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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. The bulk of the attention stems from the HIV/AIDS epidemic which affects many developing countries acutely, 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 is thought to be infected, is said to be about \$12,000, far beyond the means of most South Africans.¹ Only about 5 percent of the 1 million citizens of Thailand believed to be infected are able to afford the AIDS therapies prescribed to them.²

Much of the problem is attributed to the prices charged by pharmaceutical companies for their patented medications. A UN study reports, for example, that 150 mg of the HIV drug fluconazole costs \$55 in India, where the drug does not enjoy patent protection, as compared to \$697 in Malaysia, \$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.³

Developing nations where patents are in place 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 pharmaceutical manufacturers over South Africa’s Medicines and Related Substances Control Act of

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1. Judy Rein, *International Governance Through Trade Agreements: Patent Protection for Essential Medicines*, 21 Nw J Intl L & Bus 379, 400 (2001). See also Frederick Abbott, *The TRIPS—Legality of Measures Taken to Address Public Health Crises: A Synopsis*, 2001 Widener L Symposium J 71.
2. Rein, 21 Nw J Intl L & Bus at 400 (cited in note 1).
3. United Nations, Report of the High Commissioner of the Human Rights Commission on Economic, Social and Cultural Rights, *The Impact of the Agreement on Trade-Related Aspects of Intellectual Property Rights on Human Rights*, UN Doc E/CN.4/Sub.2/2001/13 at 14, para 44 (2001) (“UNCHR Report”).

1997.⁴ The US government also initiated an action against Brazil within the World Trade Organization ("WTO") over the compulsory licensing provisions in Brazil's Industrial Property Law.⁵

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" or "Agreement"). 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.⁶ 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 ("Doha Declaration" or "Declaration").⁷ 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 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 patent holders, and creating deadweight losses by pricing

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4. Duane Nash, *South Africa's Medicines and Related Substances Control Amendment Act of 1997*, 15 Berkeley Tech L J 485, 493 (2000).
 5. International Centre for Trade and Sustainable Development, *U.S. Drops TRIPs Dispute Against Brazil's Patent Law*, in *Bridges Between Trade and Sustainable Development*, Year 5, No 5 at 5 (June 2001).
 6. *WTO Ministers Likely to Face Difficult Choice on TRIPS, Public Health*, Inside US Trade Special Report 1 (Oct 30, 2001).
 7. World Trade Organization, *Declaration on the TRIPS Agreement and Public Health*, WTO Doc WT/MIN(01)/DEC/2 (Nov 14, 2001).

consumers out of the market who are willing to pay the marginal cost of medicines but not the monopoly markup charged by the patent holder.

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 diseases such as malaria and drug-resistant tuberculosis that are of particular importance to these nations. 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 are beginning to take hold, the Doha Declaration casts great doubt on the future credibility of patent rights for pharmaceuticals in 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.⁸

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 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 will often benefit from the opportunity to use technology developed and patented elsewhere without the need to pay royalties. Consequently, patent protection in developing countries historically has been lax by comparison to the developed world.

8. John H. Jackson, *The World Trading System* 310–13 (MIT 2d ed 1997).

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 US 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.⁹ 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.¹⁰

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 US-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 in the United States and Canada.¹¹ 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.

The Uruguay Round of negotiations under the auspices of GATT was 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 results of the Uruguay Round. Resistance from developing countries was intense, but ultimately they acceded to the inclusion of what is now known as the WTO TRIPS Agreement.¹²

A. PERTINENT PROVISIONS OF TRIPS

The patent requirements of TRIPS are contained in Articles 27–34. Patents must be made available for all “inventions, whether products or processes,”¹³ and must

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9. See 19 USC § 2411(d) (2001); 19 USC § 2242 (2001). The history of these statutory provisions is discussed briefly in John H. Jackson, William J. Davey, and Alan O. Sykes, *Legal Problems of International Economic Relations: Cases, Materials and Text on the National and International Regulation of Transnational Economic Relations* 818–20, 832–35 (West 3d ed 1995).
 10. Targets of US 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 in Intl Bus 263, 318 (1992) (a table of disputes is set out in the Appendix).
 11. Jackson, Davey, and Sykes, *Legal Problems of International Economic Relations* at 491 (cited in note 9).
 12. See Agreement on Trade Related Aspects of Intellectual Property Rights, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 33 ILM 81 (1994) (“TRIPS”).
 13. *Id.* at art 27.1.

