (for example, the United States might deny a patent on a new type of water pipe designed to enhance the pleasures of opium smoking).

Another exception that on its face might seem to provide some opportunity to reduce protection for pharmaceuticals is that of Article 30, which states: “Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not reasonably conflict with normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner...” This exception has been given limited scope in WTO disputes, however, and it is doubtful that a refusal to patent a particular drug at all or to enforce exclusive rights to sell during the mandatory period of the patent could be viewed as a “limited exception.”²⁶ To my knowledge, developing nations have not suggested that they may rely on Article 30 to deal with the pharmaceutical issue.

²⁴TRIPs Article 65.4.

²⁵See WTO, Overview: the TRIPs Agreement, p. 8 (October 30, 2001), available at www.wto.org/english/tratop_e/trips_e/intel2_e.htm.

²⁶In Canada -- Pharmaceuticals [full cite], Article 30 was found to permit governments to allow the production of a patented drug by competitors before the patent runs out for the purpose of conducting the clinical trials necessary to secure regulatory approval of a generic substitute to be introduced upon the expiration of the patent. In the same proceeding, Article 30 was found not to authorize the production of a patented medication during the life of the patent by competitors who wished to stockpile it for sale as a generic following the expiration of the patent.

Instead, much of their attention has been directed to Article 31, concerning “use without authorization of the right holder” or, in more conventional parlance, compulsory licensing. A “compulsory license” is a license to manufacture the patented product that is granted over the objection of the patent holder. Domestic laws that authorize compulsory licensing are permissible under Article 31 but must satisfy a number of conditions. Among other things, compulsory licensing must be preceded by an effort over a “reasonable period of time” to negotiate a license from the right holder on “reasonable commercial terms.” This limitation may be waived by a Member in the event of a “national emergency.” [Art. 31(b)] In addition, any such use must be “predominantly for the supply of the domestic market.” [Art. 31(f)] Further, “the right holder shall be paid adequate remuneration...taking into account the economic value of the authorization.” [Art. 31(h)]

These provisions raise a number of interpretive issues. How long must a Member attempt to negotiate a license from the right holder in the face of apparent impasse? When does a “national emergency” exist that allows the prior negotiation to be avoided? What is “adequate remuneration” to the right holder? The developing nations sought favorable “clarification” on these and related issues at the Doha ministerial meeting.

Another provision that may afford developing nations an opportunity to lower pharmaceutical prices relates to an important qualification on the exclusive right to import under Article 27. That Article cross-references Article 6 of TRIPs, which provides that “nothing in this Agreement shall be used to address the issue of the exhaustion of intellectual property rights.” This obscurely worded provision concerns the question whether a patent holder retains any rights over the resale of a product once it has been introduced into the stream of commerce, or whether the initial sale by the right holder “exhausts” its rights. The issue becomes relevant as follows: Suppose that a pharmaceutical patent holder sells a drug into country A’s market for \$1 per unit. In country B’s market, by contrast, the patent holder prefers to charge \$2 per unit. If the patent holder’s rights are “exhausted” following the sale in country A, the patent holder is said to have no right to prevent buyers in country B from importing the drug from country A and undercutting the patent holder’s desired price in country B. In that event, the ability of patent holder to price discriminate across markets (absent substantial transport costs or important tariff barriers) will be destroyed. Likewise, developing countries that face relatively high prices for a particular drug when it is sold directly into its market by a patent holder may be able to ameliorate the problem by importing the drug from another country where a lower price is charged. Such imports are termed “parallel imports” in WTO parlance, and the resolution of the “exhaustion” issue thus determines whether a patent holder has

a legal right to require nations in which it holds a valid patent to prevent parallel imports.

B. The Prelude to Doha and the Doha Declaration

The AIDS crisis in the developing world and the financial obstacles to addressing it have understandably evoked much sympathy, and the developing nations are not without powerful political allies in the developed world. The litigation initiated against South Africa by international pharmaceutical companies resulted in a flurry of unfavorable commentary in the press, and the litigation was eventually dropped in April, 2001.²⁷ Political considerations also led the United States to drop its WTO challenge to Brazil's Industrial Property Law, in return for a promise by Brazil to consult in advance with the United States before invoking its domestic legislation on compulsory licensing.²⁸ The United Nations Commission on Human Rights weighed in on the matter as well, arguing that access to drugs is a human right, and that TRIPs should be interpreted flexibly to promote access to drugs.²⁹

Accordingly, the political climate prior to the Doha meeting was favorable to the objectives of the developing countries, and the resulting ministerial declaration gave them much of what they had sought. It acknowledges the "gravity of the public health problems afflicting many developing and least-developed countries, especially those resulting from HIV/AIDS, tuberculosis, malaria and other epidemics."³⁰ The ministers "agree that the TRIPs Agreement does not and should not prevent Members from taking measures to protect public health," and state that it "can and should be interpreted and implemented in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all."³¹

With regard to specifics, the Declaration provides:³²

(a) In applying the customary rules of interpretation of public international law, each provision of the TRIPs Agreement shall be read in the light of the object and purpose of the Agreement as expressed, in particular, in its objectives and principles.

