

The Impact of Compulsory Licensing on Foreign Direct Investment: A Collective Bargaining Approach

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I. INTRODUCTION

The need to facilitate access to essential medicines for those with life-threatening or fatal diseases like HIV, tuberculosis, and malaria has generated significant interest. Yet, an inevitable tension exists between the need for pharmaceutical companies to profit from their patented inventions and the desire to provide access for impoverished persons. Developing nations have attempted to resolve this tension through the issuance of patent compulsory licenses — authorizations for government-approved generic copies¹ — so that those in need of the most important new treatments can obtain them at an affordable price.²

However, the practice of compulsory licensing comes with a price: the temporary or permanent deprivation of some part of a patent owner's right to exclude disrupts the investment-backed expectation of the property right. In the future, pharmaceutical companies and other industries dependent upon intellectual property rights may mistrust licensing nations' promises to protect and enforce patent rights, not to mention copyrights, and trademarks. As a result, industries that find the security of property rights lacking in a given nation may avoid engaging in foreign direct investment with that nation. Because foreign direct investment ("FDI")³ is

¹ The term "compulsory license" can refer to any compelled relaxation of an intellectual property owner's right to exclude in exchange for a licensee's payment. Generally, it is used in the context of an unexpected, *ex post* deprivation of property rights in response to some emergent need. See Daniel R. Cahoy, *Confronting Myths and Myopia on the Road from Doha*, 42 GA. L. REV. 131, 141-145 (2007); Jerome H. Reichman & Catherine Hasenzahl, *Non-Voluntary Licensing of Patented Inventions*, UNCTAD-ICTSD Issue Paper No. 5, at p. 10 (2004), available at http://www.ictsd.org/pubs/ictsd_series/iprs/CS_reichman_hasenzahl.pdf. The term could also be used to refer to a remedial measure in antitrust law (United States v. Besser Mfg. Co., 343 U.S. 444, 447 (1952) (compulsory licensing is "a well-recognized remedy where patent abuses are proved in antitrust actions and it is required for effective relief.")), an *ex ante* IP limitation such as the copyright phonorecord compulsory license (17 U.S.C. § 115 (2000)) or even a court's refusal to grant permanent injunctive relief in favor of continued royalty payments (see Jessica E. Vascellaro, *Vonage Can Sign Up Users During Appeal*, WALL ST. J., Apr. 25, 2007, at A11). Due to its social importance and, as described *infra*, its great ability to impact foreign direct investment, the "emergent need" context is the primary focus of this article's discussion.

² See, e.g., James Hookway & Nicholas Zaminska, *Harsh Medicine: Thai Showdown Spotlights Threat to Drug Patents*, WALL ST. J., Apr. 24, 2007, at A1 (describing Thailand's imposition of several patent compulsory licenses in order to provide low-cost medicines to its citizens).

³ Foreign direct investment can be defined as a firm's transfer of assets from one country to another in order to generate wealth for the owner of the assets. See Joshua

a major potential source of economic growth for recipient nations, the loss of such investment resources arising from compulsory licensing practices could force developing nations to pay a particularly heavy cost for providing needed medicines for its citizens.

This article examines the interrelationship between the issuance of compulsory licenses for essential medicines and the influx of FDI. Specifically, it explores the potential for collective action and bargaining on the part of licensing nations to minimize FDI losses while preserving access. Middle-developed countries such as Egypt and Brazil are highlighted to demonstrate the extent to which nations with differing abilities to resist political pressure can influence FDI losses. The article concludes by presenting optimal negotiating strategies for nations wishing to impose compulsory licenses. It demonstrates the effectiveness of the strategies using a unique game theory framework that models real-world licensing decisions.

II. A SIMPLE DYNAMIC: THE RELATIONSHIP BETWEEN PATENT COMPULSORY LICENSES AND FOREIGN DIRECT INVESTMENT

Intellectual property rights at their core are investment-inducing mechanisms.⁴ The idea is to trade limited market exclusivity for the increased production and disclosure of useful goods, research or services.⁵ Not surprisingly, strict innovation investment may be accompanied by substantial parallel investment in business facilities and personnel, amplifying the effect of the rights on economic development.⁶ In developing countries, a significant amount of such investment may come from outside the country, stimulating the growth of local industry beyond

Robbins, *The Emergence of Positive Obligations in Bilateral Investment Treaties*, 13 U. MIAMI INT'L & COMP. L. REV. 403, 406-07 (2007).

⁴ See, e.g., SUZANNE SCOTCHMER, INNOVATION AND INCENTIVES 43-39 (2004) (explaining the rationale for intellectual property rights in terms of providing a mechanism for recouping investment that would otherwise be lost to free riders).

⁵ *Id.*

⁶ Bronwyn H. Hall, *The Private and Social Returns to Research and Development*, in TECHNOLOGY, R&D, AND THE ECONOMY 140, 140-41 (Bruce L.R. Smith & Claude E. Barfield eds., 1996) (summarizing positive spillover effects from innovative activity); Roberto Mazzoleni & Richard R. Nelson, *Economic Theories About the Benefits and Costs of Patents*, 32 J. ECON. ISSUES 1031, 1033 (1998); Robert W. Hahn, *The Economics of Patent Protection: Policy Implications from the Literature* 14-37 (2003), http://papers.ssrn.com/sol3/papers.cfm?abstract_id=467489.

that which would be possible through endogenous investment alone.⁷ It is this broad impact on a country's economic wealth that purportedly justifies the global establishment of strong intellectual property regimes.⁸ Strong rights should lead to greater investment, all things being equal.⁹

Yet, there remain great differences in intellectual property rights between countries,¹⁰ suggesting that the investment incentives can be different as well. Moreover, flexibilities inherent in international intellectual property agreements permit the relaxation of rights in certain circumstances.¹¹ The imposition of a compulsory license — explicitly endorsed in international law¹² — is one of the most significant reductions in rights, and it has great potential to impact both local and foreign investment practices. Nowhere is this relationship more visible than in the context of the invention and delivery of essential medicines. Factors such as the amount of investment at stake, dependence on intellectual property rights, great likelihood of rights reduction, and social importance combine

⁷ Margaret Chon, *Intellectual Property and the Development Divide*, 27 CARDOZO L. REV. 2821, 2863 (2006) (“Foreign direct investment is thought to be an optimal way for developing countries to increase their knowledge capacity, technical innovation and ultimately their economic growth.”).

⁸ Convincing countries of this benefit has taken some effort on the part of developed countries. See Peter Yu, *TRIPS and Its Discontents*, 10 MARQ. INTELL. PROP. L. REV. 369, 375-76 (2006) (describing an “ignorance narrative,” in which developing countries were convinced to adopt TRIPS protections for intellectual property because of their inability to see the benefits of doing so unilaterally); Robert C. Bird, *Defending Intellectual Property Rights in the BRIC Economies*, 43 AM. BUS. L.J. 317, 319-29 (2006) (describing coercion on the part of developed nations as a primary reason for the adoption of intellectual property rights by developing countries).

⁹ In fact, the evidence supporting this proposition is a bit muddled due to the complex interaction of a number of factors. See Keith Maskus, *Intellectual Property Challenges for Developing Countries: An Economic Perspective*, 2001 U. ILL. L. REV. 457, 464-66 (2001).

¹⁰ See Jerome Sgard, *Are There Such Things as International Property Rights?*, 27 WORLD ECON. 387, 388 (2004) (suggesting that variations in national property rights regimes are an obstacle to globalization and stating that “[a] series of empirical elements suggest that the institutions, which define and enforce property rights, tend to remain strongly attached to the legal and judicial framework of each country: their resistance to convergence is apparently strong.”).

¹¹ See, e.g., World Intellectual Property Organization (“WIPO”), *Advice on Flexibilities Under the TRIPS Agreement*, http://www.wipo.int/ip-development/en/legislative_assistance/advice_trips.html (last visited Dec. 8, 2007).

¹² Agreement on Trade-Related Aspects of Intellectual Property Rights, art. 31, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, Legal Instruments—Results of the Uruguay Round, 33 I.L.M. 81 (1994) [hereinafter TRIPS].

to create a useful framework for study.

A. Public Health, Compulsory Licenses and the Innovation Feedback Loop

Public health has emerged as a major international political priority because it has become ever clearer that improving the health of a nation's citizens provides economic and moral rewards.¹³ Such impacts justify great expenditures because rampant disease can have demonstrable effects on a nation's health, economic stability,¹⁴ and national security.¹⁵ Importantly, these problems are no longer country-specific; public health issues reach across international boundaries. In a physical sense, modern air travel permits diseases to spread more easily than ever, making one country's crisis a potential concern to all.¹⁶ In an economic sense, the extreme disease burden of a particular country or region removes

¹³ See, e.g., David E. Bloom & David Canning, *The Health and Wealth of Nations*, 287 SCIENCE 1207, 1207 (2000) (describing empirical work demonstrating that health improvements stimulate economic development); Michael A. Santoro, *Human Rights and Human Needs: Diverse Moral Principles Justifying Third World Access to Affordable HIV/AIDS Drugs*, 31 N.C. J. INT'L L. & COM. REG. 923, 932-33 (2006) (discussing the moral benefits to human betterment).

¹⁴ WHO, COMM'N ON MACROECONOMICS & HEALTH, MACROECONOMICS AND HEALTH: INVESTING IN HEALTH FOR ECONOMIC DEVELOPMENT 22-25 (2001) [hereinafter MACROECONOMICS & HEALTH] (stating that the economic costs of avoidable disease are "staggeringly high" and result in losses of "dozens of percent of GNP of the poorest countries each year"), available at <http://whqlibdoc.who.int/publications/2001/924154550X.pdf>; John L. Gallup & Jeffery D. Sachs, *The Economic Burden of Malaria*, 64 AM. J. TROPICAL MED. HYG. 85, 91 (2001) ("Countries with severe malaria in 1965 had much lower economic growth, amounting to 1.3% lower growth per year, even after other factors such as initial income level, overall health and tropical location are taken into account."). There is perhaps no better illustration than the global AIDS crisis. Its medical care costs sap precious financial resources and create real deficits in labor capital. See Anthony S. Fauci, *The AIDS Epidemic – Considerations for the 21st Century*, 341 N.E. J. MED. 1046, 1047 (1999) (noting that the estimated economic burden of HIV infection is \$14 billion for costs associated with prevention and treatment).

¹⁵ See S.C. Res. 1308, U.N. Doc. S/RES/1308 (July 17, 2000), available at <http://domino.un.org/UNISPAL.NSF/eed216406b50bf6485256ce10072f637/f897cd0e6cc680da85256d3b006a37d3!OpenDocument> ("Stressing that the HIV/AIDS pandemic, if unchecked, may pose a risk to stability and security").

¹⁶ See, e.g., WHO, WORLD HEALTH REPORT 2003 79-80 (2003) (describing the significance of air travel in the spread of SARS, and the need to impose travel restrictions in the case of future epidemics), available at http://www.who.int/whr/2003/en/whr03_en.pdf.

resources that could otherwise be used in global trade.¹⁷ And in a social sense, the prospect of profound human suffering compels nominally self-interested parties to care and participate in its alleviation.¹⁸ The international community has therefore searched for solutions through various organizations that target public health issues.

In large part, medical science has responded to the need. Recent advancements in pharmaceuticals and biotechnology provide the possibility of reducing or eliminating a number of the world's most dread diseases. Millions of lives have likely been saved due to modern medical technology.¹⁹ But the development of these medicines comes at a cost. It is estimated that global medical research and development funding was over \$100 billion in 2001.²⁰ Of this total, approximately forty-four percent was provided by the public sector in the form of funds flowing to government research entities like the U.S. NIH or government grants provided to private entities.²¹ The remaining fifty-six percent is provided

¹⁷ MACROECONOMICS & HEALTH, *supra* note 14, at 38.

¹⁸ See generally Nancy Gibbs, *Persons of the Year*, TIME, Dec. 26, 2005, at 38 (naming Bono, Bill Gates and Melinda Gates Time Magazine's Persons of the Year for their efforts to alleviate global poverty and disease).

¹⁹ Diseases that once appeared unshakable scourges to humanity like polio, smallpox and leprosy have now been eliminated or controlled to the level that few people give them a second thought. See, e.g., WHO, WORLD HEALTH REPORT 2004 85, ann. tbl. 2 (2004) (hereinafter, "WHO HEALTH REPORT") (describing the polio eradication programs in the context of collaborative efforts to address the AIDS crisis, and showing in tabular form that polio and leprosy account for an almost immeasurable percentage of the world's disease burden, with smallpox not evident at all), *available at* http://www.who.int/entity/whr/2004/en/report04_en.pdf. See also WHO, LEPROSY ELIMINATION PROJECT: STATUS REPORT 2003 7 (2003) (noting that leprosy was eliminated as a public health problem at the global level in 2000). Infant mortality rates in most countries are so low that death is an unexpected asterisk rather than a substantial probability. See, e.g., WHO HEALTH REPORT at 156. We live longer with less chronic illness and pain. *Id.* at Ann. Tbl.4 (statistical evidence of Healthy Life Expectancy (HALE), which is dramatically higher in high income countries). Even "senility," once thought to be an inevitable consequence of aging, has been characterized as a specific neurological disorder that could potentially be cured. Advances in health care have truly redefined what it means to live a human life. See, e.g., WHO, WORLD HEALTH REPORT 1999 1-3 (1999) ("[T]he 20th century health revolution appears to have resulted far more substantially from the generation and application of new knowledge."), *available at* http://www.who.int/entity/whr/1999/en/whr99_en.pdf.

²⁰ GLOBAL FORUM FOR HEALTH RESEARCH, MONITORING FINANCIAL FLOWS FOR HEALTH RESEARCH 2005: BEHIND THE GLOBAL NUMBERS 38 tbl.1 (2006), *available at* http://www.globalforumhealth.org/filesupld/monitoring_financial_flows_05/mff05_chap3.pdf.

²¹ *Id.*

by the private sector.²²

To encourage the private funding of public health, it is generally accepted that intellectual property rights — in particular, patents — are necessary.²³ By providing a limited right to exclude competitors from qualifying inventions, patents permit their owners the ability to extract monopoly rents, thus providing the primary investment incentive.²⁴ In exchange, society obtains access to goods or services that may not have been invented but for the patent incentive, or at least not widely disclosed.²⁵ While some view monopoly rents as a reward for invention,²⁶ most consider it better articulated as the product of an *ex ante* gamble: make an intelligent investment and, depending on the market, you may win.²⁷ In that regard, it is similar to any business investment seeking the

²² *Id.*

²³ This is an extension of the general argument for intellectual property rights. See Keith E. Maskus & Jerome H. Reichman, *The Globalization of Private Knowledge Goods and the Privatization of Global Public Goods*, in KEITH E. MASKUS & JEROME H. REICHMAN, *INTERNATIONAL PUBLIC GOODS AND TRANSFER OF TECHNOLOGY* 8 (2005) (explaining that the underproduction of public good results without some public/government intervention). To be sure, other models of innovation, have been proposed. Michael Kremer, *Patent Buyouts: A Mechanism for Encouraging Innovation*, 113 Q.J. ECON. 1137 (1998) (proposing a system wherein property rights for important innovations are purchased by the public and freely available for developmental research). However, it is not at all clear that such models can replace even a significant proportion of private research. Michael Abramowicz, *Perfecting Patent Prizes*, 56 VAND. L. REV. 115, 170–71 (2003) (introducing a detailed discussion as to why such “patent prize” systems are inherently flawed). At best, they may provide an important complement to patent-incentivized innovation.

