

MARKET FUNDAMENTALISM AND THE TRIPS AGREEMENT

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TABLE OF CONTENTS

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| INTRODUCTION | 307 |
| I. THE ROAD TO DOHA | 310 |
| II. THREE CRITIQUES OF THE TRIPS DECLARATION | 320 |
| III. RESPONSE TO THE CRITIQUES | 326 |
| A. <i>The Revision Argument</i> | 326 |
| B. <i>The Collective Action Argument</i> | 333 |
| C. <i>The Externality Argument</i> | 336 |
| CONCLUSION | 341 |

As a modern and secular form of natural-law theology, Chicago economics thus might “work” for its true believers, not in a scientific but in the old-fashioned manner of a religious belief Chicago proselytizes a set of values that it believes should be common to all, even as these very same values seemingly deny the existence of any common truth that transcends individual motives. It is not the first time in history that a powerful religious commitment and sense of deep personal satisfaction in the lives of the followers in a set of church dogmas have been derived from a confused – if not internally contradictory – theology.

— ROBERT H. NELSON, *ECONOMICS AS RELIGION:
FROM SAMUELSON TO CHICAGO AND BEYOND* 191 (2001)

INTRODUCTION

At the World Trade Organization (WTO) Doha Ministerial Conference held in Doha, Qatar, in November 2001, ministers from the member nations of the WTO adopted, among other documents, a “Declaration on the TRIPs Agreement and Public

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Health,” which I will refer to herein as the “TRIPs Declaration.”¹ The TRIPs Declaration states, among other things, that the TRIPs Agreement² permits member nations to grant compulsory licenses for patented inventions; to determine the grounds upon which such licenses may be granted; to determine what constitutes a national emergency for purposes of determining whether certain procedures relating to compulsory licenses must be followed; and to establish either a national or international exhaustion regime, as they see fit, with respect to patent rights.³ The TRIPs Declaration has met with approval from many academic commentators and public health activists, although some feel that the Declaration does not go far enough toward alleviating the problem of access to essential medicines in developing countries.⁴

Inevitably, there has been a (small) backlash from commentators who view the TRIPs Declaration as a step in the wrong direction. Among academic commentators, one of the more thoughtful and articulate of these opponents is Professor Alan Sykes of the University of Chicago Law School. In a recent paper, titled *TRIPs, Pharmaceuticals, Developing Countries, and the Doha “Solution,”*⁵ Professor Sykes argues that the TRIPs Declaration threatens to reduce social welfare by reducing research incentives.⁶ I suspect that many academic commentators and public health activists will find little to recommend in Professor Sykes’ paper. As someone who often em-

¹ WTO Ministerial 2001, *Declaration on the TRIPs agreement and public health*, WT/MIN(01)/DEC/2 (Nov. 14, 2001), [hereinafter TRIPs Declaration], available at http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm. (last visited Oct. 11, 2004).

² The “TRIPs Agreement” (or “TRIPs”) is short for the Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, LEGAL INSTRUMENTS—RESULTS OF THE URUGUAY ROUND vol. 31, 33 I.L.M. 1197 (1994) [hereinafter TRIPs Agreement].

³ See TRIPs Declaration, *supra* note 1, ¶¶ 5(b), (c), (d).

⁴ See, e.g., Frederick M. Abbott, *The Doha Declaration on the TRIPs Agreement and Public Health: Lighting a Dark Corner at the WTO*, 5 J. INT’L ECON. L. 469, 470 (2002); Debora Halbert, *Moralized Discourses: South Africa’s Intellectual Property Fight for Access to AIDS Drugs*, 1 SEATTLE J. SOC. JUST. 257, 280 (2002); Ellen T. Hoen, *TRIPs, Pharmaceutical Patents, and Access to Essential Medicines: A Long Way from Seattle to Doha*, 3 CHI. J. INT’L L. 27 (2002); Susan K. Sell, *TRIPs and the Access to Medicines Campaign*, 20 WIS. J. INT’L L. 480, 517-19 (2002); José Marcos Nogueira Viana, *Intellectual Property Rights, the World Trade Organization and Public Health: The Brazilian Perspective*, 17 CONN. J. INT’L L. 311, 314-15 (2002). Several student notes include similar assessments. See, e.g., Divya Murthy, Note, *The Future of Compulsory Licensing: Deciphering the Doha Declaration on the TRIPs Agreement and Public Health*, 17 AM. U. INT’L L. REV. 1299, 1339 (2002); Samantha Shoell, Note, *Why Can’t the Poor Access Life-Saving Medicines? An Exploration of Solving the Patent Issue*, 4 MINN. INTELL. PROP. REV. 151, 174-76 (2002); L. Danielle Tully, Note, *Prospects for Progress: The TRIPs Agreement and Developing Countries After the Doha Conference*, 26 B.C. INT’L & COMP. L. REV. 129, 142-43 (2003).

⁵ Alan O. Sykes, *TRIPs, Pharmaceuticals, Developing Countries, and the Doha “Solution,”* 3 CHI. J. INT’L L. 47 (2002).

⁶ See *id.* at 49, 60-62, 65-66.

loys law-and-economics analysis in my own scholarship, however, I am intrigued by Professor Sykes' argument that the TRIPs Declaration will decrease, rather than increase, social welfare; Sykes' arguments, and other similar arguments, need to be taken seriously.

Nevertheless, in my view, Sykes and others who argue against the TRIPs Declaration are mostly incorrect. The parade of horrors that they fear is more a spectre of their own imaginations than anything that is reasonably likely to occur. Moreover, by recognizing the need for exceptions to patent protection in emergency situations, the TRIPs Declaration hardly constitutes a radical gloss on the text of the TRIPs Agreement. While it is certainly possible that developing nations may abuse the "Doha solution," as I will explain, this risk appears minimal, particularly in comparison to the risk of doing nothing. More generally, the challenges raised by Sykes and others to the TRIPs Declaration betray what another economist, the Nobel laureate Joseph Stiglitz, refers to as "market fundamentalism."⁷ "Market fundamentalism" might be defined as the idea that markets are *a priori* the solution to all problems, without taking into account the defects that sometimes (not always, but sometimes) beset markets.⁸ These problems may include imperfect information and a lack of institutions to support the sort of markets that we in the developed world often take for granted.⁹ Reliance upon institutions other than markets to allocate resources carries with it a set of problems, but blind reliance upon markets, without a careful consideration of their strengths and weaknesses in comparison with other institutions is, well, blind.¹⁰ Just as one can be a good Jew or Christian or Muslim without being a fundamentalist, one can be a good lawyer or a good economist (indeed, a Nobel laureate) without being a market fundamentalist.

I shall argue that the TRIPs Declaration is consistent with both a mainstream interpretation of the TRIPs Agreement and with mainstream economic theory. I shall also explain, however, why the Declaration is unlikely to be a panacea for the developing

⁷ See JOSEPH E. STIGLITZ, *GLOBALIZATION AND ITS DISCONTENTS* 35, 73-74 (2002). Since I first wrote a draft of this article, I have discovered that the term "market fundamentalism" is not original to Stiglitz. In his 1998 book *The Crisis of Global Capitalism*, George Soros used the term "market fundamentalism" to refer to nineteenth-century style *laissez faire*—a system that Soros believes "has rendered the global capitalist system unsound and unsustainable." GEORGE SOROS, *THE CRISIS OF GLOBAL CAPITALISM: OPEN SOCIETY ENDANGERED* XX (1998). I do not know whether the term pre-dates Soros's use.

⁸ See *id.*

⁹ See *id.*

¹⁰ For a fuller explication of this thesis, see NEIL KOMESAR, *IMPERFECT ALTERNATIVES: CHOOSING INSTITUTIONS IN LAW, ECONOMICS, AND PUBLIC POLICY* (1994). See also STIGLITZ, *supra* note 7, at 218-20.

world; its overall effects, for good or ill, may not be as significant as some had hoped. In Part I, I briefly sketch the background and relevant text of the TRIPs Declaration. In Part II, I present three critiques of the Declaration. In Part III, I present my reasons for rejecting these critiques in favor of a more nuanced, less fundamentalist, view. Part IV concludes.

I. THE ROAD TO DOHA

The story of how the developed nations succeeded in including protection for intellectual property rights (IPRs) within the Uruguay Round Agreements in the early 1990's has been extensively addressed elsewhere. The prevailing theoretical rationales were that IPRs do not necessarily conflict with the principle of free trade, and that, absent binding international constraints, nations could manipulate the rules relating to intellectual property so as to serve protectionist ends.¹¹ As a matter of political reality, the United States and other Western nations that are largely exporters of intellectual property wanted to ensure that their property rights would be respected throughout the world, and would be subject to the WTO Agreements' relatively strong dispute resolution procedures.¹² Partially as a consequence of the Western nations' bargaining power, and partially in exchange for certain concessions to the developing countries, the Uruguay Round Agreements came to include the TRIPs Agreement.¹³ The Agreement requires the member nations of the WTO to institute certain minimal levels of protection for patents, copyrights, and trademarks, among other things.¹⁴

With respect to patent rights in particular, TRIPs article 27 states that member nations shall, subject to certain exceptions,

¹¹ See TRIPs pmb. (stating that the member nations desire "to reduce distortions and impediments to international trade . . . and to ensure that measures and procedures to enforce intellectual property rights do not themselves become barriers to legitimate trade"). See also NUNO PIRES DE CARVALHO, *THE TRIPs REGIME OF PATENT RIGHTS* 31 (2002) (stating that the lack of protection for IPRs can "amount[] to non-tariff barriers against foreign exports," but also that some measures to enforce IPRs "may themselves become barriers to trade, when used inappropriately."); Thomas Cottier, *The Prospects for Intellectual Property in GATT*, 28 COMMON MKT. L. REV. 383, 383 (1991).

¹² See CHRISTOPHER MAY, *A GLOBAL POLITICAL ECONOMY OF INTELLECTUAL PROPERTY RIGHTS: THE NEW ENCLOSURES?* 80-85 (2000); SUSAN K. SELL, *POWER AND IDEAS: NORTH-SOUTH POLITICS OF INTELLECTUAL PROPERTY AND ANTITRUST* 220-22 (1998); JAYASHREE WATAL, *INTELLECTUAL PROPERTY RIGHTS IN THE WTO AND DEVELOPING COUNTRIES* ch. 2 (2001); Abdulqawi A. Yusuf, *TRIPs: Background, Principles and General Provisions*, in *INTELLECTUAL PROPERTY AND INTERNATIONAL TRADE: THE TRIPs AGREEMENT* 8-9 (Carlos Correa & Abdulqawi A. Yusuf eds. 1998).

¹³ See sources cited *supra* note 12.

¹⁴ See TRIPs Agreement, *supra* note 2, arts. 9-39.

make patents available for any inventions in all fields of technology, as long as they are novel, capable of industrial application, and demonstrate an inventive step.¹⁵ Article 27 goes on to state that patent rights shall be enjoyable without discrimination as to the place of invention, the field of technology, and whether products are imported or locally produced.¹⁶ This article requires member nations to extend patent protection to pharmaceuticals.¹⁷ In addition, article 28 states that patent owners must have the exclusive rights to make, use, sell, offer to sell, and import the patented invention.¹⁸ A footnote to article 28, however, states that the importation right is subject to article 6,¹⁹ which in turn says that, subject to certain qualifications, nothing in the agreement "shall be used to address the issue of the exhaustion of intellectual property rights."²⁰ A straightforward interpretation is that nations are generally free to adopt the principle of national exhaustion of patent rights, or international exhaustion, or some variation, as long as they do so in a nondiscriminatory manner.²¹

¹⁵ See *id.* at art. 27(1).

¹⁶ See *id.*

¹⁷ See TRIPs Agreement, *supra* note 2, art. 70(8) (setting forth rules with respect to a member who does not make available, as of January 1, 1995, "patent protection for pharmaceutical and agricultural chemical products commensurate with its obligations under Article 27.") (emphasis added); WTO Panel Report, *Canada-Patent Protection of Pharmaceutical Products—Complaint by the European Communities and Their Member States*, WT/DS114/R, ¶¶ 7.85-7.105 (Mar. 17, 2000) (reviewing whether a Canadian law discriminated against pharmaceutical patents); WTO Appellate Body Report, *India-Patent Protection for Pharmaceutical and Agricultural Chemical Products*, WT/DS50/AB/R, ¶ 52 (Dec. 19, 1997).

¹⁸ See TRIPs Agreement, *supra* note 2, art. 28.

¹⁹ See *id.* at art. 28 n.9.

²⁰ *Id.* at art. 6. More precisely, article 6 states: "For the purposes of dispute settlement under this Agreement, subject to the provisions of Articles 3 and 4 above [requiring national treatment and most-favored nation status] nothing in this Agreement shall be used to address the issue of the exhaustion of intellectual property rights." *Id.*

²¹ See PIRES DE CARVALHO, *supra* note 11, at 94-95; WATAL, *supra* note 12, at 296-97. Under a regime of national exhaustion, a patent owner's right to control the use and resale of a product embodying the patented invention is exhausted, within a given country, once the patent owner sells, or authorizes the sale of, that product within that country. See PIRES DE CARVALHO, *supra* note 11, at 101. Under a regime of international exhaustion, the patent owner's right to control the use and resale of a product embodying the patented invention is exhausted, within a given country, once the patent owner sells, or authorizes the sale of, that product anywhere in the world. See *id.* Other variations are possible. For example, the European Union (EU) follows a regime of regional exhaustion, meaning that a patent owner's right to control the use and resale of a product embodying the patented invention is exhausted within the European Economic Area (EEA), once the patent owner sells or authorizes the sale of that product within the EEA. See WATAL, *supra* note 12, at 299. Under national (or regional) exhaustion, the sale of a product outside the nation (region) does not exhaust the patent owner's right to control the subsequent importation, use, or sale of the product within the nation (region), even if the first sale was a lawful sale. See PIRES DE CARVALHO, *supra* note 11, at 101.

