

CLOSING THE GLOBAL DRUG GAP: A PRAGMATIC APPROACH TO THE ACCESS TO MEDICINES PROBLEM

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I. INTRODUCTION: THE “GLOBAL DRUG GAP”

The severe disparity in the incidence of life threatening disease between developed and developing countries cannot be ignored.¹ The “[j]oint United Nations Program on HIV/AIDS (UNAIDS) estimates that 95 percent of people living with HIV/AIDS are in developing countries.”² Exacerbating this overwhelming concentration of disease is severe poverty which restricts access to preventative medicine. In order to recover the substantial costs of research, development, and marketing of new drugs, pharmaceutical companies often price those drugs well beyond the purchasing capability of consumers in developing countries.³ A stark example is the case of fluconazole, an antifungal drug that can greatly reduce the risk of death or serious harm resulting from infections to HIV/AIDS patients.⁴ In 1999, the price of this drug if purchased from Pfizer was U.S. \$9.34 per dose.⁵ A generic equivalent produced in Thailand cost U.S. \$0.60 per dose,⁶ just over a fifteen fold price reduction. In a country such as South Africa—where the HIV infection rate of women attending antenatal clinics is a staggering thirty-five percent⁷—the human cost of restrictions on the importation

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¹ Zita Lazzarini, *Making Access to Pharmaceuticals a Reality: Legal Options Under TRIPS and the Case of Brazil*, 6 YALE HUM. RTS. & DEV. L.J. 103, 104 (2003) (citing World Health Organization, *The World Health Report 1999: Making a Difference* 13-20 (1999)).

² David Barnard, *In the High Court of South Africa, Case No. 4138/98*, 12 KENNEDY INST. OF ETHICS J. 159, 159 (2002) (citing Grant and De Cock, *ABC of AIDS: HIV infection and AIDS in the developing world*, 322 BRIT. MED. J. 1475, 1475 (June 2001)).

³ Sarah Joseph, *Pharmaceutical Corporations and Access to Drugs: The “Fourth Wave” of Corporate Human Rights Scrutiny*, 25 HUM. RTS. Q. 425, 428 (2003) (citing UN General Assembly Declaration of Commitment on HIV/AIDS ¶¶ 24–25 (2 Aug. 2001)).

⁴ Barnard, *supra* note 2, at 162.

⁵ *Id.*

⁶ *Id.*

⁷ UNAIDS, *2006 AIDS Epidemic Update*, at 6 (Dec. 2006), available at http://data.unaids.org/pub/EpiReport/2006/2006_EpiUpdate_en.pdf.

of generic drugs is enormous. The prices necessitated by pharmaceutical patent protection contribute to a severe inequity in access to needed health care: a “global drug gap.”⁸

This article analyzes the global drug gap problem in context of the World Trade Organization’s (“WTO”) 1994 Trade Related Aspects of Intellectual Property (“TRIPS”) Agreement, specifically examining the TRIPS compulsory licensing mechanism as it is actually used in the area of pharmaceuticals. While the bulk of scholarship in this area has focused either on rights-based analyses, evaluations of compulsory licensing as a practice and its effects on innovation, or a micro-economic analysis of the pharmaceutical industry, this article attempts to focus on the actual gains and losses to parties from compulsory licensing as currently practiced under TRIPS. Taking into account these gains and losses, the article proposes a new interpretation of the “adequate remuneration” provision of TRIPS which not only more accurately reflects these gains and losses, but also facilitates a more transparent process that can still provide low cost pharmaceuticals to poorer countries experiencing public health crises.

Part II of this article introduces the basic tension between recognizing a right to access preventative healthcare and preserving pharmaceutical patent rights insofar as those rights are particularly necessary to generate innovation in the pharmaceutical industry. Part III examines the nature and use of compulsory licensing and gives a schematic outline of how the concept has developed within the U.S. and how it currently operates under the WTO TRIPS Agreement. After this schematic outline, Part IV of this article presents the deficiencies of the current compulsory licensing mechanism in fashioning a long term solution to the drug gap problem. Part V presents a new proposal which would reinterpret the “adequate remuneration” text of the TRIPS agreement by in light of data on the actual scope and effect of patents and compulsory licensing in international pharmaceutical trade. This article concludes in Part VI by suggesting that the foregoing approach has broad applicability to other areas in which property rights clash with positive human rights.

II. PATENT PROTECTION AND RIGHT OF ACCESS TO PREVENTATIVE HEALTHCARE THE “RIGHT TO HEALTHCARE”

In his 1992 presidential campaign, former President Bill Clinton powerfully proclaimed that “health care should be a right, not a privilege.”⁹ His

⁸ Barnard, *supra* note 2, at 164.

⁹ David Kelley, *Is There a Right to Health Care?*, THE OBJECTIVIST CENTER, http://www.objectivistcenter.org/ct-14-Is_There_Right_Health_Care.aspx.

slogan, although directed towards a domestic audience, finds good company among international statements regarding the importance of healthcare as a universal human right. The Universal Declaration of Human Rights provides that “everyone has the right to a standard of living adequate for the health and well-being of himself and his family,”¹⁰ and the European Constitution sets forth that “everyone has the right of access to preventative health care”¹¹ Kindred sentiments are expressed in the TRIPS Agreement and in the WTO’s 2001 Declaration on the TRIPS Agreement and Public Health (Doha Declaration).¹²

It is certainly debatable whether or not the purported right to access healthcare is defensible, or even coherent.¹³ However, a legal right exists in a practical sense—regardless of any such theoretical argument—whenever it can be appreciably enforced through a legal process. Under this standard, the right of access to healthcare has meaningful and practical legal content. In February of 1998, the Pharmaceutical Manufacturer’s Association of South Africa and thirty nine other multinational pharmaceutical companies filed a lawsuit in the High Court of South Africa to challenge legislation which would have greatly enhanced the South African government's ability to import generic HIV/AIDS drugs. The strong belief in a right to healthcare access by human rights activists fueled the fires of a campaign that eventually caused the PMA to withdraw the lawsuit in April of 2001.¹⁴ This right entered the courts again when it was expressly invoked

¹⁰ Universal Declaration of Human Rights, Art. 25 (1), *available at*: <http://www.unhchr.ch/udhr/lang/eng.pdf>.

¹¹ European Constitution Art. II-95, *available at*: http://www.unizar.es/euroconstitucion/library/constitution_29.10.04/part_II_EN.pdf.

¹² Agreement on Trade related Aspects of Intellectual Property Rights, Marrakesh Agreement Establishing the World Trade Organization [hereinafter TRIPS], Annex 1c, Apr. 15, 1994, 33 I.L.M. 1125, 1201 (Article 8) *available at*: http://www.wto.org/english/tratop_e/trips_e/t_agmo_e.htm; World Trade Organization, Ministerial Declaration on the TRIPS Agreement and Public Health of 14 November 2001 [hereinafter Doha Declaration], WT/MIN(01)/DEC/2, 41 I.L.M 746, 746 (¶ 6) (2002) *available at*: http://www.wto.org/english/thewto_e/minist_e/mino1_e/mindecl_trips_e.pdf.

¹³ For more on this issue, compare Kelley, *supra* note 9 (arguing that no such right of access to health care should be recognized) with Wendy E. Parmet, *Health Care and the Constitution: Public Health and the Role of the State in the Framing Era*, 20 HASTINGS CONST. L.Q. 267, 312-19 (1993) (using social contract theory and the early history of public health legislation in the United States to argue that the United States Founders understood government to have an affirmative obligation to provide health care).

¹⁴ Barnard, *supra* note 2, at 165–66; See George Annas, *The Right to Health Care and the Nevirapine Case in South Africa*, 348 NEW ENG. J. MED. 750 (2003) (“Thanks to activists in South Africa, the right to health as a human right has returned to the international stage”); See also S. AFR. CONST. 1996 Art. 27(1), (2) (stating that everyone has a right to access “health care services” and imposing an affirmative obligation on the state to “take reasonable legislative measures” in “the progressive realisation” of this right) , *available at*: <http://www.info.gov.za/documents/constitution/index.htm>.

in the 2002 decision by the Constitutional Court of South Africa invalidating a government policy of restricting access to nevirapine, a drug that reduces mother to child transmission of HIV during delivery.¹⁵ A 2002 decision by the Thai Central Intellectual Property and International Trade Court quashed the attempt by Bristol-Myers Squibb to block generic production of their patented HIV/AIDS drug, didanosine, and explicitly cited this right in its reasoning.¹⁶ Therefore, in the social and legal climate of our times, access to preventative healthcare, if not a right, is at the very least a compelling public interest that may override the obligations imposed by other rights.¹⁷

B. IMPLICATIONS OF A RIGHT TO HEALTHCARE

The principle of a right to access preventative healthcare creates deep tensions with patent rights.¹⁸ The grant of a patent is a limited grant of property rights, which includes the right to exclude others from that property.¹⁹ The right to health care is of a different kind. It is an entitlement to receive a class of goods and services, the core of which is the need of the person asserting it.²⁰ Thus, there is a clash between pharmaceutical patent rights and the claimed right of access to preventative healthcare. Nonetheless, this fundamental tension is often ignored in the access to medicines debate. In a statement before the US Senate, Senator Edward Kennedy opined that “the administration . . . should immediately stop seeking intellectual property protections that prevent access to medicines for all and should start to seek those that promote greater access to medicines for all.”²¹ Attempting to make sense of this statement is extremely difficult. The right to healthcare access cannot be fully and simultaneously enforced with the pharmaceutical patent right. Thus, to the extent that the

¹⁵ *Minister of Health v. Treatment Access Campaign* 2002 (5) SA 721, (10) BCLR 1033 (CC) (S. Afr.).

