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We Can Work It Out: Co-op Compulsory Licensing as the Way Forward in Improving Access to Anti-Retroviral Drugs

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ARTICLE

WE CAN WORK IT OUT: CO-OP COMPULSORY LICENSING AS THE WAY FORWARD IN IMPROVING ACCESS TO ANTI-RETROVIRAL DRUGS

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"Our vision is that people everywhere have access to the essential medicines they need; that the medicines are safe, effective and of assured quality; and that they are prescribed and used rationally."

World Health Organization[2]

"A lack of credible patent rights for pharmaceuticals in the developing world may do far more harm in the long run than their absence can accomplish in the short run."

Alan O. Sykes[3]

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[2] World Health Organization, Statement on Essential Medicines and Pharmaceutical Policies, http://www.who.int/medicines/en/ (last visited Nov. 21, 2009).

[3] Alan O. Sykes, *Public Health and International Law: TRIPS, Pharmaceuticals, Developing Countries, and the Doha "Solution,"* 3 CHI. J. INT'L L. 47, 68 (2002).

I. INTRODUCTION

An enduring fact of the global battle against HIV/AIDS is the problem of providing access to anti-retroviral drugs ("ARVs") to all those who need them. ARVs and other essential medicines are generally protected by patent law, and they can be prohibitively expensive for persons in the developing world.[4] A number of strategies have been employed over time to increase access to essential medicines, including exclusion of pharmaceutical inventions from patent protection, enactment of curtailed patent protection for drugs, imposition of compulsory licensing, provision of medicines at discounted prices, and implementation of drug donation programs.[5] One of the more recent attempts has been the amendment of the Agreement on Trade Related Aspects of Intellectual Property ("TRIPS") to allow countries with manufacturing capacity (most likely middle-income countries with histories of generic drug production such as Brazil and India) to manufacture generic versions of patented drugs and export them at low prices to countries lacking the ability to manufacture.

In theory, the compulsory licensing scheme created by this amendment (the "Health Flexibility Waiver" or "Waiver") should provide an avenue for increased access by allowing countries with the means and desire to manufacture to serve those countries whose public health needs are not served by the default system of strong pharmaceutical patent protection.[6] In practice, however, the Health Flexibility Waiver is severely underutilized, with only one country signing on as an exporter of a generic drug and one country signing on as an importer of that drug as of the time of this writing.[7] Commentators have

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[4] Although the access problem is not limited to HIV/AIDS and ARVs, the human impact (and the potential for improvement) of the HIV crisis in the developing world has made ARVs the most cited example in the access debate. This paper's focus on ARVs reflects their prominence in the public debate, but the hope is that the ideas developed herein may be useful in improving access with respect to other therapies and other diseases as well.

[5] *See, e.g.*, DORIS ESTELLE LONG & ANTHONY D'AMATO, INTERNATIONAL INTELLECTUAL PROPERTY 126 (West Group 2000); Merck, Fighting River Blindness, http://merck.com/responsibility/access/access-feature-mectizan.html (last visited May 22, 2010).

[6] *See* Press Release, World Trade Organization, Decision Removes Final Patent Obstacle to Cheap Drug Imports (Aug. 30, 2003), *available at* http://www.wto.org/english/news_e/pres03_e/pr350_e.htm.

[7] Canada has signed on as an exporting country, and Rwanda as an importing country. The Canadian generics producer Apotex has been authorized to manufacture and export to Rwanda 260,000 packs of TriAvir, a fixed-dose combination of the patented ARVs Zidovudine, Lamivudine, and Nevirapine. *See* 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 – Rwanda*, IP/N/9/RWA/1 (July 19, 2007), *available at* http://docsonline.wto.org/GEN_highLightParent.asp?qu=%28+%40meta%5FSymbol+IP%FCN%FC9%FC%2A+%29+&doc=D%3A%2FDDFDOCUMENTS%2FT%2FIP%2FN%2F9RWA1%2EDOC%2EHTM&curdoc=3&popTitle=IP%2FN%2F9%2FRWA%2F1; *see also* Council for Trade-Related Aspects of Intellectual Property Rights, *Notification Under*

variously attributed this underutilization to the scheme's burdensomeness and lack of implementation flexibility,[8] the scheme's failure to recognize the need for economies of scale for exporting countries,[9] political pressure and norm imposition by the West,[10] failure of antitrust and competition policy,[11] and inadequate existing market and private investment models of development and distribution of public goods.[12]