Contrary to my suggestion in the text above, some commentators have argued that article 6 does *not* mean that nations are free to adopt whichever exhaustion regime they prefer. I discuss this issue *infra* note 71.

TRIPs further provides that member nations generally are required to bring their patent laws into conformity with TRIPs within one year of the date of entry into compliance with the WTO Agreement.²² For nations that have been members of the WTO from the beginning, this date is January 1, 1996.²³ Developing countries, however, were given a further period of four years that is, until January 1, 2000, to conform their laws,²⁴ subject to certain exceptions.²⁵ Least-developed countries (LDCs) were given ten years (that is, until January 1, 2006) to conform their laws, and could request further extensions of this period.²⁶ One of the things that

²² See TRIPs Agreement, *supra* note 2, art. 65(1).

²³ See WATAL, *supra* note 12, at 119.

²⁴ See TRIPs Agreement, *supra* note 2, art. 65(2); CARLOS M. CORREA, INTELLECTUAL PROPERTY RIGHTS, THE WTO AND DEVELOPING COUNTRIES: THE TRIPs AGREEMENT AND POLICY OPTIONS 95 (1999). See also PIRES DE CARVALHO, *supra* note 11, at 294.

²⁵ Developing nations were required to apply TRIPs articles 3, 4, and 5 as of the general date of application of TRIPs, that is, as of January 1, 1996. See TRIPs Agreement, *supra* note 2, art. 65(2). They were entitled to an additional five years, however – that is, until January 1, 2005 – to delay the application of the TRIPs provisions on product patents to areas of technology not previously protectable in their territory. See *id.* at art. 65(4); CORREA, *supra* note 24, at 95; WATAL, *supra* note 12, at 118. In addition, where a member nation did not make available, as of the WTO Agreement's date of entry into force (January 1, 1995), patent protection for pharmaceutical or agricultural chemical products commensurate with its obligations under article 27, that nation was required to (1) provide, as from the date of entry into force of the WTO Agreement (January 1, 1995), a means by which applications for patents for such inventions could be filed; (2) apply to these applications, as of the date of application of the TRIPs Agreement in that nation, the criteria for patentability as laid down in TRIPs as if those criteria were being applied on the date of actual or constructive filing in that nation; and (3) provide patent protection in accordance with the TRIPs Agreement as from the grant of the patent and for the remainder of the patent term, for those applications that meet the relevant criteria for protection. See *id.* at art. 70(8). Finally, under some circumstances, a member nation is required to grant exclusive marketing rights for a pharmaceutical or agricultural chemical product that is the subject of a pending patent application. See TRIPs Agreement, *supra* note 2, art. 70(9).

To illustrate, suppose that a developing nation is a member of TRIPs as of January 1, 1995, but as of that date did not yet extend patent protection to pharmaceuticals. Company X files a patent application for a new drug in the United States on February 1, 1995, and in the developing nation on July 1, 1995. Under article 70(8), the developing nation was required to accept patent applications for such products as of January 1, 1995. Also under article 70(8), it is required to apply the criteria for patentability to such applications as of January 1, 2005, as if those criteria were being applied as of the date of filing in that nation. Here, the applicable date of filing would be the date of filing in the United States (February 1, 1995), rather than the actual filing date in the developing nation (July 1, 1995), because under Paris Convention articles 4A, 4C (which are incorporated by reference into TRIPs, see TRIPs Agreement, *supra* note 2, art. 2(1)), if a patent application is filed within twelve months of its having first been filed in another member nation, it is deemed filed on that earlier date. See Paris Convention for the Protection of Industrial Property, Mar. 20, 1883, last revised at Stockholm, July 14, 1967, arts. 4A, 4C, 21 U.S.T. 1583, 828 U.N.T.S. 305 [hereinafter Paris Convention]. If the developing nation grants the patent, the patent term will run, at a minimum, from the date of grant until twenty years from the date of its *actual* filing in the developing nation. See TRIPs Agreement, *supra* note 2, arts. 28, 70(8); Paris Convention, art. 4 bis (5).

²⁶ See TRIPs Agreement, *supra* note 2, art. 66(1). Even LDCs, however, were required to apply TRIPs articles 3, 4, and 5 as of January 1, 1996. See *id.* Additionally, as of January 1, 1995, LDCs were required to: (1) accept for filing patent applications for pharmaceuti-

the TRIPs Declaration accomplishes is to extend the date for LDCs to conform their patent laws with respect to pharmaceutical products by another ten years, to January 1, 2016.²⁷

Opinions vary as to whether the developing countries obtain many benefits from the TRIPs Agreement. Skeptics argue that strong patent rights serve principally to transfer income from poor countries to rich countries, and until a country is ready to enter a highly industrialized phase of its development, the social costs of patent rights are likely to outweigh any potential benefits.²⁸ Advocates of strong IPRs, on the other hand, argue that the protection of intellectual property is in the interest of the developing world.

cal and agricultural chemical products, *see id.* art. 70(8)(i), and (2) grant exclusive marketing rights under the conditions set forth in article 70(9). *See id.* arts. 70(8)(i) and 70(9).

The TRIPs Agreement does not define the terms “developing country” or “least-developed country.” The WTO states that “[a]bout 100” of its 146 members are developing countries. *See Trading into the Future: The Introduction to the WTO: Developing Countries: Overview*, at http://www.wto.org/english/thewto_e/whatis_e/tif_e/dev1_e.htm (last visited Oct. 11, 2004). It also notes, however, that developing countries “are designated on the basis of self-selection although this is not necessarily automatically accepted in all WTO bodies.” *See Trading into the Future: The Introduction to the WTO: The Organization: Least Developed Countries*, at http://www.wto.org/english/the_wto_e/whatis_e/tif_e/org7_e.htm (last visited Oct. 11, 2004). In addition, “[t]he WTO recognizes as least-developed countries (LDCs) those countries which have been designated as such by the United Nations.” *Id.* Thirty of the forty-nine countries on the UN’s list are WTO members, and nine more are in the process of becoming WTO members. *See id.*

²⁷ *See* TRIPs Declaration, *supra* note 1, ¶ 7. The TRIPs Council subsequently affirmed this extension, and in addition exempted the LDCs from affording exclusive marketing rights to pharmaceutical products until January 1, 2016 – a matter not specifically addressed by the TRIPs Declaration. *See* PIRES DE CARVALHO, *supra* note 11, at 299-301 (citing IP/C/25 (July 1, 2002) and IP/C/W/359 (June 28, 2002)).

²⁸ For a concise summary of the arguments, pro and con, see Carlos A. Primo Braga & Carsten Fink, *The Economic Justifications for the Grant of Intellectual Property Rights: Patterns of Convergence and Conflict*, in PUBLIC POLICY AND GLOBAL TECHNOLOGICAL INTEGRATION 99, 102-03 (Frederick M. Abbott & David J. Gerber eds. 1997) (citations omitted), which states in part:

If a country is small (i.e., its IPR regime does not affect world research and development) and it has limited production and innovation capabilities, higher standards of protection are likely to be welfare improving as long as they permit access to products that would not be available otherwise. If, however, the country has some production capabilities . . . but limited innovative capacity . . . higher standards of protection are likely to have a negative welfare impact, as local producers are displaced, prices rise and a rent transfer from local consumers and producers to foreign titleholders ensues. Finally, if the small country has both well developed production and innovative capabilities . . . the result will be indeterminate, depending on the elasticity of supply of domestic innovations with respect to IPRs protection

[I]f one assumes that the supply of innovations in the South . . . is rather inelastic and that IPRs regimes are of limited relevance in influencing trade, foreign direct investment and technology transfer[,] then it follows that the [TRIPs] Agreement is in essence an exercise in rent transfer. A much more optimistic view of its welfare implications for developing countries, however, can be put together if the opposite assumptions are held.

Id. *See also* Frederick M. Abbott, *The WTO TRIPs Agreement and Global Economic Development*, in PUBLIC POLICY AND GLOBAL TECHNOLOGICAL INTEGRATION 39, 43-46 (summarizing arguments, and evidence, pro and con as of 1997).

Strong IPRs, including strong patent rights for pharmaceuticals, may provide an incentive for firms to invest in research and development that is of interest to the developing world (such as research into cures for diseases that are endemic to these countries but not to the developed countries).²⁹ More generally, Professor Kitch and others have argued that strong IPRs provide a framework within which firms in the developed countries will be more willing to engage in foreign investment and technology transfer to developing countries.³⁰ According to Keith Maskus, there is some empirical evidence that supports Kitch's view.³¹ Maskus claims that nations with strong IPRs have benefited from a greater willingness on the part of the developed countries to engage in foreign investment and technology transfer, although other conditions must be present as well; patents are not a panacea.³² I am willing to assume that this view is correct: that is, that the extension of patent protection in developing countries is, *in general*, probably a good thing. If exceptions to patent rights are invoked too readily, they may deter foreign investment and reduce the incentives for domestic industry to innovate. The question nevertheless remains how strong these rights must be, and in what circumstances, if any, exceptions should be permitted.

TRIPs permits member nations to recognize a variety of exceptions to patent rights. First, article 30 states that member nations may provide limited exceptions to the patentee's exclusive rights, as long as these exceptions do not unreasonably conflict with the normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.³³ This language is similar, though not identical, to language found in the Berne Convention and also in TRIPs with respect to copyright rights.³⁴ Article

²⁹ See KEITH E. MASKUS, *INTELLECTUAL PROPERTY RIGHTS IN THE GLOBAL ECONOMY* 164 (2000); Sykes, *supra* note 5, at 62. See also sources cited *supra* note 27. Cf. Jean O. Lanjouw, *A New Global Patent Regime for Diseases: U.S. and International Legal Issues*, 16 HARV. J.L. & TECH. 85 (2002) (arguing in favor of patent protection for drugs that treat diseases endemic to the developing world).

³⁰ See MASKUS, *supra* note 29, at 142; Edmund W. Kitch, *The Patent Policy of Developing Countries*, 13 UCLA PAC. BASIN L.J. 166, 169-78 (1994); Primo Braga & Fink, *supra* note 28, at 116-17.

³¹ See MASKUS, *supra* note 29, chs. 4, 5.

³² See *id.* at 169, 199-205 (arguing that IPRs, in combination with other factors including an open economy, foreign direct investment, and human capital development, can enhance economic growth in developing countries); see also Cottier, *supra* note 11, at 391-92; Primo Braga & Fink, *supra* note 28, at 113.

³³ See TRIPs Agreement, *supra* note 2, art. 30.

³⁴ See Berne Convention for the Protection of Literary and Artistic Works, Sept. 9, 1886, art. 9(2), as last revised, Paris, July 24, 1971, 25 U.S.T. 1341, 828 U.N.T.S. 221 (stating that member nations may permit the unauthorized reproduction of copyrighted literary and

30 is commonly viewed as permitting exceptions for such things as private noncommercial uses (which many countries, though not our own, exempt from the scope of patent liability); prior user rights (which are more important in a first-to-file system than in our rather peculiar first-to-invent system); and some experimental uses.³⁵ Article 31 then imposes some rules for cases in which governments impose compulsory licenses.³⁶ Among these requirements are that applications for licenses must be considered on their individual merits;³⁷ the applicant must first seek authorization from the patent owner on reasonable commercial terms, except in cases of national emergencies or other circumstances of extreme urgency or public noncommercial use;³⁸ the scope and duration of the use must be “limited to the purpose for which it was authorized[;]”³⁹ licenses must be non-exclusive,⁴⁰ generally non-assignable,⁴¹ and “authorized predominantly for the supply of the domestic market[;]”⁴² authorization “shall be liable . . . to be terminated if and when the circumstances which led to it cease to exist and are unlikely to recur;”⁴³ the rightholder must be paid adequate

artistic works “in certain special cases, provided that such reproduction does not conflict with a normal exploitation of the work and does not unreasonably prejudice the legitimate interests of the author.”); TRIPs Agreement, *supra* note 2, art. 13 (imposing the same conditions on any “limitations or exceptions” to authors’ exclusive rights). The corollary patent provision of TRIPs differs in that it refers to (1) “limited exceptions” to patent owners’ exclusive rights; (2) states that exceptions may not “unreasonably conflict” with the normal exploitation of the patent; and (3) makes explicit reference to “the legitimate interests of third parties.” *Id.* art. 30. *See also* WTO Panel Report, *Canada-Patent Protection of Pharmaceutical Products—Complaint by the European Communities and Their Member States*, WT/DS114/R, ¶¶ 7.70-7.72 (Mar. 17, 2000) (noting that TRIPs article 30 is based upon Berne article 9(2)).

³⁵ *See* CARLOS CORREA, *Patent Rights, in* INTELLECTUAL PROPERTY AND INTERNATIONAL TRADE, THE TRIPs AGREEMENT, 207-08 (Carlos Correa & A. Yusef eds., 1998); CORREA, *supra* note 24, at 75-76, 240-41; MARKUS NOLFF, TRIPs, PCT AND GLOBAL PATENT PROCUREMENT 19-21 (2001).

³⁶ *See* TRIPs Agreement, *supra* note 2, art. 31. To put the compulsory licensing issue in context, the Paris Convention imposes some limited requirements on compulsory licensing in cases in which a nation imposes compulsory licensing to remedy “abuses,” such as “failure to work” the patent. *See* Paris Convention, *supra* note 25, art. 5A(2); 1 STEPHEN P. LADAS, PATENTS, TRADEMARKS, AND RELATED RIGHTS: NATIONAL AND INTERNATIONAL PROTECTION §§ 245-49 (1975) (discussing compulsory licenses in the context of the Paris Convention). The relevant provisions of the Paris Convention relating to compulsory licensing are also incorporated by reference into TRIPs, *see* TRIPs Agreement, *supra* note 2, art. 2(1), but TRIPs article 31 goes beyond the Paris Convention by imposing additional requirements with respect to compulsory licenses generally, whether these licenses are issued to remedy abuses or for other reasons.