²⁷International Centre for Trade and Sustainable Development, U.S. Drops TRIPs Dispute Against Brazil's Patent Law, *Bridges Between Trade and Sustainable Development*, Year 5, No. 5, p.5 (June 2001).

²⁸*Id.*

²⁹See generally UNCHR Report.

³⁰Doha Declaration ¶1.

³¹Doha Declaration ¶4.

³²Doha Declaration ¶5.

(b) Each Member has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted.

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

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

Paragraph (a) urges that interpretive issues be resolved with reference to the stated object and purposes of the TRIPs agreement, a familiar notion of treaty interpretation under the Vienna Convention on the Law of Treaties. Most pertinent in this regard is the “principle” found in TRIPs Article 8, to the effect that “Members may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health...”³³ Paragraph (b) affirms that the grounds for the issuance of compulsory licensing are a matter of national discretion, while paragraph (c) provides that the current public health “crises” in the developing world may be defined as national emergencies, thereby obviating the need for prior negotiations with the right holders before issuing compulsory licenses. Paragraph (d) states that nations may determine for themselves that the first sale of a patented product “exhausts” the patent holder’s rights, so that parallel imports may be allowed (subject to the proviso that this policy must be followed in a nondiscriminatory fashion).

It should be noted that ministerial declarations within the WTO are not “legally binding,” and in the event of a dispute the language of the treaties as approved by national governments would prevail over any contradictory declaration by the ministers. But the Doha declaration is primarily interpretive of imprecise obligations in TRIPs, and does not appear to contradict any textual provision. As such, it is likely to be persuasive authority in the interpretation of TRIPs in the event of a dispute.

It also bears noting that the developing nations did not receive everything on their “wish list” at Doha. Recall that TRIPs Article 31(f) provides that compulsory licensing shall be “predominantly for the supply of the domestic

³³TRIPs Art. 8.1.

market.” Developing nations nevertheless sought language in the ministerial declaration to the effect that “nothing in the TRIPs Agreement prevents Members from granting compulsory licenses for foreign suppliers to provide medicines in the domestic market,” and “nothing in the TRIPs Agreement will prevent Members to grant compulsory licenses to supply foreign markets.”³⁴ The importance of this issue is considerable, as some developing nations lack the technical capacity to manufacture pharmaceuticals domestically. Thus, if Article 31(f) is interpreted to allow compulsory licenses only for domestic manufacturers serving the domestic market, the compulsory licensing option may not be useful in some cases. The Doha Declaration defers resolution of the issue, stating only that: “We recognize that WTO Members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPs Agreement. We instruct the Council for TRIPs to find an expeditious solution to this problem and to report to the General Council before the end of 2002.”³⁵

II. Legal and Economic Analysis

The Doha declaration opens the door wider to compulsory licensing and parallel importation of patented pharmaceuticals by developing countries. Subject to the proviso that countries with little domestic manufacturing capability may have difficulty taking advantage of compulsory licensing, and depending on the ultimate legal standard for “adequate remuneration” under Article 31 of TRIPs, developing nations may well have gained considerable leeway to undercut the rents that patentholders could otherwise earn from the sale of patented medications in the developing world. Indeed, the mere threat to invoke rights of compulsory licensing and parallel importation may suffice to extract much of those rents in the form of lower prices from patentholders. It remains to be seen how widely developing nations will avail themselves of such policies, but this section explores their wisdom.

I begin with a question that a Socratic teacher might ask. Imagine a developing nation with a severe housing crisis, or perhaps a famine, or an extraordinary natural disaster. It believes itself to have a desperate need for funds as a result, and asserts that it cannot obtain the needed funds through general taxation or available aid programs. Would we then think it appropriate for the nation in question to expropriate the property of foreign corporations (say, their mineral rights and manufacturing facilities), and to auction it off to

³⁴Developing Countries Push for TRIPs to Allow Cheaper Medicines, Inside U.S. Trade, vol. 19, No. 25, p. 7 (June 22, 2001).

³⁵Doha Declaration ¶6.

raise needed funds? Or would we think it appropriate for the nation simply to repudiate its external public debt, leaving foreign lending institutions as the parties implicitly “expropriated?” If not, how would we distinguish measures that “expropriate” the rents otherwise due to pharmaceutical patentholders in the face of public health crises?

The most obvious response to this question is that a property right cannot be “expropriated” unless it exists in the first instance. If the TRIPs agreement affords developing countries the right to respond to public health emergencies through compulsory licensing and the right to allow parallel imports on a non-discriminatory basis, the argument would run, these policies are readily distinguishable from my hypothetical on the grounds that they do no violence to the legitimate entitlement of the right holder.

This argument is at least partially unsatisfactory on the issue of compulsory licensing (not on parallel importation, however, given Article 6 of TRIPs). The apparent position of the developing nations and their supporters is that they can now declare a “national emergency” at their sole discretion on grounds of a public health problem, and thereafter issue compulsory licenses for production to serve their domestic markets without prior negotiation and with minimal royalties payable to the patentholder. One may argue forcefully that such a construction of TRIPs would indeed do considerable violence to the rights that pharmaceutical patentholders thought they had under the Agreement. Article 31 of TRIPs seemingly limits compulsory licensing without prior negotiation to genuinely extreme circumstances, and even then ensures “adequate remuneration” to the compulsory licensor. It is difficult to square its text with the proposition that developing countries can unilaterally determine that they are unable to afford pharmaceuticals at current prices, declare that a “national emergency” results as a consequence, and then implement policies that leave patentholders with rents near zero.