None of these rationales, however, paints a complete picture of the shortcomings of the Waiver. The real problem is one of misaligned incentives. Despite the short-term losses that a compulsory licensing scheme like the Waiver creates for drug company owners of IP, there are sound long-term economic incentives for increasing access; today's ARV consumers can become tomorrow's Lipitor consumers only if they get cheap access to ARVs in the present. However, the possibility of strategic behavior on the part of developing nations and third parties, particularly with regard to diversion, has instead given patent owners the incentive to undermine the Waiver by way of Free Trade Agreements ("FTAs") and unilateral trade actions. Only by realigning the incentives of all parties can the Waiver be of any use in solving the access problem.

Paragraph 2(C) of the Decision of 30 August 2003 on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health – Canada, IP/N/10/CAN/1 (Oct. 8. 2007), *available at* http://docsonline.wto.org/GEN_highLightParent.asp?qu=%28+%40meta%5FSymbol+IP%FCN%FC10%FC%2A+%29+&doc=D%3A%2FDDFDOCUMENTS%2FT%2FIP%2FN%2F10CAN1%2EDOC%2EHTM&curdoc=3&popTitle=IP%2FN%2F10%2FCAN%2F1.

[8] *See* Amir Attaran, *Assessing and Answering Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health: The Case for Greater Flexibility and a Non-Justiciability Solution*, 17 EMORY INT'L L. REV. 743 (2003); 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, 97 (2004).

[9] *See* Mike Gumbel, Comment, *Is Article 31 bis Enough? The Need to Promote Economies of Scale in the International Compulsory Licensing System*, 22 TEMP. INT'L & COMP. L.J. 161 (2008).

[10] *See, e.g.*, Cynthia M. Ho, *Biopiracy and Beyond: A Consideration of Socio-Cultural Conflicts with Global Patent Policies*, 39 U. MICH. J.L. REFORM 433 (2006); James Thuo Gathii, *The Structural Power of Strong Pharmaceutical Patent Protection in U.S. Foreign Policy*, 7 J. GENDER RACE & JUST. 267 (2003).

[11] *See, e.g.*, Uché Ewelukwa, *Patent Wars in the Valley of the Shadow of Death: The Pharmaceutical Industry, Ethics, and Global Trade*, 59 U. MIAMI L. REV. 203 (2005).

[12] *See, e.g.*, Taiwo A. Oriola, *Strong Medicine: Patents, Market, and Policy Challenges for Managing Neglected Diseases and Affordable Prescription Drugs*, 7 CAN. J.L. & TECH. 57 (2009); Keith E. Maskus & Jerome H. Reichman, *The Globalization of Private Knowledge Goods and the Privatization of Global Public Goods*, 7 J. INT'L ECON. L. 279 (2004); Jean O. Lanjouw, *Intellectual Property and the Availability of Pharmaceuticals in Poor Countries*, *in* 3 INNOVATION POLICY AND THE ECONOMY 91 (Adam B. Jaffe et al. eds. 2003); James Love, *Developing Drugs for the Developing World: Measures to Enhance Access to Medical Technologies, and New Methods of Stimulating Medical R & D*, 40 U.C. DAVIS L. REV. 679 (2007).

The way forward may lie in realignment of the incentives under the Waiver regime by promoting co-op licensing treatment. A "co-op" compulsory licensing approach, emphasizing shared investment, shared work, and shared participation in future benefits, may be the best hope for altering the cost-benefit calculus of diversion for all parties involved. Such an approach would provide short-term remuneration for patent owners while guarding against diversion and fostering development of local knowledge and industry.