¹⁶ In deciding the validity of an amendment to the didanosine patent, an amendment which would have hugely expanded the scope of the original claims, the court expressly invoked the Doha Declaration and ideas of a right of access to medicines. *AIDS Access Found. v. Bristol-Myers Squibb*, Central Intellectual Property and International Trade Court, 2002 (10) BC Tor Por 34/2544, RC Tor Por 93/2545; Ford et al., *The Role of Civil Society in Protecting Public Health Over Commercial Interests: Lessons from Thailand*, 363 THE LANCET 560, 560 (2004)

¹⁷ Doha Declaration, *supra* note 12 at 746 (¶ 6).

¹⁸ Kelley, *supra* note 9.

¹⁹ *Id.*

²⁰ *Id.*

²¹ Statement by Senator Edward Kennedy to the US Senate on the DOHA Declaration and the Trade Promotion Authority Act of 2002 pp. S1498–99 (Senate Feb. 16, 2005), available at: http://64.233.169.104/search?q=cache:cMqy6kZfrlQJ:www.twinside.org.sg/title2/FTAs/Intellectual_Property/IP_and_Access_to_Medicines/StatementBySenatorEdwardKennedyToTheUSSenate.doc (html version of .doc file).

international community desires both patent protection and access to medicines, a rights approach necessarily sacrifices one or the other, leading to an impasse.

One could simply do away with the problem by stating that there is a fundamental right of property which precludes the right of access to healthcare insofar as the right of access would require an invasion of the patent right to exclude: “for what property have I in that, which another may by right take, when he pleases, to himself?”²² However, this argument bypasses the problem altogether. As famously articulated by Judge Weintraub in *State v. Shack*,²³ “[p]roperty rights serve human values.”²⁴ Property rights have their origin and justification in the need for allocation of resources among people in light of scarcity.²⁵ As such, the formulation of such rights necessarily hinges on normative determinations involving the weighing of competing interests. In this sense, a right to healthcare access and pharmaceutical patent rights need not be entirely incompatible. Nonetheless, without some framework in which to evaluate these competing rights and duties,²⁶ it is almost impossible to produce reasonable solutions to the tension between an asserted right to healthcare access and the pharmaceutical patent right. In fact, the patent right to exclude is particularly important in the pharmaceutical industry, such that merely advocating increased attention to healthcare as a human rights issue results in a confusing and unsatisfying resolution to the global drug gap problem.

C. THE NEED FOR PHARMACEUTICAL PATENTS

It is axiomatic that in the absence of third parties—such as pharmaceutical companies—capable of providing healthcare, any asserted right to access healthcare becomes inconsequential. Without patent rights, pharmaceutical companies would have little ability to manage the vast enterprise of producing new drugs. The costs are significant: The current cost of producing one new drug is estimated to be approximately 800 million dollars, spread out over a sixteen year development process.²⁷ Much effort goes into the discovery of just one

²² JOHN LOCKE, *SECOND TREATISE OF GOVERNMENT* 125 §140 (C. B. Macpherson ed., Hackett Pub. Co. 1980) (1690).

²³ 277 A.2d 369 (N.J. 1971).

²⁴ *State v. Shack*, 277 A.2d 369, 372 (N.J. 1971).

²⁵ See e.g., Eleanor Leacock, *The Montagnais 'Hunting Territory' and the Fur Trade*, 56 AM. ANTHROPOLOGIST No. 5 Part 2, Memoir No. 78 (1954) (describing how the huge increase in the value of hunting after the advent of fur trade among the Montagnais Indians of Quebec caused a corresponding increase in the negative externalities of free hunting and eventually resulted in a system of land ownership and property rights among the Montagnais).

²⁶ Wesley Newcomb Hohfeld, *Some Fundamental Legal Conceptions as Applied in Judicial Reasoning*, 23 YALE L. J. 16 (1913).

²⁷ Giaccotto, et. al., *Drug Prices and Research and Development Investment Behavior in the Pharmaceutical Industry*, XLVIII J. L. & ECON. 195, 196 (2005) (citing DiMasi et. al., *The Price*

medically promising compound. As of 1994, “[o]nly five out of every 4,000 chemical compounds that pharmaceutical research discover[ed] demonstrate[d] a level of effectiveness sufficient to warrant trial testing on humans . . . [and] only one of 4,000 new chemical compounds discovered in the laboratory [was] ever marketed.”²⁸

The incredible amount of time and money required to produce one patentable drug cannot be recouped in a perfectly competitive market (where goods are sold at a price close to the marginal cost of production).²⁹ Indeed, “only 30% of drug products introduced from 1980 to 1984 generated returns higher than their average after-tax R&D costs,”³⁰ and a 1993 study found that “55% of industry profits came from just 10% of drugs.”³¹ Thus, even with patent protection, many drugs do not return profits once initial investment costs are accounted for. Furthermore, costs besides those arising from research and development efforts must be defrayed through patent rents: “Pharma companies spend about 15 percent of their revenues on research and development, but a much larger portion of expenditures goes to administration, advertising, and promotion, which are also covered by patent rents.”³² Nonetheless, real (i.e. inflation adjusted) drug prices and research and development expenditure are positively correlated, empirically confirming the theory that price increases resulting from patents produce increases in drug innovation efforts.³³ Because of

of Innovation: New Estimates of Drug Development Costs, 22 J. HEALTH ECON. 151 (2003)); F.M. Scherer, *The Pharmaceutical Industry: Prices and Progress*, 351 NEW ENG. J. MED. 927, 928 (Aug. 2004) (citing DiMasi et. al., *The Price of Innovation: New Estimates of Drug Development Costs*, 22 J. HEALTH ECON. 151 (2003)); See Pharmaceutical Research and Manufacturers of America, *Pharmaceutical Industry Profile 2006*, at 2 (Washington, DC: PhRMA, March 2006).

²⁸ Shanker A. Singham, *Competition Policy and the Stimulation of Innovation: TRIPS and the Interface Between Competition and Patent Protection in the Pharmaceutical Industry*, 26 BROOKLYN J. INT’L L. 363, 373 (2000) (citing Alan M. Fisch, *Compulsory Licensing of Pharmaceutical Patents: An Unreasonable Solution to an Unfortunate Problem*, 34 JURIMETRICS J. 295, 302-03 (1994)).

²⁹ Singham, *supra* note 28, at 365; See also ADAM SMITH, AN INQUIRY INTO THE NATURE AND CAUSES OF THE WEALTH OF NATIONS, 129 (Modern Library, Edwin Cannan ed., 1994) (1776) (“Apothecaries profit is become a bye-word, denoting something uncommonly extravagant. This great apparent profit, however, is frequently no more than the reasonable wages of labour. . . . [A] thousand per cent. profit . . . may frequently be no more than the reasonable wages of his labour, charged, in the only way in which he can charge them, upon the price of his drugs. The greater part of the apparent profit is real wages disguised in the garb of profit.”).

³⁰ Singham, *supra* note 28, at 373 (citing Grabowski and Vernon, *Returns to R&D on New Drug Introductions in the 1980s*, 13 J. HEALTH ECON. 238 (1994)).

³¹ Singham, *supra* note 28, at 373 (citing F.M. Scherer, *Pricing, Profits, and Technological Progress in the Pharmaceutical Industry*, 7 J. ECON. PERSP. 86, 97 (1993)).

³² Frederick M. Abbott, *The WTO Medicines Decision: World Pharmaceutical Trade and the Protection of Public Health*, 99 AM. J. INT’L L. 317, 326 (2005).