Indeed, note that the term “national emergency” in TRIPs is in no way limited to public health issues, and that compulsory licensing under Article 31 is in no way limited to pharmaceutical patents. Thus, return again to my hypothetical regarding a housing crisis, famine or natural disaster that creates a great need for funds. Would we think it permissible for a developing nation confronting such problems to suspend foreigners’ patent rights by issuing compulsory licenses that allow domestic firms to produce the patented goods and sell them at marginal cost, with the government then imposing a tax on those sales to raise needed revenue? If not, how is that situation to be distinguished from suspending the rights of foreign pharmaceutical patentholders in the face of a public health crisis? And can one seriously doubt that violence is done to what patentholders thought they were achieving with the

TRIPs agreement if developing nations can declare a “national emergency” when they need funds for some legitimate end, and tax away the rents of foreign patentholders to raise revenue?

Even if TRIPs affords developing countries enough flexibility to distinguish their plans for compulsory licensing and parallel importation from my hypothetical case of expropriation as a legal matter, however, it remains to inquire whether policies that eliminate the rents of pharmaceutical patent holders in response to public health “emergencies” are wise. To those issues we now turn.

A. The Monopoly/Innovation Tradeoff and its General Implications

Patent rights allow inventors and their licensees to prevent potential competitors from selling products covered by the patent during its duration (now 20 years). If a product has no close substitutes and there are significant numbers of consumers willing to pay more than the cost of production to acquire the product, the patentholder will then enjoy a period of significant “monopoly power” during the life of the patent, defined as an ability to elevate price above cost.³⁶

Ordinarily, public policy is hostile to monopoly. In economic parlance, it is a source of “deadweight losses.” Monopolists charge more for goods and services than the cost of producing them, thereby pricing consumers willing to pay that cost but less than the monopoly price out of the market—their loss of “consumer surplus” represents the standard deadweight loss triangle in price theoretic discussions of the evils of monopoly.³⁷ In addition, monopolists may invest resources in obtaining monopoly, thereby dissipating monopoly profits *ex ante* and causing further deadweight losses.³⁸ With patents in particular, monopoly rents may be dissipated by excessive investment in the race to develop a new invention -- a so-called patent race.³⁹

Depending on the degree of monopoly power enjoyed by a patentholder, therefore, the existence of a patent may cause significant deadweight losses. The justification for tolerating them, of course, is that they provide a desirable return to inventors. Invention is costly, runs the argument, and if inventions can be copied and sold by competitors of the inventor immediately, their prices will be

³⁶See, e.g., William Landes & Richard Posner, *Market Power in Antitrust Cases*, 94 *Harv. L. Rev.* 937 (1981); Janusz Ordover, Alan Sykes & Robert Willig, *Herfindahl Concentration, Rivalry and Mergers*, 95 *Harv. L. Rev.* 1857, 1859–60 (discussion of Lerner index).

³⁷See Frederic M. Scherer, *Industrial Market Structure and Economic Performance* 14–19 (2d ed. 1980).

³⁸See Landes & Posner, *supra*.

³⁹See Jean Tirole, *The Theory of Industrial Organization* 394–99 (1988).

driven down to the marginal cost of producing them exclusive of the cost of innovation. As a result, inventors will be unable to recoup research and development costs. Knowing that fact ex ante, potential inventors will be unwilling to incur such costs and technical progress will be stifled. Patent rights overcome this problem by affording the patentholder a period of monopoly rents that allow the recoupment of research and development costs. Moreover, the magnitude of the rents to inventors under a patent system is reasonably correlated with the value of an invention -- monopoly rents will be greater, as indicated, the lesser the extent to which close substitutes for the patented good exist, and the greater the degree to which consumers value it in excess of its cost. Those are precisely the factors that determine the value of an invention to society in general.

Although the theoretical rationale for a patent system is easily stated,⁴⁰ the proper calibration of a patent system is not. Patent systems traditionally provide a fixed term of patent, regardless of the type of invention or the costs of innovation that need to be recouped. It thus will tend to overreward some inventions (relative to what is necessary to induce them) and to underreward others. Yet, the information necessary to refine the system is not easy to come by—after all, what matters to the pace of research and development is its expected returns ex ante, and those are exceedingly difficult to observe. At best, therefore, modern patent systems provide a crude way for rewarding inventors in the face of great uncertainty about the optimal rewards in each case.

This observation provides a window into a possible line of argument that might distinguish the “expropriation” of rents owing to patentholders from the expropriation of other property. The standard argument for property rights in general is that they create proper incentives for exploitation of resources—no one will bother to cultivate the land, for example, if they cannot lay claim to the crops that they produce.⁴¹ But if one had reason to believe that the patent protection afforded in a particular context was excessive, such a “property right” could not be defended as important to valuable incentives. Quite the contrary, it could become counterproductive, imposing unnecessary deadweight costs of

⁴⁰Note that some commentators argue for an alternative system in which the government rewards innovation directly instead of affording a patent -- they claim that such a system of rewards provides adequate incentives for innovation without introducing the deadweight costs of monopolies conferred by patents. See Steven Shavell and Tanguy van Ypersele, Rewards versus Intellectual Property Rights, 44 J. L. & Econ. 525 (2001). Critics respond that the taxes to fund such a system create their own distortions, and that a combination of information problems and political pressures will discourage the government from calibrating rewards properly. The patent system relies on the market to reward innovators, rather than a bureaucratic estimate of an invention’s value.