The co-op license notion builds on Kevin Outterson's idea that there is a need to maximize adaptive research and development to tailor medicines originally introduced in high income countries to local conditions, so that medicines may be viable therapies in lower income countries.[13] Some combination of local adaptive R&D (or "local innovation"), financial participation in the upside of such local innovation, and penalties for diversion may reduce any locally-perceived need to game the system and may lead to improved short and long-term outcomes for all parties.

Part II of this Article explores the social and developmental underpinnings of the access problem and describes the legal framework that provides the backdrop for the Waiver's licensing scheme. Part III examines the various lenses, humanitarian, economic, and political, through which the underutilization problem may be viewed and explained. Part IV sets out the structural heart of the Waiver scheme's deficiencies: the notion of the "compulsory" license itself. Part V posits a co-op scheme of licensing that aligns the concerns, goals, and incentives of IP owners, importers, exporters, and consumers. Finally, the Article relates the proposed scheme to more general trends in thinking regarding the deployment of intellectual property assets.

II. THE PROBLEM

A. The Social Landscape

The basic social problem is simply stated: the world needs more ARVs and other essential medicines at reasonable prices. Worldwide, an estimated 33 million people are living with HIV/AIDS, including some 2.7 million people newly infected in 2007.[14] In the developed world, the introduction of anti-retroviral therapies has improved the prospects for people living with the virus. By some measures, in countries like the United States, HIV/AIDS has become a disease that can be managed and lived with, rather than the sure and quick

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[13] Creation of heat-stable formulations, shelf-stable formulations, and fixed-dose combinations would be examples of the fruits of such adaptive research. *See* Kevin Outterson, *Disease-Based Limitations on Compulsory Licenses Under Articles 31 and 31 bis16* (Boston Univ. Sch. of Law, Working Paper No. 09-26, 2009), *available at* http://www.bu.edu/law/faculty/scholarship/workingpapers/documents/OuttersonK052009.pdf.

[14] UNAIDS, 2008 REPORT ON THE GLOBAL AIDS EPIDEMIC 16 (2008), http://www.unaids.org/en/KnowledgeCentre/HIVData/GlobalReport/2008/2008_Global_report.asp.

death sentence it was in the past. By contrast, in developing countries where ARVs are not widely available, people who contract the disease simply die. A disproportionate number of the three million people that die from HIV/AIDS annually live in low-access regions such as sub-Saharan Africa (where some 22 million people have HIV) and Southeast Asia (where the infection rate is estimated at 2%).[15]

The terminal nature of the disease when untreated has a particularly jarring impact on societies with very high infection rates. For example, in Botswana, where the adult HIV/AIDS infection rate has been estimated at 37%, the disease has produced in excess of 120,000 orphans in a total population of 1.76 million.[16] In Cambodia, life expectancy is estimated to have decreased by four years due to HIV/AIDS.[17] Such high infection and mortality rates are bound to have an impact on family structure, social stability, and economic development.

B. The Role of Development

According to commentators and participants in the global market for essential medicines, development is all at once a cause of the access problem, a partial solution to the problem, and the ultimate prize for finding a solution. Lack of development limits access, increased development improves access, and solving public health crises and improving public health outcomes should lead to long-term economic development.

One of the major obstacles to ARV access is price. The countries where AIDS/HIV is most devastating tend to be low GDP countries. Market prices for some therapies exceed US$10,000 per patient per year.[18] For some developing countries where the government is the major healthcare provider for the populace, the aggregate market cost of providing ARVs for all who need them would represent a multiple of the total national health budget. One 2001 estimate put the theoretical price tag for South Africa to supply its infected population with market-rate ARVs at US$24-42 billion – one hundred times South Africa's national public health budget at the time.[19]

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[15] *See id.* at 39, 48.

[16] Botswana has actually experienced improved access to ARVs in the last few years relative to its neighbors, but this data gives an idea of the social impact produced by years of low access. *See* UNAIDS/WHO, EPIDEMIOLOGICAL FACT SHEETS ON HIV/AIDS AND SEXUALLY TRANSMITTED INFECTIONS: BOTSWANA 3, 7 (2006), http://apps.who.int/globalatlas/predefinedReports/EFS2006/EFS_PDFs/EFS2006_BW.pdf.