last for at least twenty years from the date of the filing of a patent application.¹⁴ The clear inclusion of process patents within the required scope of coverage was of particular interest to the pharmaceutical industry.¹⁵ 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).¹⁶ 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, or until January 1, 2000.¹⁷ The least developed countries have until January 1, 2006 to comply with most TRIPS obligations.¹⁸ Finally, developing nations that did not provide patent protection for a particular area of technology (such as pharmaceuticals) prior to the entry into force of TRIPS have until January 1, 2005 to enforce patent rights in that area¹⁹—this transition rule explains the present lack of patent protection for pharmaceuticals in India that was noted in the introduction to this essay. As these transitional exemptions run out, developing nations must look for 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 such an exception 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 it is not so interpreted. Rather, it is understood to refer to inventions that are themselves harmful to the *ordre public*, and that cannot be

14. Id at art 33.

15. New 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. 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.

16. TRIPS at art 28 (cited in note 12).

17. Id at art 65.2–3.

18. Id at art 66.1.

19. Id at art 65.4.

exploited under national law²⁰ (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 unreasonably conflict with a 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."²¹ To my knowledge, developing nations have not suggested that they may rely on Article 30 to deal with the pharmaceutical issue.

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." Article 31(b) provides that this limitation may be waived by a Member in the event of a "national emergency." In addition, under Article 31(f), any such use must be "predominantly for the supply of the domestic market." Further, "the right holder shall be paid adequate remuneration . . . taking into account the economic value of the authorization," as provided for by Article 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.

20. World Trade Organization, *Overview: The TRIPS Agreement* 8, available online at <http://www.wto.org/english/tratop_e/trips_e/intel2_e.htm> (visited Mar 24, 2002).

21. In *Canada—Patent Protection of Pharmaceutical Products*, 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. World Trade Organization, Report of the Panel, *Canada—Patent Protection of Pharmaceutical Products*, WT/DS114/R (Apr 7, 2000), available online at <http://www.wto.org/english/tratop_e/dispu_e/distabase_wto_members1_e.htm> (visited Mar 24, 2002) (listing panel and appellate body reports by country).

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 of 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 in the following example. 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, then the patent holder has 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 the 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 suit was eventually dropped in April 2001.²² 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 with the United States before invoking its domestic legislation on compulsory licensing.²³ The UN 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.²⁴

22. International Centre for Trade and Sustainable Development, *U.S. Drops TRIPs Dispute Against Brazil's Patent Law* (cited in note 5).

23. *Id.*

24. UNCHR Report (cited in note 3).

Accordingly, the political climate prior to the Doha meeting was favorable to the objectives of the developing countries, and the resulting Declaration gave them much of what they 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."²⁵ The ministers "agree that the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health," and state that the agreement "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."²⁶

With regard to specifics, the Declaration provides:²⁷

- (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.
- (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 [certain limitations related to nondiscrimination].

It should be noted that ministerial declarations within the WTO are not legally binding in the dispute resolution process, 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 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

25. World Trade Organization, *Declaration on the TRIPS Agreement and Public Health* at para 1 (cited in note 7).

26. *Id.* at para 4.

27. *Id.* at para 5.

"nothing in the TRIPs Agreement will prevent Members to grant compulsory licenses to supply foreign markets."²⁸ 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 2002.²⁹

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 patent holders 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 patent holders. The extent to which developing nations will avail themselves of such policies remains to be seen, but this section explores their wisdom.

I begin with some questions that a Socratic teacher might ask. Imagine a developing nation with a severe housing crisis, 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 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 patent holders in the face of public health crises?

28. *Developing Countries Push for TRIPS to Allow Cheaper Medicines*, 19:25 Inside US Trade 7 (June 22, 2001).

29. World Trade Organization, *Declaration on the TRIPS Agreement and Public Health* at para 6 (cited in note 7).

The most obvious response 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 patent holder. One may argue forcefully that such a construction of TRIPS would indeed do considerable violence to the rights that pharmaceutical patent holders 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, and then implement policies that leave patent holders 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 patent holders in the face of a public health crisis? And can one seriously doubt that violence is done to what patent holders 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 patent holders 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 twenty 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 patent holder will then enjoy a period of significant "monopoly power" during the life of the patent, defined as an ability to elevate price above cost.