²⁴ WILLIAM D. NORDHAUS, *INVENTION, GROWTH, AND WELFARE: A THEORETICAL TREATMENT OF TECHNOLOGICAL CHANGE* 70 (1969) (stating patents create incentives by conferring monopoly power for a limited period of time).

²⁵ This concept was extraordinarily well articulated by the United States Supreme Court in the context of delimiting the proper role of federal patents and state trade secret rights. *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 151 (1989) (“In consideration of its disclosure and the consequent benefit to the community, the patent is granted.”).

²⁶ Edmund W. Kitch, *The Nature and Function of the Patent System*, 20 J.L. & ECON. 265, 266 (1977) (restating the basic notion historically agreed upon by economists: “The patent is a reward that enables the inventor to capture the returns from his investment in the invention, returns that would otherwise (absent secrecy) be subject to appropriation by others.”); *Aronson v. Quick Point Pencil Co.*, 440 U.S. 257, 262 (1979) (“First, patent law seeks to foster and reward invention . . .”).

²⁷ See Mark A. Lemley, *Ex Ante versus Ex Post Justifications for Intellectual Property*, 71 U. CHI. L. REV. 129, 148–49 (2004) (arguing that many economic theorists improperly focus on patent rules as a means of controlling already-created innovation, rather than on incentives to produce the innovation).

greatest return for the least investment.²⁸

The primary downside to patent rights, of course, is that the lack of competition will usually result in higher prices than would otherwise exist.²⁹ Significant advancements in medicine are often accompanied by a cost premium.³⁰ This tradeoff is the classic conundrum in the use of intellectual property rights in the context of socially-important goods.³¹ A nation with sufficient wealth may be able to shoulder the burden of high costs if the treatment provides important advantages, but for impoverished nations, even moderate costs may mean that some individuals simply do not receive treatment.³² A second obstacle stemming from patents is the potential for conflicting rights to preclude optional treatment. A combination of several treatments may be required when an integrated delivery mechanism would be preferable and available, if not for the intellectual property rights.³³ The lack of a convenient form could actually reduce the effectiveness and translate into lives lost.

Patent compulsory licenses provide a means for addressing the effects of property hold-ups without entirely eliminating the right.³⁴ By

²⁸ Although one could argue that patents on medical products should provide only a “reasonable” return on investment, it is unlikely that a company would rationally risk millions to merely capture a modest profit.

²⁹ ROBERT COOTER & THOMAS ULEN, *LAW & ECONOMICS* 122–23 (4th ed. 2004) (“[A] patent enables the inventor of something valuable to earn profits that exceed the ordinary rate of return on investment.”). Of course, whether a patent owner actually has monopoly power depends on the market. See Edmund W. Kitch, *Elementary and Persistent Errors in the Economic Analysis of Intellectual Property Law*, 53 *VAND. L. REV.* 1727, 1730 (2000).

³⁰ See JOSEPH A. DiMASI, *PRICE TRENDS FOR PRESCRIPTION PHARMACEUTICALS: 1995–1999* (2000), <http://aspe.hhs.gov/health/reports/Drug-papers/dimassi/dimasi-final.htm>.

³¹ See Daniel R. Cahoy, *An Incrementalist Approach to Patent Reform Policy*, 9 *N.Y.U. J. LEGIS. & PUB. POL’Y* 587, 641–44 (2006).

³² Amy Kapczynski et al., *Addressing Global Health Inequities: An Open Licensing Approach for University Innovations*, 20 *BERKELEY TECH. L.J.* 1031, 1047–49 (2005).

³³ It is particularly difficult in developing countries to ensure that patients are taking the multiple drugs at correct intervals in order to complete the “cocktail” required for AIDS treatment. David P. Hamilton, *New AIDS Pill Simplifies Treatment*, *WALL ST. J.*, July 10, 2006, at B8 (noting that, due to the phenomenon of patients skipping their medication, the need for a single daily pill is “significant for the U.S. and other industrialized countries, but potentially groundbreaking for Africa and the rest of the developing world.”). Combination treatments may alleviate this problem. *Id.* To date, such solutions have been prevented due to the separate ownership of different patents on components of the cocktail. See *Simplifying AIDS Cocktail*, *S.F. CHRON.*, Aug. 4, 2004, at B8.

³⁴ In addition to the aforementioned pricing effects, patent compulsory licenses can

intruding on the right to exclude, a government (or entity specifically authorized by the government)³⁵ can more flexibly make use of the intangible information. Essentially, the patent holder is forced to give up a bit of her property right to benefit the public.³⁶ The loss is usually restricted in time or by the continued occurrence of a triggering event.³⁷

Significantly, the act of compulsory licensing is usually retrospective in nature. Such measures are generally imposed only after considering property that already exists,³⁸ and then reallocating ownership

also address concerns regarding a patent's ability to convey paternalistic control or exploitation on the part of industrialized countries over developing nations. *See, e.g.*, CHRISTOPHER MAY & SUSAN K. SELL, *INTELLECTUAL PROPERTY RIGHTS: A CRITICAL HISTORY* 170 (2006) ("Rather than facilitating the importation of new technologies for production (or service fulfillment), patents have historically been used to maintain import monopolies."); Peter K. Yu, *The International Enclosure Movement*, 82 *IND. L.J.* 827, 888 (2007) (arguing that "there is no denial that the TRIP[S] agreement is biased against less developed countries"). Under this view, compulsory licensing could be a mechanism for reasserting indigenous power and promoting the development of home industries. While this is not necessarily a view adopted by the major trade organizations, it can be evidenced by various grass roots movements to oppose particularly troubling trends in intellectual property ownership, such as the patenting of traditional medicines. *See, e.g.*, Peter Drahos, *Indigenous Knowledge, Intellectual Property and Biopiracy: Is a Global Bio-Collecting Society the Answer?*, *E.I.P.R.* 2000, 22(6), 245-250; Paul J. Heald, *The Rhetoric of Biopiracy*, 11 *CARDOZO J. INT'L & COMP. L.J.* 519 (2003); Naomi Roht-Arriaza, *Of Seeds and Shamans: The Appropriation of the Scientific and Technical Knowledge of Indigenous and Local Communities*, 17 *MICH. J. INT'L L.* 919 (1996).

³⁵ Reichman & Hasenzahl, *supra* note 1, at 10. As a general matter, the patent holder retains the right to exclude others not licensed by the government and to compete against the licensee. *Id.* at 23 ("[T]he issuance of a non-voluntary license cannot normally impede a patent holder from entering the market in competition with the licensee."). The most powerful general international intellectual property treaty, the TRIPS, actually requires that compulsory licenses be non-exclusive. TRIPS, *supra* note 12, art. 31(d).

³⁶ The benefit to the public can be direct, as in the case of a license in the public interest, or indirect, as in the case of a license to increase competition in the marketplace. *See* Carlos M. Correa, *Intellectual Property Rights and the Use of Compulsory Licenses: Options for Developing Countries* 10-22 (Ctr. for Advanced Studies at the Univ. of Buenos Aires, Arg., Working Paper No. 5, 1999), <http://www.southcentre.org/publications/workingpapers/wp05.pdf>.

³⁷ The event limitation is also an explicit part of the TRIPS agreement. TRIPS, *supra* note 12, art. 31(g) (requiring that a compulsory license be "terminated if and when the circumstances which led to it cease to exist and are unlikely to recur.").

³⁸ However, this *ex post* approach is not a requirement. In other intellectual property contexts, there are compulsory licenses that apply to all property rights of a certain type, without regard to individual value or the predilections of the owner. *See* 17 U.S.C. § 115 (2000) (compulsory license for making and distributing copyrighted phonorecords); Robert P. Merges, *Contracting into Liability Rules: Intellectual Property*

rights by nationalizing them. Although the incentive to invent with respect to the licensed invention cannot be changed (since invention has already taken place), innovation policy advocates argue that the incentive to create future inventions is decidedly reduced.³⁹ In other words, it is posited that some inventions that would have been created in view of the full power of the patent rights, will never come to be in the face of compulsory licensing. This may be an acceptable tradeoff: a compulsory license is predicated the assumption that the beneficial health effects from the limitation will be significant,⁴⁰ outweighing the loss of any innovation investment.

At least one hundred countries make compulsory licenses available in one form or another.⁴¹ Additionally, there has been support for

Rights and Collective Rights Organizations, 84 CAL. L. REV. 1293, 1295 (1996).

³⁹ For an overview of this position, see Colleen Chien, *Cheap Drugs at What Price to Innovation: Does the Compulsory Licensing of Pharmaceuticals Hurt Innovation?*, 18 BERKELEY TECH. L.J. 853, 856 (2003) (stating that there is a perception that compulsory licenses harm the incentive for innovation and quoting an executive from the pharmaceutical industry). *But see* Kevin Outterson, *Pharmaceutical Arbitrage: Balancing Access and Innovation in International Prescription Drug Markets*, 5 YALE J. HEALTH POL'Y, L. & ETHICS 193, 230 (2005) (arguing that if patent rents are "supra optimal," compulsory licensing at marginal costs will not reduce innovation).

⁴⁰ To be sure, compulsory licensing is not a comprehensive answer to global health; it is only one tool in much larger toolbox. *See, e.g.*, Amir Attaran & Lee Gillespie-White, *Do Patents for Antiretroviral Drugs Constrain Access to AIDS Treatment in Africa?*, 286 J. AM. MED. ASSN. 1886, 1891 (Oct. 2001) (concluding that "the extreme dearth of international aid finance, rather than patents, is most to blame for the lack of antiretroviral treatment in Africa."). In fact, it is probable that other methods for improving public health may actually be more important in the long term. Many problems in the developing world are remedied by ensuring a sufficient supply of clean water, nutritional food, and even education on the dangers of certain social behaviors. WHO, BURDEN OF DISEASE AND COST-EFFECTIVENESS ESTIMATES, http://www.who.int/water_sanitation_health/diseases/burden/en/ (last visited Dec. 10, 2006) ("A significant amount of disease could be prevented especially in developing countries through better access to safe water supply, adequate sanitation facilities and better hygiene practices."); Tina Rosenberg, *When a Pill is Not Enough*, N.Y. TIMES MAG., Aug. 6, 2006, at 40 (describing South African women with AIDS who refuse free treatment rather than admit that they have the disease). But there is no denying that the option of compulsory licensing of pharmaceuticals is gaining an ever more prominent place in world health policy, and it appears to be a permanent fixture of international law. A single major health crisis could prove the tipping point toward increased use of this exception to established intellectual property rights.

⁴¹ Correa, *supra* note 36, at Part II. *See also* JAY DRATLER, JR., LICENSING OF INTELLECTUAL PROPERTY § 3.03 (2001) ("Many foreign countries have provisions for compulsory licensing in their patent and copyright laws, which are designed to insure that innovation is not neglected or suppressed by private forces within or without their

compulsory licenses in international law since the 19th-century Paris Convention for the Protection of Industrial Property.⁴² The most prominent and specific modern treaty to address compulsory licensing is the Trade-Related Aspects of Intellectual Property (“TRIPS”) agreement,⁴³ which came into effect in 1995 as part of the Uruguay Round of trade discussions.⁴⁴ Referring to “use without the authorization of the right holder,” article 31 explicitly permits member states to issue licenses under three circumstances: (1) after efforts to obtain a license from the patent holder on “reasonable commercial terms and conditions” have failed, (2) in the case of “national emergency or other circumstances of extreme urgency” and (3) for public non-commercial use.⁴⁵ The latter two circumstances are significant in that they do not require prior negotiation with the patent holder (which should theoretically make a compulsory license easier to obtain).⁴⁶ An important limitation to TRIPS article 31

borders.”); Reichman & Hasenzahl, *supra* note 1, at 10-11 (noting that compulsory licensing was originally an alternative to forfeiture for violating numerous restrictions in early patent law).

⁴² Art. 5(a), July 14, 1967, 21 U.S.T. 1583, 828 U.N.T.S. 305 [hereinafter Paris Convention], *available at* http://www.wipo.int/export/sites/www/treaties/en/ip/paris/pdf/trtdocs_wo020.pdf. The convention was originally signed in 1883, but many of the 171 member countries joined much later. *See* WIPO, *Contracting Parties: Paris Convention*, http://www.wipo.int/treaties/en/ShowResults.jsp?country_id=ALL&start_year=ANY&end_year=ANY&search_what=C&treaty_id=2 (last visited Dec. 26, 2007). The push for specific international standards truly began in earnest in the late 1970s. UNITED NATIONS CONFERENCE ON TRADE AND DEVELOPMENT (“UNCTAD”) & INTERNATIONAL CENTRE FOR TRADE AND SUSTAINABLE DEVELOPMENT (“ICTSD”), *RESOURCE BOOK ON TRIPS AND DEVELOPMENT* 462-63 (2005) [hereinafter UNCTAD-ICTSD RESOURCE BOOK]

⁴³ TRIPS, *supra* note 12.

⁴⁴ MAY & SELL, *supra* note 34, at 161-62 (2006). The Uruguay Round was also significant for creating the World Trade Organization (“WTO”), which as the co-overseer of TRIPS with the World Intellectual Property Organization (“WIPO”), provided significant enforcement powers. *Id.*

⁴⁵ *See* TRIPS, *supra* note 12, art. 31. Additionally, Article 30 allows members to create exceptions to patent rights if such exceptions do not “unreasonably conflict with a normal exploitation of the patent” or “unreasonably prejudice the legitimate interests of the patent owner.” *Id.* The latter provision may appear to create a wide opening for unfettered compulsory licensing, but it has been generally viewed as relatively narrow in application and limited to circumstances like experimental use. *See* UNCTAD-ICTSD RESOURCE BOOK, *supra* note 42, at 432-39.