⁴¹See generally Richard Posner, *Economic Analysis of Law*, Chapter 3 (4th ed. 1992).

monopoly, and perhaps inducing further waste through ancillary patent races in pursuit of patent monopolies.

The overall evidence on the economic efficiency of the patent system, however, is mixed. Although critics at times suggest that patent protection is excessive, and others find it inadequate, there is surely no consensus on the matter as a general proposition.⁴² It is possible that a general curtailment of patent rights might do little harm or even do some good, but no one really knows. Further, legislatures around the world have for centuries confronted the essential monopoly/innovation tradeoff of the patent system, and have collectively settled on a 20 year patent as a system that apparently is thought to strike a sensible balance. It simply cannot be argued, therefore, that patent rights are excessive as a general proposition (more on the special case of pharmaceuticals in a moment).

B. Patents and Developing Nations

Just as theory alone cannot tell us what constitutes an optimal patent system in any detail, economic theory suggests that the effect on *global economic welfare* (by which I mean the sum of the welfare effects on all nations) of an agreement requiring developing countries to afford patent protection is ambiguous. It is possible that geographically broader patent protection will induce innovation at a rate that more than offsets the additional monopoly losses, but it is also possible that it will have the reverse effect.⁴³

If one focuses not on global economic welfare but on the *economic welfare of developing countries*, by contrast, conventional wisdom holds that the extension of patent protection to developing countries is harmful. This proposition is based on the empirical premise that most innovations occur in developed nations, so that patent rights will result in a large transfer of rents from developing countries to developed ones.⁴⁴ Although some larger developing nations (perhaps those in the “newly industrialized” category) may have enough domestic inventive activity to profit from patent protection,⁴⁵ smaller and less developed economies are likely to be net losers. Some commentators have argued on this basis that the least developed countries should be exempt from intellectual property

⁴²See Id. 399–400; Frederic M. Scherer, *supra* at 439–58.

⁴³See Alan Deardorff, Should Patent Protection Be Extended to All Developing Countries?, in *The Multilateral Trading System: Analysis and Options for Change* 435 (Robert Stern ed. 1993).

⁴⁴See *id.* at 442–43.

⁴⁵See Carlos Prima Braga, *The Newly Industrializing Economies and Intellectual Property Rights* (World Bank: 1992); I. Diwan & Dani Rodrik, Patents, Appropriate Technology and North-South Trade, 30 *J. Int’l Econ.* 27 (1991).

obligations,⁴⁶ and as noted TRIPs allows them until 2006 to implement their commitments.

Can one fashion an argument from the fact that developing nations as a whole may suffer a welfare reduction as result of TRIPs for relaxing the intellectual property protections of TRIPs in particular settings, such as pharmaceuticals? The answer would seem to be no, at least from an economic standpoint.

Developing countries in the main were initially hostile to the TRIPs Agreement when it was proposed during the Uruguay Round of GATT negotiations, a position that was not surprising given the received wisdom that they would collectively suffer under TRIPs. They nevertheless accepted TRIPs in the end, for reasons that have been summarized by Professor Bhagwati: *(i)* developing countries sought concessions on other matters (such as textiles and agriculture), and believed that the business community in the developed world would not support a package containing these concessions without TRIPs; *(ii)* developing countries anticipated that in the absence of an intellectual property agreement, large nations such as the United States would take unilateral trade measures anyway to “punish” nations that did not protect U.S. intellectual property rights; *(iii)* some developing countries anticipated that intellectual property protection would attract valuable foreign investment and technology transfer; and *(iv)* some larger developing countries (such as India) recognized that they were significant creators of intellectual property and would reap benefits from the growth of their creative industries.⁴⁷

In short, developing countries accepted the commitments of TRIPs because it was in their mutual interest when coupled with the concessions that they received on other issues. A treaty such as TRIPs is in this respect much like any contract—each party gives something and gets something in return, and on balance all parties expect net benefits. Were it otherwise, parties would not enter the agreements at all. And if parties deviate from their commitments after the fact, the value of their commitments is diminished in the future. Trade agreements will become less valuable to signatories, and fewer of them will be entered, if commitments are not kept. This observation argues for adherence to the bargain after the fact.

Of course, to say that developing countries should respect their commitments under TRIPs begs the question of what those commitments are.

⁴⁶See Deardorff, *supra* at 446; Keith Maskus & Denise Konan, Trade-Related Intellectual Property Rights: Issues and Exploratory Results, in *Analytical and Negotiating Issues in the Global Trading System* 401, 440 (Alan Deardorff & Robert Stern eds. 1994).

⁴⁷See Jagdish Bhagwati, Comment on Hoekman, in *The New GATT: Implications for the United States* 112–14 (Susan Collins & Barry Bosworth eds. 1994).