³⁷ *See* TRIPs Agreement, *supra* note 2, art. 31(a).

³⁸ *See id.* art. 31(b).

³⁹ *Id.* art. 31(c).

⁴⁰ *See id.* art. 31(d).

⁴¹ *See id.* art. 31(e).

⁴² *Id.* art. 31(f).

⁴³ TRIPs Agreement, *supra* note 2, art. 31(g).

remuneration;⁴⁴ and there must be an opportunity for judicial review of the license and the remuneration.⁴⁵

TRIPs does not, in so many words, address what might appear to be the most obvious question surrounding the issue of compulsory licensing, namely the grounds which nations may invoke as reasons for requiring owners to license their patents. To the extent relevant, however, the preamble states that the TRIPs member nations desire “to reduce distortions and impediments to international trade . . . taking into account the need to promote effective and adequate protection of IPRs, and to ensure that measures and procedures to enforce IPRs do not themselves become barriers to legitimate trade.”⁴⁶ It also states that the members recognize “the special needs of the least-developed country members in respect of maximum flexibility in the domestic implementation of laws and regulations in order to enable them to create a sound and viable technological base.”⁴⁷ TRIPs article 7, titled “Objectives,” states that:

The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to the balance of rights and obligations.⁴⁸

And article 8, titled “Principles,” states that:

Members may, in formulating or amending their national laws and regulations, adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided that such measures are consistent with the provisions of this Agreement. Appropriate measures, provided that they are consistent with the provisions of this Agreement, may be needed to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology.⁴⁹

⁴⁴ See *id.* art. 31(h).

⁴⁵ See *id.* arts. 31(i)-(j). Members are not obligated to apply articles 31(b) and 31(f) when the license is issued to remedy an antitrust violation. See *id.* art. 31(k). In addition, members must comply with three additional conditions if they wish to resort to compulsory licensing to resolve a blocking patents problem. See *id.* art. 31(l).

⁴⁶ TRIPs Agreement, *supra* note 2, at pmbl.

⁴⁷ *Id.*

⁴⁸ *Id.* art. 7 (“Objectives”).

⁴⁹ *Id.* art. 8 (“Principles”).

On one reading, a nation may invoke any of these grounds, including the need to protect public health and nutrition, as a reason for granting compulsory licenses, as long as the nation complies with the requirements of article 31.⁵⁰

The interplay of these various provisions is particularly salient in the context of the AIDS crisis and other public health crises that affect the developing world. Many readers are no doubt familiar with the controversies over whether the (largely successful) measures undertaken by the government of Brazil to combat AIDS comply with TRIPs,⁵¹ and over the South African Medicines Act.⁵² The TRIPs Declaration was the result of ongoing discussions among member nations of the WTO as to the proper interpretation of TRIPs in the context of public health, and is part of a wider body of work undertaken at the November 2001 Doha Ministerial Conference. The principal Ministerial Declaration adopted at this conference reaffirms the WTO members' commitment to "maintain the process of reform and liberalization of trade policies" and proposes to "continue to make positive efforts designed to ensure that developing countries, and especially the least-developed among them, secure a share in the growth of world trade commensurate with the needs of their economic development."⁵³ In this regard, the members agreed to undertake a Work Programme incorporating "both an expanded negotiating agenda and other important decisions and activities necessary to address the challenges facing the multilateral trading system," including implementation-related problems and problems specific to various sectors, including agriculture, services, environment, and intellectual property.⁵⁴ Regarding intellectual property in particular, the Ministerial Declaration "stress[es] the importance we attach to implementation and

⁵⁰ See *infra* notes 99-100 and accompanying text.

⁵¹ For discussions, see Halbert, *supra* note 4, at 269-78; Jennifer Joni, *Access to Treatment for HIV/AIDS: A Human Rights Issue in the Developing World*, 17 CONN. J. INT'L L. 273, 275-79 (2002); Lissett Ferreira, Note, *Access to Affordable HIV/AIDS Drugs: The Human Rights Obligations of Multinational Pharmaceutical Corporations*, 71 FORDHAM L. REV. 1133, 1148-58 (2002).

⁵² See Susan K. Sell, *Post-TRIPs Developments: The Tension Between Commercial and Social Agendas in the Context of Intellectual Property*, 14 FLA. J. INT'L L. 193, 215 (2002); Zita Lazarini, *Making Access to Pharmaceuticals a Reality: Legal Options Under TRIPs and the Case of Brazil*, 6 YALE HUM. RTS. & DEV. L.J. 103 (2003); Viana, *supra* note 4, at 311-13; Naomi A. Bass, *Implications of the TRIPs Agreement for Developing Countries: Pharmaceutical Patent Laws in Brazil and South Africa in the 21st Century*, 34 GEO. WASH. INT'L L. REV. 191, 206-10 (2002). More recently, China has announced plans to compel the licensing of AIDS drugs. See Elisabeth Rosenthal, *China Now Set to Make Copies of AIDS Drugs*, N.Y. TIMES, Sept. 7, 2002, at A1.

⁵³ WTO Ministerial 2001, *Ministerial Declaration*, WT/MIN(01)/DEC/1 (Nov. 20, 2001), ¶¶ 1, 2, available at http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_e.htm (last visited Oct. 11, 2004).

⁵⁴ See *id.* ¶ 11.

interpretation of [TRIPs] in a manner supportive of public health, by promoting both access to existing medicines and research and development into new medicines and, in this connection," adopts the separate TRIPs Declaration.⁵⁵ My focus here will be exclusively on the TRIPs Declaration.

In the months leading up to the TRIPs Ministerial Conference, some developing countries argued in favor of a declaration that, among other things, would recognize the right of developing countries to resort to compulsory licensing to combat public health emergencies; would establish that TRIPs must be interpreted in light of articles 7 and 8; and would permit nations to resort to compulsory licensing to supply drugs to markets which do not have the manufacturing capability to engage in meaningful compulsory licensing themselves.⁵⁶ On the other hand, the United States, Switzerland, and to a lesser extent the European Union initially objected to these proposals, arguing *inter alia* that the flexibility the developing nations wanted was already provided for in the TRIPs provisions allowing developing nations and LDCs a longer time to conform their laws to the treaty.⁵⁷ Eventually, however, the United States, Switzerland, and the European Union abandoned these positions and a compromise text was adopted.⁵⁸

According to the first paragraph of the resulting TRIPs Declaration, member nations "recognize 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."⁵⁹ Paragraph 2 "stress[es] the need" for TRIPs "to be part of the wider national and international action to address these problems,"⁶⁰ and in paragraph 3 the members simultaneously "recognize that intellectual property is important for the development of new medicines" and "the concerns about its effects on prices."⁶¹ The substantive provisions of the Declaration then begin with paragraphs 4 and 5, which state:

⁵⁵ See *id.* ¶ 17. The Ministerial Declaration also contains one paragraph on negotiations relating to geographical indications, and another instructing the Council for TRIPs to examine the relationship between TRIPs and the Convention on Biological Diversity. See *id.* ¶¶ 18, 19.

⁵⁶ See PIRES DE CARVALHO, *supra* note 11, at 123-24; Abbott, *supra* note 4, at 480-84; James Thuo Gathii, *The Legal Status of the Doha Declaration on TRIPs and Public Health Under the Vienna Convention on the Law of Treaties*, 15 HARV. J.L. & TECH. 291, 296-97 (2002); Sell, *supra* note 4, at 516.

⁵⁷ See PIRES DE CARVALHO, *supra* note 11, at 124; Abbott, *supra* note 4, at 481-83; Gathii, *supra* note 56, at 297-98.

⁵⁸ See Abbott, *supra* note 4, at 484-89; Gathii, *supra* note 56, at 298.

⁵⁹ TRIPs Declaration, *supra* note 1, ¶ 1.

⁶⁰ *Id.* ¶ 2.

⁶¹ *Id.* ¶ 3.

4. We agree that the TRIPs Agreement does not and should not prevent members from taking measures to protect public health. Accordingly, while reiterating our commitment to the TRIPs Agreement, we affirm that the Agreement can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all.

In this connection, we reaffirm the right of WTO members to use, to the full, the provisions in the TRIPs Agreement, which provide flexibility for this purpose.

5. Accordingly and in light of paragraph four above, while maintaining our commitments in the TRIPs Agreement, we recognize that these flexibilities include:
 - 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 the MFN and national treatment provisions of Articles three and four.⁶²

In paragraph 6, the members recognize that nations with insufficient pharmaceutical-manufacturing capability might not be able to make effective use of compulsory licensing, and direct "the Council for TRIPs to find an expeditious solution to this problem and to report to the General Council before the end of 2002."⁶³ Paragraph 7 "reaffirms the commitment of the developed-country members to provide incentives to their enterprises and institutions to promote and encourage technology transfer to least-developed

⁶² *Id.* ¶¶ 4-5.

⁶³ *Id.* ¶ 6. For discussion of the Council's solution, see *infra* note 114.

country members pursuant to Article 66.2.”⁶⁴ As noted above, paragraph 7 also extends the date by which LDCs must conform their patent laws with respect to pharmaceuticals to January 1, 2016, “without prejudice to the right of least-developed country members to seek other extensions of the transition periods as provided for in Article 66.1.”⁶⁵

II. THREE CRITIQUES OF THE TRIPs DECLARATION

In this Part, I present three critiques that have been leveled against the TRIPs Declaration. The first is that the Declaration misinterprets TRIPs (or is a radical reinterpretation of TRIPs, or revises the bargain reflected in TRIPs). I will refer to this as the “Revision Argument.” The second is that, even if the Declaration evidences a permissible interpretation of TRIPs, it invites abuse on the part of developing countries, which in turn will make those countries in the aggregate worse off; I will refer to it as the “Collective Action Argument.” A third argument is that the Declaration will undercut global welfare by reducing the incentive to invent products that would benefit mostly the industrialized nations – that is, the Declaration may induce the developing countries to undertake measures that will impose a substantial negative externality upon the industrialized nations. I refer to this as the “Externality Argument.”

To understand the Revision Argument, it is necessary to consider again precisely what the various parts of the TRIPs Declaration state.⁶⁶ A couple of them clearly *do* constitute a *de facto* amendment of TRIPs (although the significance of even these pro-

⁶⁴ *Id.* ¶ 7.

⁶⁵ *Id.*

⁶⁶ I leave to one side the issue of whether the TRIPs Declaration has the force of law. See, e.g., PIRES DE CARVALHO, *supra* note 11, at 125 n.362 (arguing that, in principle, the Declaration does not modify TRIPs, but that in reality it has done so); Steve Charnovitz, *The Legal Status of the Doha Declarations*, 5 J. INT’L ECON. L. 207, 211 (2002) (noting the ambiguous status of the Doha Declarations, but suggesting that some provisions might constitute a “subsequent agreement between the parties regarding ‘the application’ of a treaty’s provisions, which is recognized by the Vienna Convention on the Law of Treaties, Article 31.3(a), as a proper consideration in treaty interpretation.”); Gathii, *supra* note 56, at 292-317 (arguing that the Declaration “should now be regarded as an interpretive element in the interpretation of the TRIPs Agreement under customary international law.”); Markus Nolf, *Compulsory Patent Licensing in View of the WTO Ministerial Conference Declaration on the TRIPs Agreement and Public Health*, 84 J. PAT. & TRADEMARK OFF. SOC’Y 133-34 (2002) (arguing that the Declaration does not amend TRIPs, but must be taken into account when interpreting TRIPs); Sell, *supra* note 4, at 517-18 (noting differing interpretations); Sykes, *supra* note 5, at 54 (arguing that the Declaration is not legally binding, but would likely “be persuasive authority in the interpretation of TRIPs in the event of a dispute.”). For present purposes, I assume that the Declaration will be, at the very least, powerful persuasive authority, even if it is not legally binding.

visions is unclear, for reasons I will discuss in Part III.A).⁶⁷ Paragraph 7, which grants the LDCs an additional ten years to begin granting pharmaceutical patents, without requiring them to ask for this extension individually,⁶⁸ arguably amends article 66(1), which appears to contemplate a procedure under which LDCs could request extensions on an individualized basis.⁶⁹ In addition, paragraph 6, which directs the TRIPs Council to find an expeditious solution to the problem of nations lacking a pharmaceutical-manufacturing capability not being able to make effective use of compulsory licensing, could conflict with TRIPs article 31(f), which states that compulsory licensing “shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use.”⁷⁰ On the other hand, paragraph 5(d) of the TRIPs Declaration appears consistent with a mainstream understanding of what article 6 of TRIPs already permitted with respect to parallel importation.⁷¹

⁶⁷ See *infra* notes 93-114 and accompanying text.

⁶⁸ See TRIPs Declaration, *supra* note 1, ¶ 7.

⁶⁹ See TRIPs Agreement, *supra* note 2, art. 66(1); Peter M. Gerhart, *Slow Transformations: The WTO as Distributive Organization*, 17 AM. U. L. REV. 1045, 1076 (2002).

⁷⁰ See TRIPs Agreement, *supra* note 2, art. 31(f); TRIPs Declaration, *supra* note 1, ¶ 6. The issue of compulsory licensing will be addressed in Part III.A.