[17] Jacqueline Debarats, U.N. Dep't of Econ. & Soc. Affairs, Population Div. Workshop on HIV/AIDS and Adult Mortality in Developing Countries, *Adult Mortality in the Era of HIV/AIDS: Asia* 6, U.N. Doc. UN/POP/MORT/2003/5 (Aug. 14, 2003), *available at* http://www.un.org/esa/population/publications/adultmort/DESBARATSRev2_Paper5.pdf.

[18] *See* AVERT, AIDS, Drug Prices and Generic Drugs, http://www.avert.org/generic.htm; Mary Beth Walker, *Assessing the Barriers to Universal Antiretroviral Treatment Access for HIV/AIDS in South Africa*, 15 Duke J. Comp. & Int'l L. 193, 195 (2004).

[19] This theoretical price tag is arrived at by multiplying the estimated infected South

Price is not the only problem. As patent owners and their allies are wont to point out, developing and least-developed countries experience many non-price related challenges in providing essential medications. Developing countries may lack the necessary public health infrastructure for transporting and distributing certain drugs. Clinics and clinicians for diagnosing, prescribing, and administering medicines may be in short supply. If products require special handling, like refrigeration, the odds are against infected people in rural or otherwise isolated communities being able to use them.

Another potential non-price access obstacle is corruption. When the governments or pharmaceutical companies of rich countries create programs that give grants, discounts, or free medicines to developing countries, there is a risk that the program will end up lining the pockets of a public health official, president, or some other government minister. Shipments of discounted drugs can disappear from the supply chain and end up being sold on the black market, not necessarily to the neediest patients. Control over drug aid may even be used as a weapon by one political, ethnic, or religious faction against another, reinforcing existing divisions rather than alleviating the public health crisis for all.

Compounding the logistical and political challenges of getting medicines into the right hands are the educational and social barriers facing people seeking treatment in the first place. Local ignorance of a disease and the therapies for treating it, or local rejection of diagnosis of the disease and its treatment, can result in suboptimal access regardless of price. For example, in South Africa, then-president Thabo Mbeki infamously denied the causal link between the HIV virus and AIDS, created doubt about the effectiveness of the drug AZT, and derided critics of his HIV/AIDS approach as racists.[20] Even the simple act of wearing a condom, which is cheap and readily available in most countries, is fraught with so much cultural baggage that its role in disease HIV/AIDS prevention has had to be actively and expensively advocated.[21]

The nexus between economic development and access is not limited to the

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African population and the estimated cost of treatment. *See* ROB DORRINGTON ET AL., MED. RESEARCH COUNCIL, THE IMPACT OF HIV/AIDS ON ADULT MORTALITY IN SOUTH AFRICA 7 (2001), http://www.mrc.ac.za/bod/complete.pdf (estimates 4.2 million infected South Africans in 2001); UNAIDS, FACT SHEET, ACCESS TO HIV TREATMENT AND CARE (2003), http://data.unaids.org/Publications/Fact-Sheets04/fs_treatment_en.pdf (estimates the cost of highly active anti-retroviral therapy for one patient for a year to be $10,000 to $12,000). The annual health budget is estimated for purposes of this comparison at just under $1 billion. *See* Gwen Ramokgopa, Gauteng MEC for Health, Budget Vote Speech 2001/2002 (May 31, 2001), *available at* http://www.info.gov.za/speeches/2001/010531245p1001.htm ("It gives me great pleasure to present to the House today and to the Gauteng public, the Health Budget for the 2001/2002 financial year. Our budget for this year is R6.7 billion [or US$916 million].").

[20] *See* Mary Beth Walker, Note, *Assessing the Barriers to Universal Antiretroviral Treatment Access for HIV/AIDS in South Africa*, 15 DUKE J. COMP. & INT'L L. 193, 195-96 (2004).