This point brings us full circle to the issues discussed earlier, and makes the impact of TRIPs on the welfare of developing countries into an entirely irrelevant consideration. The economic case for encouraging nations to respect their commitments under trade agreements has no quarrel with behavior that is consistent with those commitments. To the extent that what developing countries propose to do with pharmaceutical patents is in tension with their TRIPs commitments, however, deviation comes at the cost of undermining the credibility of commitments, now and in the future. The fact that the commitment from which a nation seeks to deviate imposes a loss on that nation is of no moment, for that is always the case when a nation seeks to deviate. The quid pro quo for compliance with such commitments is the equivalent behavior by other parties, which ensures a reciprocal balance of exchange that yields net benefits to all.

C. Patents on Pharmaceuticals and “Essential Medicines”

The case for protecting the rents of patentholders is particularly strong in the pharmaceutical sector. Even though the rents earned on pharmaceutical patents in developing countries are in general a modest fraction of global patent rents, they may be vital to the incentive for research and development in certain key areas as explained below.

Pharmaceuticals are unusual in the extent to which R&D and regulatory approval costs are a large part of their total production cost. Indeed, the marginal cost of producing pharmaceuticals is often trivial after a drug has been developed and approved by regulators.⁴⁸ R&D and regulatory approval costs are incurred in the main by the company that develops a drug initially—subsequent producers of the same drug face much lower costs (although costs of obtaining approval for a generic version of a drug are not trivial). Without some period of restricted competition, the developers of new drugs will be unable to recoup R&D and regulatory approval costs, and the incentive to develop new drugs will diminish greatly.

For this reason, conventional wisdom has it that patent protection is especially important to the rate of technical progress in pharmaceuticals. In one survey by Professor Mansfield, executives in a range of industries were asked to estimate what percentage of inventions commercialized in the early 1980’s would not have been developed without patent protection. The average response for all industries was only 14%, but for pharmaceuticals the average was 60%.⁴⁹ Studies that examine the rate of return on pharmaceutical research also underscore the

⁴⁸cite David Meltzer piece in JLE conference issue, forthcoming.

⁴⁹Edwin Mansfield, *Patents and Innovation: An Empirical Study*, 32 *Man. Sci.* 175 (1986).

importance of patent protection for recoupment of R&D costs -- they show how many R&D expenditures fail to produce valuable new drugs, and how the funding of pharmaceutical research as a whole requires substantial rents on the modest subset of products that prove particularly successful.⁵⁰ Patents are essential in this regard.

Indeed, some researchers question whether the patent protection available widely in the developed world is sufficient to induce all desirable research. Professors Murphy and Topel have studied the social returns to pharmaceutical research by estimating the willingness to pay of global consumers for new drugs. In the case of drugs that address serious diseases that affect a large number of people, they find consumer willingness to pay to be staggeringly high, the combined effect of the importance of health to consumers generally, and the fact that the world has 5 billion of them. Hence, they argue that research projects with even a tiny probability of success are socially worthwhile when they address serious health conditions, and find that far too little research seems to be undertaken. The reason, they conjecture, likely relates to the difficulty of appropriating the returns to innovation.⁵¹

Despite the apparent importance of patent protection to pharmaceutical R&D, some commentators have been critical of the effort to extend pharmaceutical patent protection to developing countries. Professor Scherer offers such a skeptical view based on a variant of the general argument considered earlier regarding the welfare effect of patents on developing countries. Scherer notes the GDP of the developing countries is only about one-fifth that of the developed countries, and from that fact infers that patent rights in developing countries could generate only about 20% or so of the available global rents. He further makes what he believes to be reasonable assumptions about the impact of increased rents from patents in developing countries on the development of new drugs. He then concludes that losses to developing countries from the transfer of monopoly rents from developing nations to developed nations as a result of patents are likely to exceed by a wide margin any benefits to developing countries from the new drugs that result from broader patent protection.⁵²

⁵⁰See, e.g., Martin Baily, Research and Development Costs and Returns: The U.S. Pharmaceutical Industry, 6 J. Pol. Econ. 232 (1972); Henry Grabowski & John Vernon, Returns to R&D on New Drug Introductions in the 1980's, 13 J. Health Econ. 238 (1994); Frederic M. Scherer, Pricing, Profits, and Technological Progress in the Pharmaceutical Industry, 7. J. Econ. Persp. 86 (1993).

⁵¹See Kevin Murphy & Robert Topel, The Economic Value of Medical Research, forthcoming J. L. & Econ.

⁵²See Frederic M. Scherer, Industry Structure, Strategy and Public Policy 362-66 (1996).

Scherer's argument is less than fully convincing for two reasons. First, given the apparent value of pharmaceutical research and the importance of patent protection to inducing it, the case for global patent protection in the pharmaceutical industry is stronger than it is in most other industries. Even if Professor Scherer were right about the welfare impact of pharmaceutical patents on developing countries viewed in isolation, the odds that such patents will nevertheless enhance global welfare appear particularly favorable in this sector.

Second and perhaps more important, it is a mistake to assume that because developing nations are only about 20% of global GDP, they in turn represent only about 20% of global willingness to pay for pharmaceuticals (and are thus a potential source of only about 20% of the total possible rents). The reason is that the incidence of disease is not uniform around the globe.