⁷¹ See CORREA, *supra* note 24, at 81-88 (arguing that international exhaustion is “fully consistent” with TRIPs); WATAL, *supra* note 12, at 296-97; Abbott, *supra* note 4, at 77-79; Marco C.E.J. Bronckers, *The Exhaustion of Patent Rights Under World Trade Organization Law*, 32 J. WORLD TRADE L. 137, 142 (1998); Ana Maria Pacón, *What Will TRIPs Do for Developing Countries*, in FROM GATT TO TRIPs—THE AGREEMENT ON TRADE-RELATED ASPECTS OF INTELLECTUAL PROPERTY 329, 337 (Friedrich-Karl Beier & Gerhard Schriker eds., 1996); Sykes, *supra* note 5, at 56, 67; J.H. Reichman, *The TRIPs Agreement Comes of Age: Conflict or Cooperation with the Developing Countries?*, 32 CASE W. RES. J. INT’L L. 441, 460-61 (2000); Yusuf, *supra* note 12, at 18.

I recognize that this issue may not be entirely free from doubt, for three reasons. First, some commentators have argued that, while article 6 would prevent a TRIPs panel from considering the legality of a nation’s exhaustion regime, WTO member nations may remain free to commence a challenge under other provisions of GATT or to retaliate with trade sanctions. Some commentators favoring this view have suggested that a regime of national or regional exhaustion might violate GATT under some circumstances. See Thomas Cottier, *The WTO System and the Exhaustion of Rights*, draft of Nov. 6, 1999, for Conference on Exhaustion of Intellectual Property Rights and Parallel Importation in World Trade, Geneva, Nov. 6-7, 1998, WIPO Committee on International Trade Law, *excerpted in* 2 FREDERICK ABBOTT ET AL., *THE INTERNATIONAL INTELLECTUAL PROPERTY SYSTEM: COMMENTARY AND MATERIALS* 1796, 1798-1800, 1804 (1998); *but see* WATAL, *supra* note 12, at 297 n.15 (questioning this position); Abbott, *supra* note 4, at 77-78 (same); Bronckers, *supra*, at 157. Others have argued that a regime of *international* exhaustion interferes with the patent owner’s right to prevent unauthorized importation, or with other rights guaranteed under TRIPs; and that (at least in the absence of the TRIPs Declaration) member nations could challenge such a regime under GATT, even if article 6 precluded such a challenge under TRIPs. See PIRES DE CARVALHO, *supra* note 11, at 94-97, 129-30 (arguing that paragraph 5(d) of the TRIPs Declaration effects a substantial change, because it appears to (1) make it impossible to commence a GATT challenge against, for example, a rule of international exhaustion that applies only with respect to non-locally worked patents; (2) permit a nation to share test data under some circumstances that otherwise would not be permitted under TRIPs article 39(3); and (3) undermines the patent owner’s ability

For the most part, however, the Revision Argument focuses on paragraphs 5(a) through 5(c) of the TRIPs Declaration. As noted above, paragraph 5(a) of the Declaration states that each provision of TRIPs should be read in light of the “objectives and principles” of TRIPs as set forth in TRIPs articles 7 and 8. Paragraph 5(b) states that “[e]ach member has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted.” Paragraph 5(c) states that “[e]ach 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.”⁷² Professor Sykes argues that these paragraphs of the TRIPs Declaration permit developing countries to “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.”⁷³ Professor Gerhart does not agree with Sykes’ assessment that the TRIPs Declaration is ill-advised, but he does conclude that the Declaration to some extent rewrites TRIPs by rendering unreviewable a nation’s determination of the circumstances under which a compulsory license may issue.⁷⁴ Recall from above that the practical conse-

to enter into some exclusive licenses that otherwise would be permitted under TRIPs article 28(2)); Joseph Straus, *Implications of the TRIPs Agreement in the Field of Patent Law*, in FROM GATT TO TRIPs—THE AGREEMENT ON TRADE-RELATED ASPECTS OF INTELLECTUAL PROPERTY 160, 192-94 (Friedrich-Karl Beier & Gerhard Schricker eds. 1996). *But see* CORREA, *supra* note 24, at 90-91 (arguing that local working requirements may be consistent with TRIPs); WATAL, *supra* note 12, at 297 n.15 (doubting the viability of a GATT challenge); *id.* at 200-01 (noting alternate interpretations of article 39(3)). Finally, some have argued that TRIPs does not permit the parallel importation of products made under a compulsory license, because a patent owner’s rights are exhausted only by the sale of a patented product with the patent owner’s consent; and that neither TRIPs article 6 nor TRIPs Declaration paragraph 5(d) precludes a challenge on this basis because, among other things, TRIPs does not define the term “exhaustion.” *See* PIRES DE CARVALHO, *supra* note 11, at 97-100 (advocating this view); *but see* Abbott, *supra* note 4, at 494-97 (presenting, but disputing, these arguments). The predominant view nevertheless appears to be that TRIPs left the choice of exhaustion regime open for individual members to decide for themselves, in which case the TRIPs Declaration merely confirms what the rule has been all along.

⁷² TRIPs Declaration, *supra* note 1, ¶¶ 5(a)-(c). In effect, these paragraphs repudiate the initial American position, which was that the purposes and objectives specified in articles 7 and 8 are not relevant to the issue of when compulsory licenses may be granted. *See supra* text accompanying note 57.

⁷³ *See* Sykes, *supra* note 5, at 56.

⁷⁴ Peter M. Gerhart, *Slow Transformations: The WTO as Distributive Organization*, 17 AM. U. INT’L L. REV. 1045, 1077-78 (2002). *See also* Johanna Kiel, Note, *TRIPs Article 31(b) and the HIV/AIDS Epidemic*, 10 J. INTELL. PROP. L. 143, 165-71 (2002). Kiel argues that a TRIPs panel probably would find that national legislation authorizing the use of compulsory licensing to produce AIDS drugs would violate the Agreement, on the grounds that such legislation (1) would discriminate against a field of technology (pharmaceuticals), in viola-

quence of a nation declaring a “national emergency or other circumstances of extreme urgency” is that the nation may then impose compulsory licensing without first requiring the would-be user to make “efforts to obtain authorization from the right holder on reasonable commercial terms and conditions.”⁷⁵

The Collective Action Argument contends that the interpretation embodied in the TRIPs Declaration, even if permissible as a matter of treaty construction, nevertheless will induce developing countries to adopt compulsory licensing in a wide variety of circumstances, and that this inducement will work to the detriment of these countries. To put the argument in context, it is important to understand that many law-and-economics scholars have argued that, in general, compulsory licensing of patents is a bad idea.⁷⁶ The principal assumption is that patents induce invention and disclosure that is socially beneficial, but which otherwise might not occur due to the free-rider problem.⁷⁷ Empirical evidence on this point is equivocal, but it does provide some support for the proposition that patents encourage research and development in the pharmaceutical industry in particular.⁷⁸ If so, then compulsory li-

tion of article 27(1); (2) would not be, in the language of article 8(1), “necessary to protect public health,” in light of other possible alternatives; and (3) would be difficult to reconcile with the other provisions of article 31, such as the requirement that the license persist only for so long as is necessary, given the ongoing nature of the AIDS epidemic. *See id.* (quoting TRIPs articles 8(1), 31(c)). These arguments are not persuasive. First, the argument that a license issued in response to a national emergency would necessarily run afoul of the anti-discrimination principle is probably incorrect. *See WATAL, supra* note 12, at 293-94, 321-22 (arguing that national legislation generally authorizing the use of compulsory licensing in the public interest could comply with both articles 27(1) and 31); Frederick M. Abbott, *The TRIPs-Legality of Measures Taken to Address Public Health Crises: A Synopsis*, 7 WIDENER L. SYMP. J. 71, 75-77 (2001) (arguing that the use of compulsory licenses to combat public health crises does not constitute unlawful discrimination as to a field of technology, but rather lawful differentiation). Second, the argument that compulsory licenses may not be “necessary to protect public health,” and therefore would not be justified by article 8, assumes that a compulsory license must be justified on an article 8 ground. This may not be correct either. *See WATAL, supra* note 12, at 319; CORREA, *supra* note 24, at 90; *but see* Nolff, *supra* note 66, at 137-39 (arguing that if compulsory licensing would be insufficient to substantially alleviate a public health crisis, a grant should not be considered “necessary” for purposes of article 8(1)). Moreover, although Kiel may be right in observing that the industrialized nations could do more to provide necessary medicines and the infrastructure needed to use them in the developing world, *see* Kiel, *supra* at 168-69, it does not necessarily follow that the compulsory licensing is unnecessary if these alternative measures remain only theoretically available in sufficient quantity. Third, article 31(g) contemplates that compulsory licensing could persist indefinitely. *See* TRIPs Agreement, *supra* note 2, art. 31(g).

⁷⁵ TRIPs Agreement, *supra* note 2, art. 31(b).

⁷⁶ *See* Roger D. Blair & Thomas F. Cotter, *An Economic Analysis of Damages Rules in Intellectual Property Law*, 39 WM. & MARY L. REV. 1585, 1615-16 (1998) (discussing the literature).

⁷⁷ *See id.* at 1597-98.

⁷⁸ *See* Wesley M. Cohen et al., *Protecting Their Intellectual Assets: Appropriability Conditions and Why U.S. Manufacturing Firms Patent (or Not)*, NBER Working Paper No. 7552 (Feb. 2000), at table 1, available at <http://www.nber.org/papers/w7552.pdf> (last visited Oct. 11,

censing may be undesirable, because it threatens to reduce the incentive to invent and disclose by limiting the patent owner's reward to something less than it would have received from a voluntary transaction.⁷⁹ In addition, compulsory licensing ultimately depends upon some government agency determining what the amount of the license will be, and this is problematic. The theory is that private actors – the patent owner and the would-be user – have superior information concerning the value of the patent, and that private bargaining therefore will result in the right to use the patent being allocated efficiently.⁸⁰ When the government steps in to value the patent, it may not choose the correct amount, or it may allocate the right to use the patent inefficiently. Nevertheless, many mainstream scholars would still argue that compulsory licensing might make sense in some extreme cases, when the social costs of exclusive rights threaten to outweigh the social benefits.⁸¹

Sykes goes beyond the traditional arguments against compulsory licensing to make the following point. Developing countries in the aggregate may benefit from having strong patent laws, if (for reasons alluded to above)⁸² these laws induce firms to invent things of particular interest to the developing countries (e.g., anti-malaria drugs) and to engage in technology transfer – but there is a collective action problem.⁸³ The problem arises because an individual developing country may be even better off if it chooses to have weak patent laws, while the other developing countries have strong patent laws; that way, an individual country can obtain the benefits of inducing the invention of things of particular interest to devel-

2004) (suggesting that firms often rank patents below other reasons for engaging in research and development, but that patents may be relatively more effective at inducing research and development in some industries, including pharmaceuticals, than in others); Edwin Mansfield, *Patents and Innovation: An Empirical Study*, 32 MGT. SCI. 173, 175 (1986) (cited in Sykes, *supra* note 5, at 60-61).

⁷⁹ See, e.g., Keith E. Maskus, *Ensuring Access to Essential Medicines: Some Economic Considerations*, 20 WIS. INT'L L.J. 563, 572-73 (2002) (noting that, when the developed countries have resorted to compulsory licensing, fees typically have been modest, and that the prospect of modest fees could deter investment in research and development); F.M. Scherer & Jayashree Watal, *Post-TRIPs Options for Access to Patented Medicines in Developing Nations*, 5 J. INT'L ECON. L. 913, 922-24 (2002) (noting that compulsory licensing fees tend to be on the low side). Recall that, under TRIPs, a nation may resort to compulsory licensing (except in cases involving national emergencies) only when efforts to negotiate with the patent owner have failed. See TRIPs Agreement, *supra* note 2, art. 31(b). Presumably, then, a compulsory license will result in a deal that is less favorable to the patent owner than a deal which it would have struck voluntarily.

⁸⁰ See Blair & Cotter, *supra* note 76, at 1615-16.

⁸¹ For an interesting recent proposal to incorporate into patent law a fair use exception, which unlike fair use in copyright law would involve payments from the user to the owner, see Maureen O'Rourke, *Toward a Doctrine of Fair Use in Patent Law*, 100 COLUM. L. REV. 1177 (2000).

⁸² See *supra* notes 29-31 and accompanying text.

⁸³ See Sykes, *supra* note 5, at 65-66.

oping countries, without having to pay the costs.⁸⁴ Sykes argues that TRIPs solves the collective action problem by requiring all of the member nations to have strong IPRs, but that the TRIPs Declaration undoes the bargain by inviting an expansive interpretation of article 31.⁸⁵ Developing countries can now effectively opt out of the patent provisions of TRIPs, and each will have an incentive to do so; thus the collective action problem returns.⁸⁶

Finally, the Externality Argument goes a step further by suggesting that the TRIPs Declaration could have a negative effect on the developed world as well. In this regard, Sykes argues that "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."⁸⁷ Richard Adelstein⁸⁸ and my colleague Bob Moffat⁸⁹ both make similar arguments. In support of this thesis, Sykes notes one study by Murphy and Topel suggesting that "the

⁸⁴ *See id.*

⁸⁵ *See id.*

⁸⁶ *See id.*

⁸⁷ *See id.* at 60.