³³ Giaccotto, *supra* note 27, at 204.

the substantial investment risks and maintenance costs that pharmaceutical companies incur, action “that would reduce patent revenues to Pharma would have the negative effect of reducing the pool of funds for research and development, and inhibiting the development of new drugs that benefit all countries and individuals.”³⁴

Patents may provide other benefits besides simply allowing pharmaceutical innovators to pay the costs of research and development. Indeed, Shanker Singham argues that patents facilitate efficient and non-redundant uses of innovative resources as well as efficient transfers and sharing of knowledge.³⁵ He cites further evidence to suggest that strong patent regimes actually promote healthy competition in the market. According to Singham:

Weak patent regimes, on the other hand, encourage anticompetitive and exclusionary behavior that permits the abuse of monopoly power in defending home markets or in penetrating foreign markets. This manifests itself in a number of different ways: export cartels, predatory dumping in the export of copied drugs, and collusive agreements among firms to divide markets in the internal sale and distribution of copied drugs. Such firms may behave in an oligopolistic manner in which each copycat firm is assigned a particular part of the domestic market. The firms could then enforce their pricing scheme through the threat of disciplining a member of the oligopoly through predatory pricing that would attempt to increase its market share. . . . Indeed the evidence from Argentina, where the average imitation product is actually more expensive than the patented product, strongly suggests price-fixing or other anti-competitive behavior by copycat firms.³⁶

Thus, available data confirms the positive role of patents and strongly suggests that a reduction of patent rights would curtail innovation in the pharmaceutical industry. This would ultimately harm consumers, since it is “better that a drug is available to some rather than nonexistent and available to no one.”³⁷

The right to access preventative healthcare, then, in so far as it depends on the viability of the pharmaceutical industry, also depends in a necessary way on patent protection.

³⁴ *Id.*

³⁵ Singham, *supra* note 28, at 366–68.

³⁶ *Id.* at 377–78.

³⁷ Joseph, *supra* note 3, at 431; *see also*, Singham, *supra* note 28.

III. THE COMPULSORY LICENSING SOLUTION

A. OVERVIEW OF COMPULSORY LICENSING IN THE U.S.

Compulsory licensing is a procedure by which a person (usually a government entity) compels a patent holder to license their patent to a third party. In the United States, the compulsory licensing mechanism has evolved mainly as a tool to combat anticompetitive behavior by patent holders. In the years following the 1890 Sherman Act, courts in the United States viewed antitrust and patent laws as belonging to separate domains with different underlying rationales; thus, they were wary of compelling the licensing of a patent as a remedy for monopolistic behavior (since they saw the patent itself as a temporary monopoly grant).³⁸

This view changed within a few decades,³⁹ such that the Supreme Court's 1952 opinion in *Besser Mfg. v. U.S.*⁴⁰ represents a clear shift towards the application of antitrust reasoning to patents. *Besser* concerned an alleged concrete block cartel which arose because "appellants sought to eliminate competition through outright purchase of competitors and strict patent-licensing arrangements"⁴¹ As part of the remedy, *Besser* was compelled to license some of its patents for a "fair" royalty (where the royalty rate was eventually set by the trial judge).⁴² The Supreme Court upheld the trial court's judgment and affirmed the method of setting the rates as it didn't evidence "glaring error"⁴³ by the lower court. Tellingly, the court noted that "compulsory patent licensing is a well-recognized remedy where patent abuses are proved in antitrust actions and it is required for effective relief."⁴⁴

This trend was reinforced in the Supreme Court's opinion in *U.S. v. Glaxo Group*.⁴⁵ The case concerned a licensing agreement for an antifungal medicine between two British patent holders, Imperial Chemical Industries ("ICI") and

³⁸ Michael Carrier, *Unraveling the Patent-Antitrust Paradox*, 150 U. PA. L. REV. 761, 775 n. 35. (2002), (citing, inter alia, *Nat'l Folding Box & Paper Co. v. Robertson*, 99 F. 985, 989 (C.C.D. Conn. 1900) for the doctrine that a patent infringer can not assert as a defense the claim that the original patent was assigned for the purpose of obtaining a monopoly and exerting control over prices).

³⁹ *Id.*

⁴⁰ *Besser Mfg. v. U.S.*, 343 U.S. 444, 447 (1952).

⁴¹ *Id.*

⁴² *Id.* at 447-48.

⁴³ *Id.* at 448.

⁴⁴ *Id.* at 447.

⁴⁵ 410 U.S. 52, (1973).

Glaxo Group (“Glaxo”).⁴⁶ ICI attempted to apply the terms of its licensing agreements with Glaxo to various licensees in the United States, culminating in a challenge by the United States to the licensing agreement as a violation of the Sherman Antitrust Act as well as a challenge to ICI's patent as invalid for lack of enablement.⁴⁷ After ICI filed an affidavit with the lower court disclaiming any patent defense to its allegedly monopolistic behavior, the court “struck the claims of patent invalidity from the Government's complaint” and reasoned that the patent could not be challenged if ICI chose not to rely on it in defense.⁴⁸ The Supreme Court reversed this part of the lower court's holding, further eroding the barrier between lawful exercise of patents and unlawful monopolistic behavior: “although a patent licensee . . . [is] normally foreclosed from questioning the validity of a patent he is privileged to use, the bar is removed when he alleges conduct by the patentee that would be illegal under the antitrust laws, *absent the patent*.”⁴⁹ In this statement, the *Glaxo* Court severed the consideration of patent validity from the determination of monopolistic behavior on the part of the patent holder.

The relationship between monopolistic behavior and patenting changed under later Federal Circuit jurisprudence which took a more expansive view of the patent “monopoly” right. In the case *In re Independent Service Organizations Antitrust Litigation* (“*Xerox*”),⁵⁰ the Federal Circuit took an approach kinder to patentees and held that patents do confer a general immunity to antitrust actions.⁵¹ The *Xerox* court outlined three exceptions to this immunity, namely cases of: 1) patent misuse⁵² 2) fraudulently obtaining the patent, and 3) engaging in sham litigation. A recent 2006 decision by the Supreme Court⁵³ aligns with this trend in holding that a patent does not give rise

⁴⁶ *Id.* at 53–54.

⁴⁷ *Id.* at 55 & n.4.

⁴⁸ *Id.* at 56.

⁴⁹ *Id.* at 57 (emphasis added).

⁵⁰ 203 F.3d 1322.

⁵¹ “[T]he patent holder may enforce the statutory right to exclude others from making, using, or selling the claimed invention free from liability under antitrust laws.” *Xerox*, 203 F.3d 1322, 1323 (Fed. Cir. 2000)

⁵² Patent misuse occurs when a patent holder engages in conduct that effectively extends the scope of the patent beyond the statutory grant. *Xerox*, 203 F.3d at 1326. This could occur, for example, through “tying” the patented invention to other products outside the patent or through a patentee's control of an “essential facility” which extends monopoly power through many stages of production of a product. *MCI Communications Corp. v. American Tel. and Tel. Co.*, 708 F.2d 1081 (7th Cir. 1983); Burk and Lemley, *Policy Levers in Patent Law*, 89 VA. L. REV. 1575, 1662–63 (2003).

⁵³ *Indep. Ink v. Illinois Tool Works*, 126 S. Ct. 1281 (2006).

to a presumption of market power (for antitrust analysis) and that “[m]any tying arrangements, even those involving patents and requirements ties, are fully consistent with a free, competitive market.”⁵⁴ Thus, under current law in the U.S., it is only under specific, narrowly defined circumstances that a compulsory license remedy can issue against the owner of a valid patent.⁵⁵

Throughout the shifting jurisprudence surrounding this issue, U.S. courts have vacillated between lesser and greater views of patent monopoly rights; but they have always confronted the essential conflict between antitrust and patent law by tending towards the idea that compulsory licensing is a remedy of last resort, to be used only when necessary.⁵⁶ Thus, compulsory licensing in the U.S. is primarily a mechanism to combat allegedly anticompetitive behavior under antitrust law, although there exist statutorily created frameworks for compulsory licensing which look to the public interest.⁵⁷ As articulated under the TRIPS agreement and the Doha Declaration, the desire to inhibit anticompetitive behavior is just one rationale for compulsory licensing. Under TRIPS, compulsory licensing is an option available to all countries so long as they have made good faith efforts to obtain voluntary licensing; and the requirement to make good faith efforts is waived in cases of anticompetitive behavior by the patent owner, public health emergencies, or other situations of great urgency.⁵⁸ In addition to discouraging anticompetitive behavior, TRIPS and the Doha

⁵⁴ *Id.* at 1292.

⁵⁵ See Carrier, *supra* note 38, at 776–77; Singham, *supra* note 28, at 396.

⁵⁶ Singham, *supra* note 28, at 394, 398–99.

⁵⁷ *Id.* Some statutorily created compulsory licensing options are available to the government. For example, under the Bayh-Dole Act, codified at 35 U.S.C. Chapter 18, the government has the right to “march-in” on patent rights (and compel licensing) when those patents result from Federal Funding; under the Clean Air Act, the government can compel licensing of inventions related to fighting air pollution (42 U.S.C §7608); 30 U.S.C. §937 provides exceptions for black-lung related inventions; 42 U.S.C. §2183 provides a compulsory licensing procedures in the case of atomic energy inventions; and under the Federal Insecticide, Fungicide, and Rodenticide Act, firms must provide certain data to the government which is subject to compulsory licensing (7 U.S.C. Chapter 6, § 136). Furthermore, the holding of *Fla. Prepaid Postsecondary Educ. Expense Bd. v. Coll. Sav. Bank*, 527 U.S. 627 (1999) reaffirms the long standing sovereign immunity of State governments with respect to patent and copyright infringement.