⁴⁶ TRIPS, *supra* note 12, art. 31 (“[The negotiation] requirement may be waived by a member in the case of a national emergency or other circumstances of extreme emergency or in cases of public non-commercial use”).

was a provision requiring that licensed rights be practiced domestically, for the benefit of the home market.⁴⁷ Recently, WTO members agreed to relax the domestic production rule in the context of essential medicines by permitting the manufacture and export of products from a non-licensing country to a licensing country.⁴⁸ In response, several governments amended or proposed to amend their patent laws to permit the manufacture and sale of pharmaceuticals under such circumstances.⁴⁹ However, only

⁴⁷ *Id.* art. 31(f). See Frederick M. Abbott & Rudolf V. Van Puymbroeck, *Compulsory Licensing For Public Health: A Guide and Model Documents for Implementation of the Doha Declaration Paragraph 6 Decision* 8-9 (World Bank, Working Paper No. 61, 2005). Under this restriction, third-party countries with a large generic pharmaceutical manufacturing base could not take full advantage of another country's compulsory license. It might be possible for a country such as India or Brazil to impose a compulsory license "predominantly for the supply of the domestic market," and export additional production to non-manufacturing developing countries under a separate license. *Id.* at 9. However, that non-predominant quantity of drugs may be insufficient to satisfy the needs of a country facing a growing public health crisis. *Id.*

⁴⁸ Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health, ¶ 1(b) n.3, WT/L/540 (Aug. 30, 2003) [hereinafter Paragraph 6 Decision], available at http://www.wto.org/English/tratop_e/trips_e/implem_para6_e.htm. (noting that the following countries agree not to use the Paragraph 6 provisions as importing members: Australia, Austria, Belgium, Canada, Denmark, Finland, France, Germany, Greece, Iceland, Ireland, Italy, Japan, Luxembourg, Netherlands, New Zealand, Norway, Portugal, Spain, Sweden, Switzerland, United Kingdom and United States of America); Frederick M. Abbott, *The WTO Medicines Decision: World Pharmaceutical Trade and the Protection of Public Health*, 99 AM. J. INT'L L. 317, 336 (2005). Since they joined the European Union, the list now includes ten more: Czech Republic, Cyprus, Estonia, Hungary, Latvia, Lithuania, Malta, Poland, Slovak Republic and Slovenia. WTO, *Compulsory Licensing of Pharmaceuticals and TRIPS* (Oct. 2005), available at http://www.wto.org/English/tratop_e/trips_e/public_health_faq_e.htm. Eleven other members announced voluntarily that they would only use the system as importers in situations of national emergency or other circumstances of extreme urgency: Hong Kong China, Israel, Korea, Kuwait, Macao China, Mexico, Qatar, Singapore, Chinese Taipei, Turkey, and United Arab Emirates. *Id.*

⁴⁹ See, e.g., Bill C-9, An Act to Amend the Patent Act and the Food and Drugs Act, R.S.C., ch. P-4 (2004) (Canada), available at http://www.parl.gc.ca/common/Bills_ls.asp?Parl=37&Ses=3&ls=C9; Regulation 816/2006 of the European Parliament and of the Council, 2006 O.J. (L 157) (EC); State Gazette of the Kingdom of the Netherlands, Policy Rule Change to Section 57, Subsection 1 of the Kingdom Act on Patents of 1995 art. 1(c); Regulations Amending the Patent Regulations (in Accordance with the Decision of the WTO General Council of 30 August 2003, Paragraphs 1(b) and 2(a)) (June 1, 2004) (Norway), available at http://www.regjeringen.no/nb/dep/ud/dok/rapporter_planer/rapporter/2004/Regulations-amending-the-Patent-Regulations-in-accordance-with-the-decision-of-the-WTO-General-Council-of-30-August-2003-Paragraphs-1b-and-2a.html?id=420373.

one country, Rwanda, has notified the WTO of its intent to use the amended importation provisions.⁵⁰

B. Retribution through Foreign Direct Investment Disincentives

Stated simply, FDI is the flow of people, capital, and technology from a source country to a destination country.⁵¹ FDI frequently takes the form of the acquisition or production of subsidiaries in the host country by a multinational enterprise (“MNE”).⁵² FDI usually grants control through management or outright ownership of the enterprise in the host country to the MNE.⁵³ Passive investment or non-equity investment through instruments such as bonds, debt securities, and notes does not generally constitute FDI activities.⁵⁴

MNEs may pursue three types of FDI -- vertical, horizontal, and distribution.⁵⁵ Distribution FDI, the least discussed and least invasive of the three, involves establishing sales offices, distribution networks, and services facilities in the target nation.⁵⁶ Vertical FDI (“VFDI”) refers to investment of a component of a larger product in different countries. The location of each stage of product production is chosen to minimize

⁵⁰ Council for Trade-Related Aspects of Intellectual Property Rights, *Notification under Paragraph 2(a) of the Decision of 30 August 2003 on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health*, IP/N/9/RWA/1 (July 19, 2007), available at http://www.wto.org/english/tratop_e/trips_e/public_health_notif_import_e.htm. Note that until July 2007, the Paragraph 6 provisions were entirely unused. Press Release, WTO, Patents and Health: WTO Receives First Notification Under ‘Paragraph 6’ System (July 20, 2007), http://www.wto.org/english/news_e/news07_e/public_health_july07_e.htm.

⁵¹ Todd S. Shenkin, *Trade Related Investment Measures in Bilateral Investment Treaties and the GATT: Moving Toward a Multilateral Investment Treaty*, 55 U. PITT. L. REV. 541, 567 (1994); See also 15 C.F.R. § 806.15(a) (2006)(defining foreign direct investment in the United States as, “the ownership or control, directly or indirectly, by one foreign person of 10 per centum or more of the voting securities of an incorporated U.S. business enterprise or an equivalent interest in an unincorporated U.S. business enterprise, including a branch.”).

⁵² Keith E. Maskus, *The Role of Intellectual Property Rights in Encouraging Foreign Direct Investment and Technology Transfer*, 9 DUKE J. COMP. & INT’L L. 109, 111 (1998).

⁵³ Richard J. Hunter et al., *Legal Considerations in Foreign Direct Investment*, 28 OKLA. CITY U. L. REV. 851, 853 (2003).

⁵⁴ *Id.* at 854.

⁵⁵ Kevin C. Kennedy, *A WTO Agreement on Investment: A Solution in Search of a Problem?*, 24 U. PA. J. INT’L ECON. L. 77, 79 n.5 (2003).

⁵⁶ *Id.*

production costs.⁵⁷ Firms locate facilities to mine mineral resources near the mineral itself. Intensive labor processes exist where labor costs are lowest. Horizontal FDI comprises the manufacture of the entire good in one place.⁵⁸ This may include manufacturing, research and development, and distribution of the product. As firms mature they generally move from vertical to horizontal FDI activities.⁵⁹

The choice to pursue FDI by an MNE is principally a profit motive, but the factors that impact that decision are more complex. An MNE planning FDI must have some efficiency advantages that can be leveraged by placement of production assets within a foreign country. These efficiency advantages may manifest in three forms — ownership, localization, and internalization — known collectively as the “OLI” theory.⁶⁰

An ownership advantage usually involves the exportation of an intangible asset such as marketing power, technological expertise, and intellectual property ownership to a foreign country where those assets can be optimally utilized. MNEs export such knowledge-based assets to take advantage of a supportive information infrastructure.⁶¹ Through multi-plant production, MNEs receive economies of scope by producing technical knowledge in one location and applying to plants across different nations.⁶² Less commonly, ownership advantages may manifest in tangible forms, such as an exclusive claim to a valuable natural resource.⁶³

Location advantages provide geographic efficiency benefits to MNE production in target countries.⁶⁴ Such advantages include distance to markets, low wage costs, natural resources, and even trade protection from manufacturing “inside” an external trade barrier.⁶⁵ MNEs also seek supporting infrastructure, such as transportation in order to bring goods to market, marketing outlets in order to develop brand equity reliably, and a financial network from which to receive loans, grant credit, or pursue

⁵⁷ *Id.*

⁵⁸ *Id.*

⁵⁹ Maskus, *supra* note 52, at 125.

⁶⁰ *Id.* at 121 (citing JOHN H. DUNNING, INTERNATIONAL PRODUCTION AND THE MULTINATIONAL ENTERPRISE 110, 113 (1981)). *See also* Kennedy, *supra* note 55, at 146 n. 273.

⁶¹ Maskus, *supra* note 52, at 121

⁶² *Id.* at 122.

⁶³ *Id.* at 121.

⁶⁴ *Id.* at 123.

⁶⁵ *Id.*

local investments.⁶⁶

Finally, internalization advantages occur when MNEs exploit advantages in multinational operations by acquiring established enterprises in the region. In essence, this involves buying a subsidiary with the local knowledge and expertise to produce the product for a given national or regional market.⁶⁷ An internalization advantage occurs when the profits gained from exploiting the firm's assets are greater when the assets are kept within the company as compared to licensing the use of those assets to a foreign firm.⁶⁸

One ameliorating factor to external impacts on the FDI profit motive is the vertical nature of certain industries. High barriers to entry and lower level of competition between countries can make it somewhat less likely that a compulsory license imposed on one product will impact FDI related to other companies or have horizontal effects across other industries.⁶⁹ In other words, if an individual nation is willing to accept the possible loss of investment in this segregated industry segment, FDI in other areas may make it less significant.

III. COMPLEX REALITIES: DIFFERENTIAL IMPACT OF FOREIGN DIRECT INVESTMENT THREATS

Nations improve their intellectual property rights for a variety of reasons, not the least of which is to improve the effectiveness of domestic industries in global markets. Intellectual property laws can protect local producers from foreign pirates in the domestic market. Strong intellectual property protections are also a pre-requisite for admission into the WTO. In spite of the significant administrative and enforcement costs that TRIPS requires, developing nations seek admission to the WTO in order to obtain access to markets that the WTO promises to open.⁷⁰ The result is that

⁶⁶ *Id.*

⁶⁷ *Id.* at 126.

⁶⁸ Kennedy, *supra* note 55, at 146 n.273

⁶⁹ See ROY LEVY, *THE PHARMACEUTICAL INDUSTRY: A DISCUSSION OF COMPETITIVE AND ANTITRUST ISSUES IN AN ENVIRONMENT OF CHANGE* 7-8 (1999) (Federal Trade Commission Bureau of Economics Staff Report), available at <http://www.ftc.gov/reports/pharmaceutical/drugrep.pdf>.

⁷⁰ Paul J. Heald, *Mowing the Playing Field: Addressing Information Distortion and Asymmetry in the TRIPS Game*, 88 MINN. L. REV. 249, 250 (2003). Critics charge, among other contentions, that the WTO rules fail to significantly protect traditional knowledge and folklore that citizens of developing countries value. See, e.g., Doris Estelle Long, "Globalization": A Future Trend or a Satisfying Mirage?, 49 J. COPYRIGHT SOC'Y U.S.A.

accession to WTO standards may be viewed as the “cost of admission” to the global marketplace.⁷¹

Intellectual property laws are also widely believed to have a signaling effect for the nations that enact them. The passage of such laws indicates to investors that a nation recognizes the rights of foreign firms and a government is willing to let foreign investors make strategic business decisions without undue government interference. Stronger intellectual property rights also signal a nation’s shift toward a more transparent legal system with unbiased application of commercial laws and reduced corruption in government activities.⁷² Although the evidence supporting the conclusion that these signals impact MNE behavior is inconclusive, several poor nations including those with limited technical capabilities have unilaterally improved their intellectual property rights during the 1990s.⁷³

There is also significant evidence that patents work as signaling devices for the firms that own them. Patents signal to financial markets and customers that a firm holds a strong market position and can potentially achieve dominant status.⁷⁴ Patents also act as symbolic markers of progress in research and development and product as product differentiators.⁷⁵ Patents also signal strong firm productivity, innovation, and research and development activity.⁷⁶ Patents signal to venture capitalists that a company is well managed and has defined a market niche for itself.⁷⁷

If patents can readily convey broad information beyond the mere possession of an intellectual property, presumably when a patent is placed in jeopardy in a particular market it may send a variety of negative signals about the firm. A pharmaceutical enterprise entering a market where its patents are readily vulnerable to a compulsory license may cause firm observers, such as those who recommend or sell the firm’s stock, to question the firm’s projected revenue streams from conducting FDI in that

313, 342 (2001).

⁷¹ See generally THOMAS L. FRIEDMAN, *THE LEXUS AND THE OLIVE TREE* (2000) (describing the tension between the forces of globalization and ancient practices of culture, tradition, and community).

⁷² Maskus, *supra* note 52, at 137.

⁷³ *Id.* at 138 (citing Keith E. Maskus, *Implications of Regional and Multilateral Agreements for Intellectual Property Rights*, 20 *WORLD ECON.* 681, 682 (1997)).

⁷⁴ Mark A. Lemley, *Reconceiving Patents in the Age of Venture Capital*, 4 *J. SMALL & EMERGING BUS. L.* 137, 143-44 (2000).

⁷⁵ *Id.* at 144.

⁷⁶ Clarissa Long, *Patent Signals*, 69 *U. CHI. L. REV.* 625, 651-53 (2002).

⁷⁷ *Id.* at 653.

new market. Questions may arise whether the target nation's economy will be a breeding ground for sales-impeding parallel imports. Just as the sale of a product through a low-status selling channel of a product can signal a diminution in brand status to the consumer, exposure of a patent to an uncertain legal environment can signal that the firm may not consider the patent to be as valuable as others believe. Even the threat of an "anti-patent" such as a compulsory license can impair firm equity, thereby reducing the attractiveness of a country as an investment partner. Any firm calculating its returns from FDI will have to account for the possibility of these signaling-based losses.

While the relationship between compulsory licensees and FDI is straightforward in theory, the actual economic mechanism can vary dramatically in practice.⁷⁸ Most pronounced is the difference between countries at different income and investment attraction levels. Depending on inflow of FDI relative to compulsory licensing savings, the association may or may not be strategically important. Some general observations are possible using the broad categories of "least-developed countries" and "middle-developed countries."

A. The Susceptibility of Middle Developed Countries to FDI Losses

A least-developed country's ("LDC")⁷⁹ issuance of a compulsory license might not impact future FDI decisions of an MNE. LDCs cannot significantly impact the ownership advantage of a large firm. LDC markets are generally too small and not lucrative enough to impact the

⁷⁸ A recent paper by Abbott and Reichman questions whether compulsory licenses would result in a "palpable" reduction in foreign direct investment given the pragmatic nature of most companies. Frederick M. Abbott & Jerome H. Reichman, *The Doha Round's Public Health Legacy: Strategies for the Production and Diffusion of Patented Medicines Under the Amended TRIPS Provisions*, 10 J. INT'L ECON. L. 921, 938-39 (2007). However, it is just as reasonable to suggest that companies in industries that fear a burgeoning trend of compulsory licenses, such as pharmaceuticals, may undertake outsized retribution to protect the long term gains provided by the current business model.

⁷⁹ The WTO defines the voluntary category of least-developed country. See WTO, *Least Developed Countries*, http://www.wto.org/english/thewto_e/whatis_e/tif_e/org7_e.htm. The countries falling under this definition are: Angola, Bangladesh, Benin, Burkina Faso, Burundi, Cambodia, Central African Republic, Chad, Democratic Republic of the Congo, Djibouti, Gambia, Guinea, Guinea Bissau, Haiti, Lesotho, Madagascar, Malawi, Maldives, Mali, Mauritania, Mozambique, Myanmar, Nepal, Niger, Rwanda, Senegal, Sierra Leone, Solomon Islands, Tanzania, Togo, Uganda, and Zambia. *Id.*

decision to pursue the exportation of an intangible asset abroad. LDCs also will have little influence over the location advantage. LDCs usually lack the infrastructure to present a location advantage to an MNE and are usually located geographically distant from key markets. Given the lack of influence of ownership and location advantages that LDCs can offer, there is little influence that an LDC can offer in an internalization advantage. Instead of licensing the drug or building a plant, a pharmaceutical MNE might simply resort to exporting that drug from a foreign manufacturer, thus keeping investment in LDCs as limited as possible.