⁸⁸ *See* Richard Adelstein, *Equity and Efficiency in Markets for Ideas*, 17 CONN. J. INT'L L. 249, 260-61 (2002):

Now, one might object to the patent monopoly by saying that it allows the pharmaceutical company to focus its efforts on drugs that rich people want rather than on those that poor people want. This is entirely correct and in fact . . . this is exactly what markets are supposed to do: produce the goods that people willing and able to pay the costs of production want. If rich people want drugs for baldness or obesity and are willing to pay for them, that is what the companies will produce. This is also why we know as much as we do about heart disease, which is certainly much further down the list of health problems in poor countries than in rich ones. One might reasonably ask whether the next million dollars worth of research should be spent on saving a few rich people from heart attacks or a great many poor people from tooth decay. But what drugs we have for AIDS were largely developed by profit-seeking pharmaceutical companies responding to the wants of people who could pay high prices for them. Dismantling the system of patent monopolies to allow more poor people access to AIDS drugs now might leave us with no way to mobilize resources against the next great global epidemic. One of the many dilemmas we face is how to balance the interests of patients in the here and now who cannot afford the drugs they need at the prices their developers must charge against the interests of patients in the future who may be denied the drugs they need at any price because no one had the incentive to invest in their development today.

⁸⁹ *See* Robert C.L. Moffat, *Science, Social Neuroses, and Trade in Post-Industrial Society*, 10 (unpublished manuscript, on file with author):

The current litigation in South Africa regarding pharmaceutical patents provides another example of the desire to obtain benefits without paying for the costs. The emotional plea is made in the setting of AIDS medications, but the South African law that violates the rules of international trade is much broader. What is conveniently overlooked is that if the intellectual property of the companies that plow billions of dollars into research is stolen without compensation, the incentive to carry on is destroyed. If medications for AIDS can be used as a pretext for stealing the benefits of the research the companies have carried out, then the goose that sometimes lays the golden egg will be killed. If

patent protection available in the developed world” may not be “sufficient to induce all desirable research.”⁹⁰ Thus, even if strong patent rights in developing countries would increase drug companies’ rents by only twenty percent (based on the premise that GDP in these countries is about twenty percent of the GDP of developed countries), this could provide a significant inducement to further research.⁹¹ On this logic, if compulsory licensing and parallel importation would benefit the developing countries, they may reduce global welfare; or, to put it another way, even if strong IPRs are bad for the developing countries, they may be good for humanity generally. Sykes is explicit on this point, arguing that “[e]ven if Professor Scherer were right about the [negative] 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.”⁹²

III. RESPONSE TO THE CRITIQUES

In this Part, I respond to the three critiques presented above. I will argue that, while each of the critiques may contain a kernel of truth, they are for the most part overstated. In particular, I will argue that the TRIPs Declaration is not a radical reinterpretation of TRIPs; that both theoretical and practical considerations will limit the potential negative consequences of the Declaration (although they will probably also constrain its potential positive consequences as well); and, more controversially, that some of the critiques owe more to ideology than to economics.

A. *The Revision Argument*

In this section, I explain why the argument that the TRIPs Declaration radically revises or misinterprets the TRIPs Agreement

the South African law is upheld, the rational response of the pharmaceutical companies would be to abandon AIDS research altogether.

⁹⁰ See Sykes, *supra* note 5, at 61. The Murphy & Topel article actually appears as chapter 2 in *MEASURING THE GAINS FROM MEDICAL RESEARCH: AN ECONOMIC APPROACH* (Kevin M. Murphy & Robert H. Topel eds., 2003). An earlier version may be found at <http://gsbwww.uchicago.edu/fac/robert.topel/research/murphy&topel.pdf>. (last visited June 27, 2003).

⁹¹ See Sykes, *supra* note 5, at 61-62.

⁹² *Id.* at 62. Scherer had argued that increased patent protection in the developing countries would cost those countries more than they would gain. See FREDERIC M. SCHERER, *INDUSTRY STRUCTURE, STRATEGY AND PUBLIC POLICY* 362-66 (1996) (cited in Sykes, *supra* note 5, at 61); see also F.M. Scherer, *The Pharmaceutical Industry and World Intellectual Property Standards*, 53 *VAND. L. REV.* 2245, 2249-51 (2000). Sykes disagrees with this conclusion, see Sykes, *supra* note 5, at 62, but also argues in the sentence quoted in the text above that, even if Scherer is right, the gains to the developed countries could outweigh the developing countries’ losses.

is not convincing. Paragraphs 4 and 5 of the Declaration are largely consistent with long-standing principles of treaty interpretation and with the pre-Declaration opinion of many commentators. Even those provisions that might, at first blush, appear more radical, probably do not effect any significant practical change in the meaning of the treaty.

As noted above, paragraph 5(a) calls for interpreting TRIPs “in the light of the object and purpose of the Agreement as expressed, in particular, in its objectives and principles.”⁹³ The words “objectives and principles” appear to refer to the preamble and to articles 7 and 8 of TRIPs, respectively titled “Objectives” and “Principles.”⁹⁴ Notwithstanding the initial objections raised by the United States and Switzerland, this provision is clearly consistent with long-standing principles of treaty interpretation as embodied in the Vienna Convention on the Law of Treaties, which permits a tribunal that must construe ambiguous language to consider the purposes and objectives of the treaty under consideration.⁹⁵ In this regard, the American/Swiss argument that the other provisions of TRIPs already reflect the purposes and objectives stated in articles 7 and 8 is not helpful, when those provisions themselves call for interpretation (for example, in determining what constitutes a “case of national emergency or other circumstances of extreme urgency” for purposes of article 31). To be sure, the objectives and principles set forth in articles 7 and 8 of TRIPs are somewhat vaguely worded, but then so are many other concepts that lawyers commonly use, such as due process; that does not necessarily mean that these concepts lack content, or are merely aspirational or unenforceable. In addition, as I argue below, it is hardly apparent that the principle of reading article 31(b) in light of articles 7 and 8 necessarily amounts to *carte blanche* for the developing countries,⁹⁶ even if one ignores the significant practical constraints that developing countries are likely to face in the real world.⁹⁷

⁹³ *Id.* ¶ 5(a).

⁹⁴ See TRIPs Agreement, *supra* note 2, arts. 7-8.

⁹⁵ See Vienna Convention on the Law of Treaties, May 22, 1969, 8 I.L.M. 679, art. 31(1) (stating that a “treaty shall be interpreted in good faith in accordance with the ordinary meaning to be given to the terms of the treaty in their context and in the light of its object and purpose.”); accord PIRES DE CARVALHO, *supra* note 11, at 111, 128; WATAL, *supra* note 12, at 293; Abbott, *supra* note 4, at 493; Jonathan Michael Berger, *Tripping over Patents: AIDS, Access to Treatment and the Manufacturing of Scarcity*, 17 CONN. J. INT’L L. 157, 185 (2002). TRIPs panels had already recognized this point. See PIRES DE CARVALHO, *supra* note 11, at 111 n.320 (citing decisions).

⁹⁶ See *infra* text accompanying notes 98-100.

⁹⁷ See *infra* notes 121-24 and accompanying text. Similar reasons lead to the conclusion that paragraph 4 of the Declaration also is consistent with TRIPs. Paragraph 4 states that TRIPs “does not and should not prevent members from taking measures to protect public

Paragraph 5(b) of the Declaration appears to authorize member nations to impose compulsory licensing for *any* reason – even one that is not grounded in the preamble or in article 7 or 8. For this reason, paragraph 5(b) might be viewed as a substantial departure from the practice contemplated under TRIPs. But even before Doha, the bulk of scholarly opinion was that TRIPs imposed few, if any, limits upon the grounds on which member nations may rely for imposing compulsory licensing.⁹⁸ In addition, the TRIPs

health” and “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.” TRIPs Declaration, *supra* note 1, ¶ 4. This paragraph is not terribly difficult to reconcile with the aforementioned objectives and principles set forth in TRIPs article 7 (stating that the “protection and enforcement of intellectual property rights” should be “conducive to social and economic welfare” and should contribute to “a balance of rights and obligations.”) and article 8 (permitting members to “adopt measures necessary to protect public health and nutrition . . . provided that such measures are consistent with the provisions of this Agreement.”). TRIPs Agreement, *supra* note 2, arts. 7-8. *See also* Abbott, *supra* note 4, at 491-93 (discussing possible consequences of paragraph 4); Amir Attaran, *The Doha Declaration on the TRIPs Agreement and Public Health, Access to Pharmaceuticals, and Options Under WTO Law*, 12 FORDHAM INTELL. PROP. MEDIA & ENTER. L.J. 859, 864-67 (2002) (arguing that paragraph 4 affects all of the WTO Agreements, not just TRIPs).

It may be worth noting, in addition, that many industrialized nations impose price controls on prescription drugs, including patented drugs. *See, e.g.*, Robert Weissman, *A Long, Strange TRIPs: The Pharmaceutical Industry Drive to Harmonize Global Intellectual Property Rules, and the Remaining WTO Legal Alternatives Available to Third World Countries*, 17 U. PA. J. INT’L ECON. L. 1069, 1074 (1996) (noting this phenomenon). Even in the United States, the federal government requires drug companies seeking Medicaid payments to provide rebates on Medicaid sales of some drugs. *See* 42 U.S.C. § 1396r-8 (2004). *See also* Pharmaceutical Research & Mfrs. of Am. v. Walsh, 123 S. Ct. 1855 (2003) (holding that a Maine statute requiring additional rebates was not preempted by federal law). From an economic perspective, there does not appear to be much of a difference between (1) a compulsory licensing system that provides the patent owner with a below-market-rate royalty, and (2) direct regulation of the price the patent owner may charge, and yet the latter is clearly permitted even under the TRIPs regime. *See* WATAL, *supra* note 12, at 293; Weissman, *supra* note 97, at 1074, 1114-15. (The preceding statement exaggerates slightly, in that a patent owner who is forced to license its invention to someone else may not be able to control the quality of the product made by the licensee. Yet, in both cases the more important consequence may be that the patent owner loses control over the price charged.) Whatever the wisdom of such price control measures, the fact that many nations have adopted them in order to ensure public access to essential medicines weakens any argument that the policy embodied in paragraph 4 is a radical departure from long-tolerated practices.

⁹⁸ *See, e.g.*, CORREA, *supra* note 35, at 90 (stating that TRIPs “does not limit the Members’ right to establish compulsory licenses on other grounds not explicitly mentioned therein.”); WATAL, *supra* note 12, at 319 (arguing that “[o]thers have rightly pointed out that there [are] no restrictions whatsoever on the purposes for the grant of compulsory licenses,” and that the grounds set forth in articles 7, 8, and 31 are “by no means the only grounds allowed.”); Abbott, *supra* note 4, at 493 (noting that paragraph 5(b) “states propositions that are clear from the text of Article 31 of the TRIPs Agreement, but which Pharma, among others, has attempted to put in doubt.”); J.H. Reichman, *Universal Minimum Standards of Intellectual Property Protection Under the TRIPs Component of the WTO Agreement*, 29 INT’L LAW. 345, 355 (1995) (asserting that “both the public-interest exception and measures to prevent abuse, respectively stipulated in articles 8(1) and 8(2) of the TRIPs Agreement, could justify resort to compulsory licensing.”); *cf.* PIRES DE CARVALHO, *supra* note 11, at 107 n.306, 129, 232-33 (arguing that “social and collective interests” can justify the granting of compulsory licenses, but that article 27(1) forbids compulsory licensing as a penalty for failure to work; that article 31(b) forbids compulsory licensing when the

Declaration leaves the remaining patent provisions of TRIPs in place, including the prohibition on discrimination as to fields of technology,⁹⁹ and (with the qualified exception of article 31(f)) all of the various requirements set forth in article 31, including adequate remuneration and judicial review.¹⁰⁰ Thus, even if a nation wanted to impose compulsory licensing for some dubious reason, it would have to do so in a manner that does not amount to discrimination with respect to a particular *type* of patent, such as pharmaceutical patents, and it would have to comply with article 31.

Some commentators have read paragraph 5(c) of the Declaration, stating that each member nation “has the right to determine what constitutes a national emergency or other circumstances of extreme urgency,” as effectively rendering a nation’s compliance with article 31(b) unreviewable, and they have argued that this constitutes a substantial revision of TRIPs.¹⁰¹ As discussed above, member nations that declare a “national emergency or other circumstances of extreme urgency” are exempt from the requirement that they first negotiate with the patent holder for permission to use the patent on reasonable commercial terms.¹⁰² But even this development is not as significant as one might think. First, it is important once again to note that all of the other rules relating to compulsory licenses, including the requirement of adequate remuneration, remain in place even in cases of national emergencies.¹⁰³ Second, it is doubtful that the Declaration contemplates an *absolute* right to declare a national emergency. There is nothing in the Declaration that would prevent a WTO challenge against a nation that abuses its right by declaring a sham emergency¹⁰⁴ (although a panel would have to develop some standards for determining what constitutes a sham). Third, even in the absence of the Declaration, it is doubtful that a TRIPs panel would often second-guess a country’s determination that it faces a national health emergency or

patent owner refuses to license for sound commercial reasons; and that “[c]ompulsory licenses may not be granted on frivolous grounds.”).

⁹⁹ See TRIPs Agreement, *supra* note 2, art. 27(1).

¹⁰⁰ See *id.* art. 31. For discussion of the article 31(f) resolution, see *infra* note 114.

¹⁰¹ See Sykes, *supra* note 5, at 56; Gerhart, *supra* note 69, at 1077.

¹⁰² See TRIPs Agreement, *supra* note 2, art. 31(b).