[21] *See* Monica Chadha, *India Fights to Promote Condoms*, BBC NEWS, July 15, 2003, http://news.bbc.co.uk/2/hi/south_asia/3067325.stm.

theory that low levels of economic development necessitate more access (i.e., less IP protection). Without some minimum level of development, questions of strong versus weak IP protection, or high versus low access, are moot inquiries. According to one commentator, before adopting strong IP (and low access) policies, least developed countries must reach a development threshold that includes a GNP significantly above subsistence level, a significant level of technical sophistication among the country's scientists and engineers, and a certain level of internal investment capital.[22]

On the other hand, a relaxation of IP protections for some period provides benefits that promote a developing country's economic growth. Domestic consumers experience increased welfare and are better off because of the availability of lower priced versions of the IP asset. Availability of the IP asset contributes to enhancement of infrastructure and human welfare within the asset's specific field or industry. The country's foreign exchange picture improves because of the lack of, or relatively low value of, royalty payments and repatriation of profits by the multinational owner of the IP. Domestic entrepreneurs are able to develop enterprises and expertise based on the IP asset. And the "imitated products" may open up new export markets for the developing country.[23]

Without some differentiation with regard to how markets for a patented drug are treated, neither access nor the patent system is served. With thoughtful differentiation, access may serve as a bridge to further economic development and optimal deployment of patented medicines.[24] The India example is instructive in this regard. India, which before 2003 provided a lower tier of protection for pharmaceutical inventions than for inventions in other fields, saw enormous growth in the value of pharmaceutical products produced and exported between 1965 and 2001.[25] Today, domestic production provides approximately 70% of the country's needs for pharmaceutical raw materials and some 80% of its needs for finished pharmaceutical products.[26] If the connection between access and development can be exploited by IP policy-makers, then it is possible for the type of technology transfer, investment, and welfare enhancement to occur that will turn today's access seeker into tomorrow's producer and exporter of essential medicines.[27] Such future producers will then be more receptive to strong IP and will set the stage for even greater domestic economic growth.[28]

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[22] *See* Dru Brenner-Beck, *Do as I Say, Not as I Did*, 11 UCLA PAC. BASIN L.J. 84, 84 (1992).

[23] *Id.* at 100.

[24] *See generally* Lanjouw, *supra* note 12.

[25] Samira Guennif & Julien Chaisse, *Present Stakes Around Patent Political Economy: Legal and Economic Lessons From the Pharmaceutical Patent Rights in India*, 2 ASIAN J. WTO & INT'L HEALTH L. & POL'Y 65, 72 (2007).

[26] *Id.*

[27] *See generally* Maskus & Reichman, *supra* note 12.

[28] Reaching the level of development of the richest countries is still associated with a strong IP regime, despite the benefits of a low IP regime at lower levels of development.

C. *The Legal Landscape*

Although the non-price factors described above are cited as significant obstacles to access to medicines, the fact remains that the debate is, for the most part, defined by price. The high price of ARVs and other essential medicines is due in part to the fact that these therapies are covered by patents for which the patent owners typically seek strong protection all over the world. Patents confer upon their owners a monopolist position with regard to the patented invention. In the United States, for example, a patent owner has the right to exclude others from making, using, selling, offering for sale, or importing the invention.[29] The national laws of any signatory to the Agreement on Trade Related Aspects of Intellectual Property ("TRIPS") must include analogous protections, and such laws may not discriminate by field of invention.[30] So, a TRIPS signatory must, in theory, grant a monopoly to the owner of any patented invention, including an invention in the pharmaceutical field.[31]

Of course, a monopolist will tend to provide fewer goods at higher prices than a firm facing competition. Any policies in favor of more monopoly control for pharmaceutical companies will then necessarily create access problems relative to policies that introduce low-priced competitive products. For their part, patent owners argue that without strong patent protection, future R&D expenditures will be greatly reduced, and long-term outcomes will suffer for the sake of a purported short-term gain in access.[32] The pharmaceutical patent holder maintains that society gains more by strengthening the patent holder's hand than by reducing its control over its inventions.[33]