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 cost but not the full monopoly price out of the market. Monopolists' loss of "consumer surplus" represents the standard deadweight loss triangle in price theoretic discussions of the evils of monopoly.³⁰ In addition, monopolists may invest resources in obtaining monopoly, thereby dissipating monopoly profits *ex ante* and causing further deadweight losses. 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.³¹

Depending on the degree of monopoly power enjoyed by a patent holder, 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 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 patent holder a period of monopoly rents that allows the recoupment of research and development costs. 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 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.

Although the theoretical rationale for a patent system is easily stated, 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 over-reward some inventions (relative to what is necessary to induce them) and to under-reward others. Yet, the information

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

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

necessary to refine the system is not easy to come by—after all, what matters to the pace of research and development are its expected returns *ex ante*, and those are exceedingly difficult to observe. At best, therefore, modern patent systems provide a crude way of 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 patent holders 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. 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 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. 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 twenty-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 below).

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.³²

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

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

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. Although some larger developing nations (perhaps those in the "newly industrialized" category) may have enough domestic inventive activity to profit from patent protection,³³ 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 obligations,³⁴ 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 US 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.³⁵ 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. 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.

33. Ishac Diwan and Dani Rodrik, *Patents, Appropriate Technology, and North-South Trade*, 30 J Intl Econ 27 (1991).

34. Alan Deardorff, *Should Patent Protection Be Extended to All Developing Countries?* at 446 (cited in note 32); Keith E. Maskus and Denise Eby Konan, *Trade-Related Intellectual Property Rights: Issues and Exploratory Results*, in Alan Deardorff and Robert Stern, eds, *Analytical and Negotiating Issues in the Global Trading System* 401, 440 (Michigan 1994).

35. Jagdish Bhagwati, *Comment on Services and Intellectual Property Rights*, in Susan Collins and Barry Bosworth, eds, *The New GATT: Implications for the United States* 111, 112–114 (Brookings 1994).

Of course, to say that developing countries should respect their commitments under TRIPS begs the question of what those commitments are. 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. But to the extent that what developing countries propose to do with pharmaceutical patents is in tension with their TRIPS commitments, deviation comes at the cost of undermining the credibility of their 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 patent holders 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 research and development ("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.³⁶ 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 1980s would not have been developed without patent protection. The average response for all industries was only

36. David Meltzer, *Commentary on "Health Insurance and the Growth in Pharmaceutical Expenditures"* by Patricia M. Danzon and Mark V. Pauly, *J L & Econ* (forthcoming 2002).

14 percent, but for pharmaceuticals the average was 60 percent.³⁷ Studies that examine the rate of return on pharmaceutical research also underscore the 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.³⁸ 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 global consumers' willingness to pay for new drugs. In the case of drugs that address serious diseases affecting a large number of people, they find consumer willingness to pay to be staggeringly high, due to the combined effect of the importance of health to consumers generally, and the fact that the world has five billion of those potential healthcare consumers. Hence, they argue that research projects with even a tiny probability of success are socially worthwhile when they address serious health conditions, yet they 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.³⁹

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 that the gross domestic product ("GDP") of the developing countries is only about one-fifth that of the developed countries, and infers from that fact that patent rights in developing countries could generate only about 20 percent or so of the available global rents. 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.⁴⁰

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

37. Edwin Mansfield, *Patents and Innovation: An Empirical Study*, 32 *Management Sci* 173, 175 (1986).

38. See, for example, Martin Neil Baily, *Research and Development Costs and Returns: The U.S. Pharmaceutical Industry*, 80 *J Pol Econ* 70 (1972); Henry Grabowski and John Vernon, *Returns to R&D on New Drug Introductions in the 1980s*, 13 *J Health Econ* 383 (1994); Frederic M. Scherer, *Pricing, Profits, and Technological Progress in the Pharmaceutical Industry*, 7 *J Econ Perspec* 97 (1993).

39. See Kevin Murphy & Robert Topel, *The Economic Value of Medical Research*, *J L & Econ* (forthcoming 2002).

40. Frederic M. Scherer, *Industry Structure, Strategy and Public Policy* 362–66 (Harper Collins 1996).

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 percent of global GDP, they in turn represent only about 20 percent of global willingness to pay for pharmaceuticals (and are thus a potential source of only about 20 percent 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 the 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.

Incentives to do research on tropical diseases generally have been weak in the past, as groups such as Doctors Without Borders have observed.⁴¹ 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 patent holders 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 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.