¹⁰³ See *id.*

¹⁰⁴ See PIRES DE CARVALHO, *supra* note 11, at 233 (arguing that a “grant of compulsory licenses on frivolous grounds” would violate TRIPs); Abbott, *supra* note 4, at 494 n.85 (noting that “[a]ll international agreements carry with them an implicit obligation to act in good faith.”); Aditi Bagchi, *Compulsory Licensing and the Duty of Good Faith in TRIPs*, 55 STAN. L. REV. 1529, 1548-53 (2003) (discussing the duty of good faith in the granting of licenses); Nolf, *supra* note 66, at 144 (suggesting that a “flagrant abuse” might be successfully challenged).

other situation of extreme urgency.¹⁰⁵ Paragraph 5(c) may not effect a substantial practical change unless TRIPs panels were predisposed to routinely engage in a *Lochner*-era type review of a country's decision to declare a national emergency.¹⁰⁶

I concede that there are parts of the Declaration that arguably go beyond what TRIPs originally contemplated. One such part is the previously-mentioned extension to January 1, 2016, for LDCs to conform their patent laws with respect to pharmaceuticals.¹⁰⁷ As some commentators have noted, TRIPs article 66 appears to contemplate that extensions of time would be negotiated on a case-by-case basis.¹⁰⁸ But even this provision may not amount to a significant change in substance, insofar as such extensions *could* have been granted on a case-by-case basis.¹⁰⁹ Moreover, a report recently issued by the U.K. Commission on Intellectual Property Rights (the CIPR Report) notes that seventy percent of the population of LDCs reside in countries which already accord patent protection to pharmaceuticals.¹¹⁰ Therefore, the extension may

¹⁰⁵ In construing TRIPs, TRIPs panels apply the rules set forth in the Vienna Convention. See WTO Panel Report on CANADA-PATENT PROTECTION OF PHARMACEUTICAL PRODUCTS—COMPLAINT BY THE EUROPEAN COMMUNITIES AND THEIR MEMBER STATES, WT/DS114/R, ¶ 7.13 (Mar. 17, 2000) (stating that a treaty must be “interpreted in good faith in accordance with the ordinary meaning to be given to the terms of the treaty in their context and in the light of its object and purpose”; that “subsequent practice” also may help to “establish[] the agreement of the parties regarding its interpretation”; and that “supplementary means of interpretation,” including drafting history, may help to confirm a meaning, to construe an “ambiguous or obscure” provision, or to avoid a “manifestly absurd or unreasonable” result) (quoting Vienna Convention arts. 31(1), 31(3)(b), 32). A textual analysis would suggest that a case of “national emergency” or “extreme urgency” would have to be something very dire; something demanding immediate action. See V OXFORD ENGLISH DICTIONARY 176, 618 (2d ed. 1989) (defining an “emergency” as, among other things, “a state of things unexpectedly arising, and urgently demanding immediate action.”); *id.* at 618 (defining “extreme” as, among other things, “very far advanced . . . utmost, uttermost”; “exceedingly great or intense”; and “presenting in the utmost degree some particular characteristic.”); XIX OXFORD ENGLISH DICTIONARY 338 (2d ed. 1989) (defining “urgency” as, among other things, “pressing importance”). These definitions would appear to me to provide substantial leeway for determining that a public health problem constitutes an “emergency” or “extreme urgency.” As far as my research assistant and I have been able to determine, there is nothing in the drafting history of TRIPs that further illuminates the meaning of these terms. See also PIRES DE CARVALHO, *supra* note 11, at 129 (arguing that nations were free to decide what constituted a national emergency even before TRIPs Declaration paragraph 5(d)); Berger, *supra* note 95, at 187 (noting that the principle of *in dubio mitius* “in essence defers to the ‘sovereignty of states’ when the extent of the international obligation that has been voluntarily assumed is unclear.”).

¹⁰⁶ As for paragraph 5(d), see *supra* note 72.

¹⁰⁷ See TRIPs Declaration, *supra* note 1, ¶ 6.

¹⁰⁸ See PIRES DE CARVALHO, *supra* note 11, at 299; Gerhart, *supra* note 69, at 1076.

¹⁰⁹ Cf. PIRES DE CARVALHO, *supra* note 11, at 300 (noting that the individualized-request requirement “is a matter of formality that does not change the contents, scope and validity of the waiver accorded by the Ministerial Conference.”).

¹¹⁰ See INTEGRATING INTELLECTUAL PROPERTY RIGHTS AND DEVELOPMENT POLICY: REPORT OF THE COMMISSION ON INTELLECTUAL PROPERTY RIGHTS 60 (Sept. 2002) [hereinafter CIPR REPORT], available at http://www.iprcommission.org/papers/text/final_report/reportweb/final.htm. (last visited Oct. 11, 2004).

benefit only a small number of countries; presumably those with existing patent protection could not change their laws retroactively.¹¹¹

A second more expansive provision of the Declaration is paragraph 6, which directs the Council for TRIPs to find an expeditious solution to the problem of some LDCs not being able to take advantage of compulsory licensing due to their lack of an adequate manufacturing sector.¹¹² In theory, this provision could effect a substantial change by overriding TRIPs article 31(f), which states that compulsory licensing “shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use.”¹¹³ Before deciding whether paragraph 6 radically changes TRIPs, it would be helpful to see what the Council proposes.¹¹⁴

¹¹¹ See *id.*

¹¹² See TRIPs Declaration, *supra* note 1, ¶ 6.

¹¹³ TRIPs Agreement, *supra* note 2, art. 31(f). Some commentators read article 31(f) to permit a nation that has authorized compulsory licensing to export up to fifty percent of the products manufactured under the license – or more, if the license is issued to remedy an anticompetitive abuse. See Abbott, *supra* note 4, at 499-500. Others take a more restrictive view. See PIRES DE CARVALHO, *supra* note 11, at 241-42 (arguing that any surplus to be exported must be either unexpected or unavoidable).

¹¹⁴ At the time I completed my initial draft of this symposium article, the TRIPs Council had missed the Ministerial Conference’s December 31, 2002 deadline for devising a solution to the article 31(f) problem. See Press Releases, WTO General Council, Supachai Disappointed over Governments’ Failure to Agree on Health and Development Issues (Dec. 20, 2002), at http://www.wto.org/english/news_e/pres02_e/pr329_e.htm (last visited Oct. 11, 2004). The failure to reach an accord on paragraph 6 had become a sore point, with the developing nations accusing the United States of bad faith. See Roger Thurow & Scott Miller, *Empty Shelves: As U.S. Balks on Medicine Deal, African Patients Feel the Pain*, WALL ST. J., June 2, 2003, at A1. As of that date, various proposals had been put forward, including amending article 31(f) so as to permit compulsory licensing for the export of products needed to address public health problems; an authoritative interpretation of TRIPs article 30, to the effect that compulsory licensing for export can in some instances constitute the type of limited exception permitted under that article; interpreting the term “domestic market” in article 31(f) to include customs unions and free trade areas, and not just individual nations (which might allow groups of developing nations to form a single “domestic market”); a temporary moratorium on the enforcement of article 31(f); a waiver of article 31(f) for a period of time; and a decision that article 31(f) is nonjusticiable. For literature discussing these alternatives, see CIPR REPORT, *supra* note 110, at 54-57; PIRES DE CARVALHO, *supra* note 11, at 242-44; Attaran, *supra* note 97, at 868-77; Amir Attaran, *Assessing and Answering Paragraph 6 of the Doha Declaration on the TRIPs Agreement and Public Health: The Case for Greater Flexibility and a Non-Justiciability Solution*, 17 EMORY INT’L L. REV. 743 (2003); Jacques H.J. Bourgeois & Thaddeus J. Burns, *Implementing Paragraph 6 of the Doha Declaration on TRIPs and Public Health: The Waiver Solution*, 5 J. WORLD INTELL. PROP. L. 835 (2002); Thomas A. Haag, *TRIPs Since Doha: How Far Will the WTO Go Toward Modifying the Terms for Compulsory Licensing?*, 84 J. PAT. & TRADEMARK OFF. SOC’Y 945 (2002); Haochen Sun, *A Wider Access to Patented Drugs Under the TRIPs Agreement*, 21 BOSTON U. L. REV. 63 (2003).

Following my submission of this article, the TRIPs Council on August 30, 2003, issued a document titled “Implementation of Paragraph 6 of the Doha Declaration on the TRIPs Agreement and Public Health,” Sept. 1, 2003, WT/L/540, available at http://www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm (last visited Oct. 11, 2004) [hereinafter Implementation]. The Implementation adopts an approach the United States had advocated, namely the waiver approach. See Paragraph 6 of the Ministerial Declaration on the

TRIPs Agreement and Public Health, Second Communication from the United States, July 9, 2002, IP/C/W/358, at http://www.ustr.gov/assets/Trade_Sectors/Intellectual_Property/Public_Health/asset_upload_file423_4114.pdf (last visited Oct. 11, 2004). Specifically, the Implementation states that:

The obligations of an exporting Member under Article 31(f) of the TRIPs Agreement shall be waived with respect to the grant by it of a compulsory license to the extent necessary for the purpose of production of a pharmaceutical product(s) and its export to an eligible importing Member(s) in accordance with the terms set out below in this paragraph:

- (a) the eligible importing Member(s) has made a notification to the Council for TRIPs that: (i) specifies the names and expected quantities of the product(s) needed; (ii) confirms that the eligible importing Member in question, other than a least developed country Member, has established that it has insufficient or no manufacturing capacities in the pharmaceutical sector for the product(s) in question in one of the ways set out in the Annex to this Decision; and (iii) confirms that, where a pharmaceutical product is patented in its territory, it has granted or intends to grant a compulsory license in accordance with Article 31 of the TRIPs Agreement and the provisions of this Decision;
- (b) the compulsory license issued by the exporting Member under this Decision shall contain the following conditions: (i) only the amount necessary to meet the needs of the eligible importing Member(s) may be manufactured under the license and the entirety of this production shall be exported to the Member(s) which has notified its needs to the Council for TRIPs; (ii) products produced under the license shall be clearly identified as being produced under the system set out in this Decision through specific labeling or marking. Suppliers should distinguish such products through special packaging and/or special colouring/shaping of the products themselves, provided that such distinction is feasible and does not have a significant impact on price; and (iii) before shipment begins, the licensee shall post on a website the following information: – the quantities being supplied to each destination as referred to in indent (i) above; and – the distinguishing features of the product(s) referred to in indent (ii) above;
- (c) the exporting Member shall notify the Council for TRIPs of the grant of the license, including the conditions attached to it. The information provided shall include the name and address of the licensee, the product(s) for which the license has been granted, the quantity(ies) for which it has been granted, the country(ies) to which the product(s) is (are) to be supplied and the duration of the license. The notification shall also indicate the address of the website referred to in subparagraph (b)(iii) above.

Implementation, *supra* para. (2). Paragraph 3 of the Implementation requires that the exporting Member pay adequate remuneration in accordance with article 31(h), but does not require the importing Member to do so. *See id.* para. (3). Importing Members are required to “take reasonable measures . . . to prevent re-exportation of the products” *Id.* para. (4). Other member nations are required to take steps “to prevent the importation into, and sale in, their territories” of any such diverted products. *Id.* para. (5). Paragraph 6 permits some use of the regional trade agreement concept referred to above. *See id.* para. (6). Finally, members may “not challenge any measures taken in conformity with the provisions of the waivers contained” in the Implementation, *id.* para. (10), and the Implementation itself is to terminate at such time as “an amendment to the TRIPs Agreement replacing its provisions takes effect” *Id.* para. (11).

By requiring member nations to comply with the procedures set forth above, the Implementation clearly evidences a compromise of the various interests. It has already met with a good deal of criticism from the developing countries, who argue that the procedural and other hurdles will severely hamper its effectiveness. *See* David W. Opderbeck, Patents, Essential Medicines, and the Innovation Game (Dec. 2003), at 12-18 (recounting criticism) (unpublished manuscript, on file with author), at <http://ssrn.com/abstract=458620> (last visited Oct. 11, 2004); Elizabeth Becker, *Poor Nations Can Purchase Cheap Drugs Under Accord*, N.Y. TIMES, Aug. 31, 2003, at A6.

B. *The Collective Action Argument*

The second critique is that the TRIPs Declaration will embolden member nations to impose compulsory licensing and other exceptions to patent rights in a broad range of situations, and that these measures herald a return of the collective action problem that TRIPs was supposed to solve.¹¹⁵ This critique is overstated, because there are important theoretical and practical constraints against the abuses that Professor Sykes and others fear.

As for the theoretical constraints, recall that one of the arguments in favor of extending strong patent rights to the developing world is that strong patent rights will facilitate foreign investment in, and technology transfer to, the developing world.¹¹⁶ One premise of the theory, developed by Kitch, is that patents do not disclose everything that one needs to know in order to practice an invention under the current state of the art.¹¹⁷ Nevertheless, the patent system, by reducing the effect of Arrow's Information Paradox, provides a framework for the transfer of unpatented know-how from the patent owner to the user.¹¹⁸ As discussed above, there is also some empirical evidence consistent with the theory, although other conditions must be present as well in order for a developing country to benefit from having a strong patent system.¹¹⁹ In any event, to the extent that strong patent rights do promise this beneficial consequence, there remains some incentive for developing countries to implement strong patent rights, regardless of what their neighbors do; at the very least, the risk of abuse may not be quite as strong as Sykes fears. In theory, then, the incentive to deviate from the collective good may not be as strong as Sykes suggests, even if each developing nation acts purely in its own selfish interest.¹²⁰

¹¹⁵ See *supra* notes 83-86 and accompanying text.

¹¹⁶ See *supra* notes 30-32 and accompanying text.

¹¹⁷ See Kitch, *supra* note 30, at 171-76; Edmund J. Kitch, *The Nature and Function of the Patent System*, 20 J. L. & ECON. 277, 287-88 (1977).

¹¹⁸ Arrow's Information Paradox is that the developer of a new idea may need to disclose the idea to a potential user in order to induce the user to license it; but that disclosure also eliminates the developer's exclusive possession of the idea, and thus may prevent the developer from acquiring any benefit from it. See Kenneth J. Arrow, *Economic Welfare and the Allocation of Resources for Invention*, in *THE RATE AND DIRECTION OF ECONOMIC ACTIVITY: ECONOMIC AND SOCIAL FACTORS* 614-16 (1962). The patent system may help to eliminate the paradox, by providing a framework for the transfer of know-how.