On the other hand, the ability of certain countries to impact MNE FDI behavior was highlighted in a thoughtful study by Lee and Mansfield, who in 1996 reviewed the perceptions intellectual property rights in various countries by 100 American firms.⁸⁰ The authors sampled one hundred major U.S. firms in the chemical (including pharmaceutical), machinery, food, metals, electrical equipment, and transportation industries.⁸¹ Each firm was asked whether any of selected group of countries had intellectual property protection that was too weak to transfer its newest technology to wholly-owned subsidiary in that country.⁸² The authors concluded that, depending upon the magnitude of the improved perception, increased perception by firm representatives that a given nation has strong intellectual property rights can result in as much as hundreds of millions of dollars in FDI.⁸³ The authors found that weak intellectual property rights more negatively impact the production of research and development facilities and less negatively impact firms with limited ownership of local affiliates.⁸⁴

While the survey establishes important evidence that U.S. firms consider intellectual property rights in FDI decisions, the other countries surveyed are particularly instructive. The authors surveyed fourteen countries — Argentina, Brazil, Chile, Hong Kong, India, Indonesia, Mexico, Nigeria, Philippines, Singapore, South Korea, Taiwan, Thailand, and Venezuela — most of which are considered Middle-developed countries (“MDC”) as opposed to LDCs. The Human Development Index (HDI), a measure used annually by the United Nations Development

⁸⁰ Jeong-Yeon Lee & Edwin Mansfield, *Intellectual Property Protection and U.S. Foreign Direct Investment*, 79 REV. ECON. & STAT. 181 (1996).

⁸¹ *Id.* at 181.

⁸² *Id.*

⁸³ *Id.* at 185.

⁸⁴ *Id.* at 185-86.

Programme to measure social welfare within and across nations according to a variety of variables,⁸⁵ lists each of the fourteen countries surveyed by Lee and Mansfield – except Nigeria – as having medium or high levels of human development.⁸⁶ More focused tables measuring technology diffusion and creation and economic performance measure these nations similarly.⁸⁷ This implies the impact of intellectual property rights practices, and by extension granting compulsory licenses, might have a greater impact on middle developed countries than their least developed brethren.

B. Egypt's Declining FDI

Consider Egypt, a developing nation that ranks 119 out of 177 countries surveyed by the HDI, above South Africa and India but a few places below Guatemala and Indonesia on a human development scale.⁸⁸ Egypt is similarly ranked on the HDI's technology diffusion and creation scale and the economic performance scale.⁸⁹ Egypt is a quintessential middle-developed country (MDC) having the potential for significant economic growth but plagued with a variety of problems such as high unemployment, inflation and massive foreign debt that hinder its

⁸⁵ Chon, *supra* note 7, at 2832.

⁸⁶ See Human Development Indicators, Table 1 (Human Development Index), http://hdr.undp.org/en/media/hdr05_hdi1.pdf.

The WTO refers to this category “developing countries.” Inclusion in this group is self-regulated under the WTO. See WTO, *Who are the Developing Countries in the WTO?*, http://www.wto.org/english/tratop_e/devel_e/d1who_e.htm (last visited Dec. 10, 2007). Members indicating developing status include: Antigua and Barbuda, Argentina, Bahrain, Barbados, Belize, Bolivia, Botswana, Brazil, Brunei Darussalam, Cameroon, Chile, Colombia, Congo, Costa Rica, Côte d'Ivoire, Cuba, Cyprus, Dominica, Dominican Republic, Egypt, El Salvador, Estonia, Fiji, Gabon, Ghana, Grenada, Guatemala, Guyana, Honduras, Hong Kong, China, India, Indonesia, Israel, Jamaica, Kenya, Korea, Kuwait, Macau, Malaysia, Malta, Mauritius, Mexico, Morocco, Namibia, Nicaragua, Nigeria, Pakistan, Papua New Guinea, Paraguay, Peru, Philippines, Poland, Qatar, Saint Lucia, Singapore, Sri Lanka, St. Kitts and Nevis, St. Vincent and Grenadines, Suriname, Swaziland, Thailand, Trinidad and Tobago, Tunisia, Turkey, United Arab Emirates, Uruguay, Venezuela, Zimbabwe. See WTO, *Frequently Asked Questions About TRIPS*, http://www.wto.org/english/tratop_e/trips_e/tripfq_e.htm (last visited Dec. 10, 2007).

⁸⁷ Human Development Indicators, Table 1, *supra* note 86, at 13-14.

⁸⁸ *Id.* at 13.

⁸⁹ *Id.* at 56, 60. The technology scale measures nations according to telephone, cellular, and Internet use. *Id.* at 56. It also measures patent granted, royalties received, and research and development commitments. *Id.* The economic performance scale measures nations according to GDP and change in consumer prices. *Id.* at 60.

advancement.⁹⁰ Most interesting, although the Egyptian government has aggressively sought to attract FDI, FDI flows have continued to decline from \$948 million in 1987 to \$598 million in 1995 to \$428.2 million in 2001-02.⁹¹

In spite of this decline, Egypt receives more FDI than most other countries in Africa.⁹² Egypt possesses an economic environment that can attract companies seeking to exploit their FDI ownership, internalization, and localization advantages. Egypt is widely believed to possess a strong education system, a cheap labor force, and citizens who speak English on a widespread basis.⁹³ Egypt has taken numerous steps to liberalize its investment laws, including allowing total ownership by foreigners, increasing the transparency of the tax system, establishing free trade zones, and allowing a non-Egyptian majority of Board of Directors.⁹⁴ The Egyptian government has also abolished export taxes, eliminated foreign exchange controls, and reduced bureaucratic procedures.⁹⁵ Egypt is also the largest consumer of medicines in Africa and the Middle East.⁹⁶

Egypt's position on intellectual property rights has shifted demonstrably over the past fifty years. Egypt's first modern patent law was enacted in 1949 and protected the manufacturing process of pharmaceutical production but excluded the product itself from

⁹⁰ Michael J. Kelly, *U.N. Security Council Permanent Membership: A New Proposal for a Twenty-First Century Council*, 31 SETON HALL L. REV. 319, 385 (2000).

⁹¹ Keith E. Maskus, *The Role of Intellectual Property Rights in Encouraging Foreign Direct Investment and Technology Transfer*, in INTELLECTUAL PROPERTY AND DEVELOPMENT: LESSONS FROM RECENT ECONOMIC RESEARCH 44 (C. Fink & K. Maskus eds., 2005); Egyptian News Digest, Feb. 7, 2002, at 2003 WL 3950525.

⁹² 2005 FOREIGN DIRECT INVESTMENT CONFIDENCE INDEX: REGIONAL FINDINGS, <http://www.atkearney.com/main.taf?p=5,3,1,140,12>. Egypt lags behind only South Africa and Nigeria in investment received and is one of only five nations that received most of the foreign direct investment that is directed towards Africa. *Id.*

⁹³ Francesco Guerrera, *Investors Rue Weak Patent Protection*, FIN. TIMES, July 22, 2002, available at <http://search.ft.com/nonFtArticle?id=020722008102>.

⁹⁴ EgyptInvest2006: Investment Climate, <http://www.egyptinvest.com/2006/docs/content.aspx?id=320&dt=650> (last visited Aug. 29, 2006).

⁹⁵ M.M. Metwally, *Impact of EU FDI on Economic Growth in Middle Eastern Countries*, 16 EURO. BUS. REV. 381, 381 (2004). See also Paul G. Johnson, Note, *Shoring U.S. National Security and Encouraging Economic Reform in the Middle East: Advocating Free Trade with Egypt*, 15 MINN. J. INT'L L. 457, 462 (2006) (stating that Egypt has been "reforming customs and income and corporate taxes, reducing energy subsidies, and moving towards further privatization" in order to attract foreign direct investment.).

⁹⁶ Guerrera, *supra* note 93.

protection.⁹⁷ This law was most recently updated in 2002, when Law No. 82 of 2002 Promulgating Intellectual Property Law was passed after seven years of drafting and two years of formal debate.⁹⁸ The 2002 law expanded protection for pharmaceutical products and other areas to comply with the TRIPS agreement, which Egypt signed.⁹⁹

Of particular interest is Egypt's compulsory licensing statute. As noted previously, TRIPS does not explicitly establish compulsory licensing rules.¹⁰⁰ Article 31, however, permits "other use of [patents] without the authorization of the right holder," effectively authorizing compulsory licenses.¹⁰¹ Egypt's compulsory licensing statute has many components that might concern foreign investors. Article 17 allows the head of the Ministry of Health, the Ministry of Internal Affairs, or other Ministers to oppose any patent application if that application "relates" or is of "significance" to those fields.¹⁰² If any of these agencies oppose the patent filing, the patent process stops and no judicial review of the decision appears available.¹⁰³ The obvious connections between pharmaceuticals and health and the limitless discretion of Ministers to halt the patent process leave drug-producing MNEs vulnerable.

Articles 23 and 24 discuss procedures and requirements for compulsory licensing. Article 23(2) allows the Minister of Health to grant compulsory licenses when the quantity of medicine available fails to meet national needs due to the poor quality or a prohibitive price or in the presence of incurable or endemic diseases.¹⁰⁴ This article also applies to inventions related to the associated manufacturing processes raw materials necessary to develop the medicines.¹⁰⁵ Article 23(1)(c) allows the

⁹⁷ See Ragaii El Dekki & Partners, Patent Law No. 132 of 1949, <http://www.reldekki.com/lib02.html>.

⁹⁸ Sahar Aziz, *Linking Intellectual Property Rights in Developing Countries with Research and Development, Technology Transfer, and Foreign Direct Investment Policy: A Case Study of Egypt's Pharmaceutical Industry*, 10 ILSA J. INT'L & COMP. L. 1, 13 (2003).

⁹⁹ Nermien Al-Ali, *The Egyptian Pharmaceutical Industry After TRIPS - A Practitioner's View*, 26 FORDHAM INT'L L.J. 274, 296-97 (2003).

¹⁰⁰ Susan Vastano Vaughan, Note, *Compulsory Licensing of Pharmaceuticals Under TRIPS: What Standard of Compensation?*, 25 HASTINGS INT'L & COMP. L. REV. 87, 98 (2001).

¹⁰¹ TRIPS, *supra* note 12, art. 31.

¹⁰² See Law on the Protection of Intellectual Property Rights art. 17, <http://www.egypt.pibs.info/brl-egypt-ipr-law-2002.pdf>.

¹⁰³ Al-Ali, *supra* note 99, at 302.

¹⁰⁴ Law on the Protection of Intellectual Property Rights, *supra* note 102, art. 23(2).

¹⁰⁵ *Id.*

Egyptian government to grant licenses of patents when necessary to support “national efforts in vital sectors for economic, social, and technological development, without unreasonable prejudice to the rights of the patent holder and taking into consideration the legitimate interests of third parties.”¹⁰⁶

Egypt’s 2002 law also addresses compensation. Article 31(h) of TRIPS requires that “the right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the [compulsory license].”¹⁰⁷ Article 24(8) of Egypt’s law by contrast states that the patent holder is entitled to “fair compensation for the exploitation of his invention. The amount of the compensation shall be fixed on the basis of the economic value of the invention.”¹⁰⁸ Egypt’s compensation provision uses the word “fair” instead of “adequate,” which may give the Egyptian government greater flexibility in establishing the appropriate level of compensation.¹⁰⁹ Whereas “adequate” may imply a compensatory quasi-contractual requirement, a “fair” determination might involve value judgments or justice considerations, a factor that MNE’s would find troubling as issues of public need might weigh against it in the equation.¹¹⁰ This interpretation may be unnecessarily nuanced. The subsequent compulsory language in the Egyptian statute fixing compensation on the basis of economic value might contain any discretion afforded by a “fair” term. Yet, at the very least, a compensation provision under Egyptian law that varies from the TRIPS language places in question whether the two systems are the same and whether Egyptian

¹⁰⁶ *Id.* art. 23(1)(c).

¹⁰⁷ TRIPS, *supra* note 12, art. 31(h). For a more comprehensive discussion of the scope of the remuneration requirement under TRIPS, *see generally* Cahoy, *supra* note 1.

¹⁰⁸ *See* Law on the Protection of Intellectual Property Rights, *supra* note 102, art. 24(8).

¹⁰⁹ For a rough contrast of the two terms compare the definition of “adequate” (“[s]ufficient; commensurate; equally efficient; equal to what is required”) with “fair” (“[h]aving the qualities of impartiality and honesty; free from prejudice, favoritism, and self-interest; [j]ust; equitable; even-handed; equal, as between conflicting interests”). BLACK’S LAW DICTIONARY 39, 525 (6th ed. 1990).

¹¹⁰ The meaning of similar terms has been subject to debate in other areas of international law. For example, the proper standard of compensation to be paid upon the taking of foreign property is “prompt, adequate and effective compensation,” a phrase whose scope and function remains discussed by scholars. *See, e.g.,* Mark B. Baker, *No Country Left Behind: The Exporting of U.S. Legal Norms Under the Guise of Economic Integration*, 19 EMORY INT’L L. REV. 1321 (2005); Detlev F. Vagts, *International Economic Law and the American Journal of International Law*, 100 AM. J. INT’L L. 769, 773 (2006).

law will provide adequate compensation for compulsory licenses.

Even more troublesome would be a differing translation of the statute described by Aziz, whose source translates the second sentence of article 24(8) as “[t]he economic value of the invention must be considered while determining said compensation.”¹¹¹ This translation of article 24(8) would merely require economic factors to be considered rather than being the sole measure, permitting more opportunity to political and social considerations to effect the appropriate compensation for a compulsory license.

Egypt’s compulsory licensing statute is broad and ambiguous.¹¹² This may be a product of legislative compromise between differing factions over a controversial provision.¹¹³ The statute’s vagueness, however, does give the Egyptian government some advantages. Under the current statute, Egypt can issue compulsory licenses for pharmaceutical drugs in a wide variety of circumstances – including whenever it determines that high prices fail to satisfy national demands.¹¹⁴ The possibility of high prices accompanying stronger patent protection is a significant one. For example, in Egypt the price of an anti-adhesive substance Intergel rose seventy percent over a four month period in 2002.¹¹⁵ In India prices of pharmaceutical drugs can increase as much as 50% after the implementation of a stronger patent regime.¹¹⁶ Maskus reported in 2001 that stronger pharmaceutical patent laws are a possible reason why pharmaceutical prices have risen as much as fourfold in small Chinese pharmacies in Beijing and Shanghai.¹¹⁷ The current statute allows Egypt

¹¹¹ Aziz, *supra* note 98, at 16 (quoting UNOFFICIAL TRANSLATION OF THE EGYPT’S IPR LAW, PUBLISHED IN THE OFFICIAL JOURNAL ISSUE, No. 22 BIS-Dated 2nd of June 2002).

¹¹² For a discussion of Egypt’s compulsory license statute in the copyright context, see International Intellectual Property Alliance 2006: Special 301 Report Egypt [p.7] (concluding that Egypt’s compulsory license is “overly broad” with regard to copying and translating works and should be repealed) , <http://www.iipa.com/rbc/2006/2006SPEC301EGYPT.pdf>.

¹¹³ See generally Joseph A. Grundfest & A.C. Pritchard, *Statutes with Multiple Personality Disorders: The Value of Ambiguity in Statutory Design and Interpretation*, 54 STAN. L. REV. 627 (2002) (discussing the causes and benefits of ambiguous statutory language).

¹¹⁴ Law on the Protection of Intellectual Property Rights, *supra* note 102, art. 23(2).

¹¹⁵ Al-Ali, *supra* note 99, at 309.

¹¹⁶ Maskus, *supra* note 9, at 469. See also Jayashree Watal, *Pharmaceutical Patents, Prices and Welfare Losses: Policy Options for India Under the WTO TRIPS Agreement*, 23 WORLD ECON. 733, 735-39 (2000).

¹¹⁷ Maskus, *supra* note 9, at 469.

to issue compulsory licenses if drugs are priced outside the reach of most consumers or simply because the high prices are politically troublesome.