The United States issued a compulsory license of the kind contemplated under paragraph 6 of the Doha Declaration in its efforts to prepare for a potential anthrax epidemic. On October 16, 2001, the United States issued a compulsory license to obtain enough ciprofloxacin to treat ten million people. See <http://www.cptech.org/ip/health/cl/us-misc.html>, Compulsory Licensing in the United States.

⁵⁸ TRIPS, *supra* note 12, at 1209–10 (Art. 31) available at http://www.wto.org/english/docs_e/legal_e/27-trips_o4c_e.htm.

Declaration look to a specific public policy concern—that of addressing urgent public needs.

B. COMPULSORY LICENSING: TRIPS & DOHA

The idea of applying the compulsory licensing concept to international trade is at least as old as 1873 when the Vienna Congress proposed the mechanism be used, but only “in cases in which the public interest should require it.”⁵⁹ Thus, compulsory licensing became a feature of the international intellectual property regime when it was formally adopted at the Paris Convention in 1884.⁶⁰ Under the convention, compulsory licenses could be granted in cases where there was a failure to practice (“work”) the invention in the country in which a patent was obtained, where there was anticompetitive pricing, or where public interest might be in conflict with the patent.⁶¹ From its earliest uses in the Vienna convention, the exact or ideal relationship between compulsory licensing and patent rights has been the subject of heated debate.⁶²

The 1994 WTO TRIPS Agreement and the 2001 WTO Doha Declaration struggle with the same tensions between protecting intellectual property rights and recognizing access to healthcare as a compelling public interest. Article 27 of TRIPS grants that “patents shall be available for any inventions . . . in all fields of technology . . . and patent rights enjoyable without discrimination as to the place of invention, the field of technology, and whether products are imported or locally produced.”⁶³ This statement expresses broad support for the creation and enforcement of patent rights. However, this support is susceptible to exceptions. Article 30 of TRIPS allows for exceptions that consider the “legitimate interests of third-parties,” and Article 31 lays out a more detailed specification of how these exceptions will operate. Most importantly, Article 31 contains procedural requirements—the unauthorized user must have (1) made efforts to get authorization from the patent holder (2) on reasonable commercial terms and

⁵⁹ Note, *Reasoned Compulsory Licensing: Applying U.S. Antitrust's "Rule of Reason" to TRIP's Compulsory Licensing Provision*, 36 NEW ENG. L. REV. 669, 674 (2003) (citing Edith Tilton Penrose, *The Economics of the International Patent System*, in THE INTERNATIONAL INTELLECTUAL PROPERTY SYSTEM: COMMENTARY AND MATERIALS PART ONE 635, 635-36 (Frederick Abbott et al., 1999)).

⁶⁰ *Reasoned Compulsory Licensing*, *supra* note 59, at 674–75 (citing Laurinda L. Hicks & James R. Holbein, *Convergence of National Intellectual Property Norms in International Trading Agreements*, 12 AM. U.J. INT'L L. & POL'Y 769, 778 (1997)).

⁶¹ WORLD INTELLECTUAL PROP. ORG. (WIPO), WIPO INTELLECTUAL PROPERTY HANDBOOK: POLICY, LAW, AND USE, 241 (2001)

⁶² See Edith Tilton Penrose, *The Economics of the International Patent System*, in THE INTERNATIONAL INTELLECTUAL PROPERTY SYSTEM: COMMENTARY AND MATERIALS PART ONE 637–40 (Frederick Abbott et al., 1999).

⁶³ TRIPS, *supra* note 12, at 1208 available at: http://www.wto.org/english/docs_e/legal_e/27-trips_04c_e.htm.

conditions (3) which efforts failed (4) after a reasonable time—and substantive requirements—the unauthorized user must pay the patent holder "adequate remuneration" based on the "economic value" of the use.⁶⁴ TRIPS allows the unauthorized user to waive the *procedural* requirements in the case of (i) anticompetitive behavior by the patent holder (ii) a "national emergency," or (iii) other cases of "extreme urgency" (but the substantive requirement of payment of "adequate remuneration" is not susceptible to waiver).⁶⁵ The Doha Declaration clarifies this procedure by explicitly giving Member nations (developed or developing) "the right to grant compulsory licenses" on patents.⁶⁶ The right to grant compulsory licenses, implicit in TRIPS and expressly granted under the Doha Declaration, is further strengthened by the WTO's 2003 declaration regarding implementation of paragraph six of the Doha Declaration.⁶⁷ The 2003 declaration allows countries to compel licensing even for substantially non domestic sales (i.e. where the licensee exports a substantial amount of the drugs to a different country).⁶⁸ These proclamations leave no doubt that the international community views compulsory licensing as an important and necessary mechanism by which patent rights can be compromised to support access to health care.⁶⁹

C. EVOLUTION OF COMPULSORY LICENSING UNDER TRIPS AND DOHA

One of the major early TRIPS disputes to frame the issue of compulsory licensing of pharmaceutical patents concerned the 1997 passage of Section 15(C) of South Africa's Medicines and Related Substances Control Act.⁷⁰ The Act allowed the South African government to import generic versions of patented HIV/AIDS drugs by compelling a license.⁷¹ When a coalition of pharmaceutical companies, the South African Pharmaceutical Manufacturers Association, brought suit in 1998 to challenge the act as non-compliant with TRIPS, activist groups and non-governmental organizations mounted an incessant negative publicity campaign that resulted in the lawsuit's withdrawal in 2001. In the end,

⁶⁴ *Id.* at 1209–10 (Art. 31).

⁶⁵ *Id.*

⁶⁶ Doha Declaration, *supra* note 12, at §5(b).

⁶⁷ Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health (Aug. 30, 2003), Doc. WT/L/540 (Sept. 1, 2003).

⁶⁸ *Id.*

⁶⁹ *See* Abbot, *supra* note 32 (detailing the reasons for and the consequences of the 2003 Declaration).

⁷⁰ Medicines and Related Substances Control Act, Act 90 of 1997, §15(C), *available at*: <http://www.pharmcouncil.co.za/documents/ACT%2090%20OF%201997.pdf>.

⁷¹ *Id.*

pharmaceutical companies donated HIV/AIDS drugs at huge discounts to the South African government to save face.⁷² Although the issue was never litigated, the subsequent 2001 Doha Declaration pointed towards a resolution of the problem by expressly giving all countries the right to grant compulsory licenses in certain circumstances.

The success of activist groups in generating negative publicity towards pharmaceutical companies trying to enforce patents has allowed Brazil to pass legislation arguably in violation of its obligations under TRIPS. Specifically, Art. 68 of Brazil's Industrial Property Act, as passed in 1996, allowed compulsory licensing of patents which are not locally manufactured (i.e. in Brazil) by the patent holder, in contravention of Art. 27 of TRIPS.⁷³ On January 8, 2001, the United States formally filed its request for a dispute resolution panel to resolve the compulsory licensing issue in the Brazilian law.⁷⁴ The resulting negative publicity caused the United States to withdraw the complaint on June 25, 2001,⁷⁵ and the end result of this dispute was a bilateral agreement between the U.S. and Brazil under which Brazil agreed to notify the U.S. before it issues a compulsory license under Article 68⁷⁶ and agreed not to export its generic drugs.⁷⁷ However, Brazilian companies subsequently entered into agreements with Medecins Sans

⁷² Barnard, *supra* note 2, at 163–66.

⁷³ Compare Lei No. 9.279, de 14 de maio de 1996, D.O.U. de 15.05 (Art. 68(1)(I)) 1996 (Brazil), available at: www.jpo.go.jp/shiryousonota_e/fips_e/pdf/brazil/industrial_property_law.pdf (specifying that a compulsory license may be granted in cases where the patent holder does not exploit "the object of the patent within the Brazilian territory" unless it is not "economically feasible" to do so) with TRIPS, *supra* note 12, 33 I.L.M. at 1208 (providing in Art. 27 that "patents shall be available . . . whether products are imported or locally produced") available at http://www.wto.org/english/docs_e/legal_e/27-trips_04c_e.htm.

⁷⁴ Request for the Establishment of a Panel by the United States, *Brazil—Measures Affecting Patent Protection*, WT/DS199/3 9 (January 2001), available at: <http://www.cptech.org/ip/health/c/brazil/Req4EstabPanel.html>; Understanding on Rules and Procedures Governing the Settlement of Disputes, Apr. 15, 1994 Marrakesh Agreement Establishing the World Trade Organization, Legal Instruments—Results of the Uruguay Round, 33 I.L.M. 1125, 1230, (Art. 6.2) (1994) [hereinafter DSU] available at: http://www.wto.org/english/docs_e/legal_e/28-dsu.pdf (see page 358 in this pdf document for Article 6.2).