¹¹⁹ See *supra* text accompanying note 28.

¹²⁰ Of course, both the analysis above and (as I understand it) Sykes' analysis assumes that the developing country will act in its rational self-interest. More realistically, one would expect a country's actions to reflect, to a greater or lesser degree, the interests of the more powerful elements within that society; what these elements are will vary from one country, and one form of government, to another. If strong patent laws are in the interest of a majority of people within a developing country, but the more powerful groups within

More importantly, a variety of practical constraints should limit the ability of developing countries to engage in the excessive use of compulsory licensing. Conceivably, the TRIPs Declaration might embolden some countries to consider compulsory licensing that they otherwise would forego, out of fear of having to incur litigation costs to defend themselves before the WTO.¹²¹ But as I have repeatedly noted above, even post-Doha, a nation must still comply with the other provisions of article 31. Thus, if the desire to avoid litigation costs is paramount, it should continue to play a role in ensuring that developing countries provide adequate remuneration, an opportunity for judicial review, and so on. These safeguards should work to reduce, even if they do not eliminate, the potential for abuse. In addition, a country that abuses its ability to engage in compulsory licensing might suffer diplomatic or other repercussions (such as, possibly, American invocation of the controversial Section 301).¹²² If developed nations remain free to retaliate outside the context of TRIPs, the risk that developing nations will abuse their rights as reflected in the Declaration will be reduced.¹²³ Finally, as the CIPR Report notes, a country's ability to

that country oppose strong patent laws for their own selfish or short-sighted reasons, then conceivably the TRIPs Declaration makes it easier for those more powerful groups to get their way. In this scenario, the collective action problem arises within each developing country, rather than across the developing countries as a whole.

¹²¹ See Paper Submitted by the EU to the TRIPs Council, IP/C/W/280 (June 12, 2001), ¶ 12, at http://www.wto.org/english/tratop_e/trips_e/paper_eu_w280_e.htm (last visited Oct. 11, 2004).

¹²² See Gathii, *supra* note 56, at 316 (citing Trade Act of 1974, tit. III, ch. 1, § 301, 19 U.S.C. § 2411(a)(1), as amended). In a recent symposium issue of the *Emory International Law Review*, Professors Margo Bagley and Susan Sell also discuss the possibility of trade sanctions, including the invocation of Section 301. See Margo A. Bagley, *Legal Movements in IP: TRIPs, Unilateral Action, Bilateral Agreements, and HIV/AIDS*, 17 *EMORY INT'L L. REV.* 781, 790 n.35 (2003); Susan K. Sell, *Trade Issues and HIV/AIDS*, 17 *EMORY INT'L L. REV.* 933, 945 (2003).

¹²³ In this regard, consider the history of compulsory licensing prior to TRIPs. Prior to TRIPs, there was no effective enforcement mechanism for any of the international intellectual property treaties. Even so, resort to compulsory licensing was relatively uncommon, even in countries that permitted it. See F.M. SCHERER, *INDUSTRIAL MARKET STRUCTURE AND ECONOMIC PERFORMANCE* 456 (2d ed. 1980); Scherer & Watal, *supra* note 79, at 916; Roger D. Blair & Thomas F. Cotter, *Rethinking Patent Damages*, 10 *TEX. INTELL. PROP. L.J.* 1, 84 n.371 (2001) (citing other sources). There are a variety of reasons for this phenomenon, some of which would still apply in the present circumstances. First, drugs were not patentable in some countries prior to TRIPs, and so the need to resort to compulsory licensing to ensure a supply of essential medicines was absent there as well. Drugs now may remain unpatentable in some least-developed countries until 2016, and in other countries patents eventually expire. Second, perhaps in some instances the mere threat of compulsory licensing might have been sufficient to extract concessions from patent owners, without having to resort to licensing itself. But even in the absence of compulsory licensing, countries often have other ways of pressuring patent owners to make price concessions. See Maskus, *supra* note 79, at 570 (price negotiations conducted in the shadow of monopsony purchasing power); see also *supra* note 97 (direct price controls). Third, Sykes' argument that small countries have an incentive to free-ride may be plausible. In the mid-nineteenth century, the Netherlands abolished its patent system, and Switzerland repeatedly rejected

engage in compulsory licensing is constrained by other practical factors – among them the need to have an established industrial sector in place that can engage in reverse engineering and production of the invention covered by the patent, and the need for an adequate legal and administrative system to oversee the compulsory licensing procedure.¹²⁴ It may be only in developing countries that are slightly more developed than others (e.g., Brazil) that large-scale compulsory licensing will even be feasible. This in turn suggests that compulsory licensing is not likely to be a panacea for the developing countries, and makes it somewhat difficult to get excited about the Declaration, either pro or con.

Sykes may be on firmer ground when he argues that compulsory licensing may reduce the pharmaceutical industry's incentive to undertake research into diseases that are endemic principally to the developing world.¹²⁵ That consequence would be perverse, but again a little dose of reality is helpful. Even in the presence of strong patent rights, the developing nations' willingness to pay may be so constrained that little incentive will exist anyway for the pharmaceutical companies to engage in much of this type of research and development. Indeed, most observers who have considered this issue have concluded that it will take much more than strong patent rights to induce this type of research.¹²⁶ Even in the United States, it took the Orphan Drug Act to make research into some drugs with relatively small demand profitable.¹²⁷ Thus, even if the TRIPs Declaration marginally decreases the incentive to engage in

proposals to establish one. See Fritz Machlup & Edith Penrose, *The Patent Controversy in the Nineteenth Century*, 10 J. ECON. HIST. 1, 4-5 (1950) (discussing Swiss and Dutch rejections); R. Carl Moy, *The History of the Patent Harmonization Treaty: Economic Self-Interest as an Influence*, 26 J. MARSHALL L. REV. 457, 486-87 (1993) (arguing that Switzerland deliberately followed a free-rider strategy). Switzerland eventually gave in to pressure from Germany, however, and established a patent office in 1887. See Machlup & Penrose, *supra*, at 6; Moy, *supra*, at 487. The Netherlands reestablished its patent office in 1912. See Machlup & Penrose, *supra*, at 6. Similar political pressures might be brought to bear against developing countries that engage in the excessive use of compulsory licenses today.

¹²⁴ See CIPR REPORT, *supra* note 110, at 50-51; Bagley, *supra* note 122, at 794; MASKUS, *supra* note 29, at 572.

¹²⁵ See Sykes, *supra* note 5, at 62, 65. See also sources cited *supra* note 28.

¹²⁶ See CIPR Report, *supra* note 110, at 39-42; MASKUS, *supra* note 29, at 568; Opderbeck, *supra* note 114, at 9-10, 51-54.

¹²⁷ Under the Orphan Drug Act, 21 U.S.C. § 360aa (2004), the United States government provides additional funding, tax benefits, and exclusive marketing rights to drug companies undertaking research into diseases affecting relatively small numbers of people. Advocates claim that, absent these additional benefits, research into these diseases probably would not be undertaken because it would not be profitable. For discussions, see, e.g., Gary A. Pulsinelli, *The Orphan Drug Act: What's Rights with It*, 15 SANTA CLARA COMPUTER & HIGH TECH. L.J. 299 (1999); David Duffield Rohde, *The Orphan Drug Act: An Engine of Innovation? At What Cost?*, 55 FOOD & DRUG L.J. 125 (2000). Professor Grabowski argues that diseases that disproportionately affect developing countries are unlikely to attract much interest on the part of the drug companies, absent a similar commitment of research

research into tropical diseases, there remain (unfortunately) other obstacles that are much more significant; to argue against the Declaration on this ground is to let the tail wag the dog.

C. *The Externality Argument*

The third critique of the TRIPs Declaration is that it will embolden developing countries to undertake policies that could have an adverse impact upon the developed world. As discussed above, Professor Sykes argues that strong patent rights in the LDCs might increase the drug companies' rents by twenty percent or more, and that this increase would induce the drug companies to invest even more in research and development. Even if this research mostly benefited the developed countries (e.g., "drugs for baldness or obesity"),¹²⁸ and even if increased patent protection resulted in a net loss to the developing countries, Sykes argues, global social welfare would increase.¹²⁹ This argument is troubling, for several reasons.

First, there is no way of knowing whether the hypothetical twenty percent increase in pharmaceutical company profits would have the predicted impact upon behavior. As discussed above, the

funds. See Henry Graboswki, *Patents, Innovation, and Access to New Pharmaceuticals*, 5 J. INT'L ECON. L. 849, 858-60 (2002).

¹²⁸ Adelstein, *supra* note 88, at 260.

¹²⁹ See Sykes, *supra* note 5, at 62 (asserting that "[e]ven if Professor Scherer were right about the [negative] 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.").

A variation of this argument, which I have occasionally heard people make but have not yet seen in print (for good reason), is easy to rebut. The argument is that if consumers in Country X can pay a low price for a drug that is subject to patent protection in the United States, the drug companies will charge the American consumer an even higher price than they otherwise would in order to make up the difference. On this logic, it is in the interest of the American consumer (though not necessarily the Country X consumer) to insist that Country X also afford patent protection to the drug in question. Given the territorial nature of patent rights, this argument is incoherent. To see why, assume that the drug in question affords the patent owner monopoly power in the United States, because there are no close substitutes for the drug (for example, a hypothetical cancer cure). The patent owner will maximize its profit by charging the American consumer a price derived from equating marginal revenue with marginal cost. See Blair & Cotter, *supra* note 76, at 1624 (presenting the standard analysis of monopoly pricing). Charging an even higher price will reduce the patent owner's profits, and so the patent owner has no incentive to increase the price it charges in the United States even if the drug is off-patent in another country. See Peter J. Hammer, *Differential Pricing of Essential AIDS Drugs: Markets, Politics, and Public Health*, 5 J. INT'L ECON. L. 883, 889 n.11 (2002). The analysis holds even if the U.S. patent affords the patent owner only some degree of market power falling short of a full-blown monopoly. See Blair & Cotter, *supra* note 76, at 1633-34. If the American patent affords no market power, because there are other nonpatented products that are just as good, then the price charged in the United States should approximate marginal cost, again regardless of the price charged elsewhere. Finally, if any of the product sold in Country X makes its way to the United States for sale here, this would have the added impact of lowering, not raising, the price in the United States.

extent to which patent laws induce invention is unknown, as Sykes recognizes.¹³⁰ To be sure, it is conceivable that a twenty percent increase in profits might have the desired effect, but against this hypothetical gain to the developed world one must balance the hypothetical loss to the developing world.¹³¹ Even if one could demonstrate a net welfare gain – that is, that the developed world's gains are greater than the developing world's losses, as measured by willingness to pay¹³² – there is nothing in economics that insists one *must* make such a tradeoff. Whether the tradeoff is desirable or not is a moral issue to which economics does not speak.¹³³ I suspect that many people – though perhaps not market fundamentalists – would be troubled by a policy that threatens to impose higher prices in the developing world, where they will have an immediate and obvious impact on the lives of real people, in exchange for a possible future benefit to people in the industrialized nations.

Moreover, even if there is a compelling need to induce more research into drugs that stand to benefit mostly the people of the industrialized nations, there may be other ways to achieve this goal that do not involve increasing the price of drugs in developing countries. We could, for example, increase the patent term.¹³⁴ We could provide more direct funding of research and development through government grants or tax benefits (which is something the United States and other countries already do, to a considerable extent).¹³⁵ We could amend the tax laws to encourage more drug

¹³⁰ See *supra* note 78 and accompanying text.

¹³¹ Sykes does not believe that the developing countries would be worse off either, because of the added incentive to conduct research into tropical diseases, but as discussed above he argues that even if the developing countries are rendered worse off, the welfare gains to the developed world probably would outweigh these losses. See Sykes, *supra* note 5, at 62.

¹³² A standard criterion of social welfare in law-and-economics analysis is Kaldor-Hicks efficiency, under which preferences are measured by persons' willingness to pay or willingness to accept. I have argued elsewhere that this criterion may be useful in some settings, but not in others. See Thomas F. Cotter, *Legal Pragmatism and the Law and Economics Movement*, 84 GEO. L.J. 2071, 2132-33 (1996). From a moral standpoint, one problem is that the Kaldor-Hicks criterion tends to privilege the preferences of those who are able to pay over the preferences of those who are not. See *id.*

¹³³ I have made this point with respect to similar issues elsewhere. See Thomas F. Cotter, *Introduction to IP Symposium*, 14 FLA. J. INT'L L. 147, 150-51 (2002).

¹³⁴ TRIPs mandates a minimum patent term, ending twenty years from the date of filing, but no maximum term. See TRIPs Agreement, *supra* note 2, art. 28. Moreover, a patent issued within one country is enforceable only within that country, so if one nation chose to adopt a patent term of, say, forty years, it could do so without affecting the patent term in any other country.

¹³⁵ See Rebecca Eisenberg, *Public Research and Private Development: Patents and Technology Transfer in Government-Sponsored Research*, 82 VA. L. REV. 1663, 1668-70 (1996) (noting that federal funding undercuts, to some extent, the conventional justification that patents are necessary to spur invention); Arti K. Rai, *The Information Revolution Reaches Pharmaceuticals:*

donations to developing countries.¹³⁶ We could negotiate with the other industrialized nations to reduce the price controls they sometimes impose on patented drugs. Of course, if we attempted this last measure, we would likely be rebuffed, but the ethical questions remain. Is it right to insist on policies that will increase prices in countries that are least able to afford them? More generally, is it right to insist upon strong IPRs in the developing countries before we have exhausted other options for encouraging innovation?