What cost, however, does Egypt's flexible compulsory license impose upon its economy? There is little doubt that reckless use of its compulsory licensing statute will provoke strong reactions from affected pharmaceutical MNEs. As the leader of a major pharmaceutical trade association is attributed as stating, "You can compel a private company once [with a compulsory license]. After that they probably leave your borders, and you lose the opportunity to get the access and the technology transfer in the future."¹¹⁸ In 2002, after four years of effort, Pfizer finally received regulatory approval to enter the Egyptian market with their popular drug Viagra.¹¹⁹ Local well-connected drug manufacturers responded by pressuring the Egyptian Ministry of Health, accusing the Ministry of helping MNEs exploit Egypt's poor.¹²⁰ Only two months after Pfizer's entry into the Egyptian market, the Ministry decided to grant similar authorization to produce Viagra to all Egyptian companies who applied to do so.¹²¹ The Ministry of Health cited the interests of the poor and the fact that the 2005 deadline for developing countries to comply with TRIPS had not yet expired.¹²² Pfizer was, naturally, "furious" at the decision.¹²³ The decision led Pfizer to "slam the brakes" on a state of the art production facility in Egypt.¹²⁴ The government's decision prompted a Pfizer Middle Eastern representative to remark that allowing generic

¹¹⁸ Haldane R. Mayer, *United States Court of Appeals for the Federal Circuit 20th Anniversary Judicial Conference: "A Salute to the Federal Circuit"*, 217 F.R.D. 548, 668 (2002). This quote is attributed to a "Harvey Bell of IPFMA" in the remarks of Susan Kling Finston, Assistant Vice President, Intellectual Property and Middle East/Africa/South Asian Affairs, PhRMA. Finston is likely referring to Harvey E. Bale, Director General of the International Federation of Pharmaceutical Manufacturers Associations (IFPMA) an organization that represents the research-based pharmaceutical industry and other manufacturers of prescription medicines through over 55 industry member associations worldwide. See Conference on Intellectual Property and International Public Health Conference Agenda, http://www.iipi.org/Conferences/IP&Health/Agenda.asp#Dr._Harvey_E._Bale,_Jr. The misstatement of the name and organization is likely a transcriber's error and not attributable Ms. Finston.

¹¹⁹ Richard A. Castellano, Note, *Patent Law for New Medical Uses of Known Compounds and Pfizer's Viagra Patent*, 46 IDEA 283, 289 (2006).

¹²⁰ Abeer Allam, *Seeking Investment, Egypt Tries Patent Laws*, N.Y. TIMES, Oct. 4, 2002, at W1.

¹²¹ *Id.*

¹²² Castellano, *supra* note 119, at 289.

¹²³ Allam, *supra* note 120, at W1.

¹²⁴ Castellano, *supra* note 119, at 289.

Viagra to be sold will “send a chill down foreign investor’s spines” and that “there are many other countries in the region who are competing for these new high-tech investments.”¹²⁵

Egypt’s stated rationale for issuing the license, to benefit the poor, appears questionable after a closer review of the facts. First, this compulsory license does not stand within idealized class of licenses such as when an LDC issues a license for an anti-AIDS drug to save the lives of citizens afflicted with the debilitating disease. Viagra treats erectile dysfunction, a significant problem but far from the life-threatening health crisis that compulsory licenses were envisioned to prevent. Second, the government process carried out to determine whether the license should be issued was far from an independent one. For example, the Chairman of a large generic drug manufacturer was also the Chairman of the Health Committee in Egypt’s upper house of Parliament at the time the compulsory license was issued.¹²⁶ Third, the decision to issue the license did not comply with TRIPS. Even though Egypt had until 2005 to comply with TRIPS, its refusal to attempt early compliance with the treaty when it had the opportunity to do so signals that its interest in compliance is at best lukewarm and that it might do only the minimum necessary to protect intellectual property rights under the agreement. Fourth, legal experts state that even without TRIPS in place, Viagra is protected by a Prime Ministerial Decree, which prohibits any company from using an undisclosed trade secret that would injure the commercial success of the firm that developed that trade secret.¹²⁷ If the Egyptian Ministry of Health is willing to flout current Egyptian law when it is to the disadvantage of local interests, then MNEs have reason to find any future claims of government adherence to intellectual property laws dubious at best. Fifth, the companies seeking the compulsory license may have little interest, beyond their own self-interest, in improving access by Egypt’s poor to Viagra. According to Dr. Ahmed El Hakim, Pfizer’s director of health policy and external relations for the Middle East, the two loudest proponents of the compulsory license have self-interested motives. One is hemorrhaging money and wants the license to staunch the flow. The other is trying to inflate his company’s net worth before placing it on the auction block.¹²⁸ This dilutes the accusations by local press supporting the license

¹²⁵ *Id.*

¹²⁶ Allam, *supra* note 120, at W1.

¹²⁷ *A Tough Pill to Swallow*, BUSINESS TODAY (EGYPT), Apr. 1, 2002, available at 2002 WLNR 3395080 (citing Prime Ministerial Decree 2211/2000).

¹²⁸ *Id.*

that Pfizer is attempting to monopolize the market and profit from the misfortunes of Egyptian men.¹²⁹

Egypt badly needs FDI from companies like Pfizer to jumpstart a faltering economy.¹³⁰ The Egyptian government has stated the importance of FDI and has made pledges in the past to raise the amount received.¹³¹ In addition, unlike LDCs that might have little to lose in issuing a compulsory license, Egypt and nations similarly positioned have much to lose when mishandling their intellectual property regime. In 2001, the year before Egypt enacted its sweeping intellectual property laws, the government suffered withering criticism for its lack of protections that impair receipt of FDI. The United States' ambassador to Egypt in 2001 stated that, "Egypt's ability to attract foreign investors in many fields will hinge on adequate protection of copyrights, patents and other intellectual property," and may be a precondition for any free trade agreement between Egypt and the United States.¹³² A U.S. official reported in 2001, "[a]t the moment Egypt is just not getting billions of foreign investment and this is the most damning evidence that the system is not working."¹³³ The Pharmaceutical Research and Manufacturers Association of American (PhRMA) informed Egypt that its weak intellectual property laws deterred PhRMA from investing \$300 million in Egypt's pharmaceutical sector.¹³⁴

The statements above were made before the passage of Egypt's 2002 law. Yet, Egypt's open-ended compulsory licensing scheme can undermine the strengthened patent protections Egypt worked so long and hard to legislate. Even if the broad compulsory licensing statute is never used, its mere presence transmits negative signals to an interested MNE that pharmaceutical patents and FDI in Egypt are vulnerable. Although compulsory licensing practices are not explicitly mentioned, Egypt remains on the "Priority Watch List," a selection of countries compiled by the United States Trade Representative that require special monitoring by the United States government for their poor enactment or enforcement of intellectual property rights.¹³⁵

If the mere presence of a broad compulsory license statute can

¹²⁹ *Id.*

¹³⁰ Guerrero, *supra* note 93, at 8.

¹³¹ *Id.*

¹³² *Id.*

¹³³ *Id.*

¹³⁴ Aziz, *supra* note 98, at 22.

¹³⁵ See U.S. TRADE REP., 2007 SPECIAL 301 REPORT 25-26 (2007), available at http://www.ustr.gov/assets/Document_Library/Reports_Publications/2007/2007_Special_301_Review/asset_upload_file230_11122.pdf.

impact the perception of its investment climate, it remains to be seen whether Egypt (or any country in a similar position) should leave the statute in place at all. The best course for Egypt might not be to revoke the statute outright, but to bargain away the statute's discretion in exchange for investment guarantees. Egyptian representatives, in a future hypothetical negotiation with pharmaceutical interests, could find low "cost" and high "benefit" in curtailing compulsory license protection in selected industries where Egypt already has a competitive foothold. Egypt's pharmaceutical industry is one of the oldest strategic industries in Egypt and produces more medicines than any country in the North Africa and Middle East region.¹³⁶ As Egyptian pharmaceutical companies mature from a distribution to a research focus, patent applications will inevitably increase.¹³⁷ Excluding or curtailing compulsory licensing powers from these industries will provide needed security for foreign enterprises without the attendant increase in risk from higher prices, national undersupply, or emergency crises because a developing industry is already in place. This concession would be far from costless, but would be negotiated in an area where Egypt would have a modicum of competitive strength.

C. *Brazil's Resistance to FDI*

Meanwhile, as Egypt struggles to attract FDI in spite of an unnecessarily broad compulsory licensing statute, Brazil has made significant steps toward solving public health problems while using its compulsory licensing statute as an asset. Brazil, like many countries, suffers from a spreading AIDS epidemic. However, the Brazilian government has responded by providing aggressive prevention services and free access to antiretroviral drugs for over ten years.¹³⁸ Brazil avoided pessimistic projections by the World Bank that Brazil would have 1.2 million citizens suffering from the HIV virus by 2000.¹³⁹ Instead, roughly 600,000, or

¹³⁶Aziz, *supra* note 98, at 22. See also Ministry of Investment: Egypt Investment Portal, *Economy*, http://www.investment.gov.eg/MOI_Portal/en-GB/Egypt+Business/Economy/

¹³⁷Aziz, *supra* note 98, at 21 (stating that local patent applications doubled between 1995 and 2000 due to improvements in the Egyptian economy).

¹³⁸ Ubirajara Regis Quintanilha Marques et al., *Brazil's AIDS Controversy: Antiretroviral Drugs, Breaking Patents, and Compulsory Licensing*, 60 *FOOD & DRUG L.J.* 471, 471 (2005).

¹³⁹ *Id.*

one percent of the adult population, are infected with the disease.¹⁴⁰ This stands in stark contrast to South Africa, which in 2000 had an infection rate of 4.2 million people, or twenty-percent of its adult population.¹⁴¹ Brazil's efforts have been used as a model around the world.¹⁴²

Why has Brazil been so successful? The primary reason has been the government's early implementation of an aggressive anti-AIDS program. Launched in 1983 when the scientists in Brazil first isolated the HIV virus, Brazil's anti-AIDS program has provided extensive support services to infected people.¹⁴³ This program includes prevention — advocating communication with controversial high-risk groups such as sex workers, drug users, and homosexuals.¹⁴⁴ These programs have included targeting intravenous drug users with methods of safe practice and an aggressive promotion of contraception devices such as condoms.¹⁴⁵ This program has grown to provide 159,000 infected Brazilians with free antiretroviral drugs and support services.¹⁴⁶

Antiretroviral drugs, however, potentially come only at a steep price. Brazil's skillful negotiation with pharmaceutical companies as well as its savvy use of its compulsory licensing statute has allowed the government to provide these drugs on a broad scale. Prior to TRIPS, Brazilian patent laws did not provide protection for pharmaceutical processes or products.¹⁴⁷ The United States responded to lobbying efforts by the Pharmaceutical Manufacturers Association by imposing Special 301 sanctions against Brazil for failing to protect intellectual property rights.¹⁴⁸ On October 20, 1988, President Reagan increased duties on various Brazilian products by one hundred percent.¹⁴⁹ The Brazilian government

¹⁴⁰ *Id.*

¹⁴¹ Sabin Russell, *AIDS Experts to Meet in Eye of Epidemic/20% of South Africa's Adults are Infected*, S.F. CHRON., July 7, 2000, available at, <http://www.aegis.com/news/sc/2000/SC000701.html>.

¹⁴² Marques, *supra* note 138, at 471.

¹⁴³ *Id.* at 472. See also Brazil Ministry of Health, National Programme History, <http://www.aids.gov.br/data/Pages/LUMISBD1B398DITEMID0FE488C7CE8E4EB1A09326528B487409ENIE.htm> (offering detailed history of Brazil's anti-AIDS program).

¹⁴⁴ Marques, *supra* note 138, at 471.

¹⁴⁵ *Id.* See also Brazil Ministry of Health, National STD and AIDS Programme, <http://www.aids.gov.br>.

¹⁴⁶ Marques, *supra* note 138, at 472.

¹⁴⁷ Naomi A. Bass, Note, *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 (2002).

¹⁴⁸ Bird, *supra* note 8, at 328.

¹⁴⁹ *Id.* (citing Increase in the Rates of Duty for Certain Articles from Brazil,

announced one year later that it would seek improved patent legislation for pharmaceutical products and processes.¹⁵⁰ During this period Brazil led a coalition of developing countries that resisted increases in global intellectual property protections through TRIPS;¹⁵¹ however, that resistance failed. After the enactment of TRIPS, Brazil enacted Intellectual Property Law number 9.279, which went into effect on May 15, 1997.¹⁵² This law recognized the relevant TRIPS provisions, including patent protection for pharmaceutical drugs and processes.¹⁵³ Drugs manufactured in Brazil before 1995, however, were not eligible for patent protection.¹⁵⁴

Embedded in the 1997 law are Brazil's compulsory licensing statutes. These statutes, like their Egyptian counterpart, are similarly broad and are thus similarly controversial to MNE pharmaceutical providers and other patent holders. For example, Article 71 states that, through an act of the Federal Executive Authorities, a compulsory license may be granted in cases of "national emergency or public interest."¹⁵⁵ Then Brazilian President Fernando Henrique Cardoso reinforced this provision through an Executive Decree.¹⁵⁶ While President Cardoso limited "national emergency" to conditions of "imminent public danger," he also declared that matters of public health were of public interest, suggesting pharmaceutical drugs are a particular focus of compulsory licensing statutes.¹⁵⁷

Brazil's most controversial provision has been the "local working" requirement of Article 68.¹⁵⁸ Article 68 requires that, within three years of obtaining a patent, the patent holder must manufacture the subject matter of the patent in Brazil, unless the patent holder can show that local production is not economically feasible or reasonable.¹⁵⁹ If the patent holder fails to do so, then Brazilian companies may apply to manufacture

Proclamation No. 5885, 53 Fed. Reg. 41,551 (Oct. 20, 1988)).

¹⁵⁰ *Id.*

¹⁵¹ *Id.* at 327 & n.65.

¹⁵² Marques, *supra* note 138, at 473. See also Araripe & Associados, Intellectual Property Law Effective as of May 15, 1997, <http://www.araripe.com.br/law9279eng.htm#patsec3f> (text of statute).

¹⁵³ Marques, *supra* note 138, at 473.

¹⁵⁴ *Id.*

¹⁵⁵ Araripe & Associados, *supra* note 152, art. 71.

¹⁵⁶ Marques, *supra* note 138, at 473.

¹⁵⁷ *Id.*

¹⁵⁸ Araripe & Associados, *supra* note 152, at art 68.