Before 1994, countries with access or other public health issues connected with patented medicines dealt with them in their own ways.[34] The territoriality of patents and the relative weakness of existing international agreements regarding intellectual property left each jurisdiction to its own devices in solving access problems. Some countries refused to recognize patents for drugs at all. Some, like India, provided weaker patent protection for drugs than for other inventions. Local manufacturers were legally allowed to recreate another's chemical compound in a generic version of the drug, so long as the generic manufacturer did not copy the branded manufacturer's process

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For a discussion of the theoretical link between strong trademark protection and product launches and development, see Keith E. Maskus, *Intellectual Property Challenges for Developing Countries: An Economic Perspective*, 2001 U. ILL. L. REV. 457, 461 (2001).

[29] 35 U.S.C. § 271(a) (2006).

[30] *See* Agreement on Trade Related Aspects of Intellectual Property Rights, art. 27, 33 I.L.M. 81 (1994).

[31] *Id.*

[32] *See generally* PhRMA, 2005 ANNUAL REPORT, http://www.phrma.org/node/38 (last visited Mar. 22, 2010).

[33] *Id.*

[34] *See* DORIS ESTELLE LONG & ANTHONY D'AMATO, INTERNATIONAL INTELLECTUAL PROPERTY 126 (West Group 2000).

for creating the drug.[35] Other nations, like Brazil, loudly proclaimed their right to impose compulsory licenses for patented drugs, especially where the owner of the drug had opted not to produce the drug locally for domestic supply. A compulsory license would be awarded to a local manufacturer, and a reasonable royalty, set by the government, would be remitted to the patent owner.[36]

TRIPS, negotiated as part of the Uruguay Round of trade talks that led to the creation of the World Trade Organization (the "WTO"), has severely weakened the ability of national governments to develop their own solutions to the access problem. Admission into the WTO, and the concomitant ability to take advantage of favorable trade treatment by the 138 other members, was conditioned on also acceding to TRIPS.[37] This requirement created potential problems for some of the most active access problem-solvers. Article 27 of TRIPS did away with the practice of discriminating against patented inventions based on field of technology, and thus limited the ability of countries to deny protection to pharmaceutical inventions.[38] Article 30 limited any exceptions to patent rights to those that "do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties."[39] Article 31 weakened compulsory licensing as an access tool by, among other things, requiring negotiations with the patent holder before issuing a compulsory license, limiting the scope and duration of uses under compulsory license, and limiting compulsory licensing to use in supplying the domestic (non-export) market.[40]

Although TRIPS allowed compulsory licensing to be used to address issues of public health, signatories were confused as to under what circumstances they would be justified in issuing such licenses. In 2001, South Africa's attempt to grant its Health Minister the power to issue compulsory licenses, weaken patent protection, and allow parallel imports of medicines in order to protect public health was challenged by the local affiliate of the Pharmaceutical Manufacturers Association, the pharmaceutical industry's main trade group.[41] In June of that year, the United States commenced WTO dispute settlement proceedings against Brazil for its attempt to grant compulsory

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[35] For a detailed treatment of the history of pharmaceutical patent protection in India, see Guennif & Chaisse, *supra* note 25, at 68-73.

[36] For a detailed treatment of Brazil's history of use of compulsory licensing in expanding access, see Ubirajara Regis Quintanilha Marques, Valeska Santos Guimarães & Caitlin Sternberg, *Brazil's AIDS Controversy: Antiretroviral Drugs, Breaking Patents, and Compulsory Licensing*, 60 FOOD & DRUG L.J. 471, 473-76 (2005).

[37] *See* HOLGER HESTERMEYER, HUMAN RIGHTS AND THE WTO: THE CASE OF PATENTS AND ACCESS TO MEDICINES xxxiv (Oxford Univ. Press 2007).

[38] *See* Agreement on Trade Related Aspects of Intellectual Property Rights, art. 27, 33 I.L.M. 81 (1994).

[39] *Id.* at art. 30.

[40] *See id.* at art. 31.