Alternatively, it may be that the real threat that compulsory licensing in the developing countries poses to research and development comes not from the pharmaceutical companies' hypothetical forgone twenty percent profit increase, but rather from the possible effect of these practices upon consumer expectations in the industrialized nations.¹³⁷ In other words, if consumers in the industrialized nations become aware that developing countries are using compulsory licensing or other measures to contain costs, and that these measures are successful in greatly reducing the price of some patented drugs, there may be pressure to implement similar measures in the developed world. Ultimately such pressure could erode the incentive to invest in research and development that is of interest to the developed world. This result would be unfortunate, but again a dose of reality is necessary. There already *is* political pressure to implement cost-containment measures in the developed countries; and there is countervailing pressure *not* to do so, precisely because of the potential impact of these measures on research incentives. Surely much of the American public is already aware that drugs are often sold at lower prices in other countries (such as Canada!), and yet, thus far at least, political leaders in the United States (and other industrialized nations) have resisted the temptation to enact some measures, such as international exhaustion of patent rights, that would reduce prices in the short run but that might threaten long-term research incentives.¹³⁸ Moreover, if

Balancing Innovation Incentives, Cost, and Access in the Post-Genomics Era, 2001 U. ILL. L. REV. 173, 185-87 (similar). Industry critics have emphasized the role of federal funding in pharmaceutical research. See Arnold S. Relman & Marcia Angell, *America's Other Drug Problem*, NEW REPUBLIC, Dec. 16, 2002, at 27; *U.S. Government Role in Health Care R & D*, at <http://www.cptech.org/ip/health/econ/govrnd.html>. (last visited Oct. 11, 2004) (website maintained by the Consumer Project on Technology).

¹³⁶ See Scherer & Watal, *supra* note 79, at 934-38. Some of the drug companies are increasing their charitable efforts toward the developing world. See, e.g., Marilyn Chase, *Lilly to Transfer TB-Drug Rights to Poor Nations*, WALL ST. J., June 5, 2003, at B1.

¹³⁷ Professor Hammer addresses this problem in a recent article. See Hammer, *supra* note 129, at 893-97.

¹³⁸ As Sykes notes, there is an incentive for nations to apply the principle of international exhaustion, which would enable them to engage in the parallel importation of drugs from lower-price countries, and article 6 of TRIPs would permit them to do this. See Sykes,

the arguments against parallel importation and other price-containment measures are indeed good ones, then perhaps we should trust the public to understand them. If the public cannot be convinced that it is in their interest to permit drug companies to price discriminate, then the public may be making a foolish decision; but the freedom to make foolish decisions is, to some degree, what democracy means. To lobby in favor of strong IPRs abroad so that the public in the developed world will remain unaware of the low marginal cost of the drugs they buy smacks of cynicism, to say the

supra note 5, at 63-64. But in fact most of the industrialized nations have resisted that temptation; most of these countries, including our own, apply some variation of national or regional exhaustion, not international exhaustion, with respect to patents. See WATAL, *supra* note 12, at 298-300. The only conclusion one can draw is that the industrialized nations do not always adopt patent policies that promise short-term gains at the expense of long-term losses – and also that legislators pay attention to the drug companies' concerns. Indeed, even if a majority of consumers would prefer the short-term gains, one cannot assume that legislators would defer to these preferences. If public choice theory teaches us anything, it is that politicians (whether in developed or developing countries) do not always do what "the majority," whatever that means, wants them to do.

Another concern of the pharmaceutical industry may be that, even under a regime of international exhaustion, some drugs that are sold at very low prices in the developing countries will find their way (illegally) into the industrialized nations, and that the resulting competition will force drug prices down in the latter countries, thus reducing research incentives. Again, the hypothetical reduction in research incentives would be an unfortunate result, but as long as the industrialized nations continue to follow a rule of national or regional exhaustion, the potential competition from low-price drugs sold in the developing countries should be reduced, even if it cannot be eliminated due to less than perfect enforceability. Indeed, in an effort to induce the drug companies to reduce their prices in the developing world, the European Union recently enacted a regulation specifically prohibiting the reimportation, from developing countries into the European Union, of AIDS, malaria, and tuberculosis drugs. See Council Regulation 953/2003/EC, 2003 O.J. (L 135) 5; *Access to Medicines: EU Clears Plan to Ensure Delivery of Cheap Medicines to Developing Countries, Trade and Development* (May 26, 2003) (discussing the regulation), available at <http://epha.org/a/347> (last visited Oct. 11, 2004); Simon King, *EU Opens Door for Cheaper Drug Exports to Developing World*, *WORLD MARKETS ANALYSIS*, May 27, 2003; see also PIRES DE CARVALHO, *supra* note 11, at 245 (concluding that "once effective border controls are put in place to avoid the deviation of products, the revenue of pharmaceutical companies will not be seriously affected by the moratorium or waiver of Article 31(f)."); Hammer, *supra* note 129, at 892-93 (proposing ways to reduce the risk of price arbitrage); MASKUS, *supra* note 29, at 567 (noting that the concern over parallel trade may induce drug companies to charge more in developing countries than they otherwise would, but that no evidence exists at present to support this hypothesis); Scherer & Watal, *supra* note 79, at 934 (discussing the need to control arbitrage). The Implementation also attempts to address the diversion issue, as noted above. See *supra* note 114.

Maskus also notes the argument that:

the practice of health authorities in some richer countries to engage in 'reference pricing' encourages pharmaceutical companies to set high prices in developing economies. In a reference pricing system, price controls in one country are based on an index of prices in comparison countries. To the extent that the comparison group includes developing economies, firms may prefer not to offer price discounts there.

MASKUS, *supra* note 29, at 567. It is conceivable that reference pricing could diminish the incentive to engage in R & D, if the prices charged in developing countries are reduced through compulsory licensing. Other commentators have noted this problem and called for limitations on the practice of reference pricing. See Hammer, *supra* note 129, at 893-94; Scherer & Watal, *supra* note 79, at 929, 934.

least. Lastly, there may be ways to finesse the problem by, for example, encouraging drug companies to make concessions to the developing countries in exchange for promises not to release sensitive cost information to the general public.¹³⁹ Surely we in the industrialized nations could explore such options before claiming that nothing more can be done.

Finally, even if some abuses are possible or even likely, perhaps some risk of abuse must be tolerated in light of the gravity of the alternatives. Most people will, if pressed, concede that sometimes our principles must give way to exceptions. People who are unwilling to make that concession go by a number of names. Sometimes we think of them as highly-principled people or heroes. In other contexts, however, these people are called fanatics, or more charitably, fundamentalists. Stiglitz has written about what he refers to as market fundamentalism in the context of the IMF imposing market reforms on countries that, in his view, were not quite ready for those reforms.¹⁴⁰ Certainly one can think of other historical examples. Some scholars argue, for example, that the British government in the 1840s was slow to respond to the Irish Potato Famine in part because of its adherence to *laissez-faire* economics.¹⁴¹ There is also the hypocrisy point. Over the years, the United States government has compelled the licensing of many inventions for its own purposes, including military uses.¹⁴² And who

¹³⁹ See Hammer, *supra* note 129, at 893-97.

¹⁴⁰ See Stiglitz, *supra* note 7.

¹⁴¹ See, e.g., J.C. BECKETT, *THE MAKING OF MODERN IRELAND 1603-1923*, 339 (2d ed. 1981) (arguing that “[s]uch assistance as the government did give was . . . made almost useless by the supposed necessity for conforming with the laws of political economy.”); CHRISTINE KINEALY, *A DEATH-DEALING FAMINE: THE GREAT HUNGER IN IRELAND* 66-91 (1997) (concluding that the Irish famine was exacerbated by a “quasi-religious belief in the sanctity of the free market, minimum intervention by the state and in the particular case of the poor, an emphasis upon the idea that poverty was a self-imposed condition.”); CORMAC Ó GRÁDA, *BLACK ‘47 AND BEYOND: THE GREAT IRISH FAMINE IN HISTORY, ECONOMY, AND MEMORY* 77-83 (1999) (arguing that English “ideology and public opinion” contributed to the Irish mortality rate); CECIL WOODHAM-SMITH, *THE GREAT HUNGER: IRELAND 1845-1849*, 375-76, 410 (1962). Some scholars also have noted the selective nature of the British government’s commitment to *laissez-faire*. See, e.g., CHRISTINE KINEALY, *THE GREAT IRISH FAMINE: IMPACT, IDEOLOGY AND REBELLION* 103-04 (2002) (noting that freight charges and navigation laws impeded the importation of food into Ireland during the early days of the famine). *But see* PETER GRAY, *FAMINE, LAND AND POLITICS: BRITISH GOVERNMENT AND IRISH SOCIETY 1843-1850* (1999) (attributing the British response to both economic and religious ideology, as well as to English public opinion); EDWARD G. LENGEL, *THE IRISH THROUGH BRITISH EYES: PERCEPTIONS OF IRELAND IN THE FAMINE ERA* 86 (2002) (arguing that “[t]he idea that the Russell administration did not respond adequately to the crisis because of a doctrinaire adherence to the principles of economic dogmatism is too simplistic and should be discarded, even though some historians like Christine Kenealy continue to cling to it stubbornly.”); Peter Gray, *Ideology and the Famine*, in *THE GREAT IRISH FAMINE* 86-103 (Cathal Póirtéir ed., 1995).

¹⁴² See CORREA, *supra* note 24, at 23; Scherer & Watal, *supra* note 79, at 916-17.

can forget the government's plans to compel the licensing of Cipro® in response to the anthrax scare of 2001?¹⁴³

None of the immediately preceding arguments are economic ones, to be sure. But market fundamentalists sometimes lose sight of some important points. First, economics can be a tool for helping us to achieve our goals. It can make useful predictions about the possible consequences of various rules, such as whether they are likely to move us toward or away from those goals. But whether economic efficiency, in the narrow, Kaldor-Hicks sense, *should be* such a goal is a moral, not an economic issue.¹⁴⁴ Second, economics is (or at least purports to be) a science. In science, elegant theories are worthless if they are not consistent with empirical evidence; a healthy skepticism is important. Nothing in science requires us to rely upon speculative theories about global welfare when real peoples' lives hang in the balance. Nothing in science compels us to make any particular moral choice. Nothing in science – so far, at least – requires us to be market fundamentalists.

CONCLUSION

I have argued above that three critiques raised against the TRIPs Declaration are unpersuasive. First, the argument that the Declaration substantially revises the TRIPs Agreement is unconvincing, both as a textual matter and in light of the Declaration's practical consequences. Second, the argument that the Declaration will render the developing countries worse off, by providing each of them with an incentive to deviate from their collective good, is overstated because both theoretical and practical constraints will likely reduce any perverse incentive. Third, the argument that the Declaration will make the industrialized nations worse off, by reducing pharmaceutical company profits that would have been used to fund research of interest to the industrialized world, is both speculative and, ultimately, cynical; it is also morally troubling, to the extent that it rests upon the premise that prices should be raised in the poor countries so as to make life easier for people in the rich countries. Economics does not compel us to shuck our moral intuitions.

I conclude this paper with two caveats. First, while I have argued above that the TRIPs Declaration can be viewed as a positive development for the developing countries, its impact may be mod-

¹⁴³ Several commentators on the Doha Declarations have noted this connection. See, e.g., Abbott, *supra* note 4, at 486-88; Gathii, *supra* note 56, at 306.

¹⁴⁴ See Cotter, *supra* note 132, at 2132-33.

est at best. Indeed, I have argued that one of the reasons the Declaration does not constitute a radical revision of TRIPs is that developing countries will continue to face many practical obstacles to the widespread use of compulsory licensing.¹⁴⁵ Moreover, although opinions differ with respect to the extent that patent protection affects access to essential medicines in developing nations, no one can reasonably deny that other factors (poverty, corruption, lack of infrastructure, and so on) often play a significant role as well.¹⁴⁶ Compulsory licensing and parallel importation will not be a panacea. Finally, differences of opinion as to what the TRIPs Declaration means have retarded its implementation, to the immense frustration of people in the developing world.¹⁴⁷ Almost two years having passed in between the TRIPs Declaration to the Implementation, arguments that the Declaration goes too far do not seem firmly grounded in reality.

Second, I hope that my analysis in the preceding pages has not appeared too harsh in its assessment of the critics' arguments, or too much in the nature of knocking down a straw man. In particular, I find Professor Sykes' analysis both thoughtful and provocative, and he is careful to stress that his conclusions are tentative.¹⁴⁸ It is important to consider the strengths and weaknesses of these arguments on their merits. It is also equally important to remember what economics can (maybe) tell us and what it cannot, lest we put too much faith in a particular version of economic reasoning – as Julie Cohen warns us in another context, to let “ideology, not science”¹⁴⁹ be our guide. As the fundamentalists sometimes forget, God is in the details.

¹⁴⁵ See *supra* notes 121-24 and accompanying text.

¹⁴⁶ See Amir Attaran & Lee Gillespie-White, *Do Patents for Antiretroviral Drugs Constrain Access to AIDS Treatment in Africa?*, J. AM. MED. ASS'N 1886, 1890 (Oct. 17, 2001) (concluding that patents are not a major barrier to access to HIV/AIDS drugs in Africa, but that other factors including poverty, tariffs, and lack of medical infrastructure are); see also MASKUS, *supra* note 29, at 565-68 (noting the importance of these other factors, though also concluding that limitations on patent rights would be useful in some instances).

¹⁴⁷ See *supra* note 114.

¹⁴⁸ See Sykes, *supra* note 5, at 68.

¹⁴⁹ Julie E. Cohen, Lochner in Cyberspace: The New Economic Orthodoxy of “Rights Management”, 97 MICH. L. REV. 462, 464 (1998).