¹⁵⁹ *Id.* See also Anthony P. Valach, Jr., *TRIPS: Protecting the Rights of Patent Holders and Addressing Public Health Issues in Developing Countries*, 4 CHI.-KENT J. INTELL. PROP. 156, 175 (2005).

the patented product through compulsory licensing in Brazil.¹⁶⁰

The United States responded to this provision by bringing a complaint against this legislation with the World Trade Organization (WTO).¹⁶¹ The U.S. argued that Article 68 was incompatible with the non-discrimination provision of Article 27(1) of TRIPS, which required that national patent protection cannot discriminate as to the place of its invention.¹⁶²

The WTO complaint triggered global criticism because it would arguably impair Brazil's ability to distribute low cost anti-AIDS drugs to its citizens.¹⁶³ At an NGO global meeting in Brazil, 250 delegates organized a march to the U.S. consulate to protest the complaint.¹⁶⁴ Similar demonstrations took place in other major Brazilian cities.¹⁶⁵ AIDS activists accused the U.S. government of prioritizing MNE profits at the expense of Brazilians infected with the HIV virus.¹⁶⁶ A widespread NGO signature campaign, that included organizations such as Oxfam and Doctors without Borders, brought further attention to the complaint.¹⁶⁷ One article called the U.S. complaint a "public relations disaster."¹⁶⁸

Most interesting was Brazil's skillful response to the American threat to its intellectual property system. First, Brazil negated the moral high ground of the United States by immediately filing its own complaint challenging portions of the U.S. patent code.¹⁶⁹ The U.S. code provision that Brazil cited requires funding arrangements with non-profits and small business to state that products made with government funding must be

¹⁶⁰ Marques, *supra* note 138, at 474.

¹⁶¹ Duncan Matthews, *WTO Decision on Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health: A Solution to the Access to Essential Medicines Problem?*, 7 J. INT'L ECON. L. 73, 80 (2004).

¹⁶² WTO, Uruguay Round Agreement: TRIPS, http://www.wto.org/english/docs_e/legal_e/27-trips_04c_e.htm.

¹⁶³ Jason R. Boyarski et. al., *United States Drops WTO Action Against Brazil*, 13 INT. PROP. & TECH. L.J. 34, 34 (2001).

¹⁶⁴ Carlos Passarelli & Veriano Terto, Jr., *Good Medicine: Brazil's Multifront War on AIDS*, 35 NACLA REP. ON AMERICAS 35, 41-42 (2002).

¹⁶⁵ *Id.* at 42.

¹⁶⁶ Bass, *supra* note 147, at 208.

¹⁶⁷ Chakravarthi Raghavan, *US Beats a (Tactical) Retreat Over Brazil's Patent Law*, THIRD WORLD NETWORK, <http://www.twinside.org.sg/title/tactical.htm>.

¹⁶⁸ *Id.*

¹⁶⁹ Gary G. Yerkey & Daniel Pruzin, *United States Drops WTO Case Against Brazil Over HIV/AIDS Patent Law*, WTO REPORTER, available at <http://www.cptech.org/ip/health/c/brazil/bna06262001.html> ("In response to the U.S. WTO complaint, Brazil initiated a tit-for-tat complaint against U.S. patent legislation which it said discriminated against foreign producers. The Brazilian counter-complaint focuses on Articles 204 and 209 of Title 35 of the U.S. patent code.").

manufactured in the United States.¹⁷⁰ Brazil also cited language requiring that licenses of federally-owned inventions be manufactured in the United States.¹⁷¹ India also wished to join Brazil in its request for consultations regarding U.S. law, claiming that it was “well known that India has a substantial trade as well as systemic interest in these consultations.”¹⁷² In the Brazilian government’s own words, “Brazil has requested consultations with the United States in order to examine these and other provisions of the US Patents Code, with a view to understand how the United States justifies the consistency of such requirements with its obligations under the TRIPs Agreement, specially Articles 27 and 28[.]”¹⁷³

Second, the Brazilian government also leveraged its role as a developing country leader to present a resolution to the United Nations Human Rights Commission.¹⁷⁴ The resolution called for making appropriate medicines available at accessible prices and that access to AIDS treatment was a human right.¹⁷⁵ The motion received the support of all but one of the fifty-two countries present: the United States.¹⁷⁶

Third, Brazilian government officials issued a number of statements framing the dispute in its favor. Jose Serra, the Brazilian Minister of Health reiterated that Brazil’s patent law complies with WTO guidelines and stated that “the simple fact that we might be prepared to [use our compulsory license] has led to a number of foreign laboratories to lower their prices, as is the case of Merck-Sharp, which reduced the price of two AIDS drugs for Brazil by two and a half times.”¹⁷⁷ Serra also characterized the dispute as a clash between a rich, bullying America and the downtrodden, stating that, “There is no way that the Brazilian

¹⁷⁰ Sue Ann Mota, *TRIPS: Ten Years of Disputes at the WTO*, 9 *COMPUTER L. REV. & TECH. J.* 455, 477 (2005) (citing 35 U.S.C. § 202 (2005)).

¹⁷¹ *Id.*

¹⁷² Request to Join Consultations by India, *United States – US Patents Code*, WT/DS2124/2 (Feb. 16, 2001), available at, <http://docsonline.wto.org/DDFDocuments/t/WT/DS/224-2.doc>.

¹⁷³ Documents Submitted to WTO Dispute Settlement Body (Feb. 1, 2001), <http://www.cptech.org/ip/health/c/brazil/otherbus.html>. See also Request for Consultations by Brazil, *United States – US Patents Code*, WT/DS224/1 (Feb. 7, 2001), available at [http://www.worldtradelaw.net/cr/ds224-1\(cr\).pdf](http://www.worldtradelaw.net/cr/ds224-1(cr).pdf).

¹⁷⁴ Passarelli & Terto, *supra* note 164, at 42.

¹⁷⁵ *Id.* See also Mark S. Langevin, *The Brazilian Model to Fight HIV/AIDS*, *THE GLOBALIST*, Jun. 28, 2005, <http://www.theglobalist.com/DBWeb/StoryId.aspx?StoryId=4605>.

¹⁷⁶ Passarelli & Terto, *supra* note 164, at 42. See also Langevin, *supra* note 175.

¹⁷⁷ Terrence M. Brennan, *The United States and Brazil Agree to Disagree over Brazil’s Patent Law*, 13 *INT. PROP. & TECH. L.J.* 1, 3 (2001).

Government will retreat on this issue. The United States is not at all accustomed to Latin American countries also defending their own interests.”¹⁷⁸ Brazilian Ambassador Celso Amorim hinted at the fallout from the complaint that would follow, stating that the U.S.’s “[complaint] is not only legally unfounded, but it may prove politically disastrous.”¹⁷⁹

Brazil’s counter-campaign combined with global public pressure forced the United States to withdraw its complaint from the WTO.¹⁸⁰ Brazil responded with a promise to consult and negotiate with the United States and its pharmaceutical manufacturers before granting any future compulsory licenses.¹⁸¹ One wonders whether the U.S. choice to file the complaint was a mistake from the start. According to one author, “Brazil could have produced the same drugs under a ‘public non-commercial use’ exception authorized in article 31 of TRIPS” because Brazil produced the medicine in state owned labs and distributed it to the public for free.¹⁸²

Brazil could defend the compulsory license because, although Brazil is a developing country, it has the resources to develop the technology necessary to manufacture pharmaceuticals. Brazil can thus more readily implement a compulsory license than its poor neighbors, giving threats to compulsory licensing a greater sense of immediacy and importance. Also, Brazil has had for years the economic resources to passively resist American sanctions that could strong arm a weaker nation into not issuing compulsory licenses. For example, in 1987 negotiations between Brazil and the United States failed to reach an agreement regarding pharmaceutical patent rights.¹⁸³ The United States announced tariffs on a variety of products, including pharmaceuticals, paper products, chemicals, television cameras, microwave ovens, answering machines, jewelry, and tape recorders.¹⁸⁴ General Electric protested the tariffs against imported electrical breakers; Xerox opposed the inclusion of copy paper; Dow Chemical objected to the tariffs on carbon tetrachloride; Ford Motor called for the removal of amplifiers and windshield wipers; and, Carrier

¹⁷⁸ *Id.* at 4.

¹⁷⁹ *Id.*

¹⁸⁰ Clark A.D. Wilson, *The TRIPS Agreement: Is it Beneficial to the Developing World, or Simply a Tool Used to Protect Pharmaceutical Profits for Developed World Manufacturers?*, 10 J. TECH. L. & POL’Y 243, 257 (2005).

¹⁸¹ *Id.*

¹⁸² *Id.* at 257-58.

¹⁸³ Bird, *supra* note 8, at 335-36; Myles Getlan, *TRIPs and the Future of Section 301: A Comparative Study in Trade Dispute Resolution*, 34 COLUM. J. TRANSNAT’L L. 173, 189 (1995).

¹⁸⁴ Bird, *supra* note 8, at 336.

sought the removal of air conditioners from the tariffs target list.¹⁸⁵ The firms claimed that the proposed sanctions harmed their interests because they relied on the importation of the targeted products to satisfy consumer needs.¹⁸⁶ Brazil's interests were protected by the American firms who reaped economic benefits from trading with Brazil and did not want to suffer the losses the tariffs would impose.

As characterized by Valach, Brazil has used a three pronged attack in order to protect its compulsory license. First, Brazil produces locally any HIV drugs that are not subject to patent protection in Brazil because they predate legal protection.¹⁸⁷ Second, if the needed drugs are covered by Brazilian patents, then the Brazilian government attempts to negotiate a deal with the patent holder for a lower price that would allow the Brazilian government to provide the drugs to citizens for free.¹⁸⁸ Over the past ten years Brazil has successfully negotiated deep discounts for different kinds of antiretroviral and other drugs from a variety of pharmaceutical enterprises.¹⁸⁹ Only when these negotiations fail does Brazil threaten to issue a compulsory license for the needed drugs. Brazil has successfully used this threat to secure an affordable price for antiretroviral drugs,¹⁹⁰ and other countries have taken notice. A not-for-profit group is coaching groups in Ghana, Kenya, South Africa, and Uganda how to mount legal bids for compulsory licenses from pharmaceutical companies.¹⁹¹ Until recently, Brazil was the only country to successfully use compulsory licenses for antiretroviral drugs.¹⁹² Other developing countries are now following in Brazil's lead.¹⁹³

¹⁸⁵ *Id.*

¹⁸⁶ *Id.*

¹⁸⁷ Valach, *supra* note 159, at 176.

¹⁸⁸ *Id.*

¹⁸⁹ *E.g.*, Brazil, AIDS, and Intellectual Property: TED Case Study No. 649 (2002), <http://www.american.edu/TED/brazil-aids.htm> (listing Brazilian successes); Press Release, Brazil's National STD/AIDS Programme Announces Largest Drug Price Reduction Deals in Five Years (Jan. 20, 2004), *available at* http://www.kaisernetwork.org/daily_reports/rep_index.cfm?hint=1&DR_ID=21751.

¹⁹⁰ Matthews, *supra* note 161, at 81.

¹⁹¹ Rory Carroll, *Africa's Aids Drugs Trapped in the Laboratory*, THE GUARDIAN, May 21, 2003, <http://www.guardian.co.uk/aids/story/0,,960116,00.html>.

¹⁹² Kapczynski et. al., *supra* note 32, at 1061.

¹⁹³ *Id.* (citing *Cipla Gets Malaysian Nod for AIDS Drugs*, BUS. STANDARD (India), Feb. 25, 2004 (reporting Malaysia's recent compulsory license); Martin Khor, *Patents vs. Access to Medicines at AIDS Conference*, DAILY NEWS (Sri Lanka), Aug. 10, 2004 (reporting Mozambique's recent compulsory license), <http://dailynews.lk/2004/08/10/fea11.html>)).

Unlike Egypt, Brazil's compulsory license statute does not appear to come at a price of lost FDI. Brazil's compulsory license practices have done little to hamper its ability to attract FDI. According to a pharmaceutical industry executive, Brazil has received \$2 billion of FDI in the pharmaceutical and chemical sectors since its modern patent law was adopted in 1996.¹⁹⁴

Although Brazil may be a useful model, not every developing country has the political savvy, economic might, and technological infrastructure to resist pressure from MNEs to avoid issuing compulsory rights. Furthermore, not every country will be able to take the moral high ground in a compulsory license dispute as Brazil did. Egypt was denied a significant public relations tool in its confrontation with Pfizer because – unlike the antiretroviral drugs, which hinder the debilitating effects of the HIV virus -- Viagra does not treat what's commonly understood to be a universal public health crisis. The next section discusses strategies for least developed countries to use compulsory license statutes for maximum effect and minimum cost.

IV. COLLECTIVE ACTION AS AN EQUALIZING MECHANISM

Certain individual nations may face significant economic drawbacks to imposing compulsory licenses in the absence of additional negotiating leverage. Unfortunately, often the countries most in need of increased access to essential medicines have the least leverage. The overall economic welfare of a country's citizens may prevent the maximization of health care interests through the utilization of the flexibility inherent in the TRIPS agreement. On the other hand, countries having no emergent need for compulsory license powers may yield to incentives and employ them for less than socially optimal reasons. Some kind of middle ground would be useful, but it is hard to identify it in the context of individual action.

The solution may be to expand the analysis by considering coordinated action among countries. Through the use of a collective action mechanism, it may be possible for a country with a certain level of immunity to share the protection with one or several countries more susceptible to FDI economic retribution. The use of coordinated behavior may bring about a more equitable result, so long as one is aware of the legal limits of such mechanisms and the anti-coordination strategies that may be employed by opponents of the system.

¹⁹⁴ Mayer, *supra* note 118, at 668.

A. *The Power of Collective Action in International Relations*

In many respects, we tend to view nation-to-nation coordination in terms of great international organizations such as the United Nations, the World Trade Organization and the World Health Organization, among others. The principle of multilateral treatment and most favored nation guarantees suggests that international interaction must be on a local scale, or global. However, there is also a place for regional coordination within the international framework. Referred to by WTO Director-General Pascal Lamy as the “pepper” in the “multilateral curry,”¹⁹⁵ regional coordination offers distinct advantages in the form of harmonizing investment, competition, technical standards, labor standards or environment rules, when international consensus cannot be achieved.¹⁹⁶ Most important in the context of FDI-retribution, it may offer a mechanism for countering the power of developed countries.

The importance of coordinating regions to achieve political or economic benefits greater than that which would be achievable by the respective individual countries is well-understood.¹⁹⁷ Moreover, various legal mechanisms to achieve such coordination are already in place across the globe. Perhaps the most prominent example is the European Union (“EU”), which provides its members with coordinated trading power, regulation and market integration, among other advantages.¹⁹⁸ In addition to the EU, there are over 250 other coordination systems currently in operation, and the number is expected to reach 400 by 2010.¹⁹⁹ Almost

¹⁹⁵ Pascal Lamy, Dir.-Gen., WTO, Regional Agreements: The “Pepper” in the Multilateral “Curry,” Speech Before the Confederation of Indian Industries (Jan. 17, 2007), http://www.wto.org/english/news_e/sppl_e/sppl53_e.htm.

¹⁹⁶ *Id.*

¹⁹⁷ For a detailed overview of the social and economic rationale for collective action by countries through formal agreement, see generally Kenneth W. Abbott & Duncan Snidal, *Why States Act Through Formal International Organizations*, 42 J. CONFLICT RESOL. 3 (1998).

¹⁹⁸ European Union, *Europe in 12 Lessons: 1. Why the European Union?*, http://europa.eu/abc/12lessons/lesson_1/index_en.htm (last visited Dec. 10, 2007). The EU’s long history began with a more narrow treaty on regional trade, the 1951 European Coal and Steel Community. See Treaty Establishing the European Coal and Steel Community (“ECSC”), Apr. 18, 1951, 261 U.N.T.S. 140.