As noted in the introduction, a high percentage of the individuals infected with HIV are located in developing countries. And as the Doha declaration itself acknowledges, diseases such as malaria and drug resistant tuberculosis are "epidemic" in developing nations. They are a relatively minor health concern, by contrast (nonexistent in the case of malaria), in developed countries. It follows that economic incentive to do research on such diseases will depend critically on the ability of pharmaceutical companies to earn rents on sales in the developing world.⁵³

Incentives to do research on tropical diseases generally has been weak in the past, as groups such as Doctors Without Borders have observed.⁵⁴ Patent protection under TRIPs can ameliorate such problems. Yet, just as the transition periods for developing countries to implement their TRIPs obligations are expiring, the Doha declaration holds out the prospect of compulsory licensing and parallel importation policies that may eviscerate the rents that patentholders might otherwise hope to earn on new drugs that address diseases of disproportionate concern to developing countries.

Does the analysis change if we label a drug "essential," or if a disease is "epidemic"—can one argue for an exception to general principles on the basis of such classifications? From an economic standpoint the answer must be no. Drugs that treat serious and widespread conditions are precisely the drugs that are the most valuable to society, and thus the types of drugs on which more research and development has the greatest potential payoff. A policy that requires the

⁵³The point has been made by others. See Shanker Singham, TRIPs and the Interface Between Competition and Patent Protection in the Pharmaceutical Industry, 26 Brooklyn L. J. 363, 384 (2000).

⁵⁴Doctors Without Borders website: www.accessmed-msf.org/campaign/tb01.shtm (lack of research on tuberculosis); <http://www.accessmed-msf.org/campaign/mlr01.shtm> (lack of research on malaria). See also the Aginam contribution to this volume.

developers of such drugs to sacrifice their intellectual property rents in the name of a “national emergency” or some similar moniker will simply discourage research in the areas where it has the most potential to yield high returns.

D. Parallel Imports and Price Discrimination

Recall that “parallel imports” occur when drug sold by a patentholder in one country is exported by a buyer to another country where the patentholder’s price for the drug is higher. Plainly, the effect of parallel importation is to undercut the ability of the patentholder to engage in price discrimination across national markets. A higher price in one market will attract parallel imports (if they are legal) whenever transportation costs and tariffs into the higher-priced market add up to less than the price differential.

Absent parallel imports, pharmaceutical patentholders will often find price discrimination attractive. In general, it pays to charge a different price across two markets if the elasticity of demand in those markets differs at a common price. The market with the low elasticity of demand—that is, where price can be raised without causing a lot of consumers to exit the market—will be charged the higher price. The high elasticity market—where a price increase causes a larger loss of consumers—will receive the lower price.⁵⁵

Demand elasticity for pharmaceuticals will routinely differ across national markets. One reason relates to differences in the availability of substitutes because of regulation—where regulators have approved close substitutes for a drug, demand elasticity will be higher than where they have not. Government price regulation of pharmaceuticals also plainly affects demand elasticity (there are no customers above the maximum allowed price absent a black market). Differences in income across countries are another important source of differences in demand elasticity. Consumers in higher income countries will typically be willing to pay more for drugs than consumers in lower income countries. This last observation might be thought to imply that parallel imports are more likely to flow into developed nations than developing nations, but it is important to recognize that great differences exist in incomes (and income distributions) across the developing world as well.

Economists have long known that price discrimination may or may not exacerbate the deadweight losses associated with monopolies as a theoretical matter. The conventional empirical wisdom, however, is that price discrimination tends to produce an expansion of output to serve consumers who would be priced out of the market by a nondiscriminating monopolist. If so, fewer consumers who are willing to pay the marginal cost of producing the

⁵⁵See Scherer, *Industrial Market Structure and Economic Performance*, supra, at 316.

monopolized good will be priced out of the market, and deadweight losses will fall.⁵⁶ One fact that is beyond dispute, however, is that price discrimination raises the profits of monopolists—a monopolist can always choose not to discriminate, and thus any observed price discrimination is presumptively more profitable than charging a single price everywhere.

These observations suggest some immediate objections to policies that permit parallel imports of pharmaceuticals.⁵⁷ Parallel importation invariably reduces the rents that are earned by pharmaceutical patentholders. To the degree that those rents are important to inducing worthwhile R&D investments, as suggested above, this effect is unfortunate. Parallel imports may also exacerbate the deadweight costs of monopoly by forcing patentholders to abandon price discrimination and revert to policies approaching those of a nondiscriminating monopolist., curtailing global output in the process.

The last point suggests why parallel importation may have especially harmful consequences for some developing countries. If trading nations as a whole ban parallel imports, pharmaceutical patentholders should be willing to sell their products at a low price to nations where customers cannot afford to pay much for them as long as that price covers the marginal cost of making the drug and delivering it. They will be willing to do so because each sale yields some profit, and they need not fear that their low-priced sales in one market will be re-exported to undercut their prices elsewhere. When parallel imports are possible, by contrast, they will likely become unwilling to sell at low prices in markets where demand is weak. Poorer countries may then find themselves largely priced out of the market for particular medications.