⁷⁵ Richard Mills, *United States and Brazil Agree to Use Newly Created Consultative Mechanism to Promote Cooperation on HIV/AIDS and Address WTO Patent Dispute*, <http://www.ustr.gov/> (follow "Document Library" hyperlink; then follow "Press Releases" hyperlink; then follow "2001" hyperlink; then follow "June" hyperlink; then follow "United States and Brazil Agree to Use Newly Created Consultative Mechanism to Promote Cooperation on HIV/AIDS and Address WTO Patent Dispute" hyperlink).

⁷⁶ *Id.*; Lazzarini, *supra* note 1, at 123.

⁷⁷ *Id.*

Frontieres (Doctors Without Borders) to purchase drug cocktails in Brazil for trials in South Africa, effectively flouting part of the agreement.⁷⁸

Brazilian efforts to obtain low cost drugs offer a good example of how the compulsory licensing option afforded by TRIPS has changed the dynamics of trade between pharmaceutical companies and developing countries. Brazil has repeatedly used the threat of compulsory licensing to negotiate hugely discounted drug deals on retroviral and antifungal drugs.⁷⁹ For example, when attempts to negotiate a discounted price for nelfinavir (a drug patented by Roche and known as “viracept”) failed, the Brazilian Health Minister announced on August 22, 2001 that Brazil would compel a license for the drug.⁸⁰ Negotiations recommenced immediately on August 28, and concluded in an agreement on August 31 under which Roche sold nelfinavir at an additional discount of forty percent.⁸¹ Around the same time, Brazil’s declared intent to pursue compulsory licensing allowed the country to negotiate a seventy-six percent discount on Atazanavir, a drug patented by Bristol-Myers Squibb, and a twenty-five percent discount on Efavirenz, patented by Merck.⁸² More recently, in March of 2005, Brazil stated its intent to compel licensing on four drugs used in anti AIDS cocktails.⁸³

While Brazil has been perhaps the most aggressive of the developing countries to leverage its compulsory licensing option to its advantage,⁸⁴ other developing countries have availed themselves of the TRIPS compulsory licensing provisions as well.⁸⁵ In almost all of these cases, “adequate remuneration” has

⁷⁸ *Id.*

⁷⁹ Lazzarini, *supra* note 1, at 130.

⁸⁰ *Brazil*, <http://www.cptech.org/ip/health/c/brazil/>.

⁸¹ Roche – Corporate Media News, *Roche and Brazilian Ministry of Health Reach Agreement for Supply of HIV Drug Viracept: Brazilian Government Honors Patent for Viracept*, Aug. 31, 2001, available at: <http://www.roche.com/media-news-2001-08-31-e.pdf#page=1>.

⁸² *New anti-HIV drug deal for Brazil*, BBC NEWS, Nov. 18, 2003, <http://news.bbc.co.uk/2/hi/americas/3281683.stm> (online version).

⁸³ The Brazilian Network for Peoples Integration, *Open Statement of the Civil Society regarding the Brazilian Negotiations for Voluntary License for aids drugs*, May 3, 2005, available at: <http://lists.essential.org/pipermail/ip-health/2005-May/007857.html>; Letter from Joe Wilson, U.S. Congress, 2nd District of South Carolina, to Rob Portman, U.S. Trade Representative, (May 24, 2005), available at: <http://www.cptech.org/ip/health/c/brazil/wilson05242005.pdf>.

⁸⁴ Letter from Ginny Brown Waite, U.S. Congress, 5th District of Florida, to Rob Portman, U.S. Trade Representative, (May 26, 2005), available at: <http://www.cptech.org/ip/health/c/brazil/brown-waite05242005.pdf>.

⁸⁵ For example: on April 5, 2004 the Government of Mozambique issued a compulsory license on three anti AIDS drugs with a royalty rate not to exceed 2% of “the total turnover” of the sale of generics (Salvador Namburete, Deputy Minister Mozambique, Compusory License no. 01/MIC/04, <http://www.cptech.org/ip/health/c/mozambique/moz-cl-en.pdf>); on September 21, 2004, the Republic of Zambia’s Minster of Commerce, Trade, and Industry, issued a compulsory

been calculated to be a royalty fee equaling a nominal percentage (between half a percent and five percent) of the sale of generics.

IV. EVALUATING THE CURRENT STATE OF COMPULSORY LICENSING

A. PROBLEMS WITH COMPULSORY LICENSING

At first sight, compulsory licensing presents an attractive solution to the problem of balancing patent protection and the right to health care access.⁸⁶ It is available only under certain conditions, usually akin to a public health emergency (in the absence of which there must be a good faith effort to negotiate with the patent holder).⁸⁷ Furthermore, there are reasons to be skeptical about the claim that pharmaceutical companies suffer a significant loss from non-payment of patent rents by developing countries. However great their health needs may be, developing countries do not represent a significant market for the pharmaceutical industry. "Africa, the Indian subcontinent, and the poorer countries of Asia total only 1.2%, 1.3%, and 2.6% of the global pharmaceutical market, respectively, and the proportions are even smaller for the sales of patented medicines."⁸⁸ A lack of

license on three anti AIDS drugs with a royalty rate not to exceed 2.5% of "the total turnover" of sales (Dipak K. Patel, Minister, Republic of Zambia Ministry of Commerce, Trade, and Industry, Compulsory License no. CL 01/2004, <http://www.cptech.org/ip/health/c/zambia/zcl.html>); on September 29, 2004, the Malaysian government issued a compulsory license to import four drugs from India for an unspecified royalty rate (Letter from Tan Sri Dato' Muhyiddin Bin Hj. Mohd. Yassin, Minister of Domestic Trade and Consumer Affairs, Malaysia to Director of Operations, Syarikat Megah Pharma & Vaccines, Oct 29, 2003, translated into English *available at*: <http://www.cptech.org/ip/health/c/malaysia/arv-license.html>); on October 5, 2004, the Indonesian government issued a compulsory license for domestic manufacture of two anti AIDS drugs at a royalty rate of 0.5% of net sales (Compulsory Licenses, <http://www.cptech.org/ip/health/cl/recent-examples.html>); on June 5, 2005, the Eritrean Minister of Health issued a general compulsory license for the importation of anti AIDS drugs (<http://www.cptech.org/ip/health/cl/Eritrea.png>); on October 26, 2005, the Ghanaian Minister of Health issued a general compulsory license for the importation of anti AIDS drugs; and on November 29, 2006, the government of Thailand issued a compulsory license on Effavirenz (patented by Merck) at a royalty rate of 0.5% of the total sale of imported and locally produced generics (Announcement of the Department of Disease Control, Ministry of Public Health, Thailand on the Public use of patent for Pharmaceutical Products, *available at*: <http://www.cptech.org/ip/health/c/thailand/thai14efavirenz.html>).

⁸⁶ Compulsory licensing is not the only method used by developing countries to obtain low cost drugs. Another significant method is "parallel importing" or "parallel trading" which takes advantage of the arbitrage opportunity created when a given drug has a variable price in different countries. Barnard, *supra* note 2, at 162–63. For a discussion of the problems created by this practice, see Singham, *supra* note 28, at 407–13.

⁸⁷ TRIPS, *supra* note 12, 33 I.L.M. 1209–10 (Article 31) *available at* http://www.wto.org/english/docs_e/legal_e/27-trips_o4c_e.htm.

⁸⁸ Friedman et al., *Out-licensing: A Practical Approach for Improvement of Access to Medicines in Poor Countries*, 361 THE LANCET 341, 341 (2003).

market demand can also be inferred from the disproportionately low investments made by pharmaceutical companies in producing drugs for developing countries. “Between 1975 and 1999, out of 1,393 new drugs developed, only 13 (less than one percent) were designed to treat tropical diseases, which account for more than 90 percent of the disease burden.”⁸⁹ The evidence overwhelmingly confirms that developing countries are priced out of the pharmaceutical market, which suggests that pharmaceutical companies do not lose significant profits from the issuance of a compulsory license by a developing country (since there would have been little to no sale in the absence of a compulsory license).

Unfortunately, the very reasons which can be marshaled in support of compulsory licenses also suggest the insufficiency of compulsory licensing as a solution to the drug gap problem. Enshrining a right to healthcare access in international proclamations is a meaningless activity if that healthcare does not exist in the first place, and pharmaceutical companies acting in an economically rational way will have little incentive to produce drugs which may be sorely needed in developing countries. Compulsory licensing can actually exacerbate this problem, because “[i]t is simply illogical to assume that a mechanism designed to encourage copying, but not research, would promote R&D for diseases which particularly affect developing countries.”⁹⁰

⁸⁹ Hale, et al., *Oxymoron No More: The Potential of Nonprofit Drug Companies To Deliver on the Promise Of Medicines for the Developing World*, 24 HEALTH AFFAIRS 1057, 1058 (2005) (citing P Trouiller et al., *Drug Development for Neglected Diseases: A Deficient Market and a Public-Health Policy Failure*, 359 LANCET 2188 (2002)).