¹⁹⁹ Pascal Lamy, Dir.-Gen., WTO, Multilateral and Bilateral Trade Agreements: Friends or Foes? Gabriel Silver Memorial Lecture at Columbia University, 2 (Oct. 31, 2006), http://www.sipa.columbia.edu/news_events/special_events/silver_lecture/Lamy_SIPASil

half have been created since the WTO came into being in 1994.²⁰⁰

The basic international legal structure supporting regional coordination comes from the 1947 General Agreement on Tariffs and Trade, art. XXIV.²⁰¹ It provides for the additional facilitation of trade between countries in a region through regional trading agreements (“RTA”) that liberalize policies.²⁰² However, it specifically prohibits the imposition of trade barriers against non-members; it is supposed to be a “building block” to multilateral treaties.²⁰³ Currently, all RTAs must be approved by the WTO.²⁰⁴ Countries can be members of several agreements,²⁰⁵ even within a region,²⁰⁶ so long as each agreement meets the GATT criteria. In fact, commentators have noted that the rules appear to be a relatively minor sticking point for RTA certification, as lax WTO oversight and enforcement has rendered article XXIV a “paper tiger.”²⁰⁷ Depending on the interpretation of phrases such as “substantially all trade,” RTAs that cover relatively narrow subject matter such as public health may be viable. In any case, revision of an existing RTA to cover public health issues is certainly possible.

Significantly, recent revisions to the TRIPS agreement concerning compulsory licensing specifically envision the use of regional coordination under the GATT. When expanding the application of compulsory licensing to include the importation from a country with manufacturing capacity to one without, a specific provision on RTAs was included:

verLecture.pdf; Lamy, *supra* note 195.

²⁰⁰ WTO, *Regional Trade Agreements*, http://www.wto.org/english/tratop_e/region_e/region_e.htm (last visited Dec. 10, 2007).

²⁰¹ General Agreement on Tariffs and Trade, Oct. 30, 1947, 61 Stat. A-11, 55 U.N.T.S. 194 [hereinafter GATT].

²⁰² *Id.*, art. XXIV, para. 4-5. See also Understanding on the Interpretation of Article XXIV of the General Agreement on Tariffs and Trade 1994, Annex 1A, para. 4.

²⁰³ Sungjoon Cho, *Defragmenting World Trade*, 27 NW. J. INT’L L. & BUS. 39, 49 (2006) (citing JAGDISH BHAGWATI, *THE WORLD TRADING SYSTEM AT RISK* 77 (1991)).

²⁰⁴ Committee on Regional Trade Agreements, *Decision of 6 February 1996*, WT/L/127 (Feb. 7, 1996).

²⁰⁵ See WTO, *Scope of RTAs*, http://www.wto.org/english/tratop_e/region_e/scope_rta_e.htm (last visited Dec. 10, 2007). See also WTO, *Regional Trade Agreements and Definitions*, http://www.wto.org/english/tratop_e/region_e/region_areagroup_e.htm (last visited Dec. 10, 2007) (providing several examples of member countries belonging to different RTAs).

²⁰⁶ See WTO, *Regional Trade Agreements and Definitions*, http://www.wto.org/english/tratop_e/region_e/region_areagroup_e.htm (last visited Dec. 10, 2007).

²⁰⁷ Cho, *supra* note 203, at 54.

(i) where a developing or least-developed country WTO Member is a party to a regional trade agreement within the meaning of Article XXIV of the GATT 1994 and the Decision of 28 November 1979 on Differential and More Favorable Treatment Reciprocity and Fuller Participation of Developing Countries (L/4903), at least half of the current membership of which is made up of countries presently on the United Nations list of least developed countries, the obligation of that Member under Article 31(f) of the TRIPS Agreement shall be waived to the extent necessary to enable a pharmaceutical product produced or imported under a compulsory license in that Member to be exported to the markets of those other developing or least developed country parties to the regional trade agreement that share the health problem in question. It is understood that this will not prejudice the territorial nature of the patent rights in question . . .²⁰⁸

Although somewhat restricted in the sense that fifty percent of the RTA members must be LDCs, the Doha Declaration creates an important opening for coordination in the distribution of essential medicines.

For the most part, commentary on the flexibilities offered by the regional trading provision of the article 31 revisions has been restricted to discussion of the economies of scale and direct economic benefits it may yield. For example, Novogrodsky has argued that RTAs could provide enhanced purchasing power and more efficient movement of AIDS medicines in Africa, suggesting the utilization of existing agreements.²⁰⁹ Abbot and Reichman discuss in detail the benefits of pooled procurement strategies, which may additionally “stimulate direct investment in local production facilities” and “support research and training” in developing countries.²¹⁰

Efficiency considerations are obviously worthwhile; however, they may neglect the potential of such agreements as a defense to FDI retribution. The use of RTAs as a framework for collective action in order to increase access to essential medicines is a significant tool that bears investigation. An economic model is helpful at this point.

²⁰⁸ Paragraph 6 Decision, *supra* note 48, at ¶6(i).

²⁰⁹ Posting of Ben Krohmal to Drug Development (with Access), *Noah Novogrodsky on “Compulsory Licensing in Ghana – the Continuing Barriers to Affordable Medicines”*, <http://www.cptech.org/blogs/drugdevelopment/2006/11/noah-novogrodsky-on-compulsory.html> (Nov. 9, 2006, 20:05) (summary of research presented by Novogrodsky, but not yet available in print).

²¹⁰ Abbott and Reichman, *supra* note 78, at 973-74. The authors propose potential models for coordination, including a “large regional” one that might utilize twelve countries and a “smaller model” that could provide benefits with as few as three. *Id.* at 974-77.

B. A Model of Collective Behavior

To better conceptualize the possibilities for developing country coordination, it is useful to think of compulsory licensing as a multi-player exercise wherein one player's choices influence the others' outcomes. In detailing the likely outcomes of various choices, it may be possible to identify optimal or dominant strategies for each player in view of the other players' moves. This should permit one to predict which choices a rational country will make, and suggest the design of relevant economic incentives to encourage that result.

The type of decision-making analysis particularly well suited to this problem is known as game theory.²¹¹ More specifically, when one excludes the possibility of binding cooperation or coordination through agreement, the analysis of various moves is known as "non-cooperative" game theory, because it is assumed that each player is trying to maximize its own payoffs.²¹² The moves of the game's participants are generally graphed out like a simple chessboard or decision tree, and the games can be represented as simultaneous decision-making or sequential.²¹³

In the context of compulsory licenses, one may apply game theory to the actions of at least two countries that may consider imposing such licenses.²¹⁴ One can model the benefits of licensing along with the

²¹¹ See Brett Frischmann, *A Dynamic Institutional Theory of International Law*, 51 BUFF. L. REV. 679, 700 (2003) ("Game theory, a form of rational choice theory, provides a useful framework for analyzing international cooperation and institutions because it provides a relatively straightforward model of rational decision-making by entities in situations where their decisions are interdependent and they face conflicting strategic incentives.").

²¹² ERIC RASMUSEN, *GAMES AND INFORMATION* 18 (2d ed. 1994).

²¹³ DOUGLAS G. BAIRD, ET AL., *GAME THEORY AND THE LAW* 6-14, 50-57 (1994).

²¹⁴ David Opderbeck used a similar approach to model the actions of a given country and an innovator pharmaceutical company. David W. Opderbeck, *Patents, Essential Medicines, and the Innovation Game*, 58 VAND. L. REV. 501, 536 (2005). The potential cooperative behavior of two or more licensing countries was therefore outside the scope of his analysis. The relationship between intellectual property rights and licensing behavior was also explored using a game theory analysis by Cahoy in 2003. Daniel R. Cahoy, *Oasis or Mirage?: Efficient Breach as a Relief to the Burden of Contractual Recapture of Patent and Copyright Limitations*, 17 HARV. J.L. & TECH. 135 (2003). Finally, in 1991, Lebron presented a highly relevant game theory analysis of the effect of regulation on FDI. David W. Lebron, *A Game Theoretic Approach to the Regulation of Foreign Direct Investment and the Multinational Corporation*, 60 CINCINNATI L. REV. 305 (1991).

retribution of FDI reduction, and consider specifically the impact of coordination.²¹⁵ A normal form game is a simple and common format, but the possibility of additional sequential decision points is easier to model with a format known as an extensive form game (mixed versions are possible as well).²¹⁶

For simplicity's sake, it is useful to imagine a two-person game with each "person" representing a middle-developed country. The players can choose to do nothing, individually impose a compulsory license on a particular pharmaceutical, or work together to impose a joint license. Long-term outcomes or payoffs can be hypothesized and added to the game to illustrate strategies. In this game, one could hypothesize payoffs for the two countries as well as the company behind the pharmaceutical product.²¹⁷ Variables that affect the payoffs in this simplified example include:

- i_s = the benefits from the standard FDI inflow into a particular country
- i_r = any reallocated benefits of FDI as a result of compulsory licensing
- p_h = the economic effects derived from a health care program utilizing pharmaceuticals. This benefit would be considered the sum of pharmaceutical health benefits minus

²¹⁵ Without empirical data to produce actual figures representing quantitative impact, one is necessarily constrained to using numbers that convey the magnitude of payoff differentials based on broad assumptions. Obviously, the choice of numbers will dictate the result of the game, and – due to the inherent uncertainty – one should be cautioned about relying too heavily on the results as a predictors of real-world economic outcomes. See BAIRD, *supra* note 213, at 9 (explaining that one posits dollar amounts to convey the idea underlying the model). Rather, it is most useful for illustrating relationships and the effect of incentives on various decision-making points. For example, Operderbeck uses fictional numbers to convey the magnitude of economic impact in compulsory license decisions on innovation investment. See Operderbeck, *supra* note 214, at 536-37. Equally important, one can derive the relevant factors that would have an effect on the relationship. Of course, future empirical data should be expected to bear out the posited economic relationships if they are indeed valid.

²¹⁶ Simultaneous decision scenarios are generally represented by grids in a normal form game, whereas sequential decision scenarios are commonly represented by decision trees in an extensive form game. BAIRD, *supra* note 213, at 6-14, 50-57; DAVID M. KREPS, *GAME THEORY AND ECONOMIC MODELING* 10-21 (1990).

²¹⁷ One could also look at the pharmaceutical company's payoffs in terms of the effect on the company's home country, though with developed countries, there would have to be a rather large exaggeration in the magnitude of economic effects to convey the impact on decision-making.

pharmaceutical expenditures: $p_h = p_b + p_e$
 p_{cl} = the savings derived from compulsorily licensing patented pharmaceuticals

Beginning with an example that highlights the case of two middle-income countries that are sensitive to FDI retribution, a baseline is set in that, if no license is imposed, a country will have a given level of economic wealth (W_{MDC}) equal to the standard FDI plus the benefits from pharmaceutical health care programs ($i_s + p_h$). The game could set the FDI figure at an arbitrary of number of 6 and the pharmaceutical health figure at 1, totaling 7.²¹⁸ Additionally, the pharmaceutical company would be at a maximum level of profit in the two countries, which could be set at 10. If one country chooses to license, but the other country does not, one might expect that there will be a short-term gain from the cost-savings on the medicine, but that it will be countered by an eventual loss in FDI:

$$W_{MDC1} = i_s - i_r + p_h + p_{cl}$$

If the FDI losses are set at 2 and the compulsory license saving set at 1, the total wealth decreases to 6. On the other hand, the non-licensing country might gain by additional FDI channeled from the licensing country:

$$W_{MDC2} = i_s + i_r + p_h$$

Using the same variable above, this yields a total wealth of 9. And the pharmaceutical company could be expected to lose some profit, having its wealth reduced to 7 (*see* Figure 1).

²¹⁸ This represents the fact that a country has significant wealth regardless of whether a license is imposed, and maintaining the status quo is always a viable, if not optimal, option.

Figure 1

Effects with Two Countries in a Given Region Susceptible to FDI Retribution

		MDC2	
		No License	License
MDC1	No License	7,7,10	9,6,7
	License	6,9,7	8,8,5

Payoffs: (MDC1, MDC2, Pharmaceutical Company). This presumes that individual country licensing leads to lower value than no licensing or coordinated licensing

On the other hand, if both countries impose compulsory licenses at the same time, one might imagine that the likelihood of FDI punishment would be reduced or eliminated (assuming that some FDI must take place in the region represented by the two countries), leaving only the economic advantages gained from the license ($i_s + p_h + p_{cl}$). Using the variable above yields a figure of 8 for each country. The pharmaceutical company's wealth could be further reduced to 5. Clearly both countries are better off licensing than both refraining from any action at all. But is this the most likely outcome?

In analyzing a normal form game as above, one does not necessarily pick the outcome that is objectively best for both players. Rather, one considers the strategies from the relative positions of the two parties, and chooses the options for each in view of the likely choices by the other parties. The identification of the coordinated best choices is termed the Nash equilibrium.²¹⁹ If a game possesses a single equilibrium, it is presumed that this will be the most likely outcome.

²¹⁹ See BAIRD, *supra* note 213, at 19-23; KREPS, *supra* note 216, at 28-36; RASMUSEN, *supra* note 212, at 22-28. The Nash equilibrium takes its name from the renowned economist John Nash who pioneered the form of analysis. See John F. Nash, Jr., *The Bargaining Problem*, 18 *ECONOMETRICA* 155, 155-62 (1950) (providing an economic analysis of the two-person bargaining situation).

Given the assumptions above, it is clear that the Nash equilibrium is not to license. For each country, the best option if the other country imposes a compulsory license is to refrain from licensing, obtaining wealth of 9 (instead of 8 with a license). On the other hand, if the other country does not license, the best option is still to refrain from licensing, retaining wealth of 7 instead of 6 due to FDI punishment. Therefore, the Nash equilibrium for two economically rational countries is for both to choose to refrain from licensing. This will occur whenever the FDI retribution outweighs the gains from compulsory licensing. In other words, there will likely be an underutilization of compulsory licenses if:

$$i_r > p_{cl}$$

Only when the compulsory license gains are greater does the equilibrium shift.