Not only may opportunities for parallel imports reduce valuable R&D, increase the deadweight costs of monopoly and harm the poorest countries, they may also create a “free rider” problem in nations where pharmaceutical distributors perform valuable and expensive services. Imagine a distributor who undertakes costly measures to inform physicians about the value of a particular drug or to secure needed regulatory approvals, for example, and who must recoup the costs of doing so through the price that it charges for the drug.

⁵⁶See *id.* at 320–21. A possible offsetting factor is that price discrimination makes monopoly more profitable, and thus more resources may be expended by companies in pursuit of a monopoly position.

⁵⁷For a more extensive survey of the issues, see Claude Barfield & Mark Groombridge, *Parallel Trade in the Pharmaceutical Industry: Implications for Innovation, Consumer Welfare, and Health Policy*, 10 *Fordham Intell. Prop., Media & Ent. L. J.* 185 (1999). See also Keith Maskus & Mohamed Lahouel, *Competition Policy and Intellectual Property Rights in Developing Countries*, in *Developing Countries and the WTO: A Pro-active Agenda* 233, 243–45 (Bernard Hoekman & Will Martin eds. 2001).

Parallel imports of the drug from abroad where distributors do not incur such costs may make it impossible for distributors who provide valuable services to recoup their costs. Parallel imports in this situation may be said to “free ride” on the services of the local distributor.

To be sure, parallel imports are not simply a potential problem in developing nations, and their costs may well be more severe when allowed into developed markets. But to the extent that the Doha declaration encourages them in the developing world, some harm will surely be done.

E. The Collective Action Problem

The need for more research and development on health problems that are particularly acute in the developing world has already been noted.⁵⁸ It is sometimes asserted that research on these health problems is lacking because developing countries are poor and hence pharmaceutical companies do not expect to make enough selling new drugs to recoup their investments in research.⁵⁹

The profit motive is undoubtedly a vital consideration in the R&D decisions of pharmaceutical companies. But one cannot simply presume that the lack of research is because comparatively low GDP per capita in developing countries makes profitable drug research infeasible. When willingness to pay for effective drug therapies is aggregated across countries containing hundreds of millions if not billions of people, the total profit potential can be substantial. This is all the more true when the governments of developing countries become actively involved in financing drug treatments.⁶⁰

It is thus likely that the dearth of research is attributable in significant part to heretofore weak intellectual property protection for pharmaceuticals in developing countries. Many developing countries have had no patent protection for pharmaceuticals at all, and in others it has been quite limited (such as an absence of process patents). Further, where patent protection has existed, it has been a matter of national (not international) law historically, and could thus be changed at any time without international penalties.

Such a situation has all the elements of a classic collective action problem (or, if you prefer, “prisoner’s dilemma”). If credible patent protection across the developing world would stimulate valuable research that was in the collective interest of developing nations, each individual nation is nevertheless a relatively modest fraction of the collective market. Thus, each nation may be tempted not

⁵⁸See note X *supra* as well as the ‘t Hoen paper in this volume and sources cited therein.

⁵⁹See *id.*

⁶⁰See the Torres paper in this volume regarding Venezuela.

to afford patent protection, secure in the knowledge that it will reap the full benefits of lower domestic drug prices as a result while its policy will have only modest impact on global research incentives. Put differently, each nation will reap all the benefits from a decision not to afford patent protection, while the costs will be borne by developing countries as a whole. With full internalization of the benefits and substantial externalization of the costs, the equilibrium behavior would likely be underprotection of patents, even if stronger protection were in the interests of developing nations as a group.

The TRIPs agreement has the potential to change this situation dramatically. Once the transition periods for developing countries expire (the year 2,000 in some cases, and 2005 or 2006 in others)⁶¹, all WTO members will be required to afford full patent rights on pharmaceuticals (although it would allow them to permit parallel imports). The requirement is backed by standard WTO sanctions for noncompliance. Thus, after the transition, TRIPs is in principle a vehicle for overcoming at least part of the collective action problem that may have been acute in the past.

But the Doha declaration does much to undermine its effectiveness in this regard. Any pharmaceutical company contemplating research on diseases of particular interest to developing nations is now on notice that in the event a successful new drug is developed, developing country customers may declare a “national emergency” and thereafter award compulsory licenses without prior negotiation, and at a royalty rate that may be minimal depending on the eventual interpretation of the “adequate remuneration” standard in Article 31.⁶² Even if such behavior is not in the collective interest of developing nations, the temptation to engage in it on an individual country basis may be great because the costs to others are externalized.

It bears noting that Article 6 of TRIPs (which effectively allows nations to choose whether or not to allow parallel imports on an individual basis) creates its own collective action problem. Even if parallel importation is not in the interests of developing countries as a whole for the reasons given earlier, a decision by a single nation to permit such imports will produce lower prices that benefit it directly while the costs will be borne mainly by others.⁶³

⁶¹See TAN xx supra.

⁶²It is of no moment whether the compulsory license is actually issued, or whether the threat to issue one is enough to induce the patentholder to slash its prices. Either way, rents on the patent are largely forfeit.