⁹⁰ Eric Noehrengberg, *Report of the Commission on Intellectual Property Rights, Innovation and Public Health: an industry perspective*, 84 BULL. OF THE WORLD HEALTH ORG. 419, 419 (May 2006); but see Colleen Chien, *Cheap Drugs at What Price to Innovation: Does the Compulsory Licensing of Pharmaceuticals Hurt Innovation?*, 18 BERKELEY TECH. L. J. 853 (Summer 2003) (looking to empirical data to argue that compulsory licensing absent other factors may not hamper innovation). Chien, looking at past studies, concludes that if licenses are *predictable*—i.e. apply to future innovations in a certain area—and *significant*—i.e. result in competition between the licensor and the licensee within markets that are significant to the licensor—then compulsory licensing may reduce innovation. In her own work, she considers six cases from the 1980s and 1990s involving FTC issued pharmaceutical compulsory licenses whose primary goal was not to increase access to medicines, but rather to remedy anticompetitive behavior. She concludes that absent the two factors of predictability and significance, compulsory licensing need not harm innovation. The compulsory licenses considered in this article, specifically pharmaceutical compulsory licenses arising under TRIPS’ public health and national urgency exceptions, are *predictable* in the sense that they cover drugs useful in combating “third-world diseases” such as malaria and HIV/AIDS. However, such licenses are not *significant* insofar as the poverty of third-world consumers ensures that the third world market is not economically significant for large pharmaceuticals. Nonetheless, the problem of drug resale in the “grey market” can create competition between licensors and licensees within significant first world markets. Thus, Chien’s findings do not contradict the proposition that the current compulsory licensing mechanism under TRIPS could pose a risk to innovation in the pharmaceutical industry.

Furthermore, the current compulsory licensing mechanism allows the issuing country's courts to decide what constitutes "adequate remuneration" for the patent holder,⁹¹ subjecting these judgments to enormous political pressures and making it less likely that the rights of patent holders are given due weight. Excessive use of compulsory licensing can have other negative effects, as it may retard the growth of local industry and production in the issuing country.⁹² And finally, compulsory licensing can open the door to an enormous "grey market" in which the generic drugs are sold back into the developed world, eating into sales of the patent holder.⁹³ These lost profits will inevitably reduce innovative work in producing needed medications.

B. PROPOSED SOLUTIONS

Many alternatives have been suggested to resolve the access to medicines problem. Almost all such proposals are of two types: the first type examines the merits of compulsory licensing and either advocates more compulsory licensing or, conversely, stronger patent protection, and the second type looks at the supply side and suggests structural changes within the pharmaceutical industry or new business models for the creation and distribution of drugs.

Some examples are considered which span the range of these possibilities. One student proposal would apply antitrust reasoning (the "rule of reason") to the determination of when a compulsory license should issue. Essentially, under this proposal, the license would be lawful only "if its pro-public health effects outweigh its anti-public health effects,"⁹⁴ a test which the author believes can provide the proper balance between the competing concerns of healthcare and patent rights. Another proposal would enshrine the "legitimate interests" of third parties in receiving access to preventative health care as a fundamental human right and change the discourse in such a way as to produce more compulsory licensing.⁹⁵ This analysis has the benefit of articulating the importance of preventative healthcare as a human value around which patent property rights can be structured, but, as with the "rule of reason" proposal, it lacks the quantitative teeth to guide the creation of an actual mechanism for ensuring that the compulsory licensing mechanism is not abused to the overall detriment of social welfare and innovation. A third approach involves pharmaceutical companies "out-licensing" needed drugs to several generic manufacturers.⁹⁶ The

⁹¹ TRIPS, *supra* note 12, at 1213–14 (Articles 41 and 42) *available at* http://www.wto.org/english/docs_e/legal_e/27-trips_05_e.htm.

⁹² Singham, *supra* note 28, at 378–79.

⁹³ Friedman et al., *supra* note 88, at 341.

⁹⁴ Reasoned Compulsory Licensing, *supra* note 59, at 702.

⁹⁵ Lazzarini, *supra* note 1, at 137–38.

⁹⁶ Friedman et al., *supra* note 88, at 341.

“out-license” would allow several generic manufacturers to compete in developing countries under the condition that they promise not to compete with the patent holder in the developed world.⁹⁷ This proposal has the advantage of directly dealing with the grey market problem; however, it does not fully explain how such non-compete promises are to be enforced or how to set up incentives for countries to follow such promises. Another proposal involves the creation of “non-profit drug companies,” essentially public-private partnerships, which could develop low cost medicines to fight diseases in the developing world.⁹⁸ The creation of such companies could be part of a strategy to close the drug gap; however, this proposal does not address problems in the current compulsory licensing system under TRIPS.

All of these approaches have varying degrees of problems of practical application, coherence, and probabilities of success. While suggestions of this type hold some promise, they do not address procedural and substantive deficiencies in the current TRIPS compulsory licensing remedy. The approach offered in this article is of a different kind. By synthesizing the insights of the human rights scholars regarding the benefits of recognizing a right to healthcare along with the insights of economic scholarship into the problem of drug resale, this article proposes a reinterpretation of the text of TRIPS that leads to a legal procedure which may resolve some of the competing interests driving the access to medicines debate.

V. A DIFFERENT APPROACH

A. PUTTING THINGS IN PERSPECTIVE

Before a proper patent solution to the global drug gap problem can be discussed, it is imperative to assess what impact patents actually have on this gap. Activists urge that pharmaceutical patents are a major cause of limited access to medicines in the developing world, and have intensified the debate with charges of “murder by patent.”⁹⁹ Empirical data however, tells a much different story. A major 2004 study examining the 319 drugs on the World Health Organization’s Model List of Essential Medicines concluded that only seventeen of these are under patent in sixty-five low and middle income countries.¹⁰⁰ In fact, the mean and mode number of patented drugs in any one of the sixty-five

⁹⁷ *Id.*

⁹⁸ Hale, et al., *supra* note 89.

⁹⁹ Friedman, et al., *supra* note 88, at 341 (citing Booker and Minter, *Global Apartheid*, THE NATION, July 9, 2001).

¹⁰⁰ Amir Attaran, *How Do Patents and Economic Policies Affect Access To Essential Medicines in Developing Countries?*, 23 HEALTH AFFAIRS 155, 155 (2004).

countries is four.¹⁰¹ This study calls into question the belief in the activist community that patents are “a barrier in many places to accessing affordable medicines”¹⁰²—a belief which has little basis when patents on essential medicines in developing countries “do not exist 98.6 percent of the time.”¹⁰³ Conversely, the assertion by pharmaceutical interests that patents are necessary to fuel research and development has to be questioned by the finding that with regard to medicines on the World Health Organization's Model List, “companies forgo [patents] 69 percent of the time.”¹⁰⁴ Most pharmaceutical companies are not willing to pursue patents in countries with weak market enforcement mechanisms,¹⁰⁵ and the impact of patents in this area is likely overestimated by both sides of the debate.

The main factors driving this inequity are not patent related, but poverty, political opportunism, and the policies perpetuating underdevelopment in the third world.¹⁰⁶ For example, huge agricultural subsidies in the U.S. and the developed world make it increasingly difficult for poor African farmers to work themselves out of poverty.¹⁰⁷ Such domestically popular measures have massive trade distorting effects which hurt developing countries, a fact which led President Yoweri Museveni of Uganda to remark (somewhat fancifully) that “if there were no agricultural subsidies . . . [Africans] would earn enough money to buy all the drugs we want.”¹⁰⁸ “Denial and incompetence on the part of government officials”¹⁰⁹ in the developing world has exacerbated and perpetuated problems as well. Thabo Mbeki, the President of South Africa, has publicly questioned the link between HIV and AIDS, expressed doubts about the

¹⁰¹ *Id.* at 158. Of course, patents in first world countries may still contribute to problems by raising the price of such drugs when no domestic pharmaceutical capacity exists in a country experiencing a health crisis. Nonetheless, this study does suggest that the role of patents in limiting access to medicines has been overstated.

¹⁰² Friedman, et al., *supra* note 88, at 341 (citing Médecins sans Frontières, Canadian HIV-AIDS Legal Network, Oxfam Canada, Interagency Coalition on AIDS and Development, Canadian Council for International Cooperation, Canadian Treatment Action Council, *An open letter to all members of parliament*, October 25, 2001, available at: http://www.msf.ca/access/pics/msf_letter_par_e.pdf).

¹⁰³ Attaran, *supra* note 100, at 158.

¹⁰⁴ *Id.*

¹⁰⁵ *Id.*

¹⁰⁶ *Id.* at 163.

¹⁰⁷ Richard Mshomba, 16 AFRICA RECOVERY 29, 29 (2002) (now AFRICA RENEWAL) available at: <http://www.un.org/ecosocdev/geninfo/afrec/>.