This conundrum, wherein two countries/players are unlikely to choose the best coordinated outcome due to the payoff disincentives is a classic example of a well-known game construct called the “prisoners’ dilemma.”²²⁰ It has been hypothesized to occur in other instances of international relations,²²¹ and provides a useful starting point for establishing a better system of coordination. In general, one can resolve a prisoners’ dilemma in one of two ways: (1) legal intervention that forces the two parties toward the more efficient solution or (2) permitting the two parties to cooperate through binding agreement.²²²

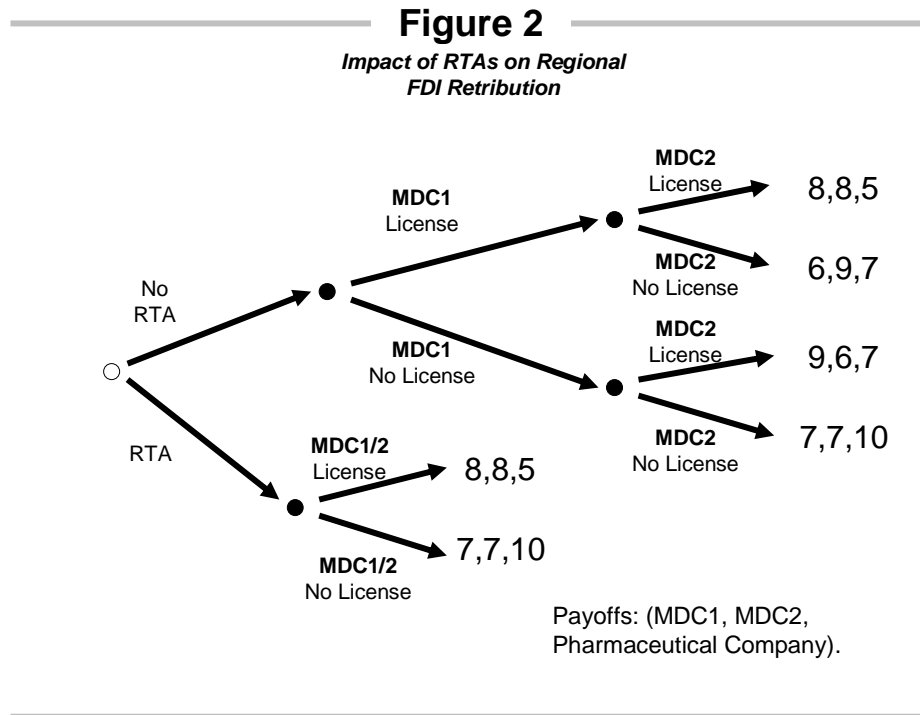
As a matter of international law, the likelihood of legally-forced

²²⁰ KREPS, *supra* note 216, at 37-39; RASMUSEN, *supra* note 212, at 16-18. *See also* BAIRD, *supra* note 213, at 48-49 (recounting the academic development of the prisoners’ dilemma). A common criticism of the use of the prisoners’ dilemma paradigm to analyze complex, multi-party interactions is that it may present an incomplete picture of the relevant decision factors. *Id.* at 188. Indeed, as the discussion *infra* demonstrates, a simple bimatrix of compulsory licensing is insufficient as a stand-alone model.

²²¹ *See, e.g.*, Donald H. Regan, *What are Trade Agreements For?-- Two Conflicting Stories Told by Economists, With a Lesson for Lawyers*, 9 J. INT’L ECON. L. 951, 956 (2006) (discussing a de facto prisoner’s dilemma in the context of international trade and tariffs.); Frederick Tung, *Is International Bankruptcy Possible?*, 23 MICH. J. INT’L L. 31, 100-01 (2001) (“Universalism presents [states] with a prisoners’ dilemma that is not easily resolved, either through the standard prescription of repeat play or more elaborate devices.”); John K. Setear, *Responses to Breach of a Treaty and Rationalist International Relations Theory: The Rules of Release and Remediation in the Law of Treaties and the Law of State Responsibility*, 83 VA. L. REV. 1, 27-32 (1997) (discussing the prisoners’ dilemma in arms control).

²²² BAIRD, *supra* note 213, at 188.

compulsory licensing is miniscule,²²³ but coordination through agreement is a real possibility. By invoking the power of regional trade agreements under TRIPS and GATT, it is possible for countries to create a system wherein licenses are coordinated to apply the benefits throughout a region.²²⁴ This would have the effect of blunting the FDI effects, due to the difficulty in punishing each member of the region. It can be represented graphically using an extensive form game to illustrate the sequential events of forming a new (or revising an existing) regional trade agreement to permit the distribution of licensed medicines, followed by the license for a particular pharmaceutical under emergency conditions (see Figure 2).



Note that the use of an RTA collapses the license/no-license options, and leaves the countries with either no license or coordinated licensing. Assuming the same wealth figures used above, the incentives are now

²²³ One possible mechanism might be to compel countries to enact compulsory license statutes that function automatically, without the need for state action. For example, in the United States, a private individual may make use of the compulsory license for copyrighted phonorecord by simply complying with the statutory requirements. 17 U.S.C. § 115 (2000).

²²⁴ See *supra* notes 201-209, and accompanying text.

shifted toward coordinated licensing, and this option would be expected to form the equilibrium under emergent conditions. Significantly, these results may be even more likely if the country initiating the license was relatively unaffected by FDI retribution and its actions could benefit a large number of members in an RTA.

It is important to note that, given the territoriality of patent rights, members of an RTA would still be required to enact individual compulsory licenses (if the patent holder has obtained rights from those members).²²⁵ Although there are a few regional patent-granting entities, including the African Regional Industrial Property Organization (“ARIPO”),²²⁶ the rights are enforced in individual nations.²²⁷ Thus, a coordinated license would actually be a group of related licenses. In addition, member states probably cannot impose a standing compulsory license contingent on an FDI-resistant country’s actions. This is because TRIPS prohibits the *ex ante* imposition of compulsory licenses over broad categories of inventions.²²⁸

To date, this level of coordination has not occurred among developing and least-developed countries. One reason may be the difficulties in negotiating an RTA framework, the content of which is often wide-ranging and significantly broader than compulsory licensing.²²⁹ Another factor might be the problem in coordinating a compulsory license response to a particular disease.²³⁰ But perhaps a greater issue may be the

²²⁵ Abbott and Reichman, *supra* note 78, at 944-45.

²²⁶ ARIPO, *About ARIPO – Membership* (last updated Sept. 9, 2006), <http://www.aripo.org/articles.php?lng=en&pg=14>. The sixteen members of ARIPO are Botswana, the Gambia, Ghana, Kenya, Lesotho, Malawi, Mozambique, Namibia, Sierra Leone, Somalia, Sudan, Swaziland, Tanzania, Uganda, Zambia and Zimbabwe. *Id.*

²²⁷ *See, e.g.* ARIPO, *About ARIPO – Legal Framework* (last updated Sept. 9, 2006), <http://www.aripo.org/articles.php?lng=en&pg=61> (noting that ARIPO examines patents, but member states have final say on whether to enforce them within their respective countries).

²²⁸ TRIPS, *supra* note 12, art. 31(a) (“[A]uthorization of such use shall be considered on its individual merits . . .”).

²²⁹ Cho, *supra* note 203, at 54 (quoting the WTO Secretariat’s description of RTAs as broadened in scope and geographic reach).

²³⁰ The most developed model for nation-nation cooperation on a particular disease relates to AIDS, and that certainly has relevance here. *See* WHO, COMMISSION ON INTELLECTUAL PROPERTY RIGHTS, INNOVATION AND PUBLIC HEALTH, PUBLIC HEALTH, INNOVATION AND INTELLECTUAL PROPERTY RIGHTS 9 (2006) [hereinafter CIPIH REPORT] (describing numerous, coordinated multinational efforts to combat AIDS). Another example might be bird flu. *See* WHO, *Ten Things You Need to Know about Pandemic Influenza* (Oct. 14, 2005), <http://www.who.int/csr/disease/influenza/pandemic10things/en/index.html> (presenting an

tactics employed by developed countries to prevent RTA-eligible nations from coordinating their compulsory license flexibilities.

C. Developed-Country Strategies: A Free Trade Agreement Layer

Given the heavy losses intellectual-property oriented companies could suffer as a result of coordinated compulsory licensing, it is reasonable that a lobby would organize to encourage a developed country response. Some mechanism for precluding the implementation of an RTA that includes regional trade in licensed medicines might be sought. Most particularly, if one could lock out individual countries from the licensing scheme, the immunizing effects of the RTA could be reduced or eliminated.

Many would argue that just such a strategy is already being employed through the use of free trade agreements (“FTA”).²³¹ FTAs are actually just a form of regional trade agreement under GATT,²³² and the terms may be used interchangeably. The distinguishing factor of the new breed of FTAs is that they are often bilateral — involving a developed country such as the U.S. and a developing or least-developed country — and they often contain terms that raise the baseline protections of

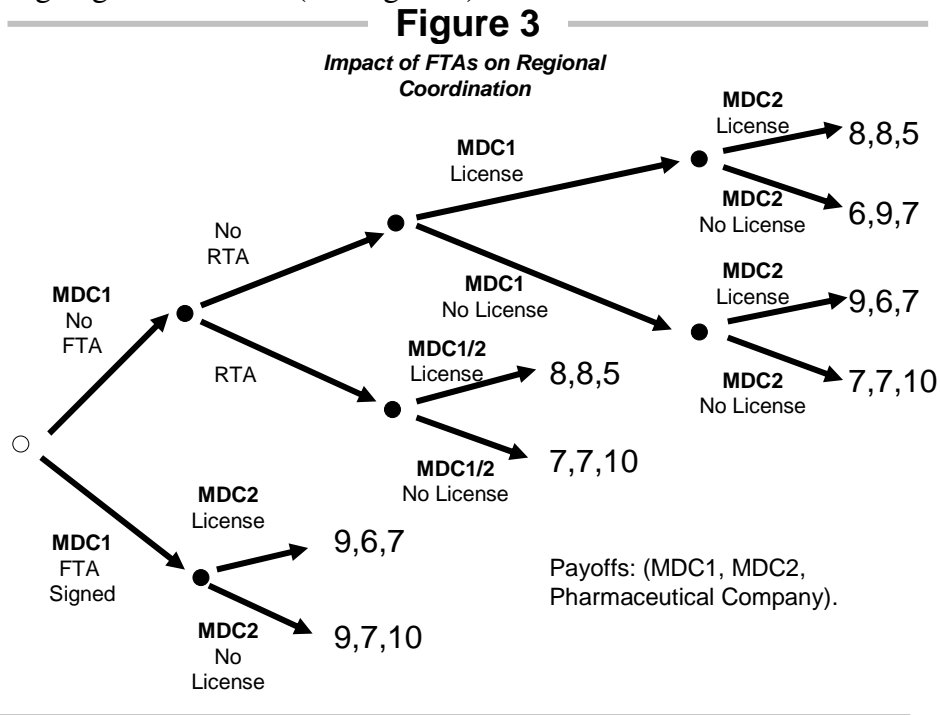
especially frightening warning about the consequences of influenza pandemics, noting that up to 7.4 million deaths may occur and that every country must be prepared). Fortunately, the predicted horrific effects have yet to materialize.

²³¹ See, e.g., Abbott and Reichman, *supra* note 78, at 963 (FTA’s “could effectively preclude use of compulsory licensing because they contained no language that expressly avoids this result.”). It is worth noting that Bilateral Investment Treaties (BITs) may inadvertently complicate the above-described strategies. As specifically noted in the most recent version of the U.S. Model Bilateral Investment Treaty, such agreements are not intended to interfere with TRIPS-compliant compulsory licenses. U.S. Trade Rep. et al., Model Bilateral Investment Treaty, art. 6(5) (Nov. 2004), available at http://www.ustr.gov/assets/Trade_Sectors/Investment/Model_BIT/asset_upload_file847_6897.pdf. But older versions employing the so-called “Hull formulation” may require a higher standard. See Jeswald W. Salacuse & Nicholas P. Sullivan, *Do BITS Really Work?: An Evaluation of Bilateral Investment Treaties and Their Grand Bargain*, 46 HARV. INT’L L.J. 67, 87 (2005) (noting that compensation for taken property shall be prompt, adequate, and effective). In a recent paper, Carlos Correa finds that compulsory licenses could indeed be considered expropriations under some interpretations, and the compensation mechanisms guaranteed in standard BITS would likely rise above that mandated by TRIPS. Carlos M. Correa, *Investment Protection in Bilateral and Free Trade Agreements: Implications for the Granting of Compulsory Licenses*, 26 MICH. J. INT’L L. 331, 348-51 (2004).

²³² Cho, *supra* note 203, at 44; Won-Mog Choi, *Legal Problems of Making Regional Trade Agreements with Non-WTO-Member States*, 8 J. INT’L ECON. L. 825, 826 n.1 (2005) (explaining the breadth of the concept of RTAs under GATT).

TRIPS.²³³ Known colloquially as “TRIPS-Plus” agreements, the FTAs are suggested to offer outside benefits for the developed country to the detriment of the public health of the developing nation’s citizens.²³⁴

If a free trade agreement were used to bind one of potential licensees in the above game theoretic model, one can imagine how the outcomes would dramatically change. The FTA essentially eliminates the possibility of coordination. So long as the benefits for entering into the FTA outweigh the likely outcome of the Nash equilibria associated with the freedom to enter into an RTA (in other words, greater than p_{ci}), a rational country should be willing to take itself out of the game. To articulate the concept graphically, one can simply add another decision-making level to the extensive form game above and set the wealth impact of signing the FTA at 9 (see Figure 3).



²³³ See Peter K. Yu, *Currents and Crosscurrents in the International Intellectual Property Regime*, 38 LOY. L.A. L. REV. 323, 392-400 (2004) (discussing the move to bilateral trade agreements as a response to resistance to multilateralism).

²³⁴ See Bryan Mercurio, *TRIPS-Plus Provisions in RTAs: Recent Trends*, in REGIONAL TRADE AGREEMENTS AND THE WTO LEGAL SYSTEM (Lorand Bartels & Federico Ortino eds., 2006); Carsten Fink & Patrick Reichenmiller, *Tightening TRIPS: The Intellectual Property Provisions of Recent US Free Trade Agreements*, TRADE NOTE, Feb. 7 2005, <http://www.cptech.org/ip/health/trade/worldbank02072005.pdf>.

Note that every country that might participate in a regional coordination scheme need not be subject to a TRIP-Plus FTA — only enough countries to disrupt the immunizing effects. And as noted above, there is significance in the RTA members that are resistant to FDI effects, as locking them out can produce the strongest anti-licensing effects.

Returning to the country examples detailed in Part III, consider the possibility that Egypt may negotiate away compulsory licensing discretion in exchange for an FTA with the United States. Currently, the United States and Egypt lack a formal FTA. An FTA can open a gateway for increased trade with the United States, granting benefits that may outweigh any costs from having a broad compulsory license statute. In 2000, Jordan formalized an FTA with the United States, in part in exchange for achieving a peace treaty with Israel.²³⁵ One year before the agreement was reached, the United States imported \$31 million worth of good from Jordan.²³⁶ By 2004, imports skyrocketed to \$1 billion.²³⁷ Exports from the United States to Jordan doubled during that time.²³⁸ Given Egypt's already existing strength as a pharmaceutical producer in the Middle East, a free trade agreement might enable increased exports of drugs to the United States and increased partnerships with technology-rich American pharmaceutical firms. That in turn may result in increased revenue available for further research of pharmaceutical drugs beneficial to Egyptian citizens. While even the full retraction of a compulsory license statute will not be a lynchpin for establishing an FTA with the United States, curtailing the statute presents another bargaining chip with which to extract concessions from the United States.

V. CONCLUSION

There is little doubt that developing countries who issue compulsory licenses also face additional risks in attracting global capital. Particularly for MDCs, a compulsory license can trigger the loss of significant FDI. Thus, each nation has to weigh the benefits as well as the disadvantages of issuing such a license for the benefit of its citizens.

Developing nations, however, may attempt to use their compulsory licenses strategically by acting collectively with countries that have similar

²³⁵ Johnson, *supra* note 95, at 485.

²³⁶ *Id.*

²³⁷ *Id.*

²³⁸ *Id.*

interests. Through the use of a collective action mechanism, it may be possible for a country with a certain level of immunity from FDI to share that immunity with other countries more susceptible to FDI economic retribution. The use of coordinated behavior may bring about a more equitable result for developing nations and equalize bargaining power between MNCs and developing nations.

The ideas presented in this manuscript present a robust opportunity for further researchers to explore how collective action by nations can foster more favorable results when compared to acting alone. Bargaining based upon collective action may also help promote an agreement that both MNCs and developing nations can find satisfactory. Perhaps most importantly, collective action by nations will help individuals who most need critical drugs have access to them and improve their quality of life.