⁶³The problem under Article 6 may be less severe, however, because of the requirement that the policy toward parallel imports be nondiscriminatory (i.e., applicable to all patented products, not just pharmaceuticals). A nation tempted to allow parallel imports on pharmaceuticals may

III. Legal and Policy Implications

The analysis to this points out the worrisome possible consequences of policies that erode the returns to pharmaceutical patents in developing countries. I stipulate that the severity of these consequences is an empirical question on which more research might usefully be done, and thus any conclusions here are necessarily tentative.

One implication of the discussion here is that other policy instruments should be considered before patent rights are eroded. One alternative policy instrument, of course, is public funding of medical therapies at current prices by the governments of developing nations. Although many such governments will argue that they cannot “afford” to do so, and that claim may often be persuasive, certainly not every developing nation is altogether unable to provide funds for public health.

Where this source of funding is unrealistically small, another obvious policy is aid from developed nations. Indeed, the recent G-8 summit in Genoa announced such a program, committing \$1.3 billion in new economic aid to assist developing nations in fighting AIDS.⁶⁴ Given the wide set of tax instruments available to developed nations to raise general revenues, it is certainly plausible that aid programs will cause fewer economic distortions than an implicit tax on the rents of pharmaceutical patentholders.⁶⁵

Whatever the merits of greater reliance on governmental assistance to people in need of medicines in developing countries, however, existing sources of such aid are widely perceived to fall short of what is needed to enable developing countries to meet their public health needs.⁶⁶ If developing countries are to address their problems some other way, what can one say about the second or perhaps third-best options?

An important implication of the analysis above is that international price discrimination by pharmaceutical patentholders may well be a useful practice. It increases the returns to patentholders and enhances research incentives, while allowing patentholders to price their medicines in a way that makes them affordable to poorer countries. Article 6 of TRIPs can stand in the way of

face constraints with respect to other products (a desire to attract technology transfer in other areas, for example) that may discourage it from allowing parallel imports of everything.

⁶⁴See Agence France Press, *Developing Countries Face Five Billion Dollar AIDS Drugs Bill*, October 6, 2001.

⁶⁵Such reasoning is common in thinking about tax policy. Taxes typically cause some economic distortion, and if one broadens the set of tax instruments available to raise any target level of revenue, one can typically (though not always) find combinations of instruments that reduce the total distortion.

⁶⁶See *Developing Countries Face Five Billion Dollar AIDS Drugs Bill*, *supra*.

successful price discrimination by authorizing nations to declare that the first sale of a patented product “exhausts” the rights of the patentholder, thereby allowing buyers to resell the product to undercut higher prices elsewhere. One might therefore consider possible changes to Article 6. Among other things, it is hardly clear that the exhaustion issue should be resolved the same way for all products, and that the nondiscrimination rule of Article 6 is desirable. One can imagine changes to TRIPs that would permit sectoral agreements on the exhaustion issue, followed by a particularized agreement discouraging parallel imports of pharmaceuticals. Amendments to WTO agreements are not easily achieved, however, and the political prospects for any such changes at the present juncture are quite another matter.

One can also imagine practices that would better facilitate price discrimination within developing countries. Governments might commit themselves to eschew compulsory licensing or parallel imports, for example, in exchange for discounted sales of medicines to be administered to its poorest citizens and not to be resold to citizens who can afford the medicines at the usual price. Such programs have the twin benefits of making medicines more affordable to the poor while increasing patentholders rents and research incentives. The prospects for such arrangements may also be dim, however, in part because of the collective action issues elaborated above.

The other options for protecting the rents of patentholders involve limitations on compulsory licensing, which could be achieved by interpretive means within the WTO dispute resolution mechanism. One possibility, notwithstanding the Doha declaration (which does not have binding legal force in a WTO dispute), is to construe the concept of “national emergency” narrowly, thereby insisting that nations ordinarily negotiate at some length with patentholders before invoking compulsory licensing with an eye toward agreement on “reasonable commercial terms.” The importance of the right to negotiate will turn in large part on the interpretation of this last phrase, but it can certainly be argued that “reasonable commercial terms” for a patent license would include a substantial royalty to the inventor if the invention has great economic value.

Another lever over compulsory licensing is Article 31’s requirement of “adequate remuneration” to the patentholder, which must be paid even in cases of “national emergency.” That provision has not yet been interpreted, but it can again be argued that remuneration is not “adequate” if it fails to take account of research and development costs, not only for the successful drug in question but also for unsuccessful research aimed at the same medical problem. Cash-strapped developing nations might be permitted to spread payments out over

time in a sensible fashion under this standard, as long as the present value of the payment stream represented a reasonable return on R&D expenditures.

I conclude by reiterating that these suggestions are tentative, and by underscoring the value of empirical research that might shed further light on these difficult issues. My goal here is not to resolve the policy issues definitively, but merely to suggest that the Doha declaration may be moving the global community in the wrong direction. Public health crises in the developing world understandably evoke great sympathy, and the political support for relieving financial pressures at Doha was readily understandable. But as the economist Alan Blinder has reminded us, these difficult humanitarian issues must be approached with both a soft heart and a hard head.⁶⁷ A lack of credible patent rights for pharmaceuticals in the developing world may do far more harm in the long run than their absence can accomplish in the short run.

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⁶⁷Alan Blinder, *Hard Heads, Soft Hearts : Tough-Minded Economics for a Just Society* (1989).

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