¹⁰⁸ Attaran, *supra* note 100, at 163 (citing Editorial, *Africans for Drug Patents*, WALL ST. J. (November 2003)).

¹⁰⁹ Barnard, *supra* note 2, at 167.

effectiveness of antiretroviral therapy, and has been willfully slow in formulating a national plan to deal with the health crisis.¹¹⁰ Even worse, some developing countries impose tariffs on imported pharmaceuticals in a short-sighted attempt to raise revenues, making it even more difficult to get affordable medicines to disease sufferers.¹¹¹ This lack of political will to deal with an ongoing crisis retards efforts to make needed changes that can help HIV/AIDS sufferers. Thus, the politics of poverty, and not patent protection, is the prime culprit in restricting access to needed medicines in the developing world.

Nonetheless, it should not be assumed that patents have no effect on access to medicines. A closer look at the seventeen essential drugs under patent reveals that many of these therapies are for HIV/AIDS.¹¹² Patents do contribute to the problem of restricted access to essential medicines in the case of HIV/AIDS, which is a relatively new disease. This is a specific example of a general phenomenon. In general, a patent contribution to the global drug gap can occur under a confluence of a set of factors, namely: 1) an epidemic of a relatively new disease 2) in poor countries 3) where most citizens cannot afford the high price of a patented drug 4) and where most of the drug treatments are still under patent. The remedy should not be an attack on pharmaceutical patenting or patent rights in general, but rather a targeted effort to address this specific type of situation and other such situations in which patents overly restrict access to needed medicines.

B. THE NEW PROPOSAL: GIVING MEANING TO "ADEQUATE REMUNERATION"

TRIPS requires that when a compulsory license is issued, "the right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization."¹¹³ One of the problems with the current compulsory licensing mechanism is the confusion surrounding the determination of "adequate remuneration." There has been little to no effort to develop distinct procedures to deal with anticompetitive behavior on the one hand and public health needs on the other. But the problem which must be addressed is often not one of antitrust—where there is anticompetitive behavior by the patent holder—but of urgent public need—where the patent holder need not be a commercially bad actor. This confusion between monopolistic patent

¹¹⁰ *Id.* at 161.

¹¹¹ Richard Trem, *Comment: Taxing Africa to Death*, SOUTH AFRICAN INSTITUTE OF INTERNATIONAL AFFAIRS, (June 2005) available at: http://www.saiia.org.za/index.php?option=com_content&view=article&id=468:commenttaxingafricatodeath&catid=74:effrica.

¹¹² Attaran, *supra* note 100, at 157.

¹¹³ TRIPS, *supra* note 12, at 1125 (Article 31(h)) available at http://www.wto.org/english/docs_e/legal_e/27-trips_o4c_e.htm.

behavior and legitimate patent use results in a lack of well defined procedures and can unfairly punish pharmaceutical companies, undermine their legitimate patent interests, and arguably result in a net social loss from reduction of innovation.¹¹⁴

Instead of mandating a royalty payment (under TRIPS' adequate remuneration provision) equal to a nominal percentage of sales of generic drugs in all cases, one could address the problems created by each situation differently. In the case of urgent public health needs, the "economic value of the authorization" on which adequate remuneration is based can be plausibly interpreted as the expected value of the authorization *to the patent holder*. This would protect the patent holder in a non antitrust situation by attempting to compensate the holder for some of the loss suffered by issuance of the license. This approach could assuage the ongoing tensions between the needs of citizens in developing countries and the rights of pharmaceutical patentees by properly accounting for the interests of both parties.

Potential Problems With the Proposal.— One could object that it does not make sense to read the same text as prescribing a royalty rate in one instance (anticompetitive behavior by the patent holder) and a different procedure in another instance (a license compelled by urgent public need). This objection is somewhat formalistic, as there is no practical reason why the same procedure must be utilized when the relationship and behavior of the parties are radically different. Furthermore, there is evidence within Article 31 of TRIPS that anticompetitive behavior and public need are to be treated differently in the context of calculating adequate remuneration. Specifically, Article 31(k) states that anticompetitive behavior "may be taken into account" in determining the amount of adequate remuneration to be paid.¹¹⁵ Implicitly then, the absence of anticompetitive behavior could (indeed should) change the determination of adequate remuneration.

One could also object that adopting this measure will lead to exorbitant payments on the part of licensees to patent holders in cases of urgent public need. While it is true that the remuneration to be paid will likely (but not necessarily) be greater than the standard 0.5–5% royalty currently being paid in such cases, the compensation will not be unreasonably high, as the calculations below will demonstrate.

¹¹⁴ Singham, *supra* note 28, at 405; See also Hughes et al., "Napsterizing" *Pharmaceuticals: Access, Innovation, and Consumer Welfare*, NBER Working Paper No. 9229 (2002) (performing an economic thought experiment in which all patent protection for pharmaceuticals is erased and finding that for every dollar saved by the current generation in reduced prices of drugs, three dollars would be lost to future generations in reduced innovation and lack of new drugs coming into the market).

¹¹⁵ TRIPS, *supra* note 12, at 1125 (Article 31(h)) available at http://www.wto.org/english/docs_e/legal_e/27-trips_04c_e.htm.

Calculating “Adequate Remuneration.”— In order to implement this proposal, it must be possible to reasonably estimate the direct economic impact to the patentee that occurs because of the issuance of a license.¹¹⁶ The calculation presented is necessarily schematic and is offered as an illustrative example—a detailed consideration of the extensive case law and literature on lost profits calculations in patent infringement cases (including market share and price erosion damages) in relation to the topic at hand is beyond the scope of this article.¹¹⁷

In this hypothetical calculation, I first consider the case where the resale rate is high. I will consider fluconazole, mentioned earlier in this article, and calculate the impact to Pfizer of a hypothetical compulsory license for fluconazole under a but-for causation test. As noted before, the 1999 price of this drug was U.S. \$9.34 per dose, while the price of a generic equivalent produced in Thailand was U.S. \$0.60 per dose.¹¹⁸ Suppose that under these price conditions, the South African government licenses a Thai Manufacturer to export “x” doses of a generic version into South Africa. Almost all of Pfizer's loss arises through resale of this drug to first world consumers who would have purchased the brand name drug instead.¹¹⁹ Available data suggests that at least a third of these doses will resell.¹²⁰

¹¹⁶ The calculation presented can be conceptualized as follows: 1) we assume that in exchange for low priced generic drugs, the country requesting the license agrees to enter into an implied “no-resale” contract with the patentee, under which the country obtaining the license agrees not to resell the imported generics into the patent holder’s protected markets and undercut its price in those markets; and 2) we presume that this agreement is breached by the licensee country (the presumption is rebuttable) and calculate damages from the contract breach as the “adequate remuneration” due. The patentee receives restitution damages since expectation damages are uncertain. *Chicago Coliseum Club v. Dempsey*, 265 Ill.App. 542 (Ill.App. 1 Dist.1932). See Roger Pilon, *Drug Reimportation: The Free Market Solution*, 541 POLICY ANALYSIS (CATO INSTITUTE) 1 (2004) (urging that no-resale contracts be implemented to foster a differential pricing mechanism and resolve the access to medicines problem).

¹¹⁷ However, such developments in techniques of lost profits calculations can be easily integrated with the proposal in this article, which is, ultimately a lost profits approach. For an example of this literature, see Roy J. Epstein, *The Market Share Rule With Price Erosion: Patent Infringement Lost Profits Damages After Crystal*, 31 AIPLA Q.J. 1 (2003), available at: http://www.royepstein.com/Epstein_AIPLA_Winter2003.pdf.

¹¹⁸ Barnard, *supra* note 2, at 162.

¹¹⁹ I will set aside the nominal profits which Pfizer could have made in the South African market in the absence of the license, essentially equating them to zero. This assumption is made to ease the burden of the calculation, but it does not overly jeopardize the accuracy of the approximation—the per case public expenditure on AIDS in South Africa in 2000 totaled a mere ten dollars. Barnard, *supra* note 2, at 163 (referencing UNAIDS, *Socioeconomic Impact of HIV/AIDS in Africa*, available at: http://www.unaids.org/publications/documents/economics/agriculture/ADF_slides2.ppt; University of California at San Francisco, *HIV InSite*, available at: <http://www.hivinsite.ucsf.edu>).

¹²⁰ Friedman et al., *supra* note 88, at 341.

I will assume that a total of half, or “ $x/2$ ” doses never reach the African market because they are resold. However, Pfizer does not lose money on all of these resales, since many consumers who buy the grey market drug purchase it precisely because they are unwilling or unable to afford the patented drug. I will assume that half of the consumers who purchase the generic would have bought a brand name instead, so Pfizer's loss comes from “ $x/4$ ” doses.¹²¹ Then, one must consider the fact that fluconazole will have brand name competitors, “me too” drugs¹²² (close substitutes) which these grey market purchasers might have purchased instead. So we must discount the calculation by the market share of fluconazole in 1999. Let us generously assume that fluconazole had a one-half market share in its therapeutic class.¹²³ Finally, one must discount the result by the price-cost margin (since Pfizer would have incurred costs on the manufacture of drugs for sales that would have been made in absence of the license). Again we will be generous in assuming that this margin is very high, say 0.75.¹²⁴ (In order that this example not become overly complex, price erosion damages are not included in this calculation.)