41. Doctors Without Borders, *Campaign for Access to Essential Medicines: Target Diseases—Tuberculosis*, available online at <<http://www.accessmed-msf.org/campaign/tb01.shtm>> (visited Mar 24, 2002) (describing lack of research on tuberculosis); Doctors Without Borders, *Campaign for Access to Essential Medicines: Target Diseases—Malaria*, available online at <<http://www.accessmed-msf.org/campaign/mlr01.shtm>> (visited Mar 24, 2002) (describing ongoing lack of research on malaria). See also Obijiofor Aginam, *From the Core to the Peripheries: Multilateral Governance of Malaria in a Multi-Cultural World*, 3 Chi J Intl L 87 (2002).

D. PARALLEL IMPORTS AND PRICE DISCRIMINATION

Recall that parallel imports occur when a drug sold by a patent holder in one country is exported by a buyer to another country where the patent holder's price for the drug is higher. Plainly, the effect of parallel importation is to undercut the ability of the patent holder 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 patent holders 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.⁴²

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 non-discriminating monopolist. If so, fewer consumers who are willing to pay the marginal cost of producing the monopolized good will be priced out of the market, and deadweight losses will fall.⁴³ One fact that is beyond dispute, however, is that price discrimination raises the profits of monopolists—a monopolist can always

42. Scherer, *Industrial Market Structure and Economic Performance* at 316 (cited in note 30).

43. *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.

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.⁴⁴ Parallel importation invariably reduces the rents that are earned by pharmaceutical patent holders. 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 patent holders to abandon price discrimination and revert to policies approaching those of a non-discriminating 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 patent holders 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. 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.

44. For a more extensive survey of the issues, see Claude Barfield and Mark Groombridge, *Parallel Trade in the Pharmaceutical Industry: Implications for Innovation, Consumer Welfare, and Health Policy*, 10 *Fordham Intel Prop, Media, & Enter L J* 185 (1999). See also Keith Maskus and Mohamed Lahouel, *Competition Policy and Intellectual Property Rights in Developing Countries*, in Bernard Hoekman and Will Martin, eds, *Developing Countries and the WTO: A Pro-Active Agenda* 233, 243–45 (Blackwell 2001); Keith E. Maskus, *Intellectual Property Rights in the Global Economy* 208–16 (Institute for International Economics 2000).

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.⁴⁵ 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.

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.⁴⁶

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 historically has been a matter of national (not international) law 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 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 under-protection 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, all WTO members will

45. See note 41. See also Ellen 't Hoen, *TRIPS, Pharmaceutical Patents, and Access to Essential Medicines: A Long Way from Seattle to Doha*, 3 Chi J Intl L 27 (2002).

46. See Mary Ann Torres, *The Human Right to Health, National Courts, and Access to HIV/AIDS Treatment: A Case Study from Venezuela*, 3 Chi J Intl L 105 (2002).

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 non-compliance. Thus, after the transition, TRIPS is, in principle, a vehicle for overcoming at least part of the collective action problem.

However, 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 31.⁴⁷ 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.

Additionally, 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.⁴⁸

III. LEGAL AND POLICY IMPLICATIONS

This analysis has highlighted 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, a claim which may often be persuasive, certainly not every developing nation is altogether unable to provide funds for public health.

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

48. The problem under Article 6 may be less severe, however, because of the requirement that the policy toward parallel imports be non-discriminatory (in other words, applicable to all patented products, not just pharmaceuticals). A nation tempted to allow parallel imports on pharmaceuticals may 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.

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.⁴⁹ 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 patent holders.⁵⁰

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.⁵¹ 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 above analysis is that international price discrimination by pharmaceutical patent holders may well be a useful practice. It increases the returns to patent holders and enhances research incentives, while allowing patent holders to price their medicines in a way that makes them affordable to poorer countries. Article 6 of TRIPS can stand in the way of successful price discrimination by authorizing nations to declare that the first sale of a patented product "exhausts" the rights of the patent holder, 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 patent

49. See *Developing Countries Face Five Billion Dollar AIDS Drugs Bill*, Agence France Presse (Oct 6, 2001).

50. Such 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.

51. *Developing Countries Face Five Billion Dollar AIDS Drugs Bill*, Agence France Presse (cited in note 49).

holders 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 patent holders 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, again, 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 patent holders 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 patent holder, 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 R&D 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. However, as the economist Alan Blinder has reminded us, these difficult humanitarian issues must be approached with both a soft heart and a hard head.⁵² 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.

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