So, to recap: “ $x/2$ ” drugs are resold on the grey market, half of these, or “ $x/4$ ” doses, are sold to consumers who would have bought brand name drugs but for the existence of the generic, of these, one half, or “ $x/8$ ” are sold to consumers who would have purchased fluconazole, and these sales are discounted by the price-cost margin to give a total loss to Pfizer of U.S. $$(9.34 * 0.75)/8 =$ U.S. $$(7.005/8 =$ U.S. $$(0.88$ per dose sold. (All estimates were resolved in favor of increasing the royalty payment to intentionally create an overestimate.) Thus, the Thai company must pay Pfizer eighty-eight cents per dose that they sell in the South African market. They could recoup this cost by selling their generic at a price of U.S. $$(1.44$ per dose, still significantly less than the price of the patented

¹²¹ Unfortunately, I do not know where to obtain reliable data on this figure. I believe that this is an overestimate (since of the people who would purchase drugs semi-illicitly through transactions on the gray market, most are likely to lack the means to purchase a brand name drug), but I cannot be sure.

¹²² Kessler et al., *Therapeutic-Class Wars – Drug Promotion in a Competitive Marketplace*, 331 NEW ENGLAND J. MED. 1350, 1350 (Nov. 1994).

¹²³ I have been unable to obtain exact data on the market share of fluconazole in 1999. However, other studies suggest that fifty percent is very high. Lipitor, one of the most prescribed drugs in the world, commanded a 2001 market share in the U.S. of just over fifty percent. Blankenhorn and Lipson, *Despite Economic Challenges, Pharmaceutical Industry Maintains Steady Growth*, MEDICAL MARKETING & MEDIA 46 (2002) available at: http://www.imshealth.com/vgn/images/portal/cit_759/2006112572bus2.pdf.

¹²⁴ This is a very high price-cost margin. A standard estimate of price-cost margins in the pharmaceutical industry as a whole places the figure between 0.59 and 0.67. Linnosmaa, et al., *Price-Cost Margin in the Pharmaceutical Industry: Evidence from Finland*, 5 EUR. J. HEALTH ECON. 122, (2004).

drug (U.S. \$9.34 per dose). Alternatively, the Thai company may choose to allocate some of the cost to itself to reduce the price.

Now I consider an alternate scenario, where the resale rate is controlled. Suppose the South African government sets up a transparent acquisition agency, with procedures to monitor the quantity of generics, procedures to identify the imported generics, and procedures to enforce their distribution and prevent resale.¹²⁵ Suppose that, as a result of these procedures the resale rate drops from fifty percent to ten percent. This will reduce the remuneration by a factor of five, from U.S. \$0.88 per dose to U.S. \$0.18 per dose. If this cost of remuneration is borne entirely by the South African government, the price of the imported generics will be a mere U.S. \$0.78 per dose (compare to the U.S. \$9.34 of the patented fluconazole, or the U.S. \$1.44 in the absence of these regulations). Alternatively, the costs may be allocated between the Thai provider and the South African government, further reducing the cost to the South African government.

Resolving Disputes.— Of course, it is impossible to know *ex ante* exactly how much a patent holder will gain or lose from the issuance of a license; but each party (i.e. the patent holder and the government) can provide estimates based at least partly on known data. The existence, for example, of a healthy regulatory regime in a developing country which would prevent resale of the generic drugs into first world markets could be used by the developing country to negotiate better licensing terms. On the other hand, a lack of enforcement could be cited by the pharmaceutical company to claim greater damages. The fact that these questions are essentially questions of mathematics and economics (to the extent that there is available data), means that some disputes about adequate remuneration could be resolved by arbitration or dispute resolution panels rather than needing to go through the full process of judicial scrutiny.

Currently under TRIPS, the grant of a compulsory license and the determination of a royalty rate is a combined process which is appealed through the domestic courts in the country requesting the license.¹²⁶ This makes the process vulnerable to political pressures arising from domestic interests, international activist groups, and pharmaceutical lobbying, and may compromise the independence of the judges making these decisions or otherwise place political pressures on judiciaries. Thus, it would arguably be beneficial, although not necessary, that some disputes over lost profits payments could be heard instead by a dispute resolution panel that would ultimately decide what adequate remuneration is due. The panel could first determine whether the license is remedying anticompetitive behavior (in this case using the normal procedure) or

¹²⁵ See Salvador Namburete, Deputy Minister Mozambique, Compusory License no. 01/MIC/04, <http://www.cptech.org/ip/health/c/mozambique/moz-cl-en.pdf>.

¹²⁶ TRIPS, *supra* note 12, at 1213–15 (Articles 41 and 42) available at http://www.wto.org/english/docs_e/legal_e/27-trips_05_e.htm.

remedying an urgent public need (in which case they would look at economic harm to the patentee). This process could utilize pre-existing WTO dispute resolution mechanisms.¹²⁷

C. BENEFITS OF THIS PROPOSAL

One of the obvious benefits of this proposal is the way it allocates incentives. The pharmaceutical companies have incentives not to use the price of the patented pharmaceutical to extract excessive remuneration for licenses: either the competitive first world market for brand name drugs will discipline prices, or, in the absence of a competitive market, antitrust concerns will trigger a much lower remuneration payment. Likewise, developing countries and the generic producers who supply their markets will have greater incentives to create practical enforcement mechanisms to prevent parallel trade: the reliability of these enforcement mechanisms correlates directly with savings in drug purchases, theoretically allowing a licensee to obtain the generic for no royalty payment at all. Finally, the availability of an appeal to a dispute resolution panel (rather than the judiciary of a country whose government is compelling a license) will encourage good faith efforts between licensors and licensees to come to voluntary licensing agreements on terms which do not overly harm patentees. This will transform many licenses from compulsory to voluntary, assuaging some of the tensions between the activist community and the pharmaceutical industry.

A less obvious benefit is that the remuneration due to a patent holder will naturally correlate to the wealth of the country compelling the license. In countries in which poverty ensures the domestic market for drugs is essentially nonexistent, losses in the domestic market will be nominal and not factor into payment.¹²⁸ Conversely, if a wealthy country were to compel a license for a public emergency (as actually occurred On October 16, 2001 when the United States issued a compulsory license on ciprofloxacin in anticipation of a potential anthrax epidemic),¹²⁹ payments due to the patentee would also take into account loss of sales in that country's market. This leads to an equitable result where payment due naturally correlates with the licensee's ability to pay.

¹²⁷ DSU, *supra* note 74, (Articles 6–8) available at: http://www.wto.org/english/docs_e/legal_e/28-dsu.pdf (see page 358 in this pdf document); TRIPS, *supra* note 12 at 1221 (Article 64) available at: http://www.wto.org/english/docs_e/legal_e/27-trips_07_e.htm.

¹²⁸ See *supra*, note 116 and accompanying text.

¹²⁹ <http://www.cptech.org/ip/health/cl/us-misc.html>, Compulsory Licensing in the United States.

VI. CONCLUSION

The problem of access to pharmaceuticals is only one part of a growing clash between property rights and human rights on the international stage. Increasingly, many goods (e.g. clean water and food) are claimed as “essential” under the rubric of human rights.¹³⁰ As these claims are in inherent conflict with certain traditional property rights, particularly patent protection, it becomes incumbent upon policy makers to understand the true nature of the debate. The problems, it seems, stem less from patenting than they do from poverty and political opportunism—with policies in both the developed and the developing world complicit in the continued economic distress of the world’s impoverished. Compromising patent protection to aid the world’s poor may provide a short term palliative effect, but it will have the long term result of reducing incentives to find solutions to existing problems. Setting aside the need to protect property rights, this chilling effect on socially beneficial innovations could be so harsh as to be unacceptable from a social welfare perspective.

Nonetheless, patents and their potential to restrict access to needed goods should not be ignored in the efforts to alleviate poverty and suffering. In the area of pharmaceutical patents, specifically in the case of a relatively new disease which causes a pandemic in the developing world, patents can be a barrier to obtaining efficacious treatment options for impoverished sufferers. In such cases, the model proposed in this article attempts to maintain the delicate balance between ensuring that drug development continues and providing access to needed health care to countries in crisis.

¹³⁰ S. AFR. CONST. 1996 Art. 27(1)(b), (2), available at: <http://www.info.gov.za/documents/constitution/index.htm>; See Kevin Watkins, *Clean Water is a Human Right*, INT’L. HERALD TRIBUNE, available at: <http://www.ihl.com/articles/2006/11/10/opinion/edwatkins.php>.