[41] *See* Matthews, *supra* note 8, at 78-79.

licenses where a patented product was not manufactured locally.[42]

Finally, in November 2001, after negotiations at Doha, Qatar, the WTO affirmed the right of nations to prioritize access to medicines over protection of IP rights, and supported use of the "legitimate interests of third parties" language of Article 30 as a basis for allowing compulsory licensing of patented drugs. The "Doha Declaration" also extended the deadline for the least-developed WTO members to become TRIPS-compliant until 2016.[43] What the Declaration did not definitively do, however, was address the ability of a country to produce generic versions of patented medicines for export to countries that need the drug but lack manufacturing capacity. In 2003, the WTO ostensibly cured that failing by issuing its Decision on Implementation of Paragraph 6 of the Doha Declaration.[44] The decision, which this author has called the Health Flexibility Waiver, temporarily allowed countries to trade in medicines manufactured under compulsory license. In December 2005, the WTO made the Health Flexibility Waiver permanent by amending the TRIPS agreement.[45]

III. DISPARATE VIEWS OF THE CURRENT LANDSCAPE

Compounding the complexity of seeking an access solution, given the difficult social, economic, and legal terrain to be navigated, the view of the terrain is not necessarily shared by all. This Section discusses the various and disparate lenses through which observers of the access situation perceive the problem.

A. The Humanitarian Lens

Viewed through a humanitarian lens, access to life-saving therapies, including ARVs, is arguably a key element of the fundamental human right of enjoyment by everyone in the world of the "highest attainable standard of physical and mental health."[46] The Office of the High Commissioner for Human Rights has expressed the need to move beyond a purely commercial view of treatment of disease and embrace an approach that creates incentives

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[42] *See id.* at 80.

[43] *See* World Trade Organization, Ministerial Declaration of 14 November 2001, ¶¶ 4-6, WT/MIN(01)/DEC/2, 41 I.L.M. 755, 755-56 (2002).

[44] *See* Decision of the General Council, *Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health*, WT/L/540 (Aug. 30, 2003) [hereinafter *Doha Declaration*].

[45] *See* Decision of the General Council, *Amendment of the TRIPS Agreement*, WT/L/641 (Dec. 6, 2005). The time set to ratify the Amendment by two-thirds of WTO members was Dec. 1, 2007, but has since been extended until Dec. 31, 2009. At the time of this article, the Amendment has not yet been ratified.

[46] International Covenant on Economic, Social and Cultural Rights, G.A. Res. 2200 (XXI), at 51, art. 12, U.N. Doc. A/6316 (Dec. 16, 1966). *See also* Universal Declaration of Human Rights, G.A. Res. 217A, at 76, U.N. GAOR, 3d Sess., 1st plen. mtg., U.N. Doc. A/810 (Dec. 12, 1948) (setting forth a standard of living adequate for health and well-being of the family as a fundamental human right).

to broaden access to medicines and fosters research into "unprofitable" neglected diseases.[47]

The pure humanitarian perspective would tend to push states and supranational institutions toward non-market or extra-market solutions that limit the control that the owners of the drugs exercise over price and supply, and perhaps to shift more of that control to national governments. For example, Professor Taiwo Oriola has advocated placing a "social lien" on medicines developed from publicly funded research. Such a lien would create a moral obligation on the part of the patent owner to facilitate access to the patented drug.[48] Arguments regarding development costs and protecting incentives to innovate hold little sway over proponents of this view, in part because research costs are so often subsidized by the state, and in part because non-research costs, such as marketing and advertising, are argued to add significantly to the total "overhead" claimed by patent owners in justifying high drug prices.[49]

Given a choice between protecting human life and protecting patent rights, proponents of this approach would nearly always choose expanding access to support human life and health. Arguments about the cost of drug development are unavailing, and greed or misplaced priorities provide a too easy explanation for the resistance of patent owners to strong implementation of human rights-based access initiatives.

B. The Market Fundamentalist Lens

If the access problem is viewed through the lens of market fundamentalism, the set of possible solutions looks very different. Under this view, the only way to persuade inventors of medicines to spend their time inventing is to reward them with a period of exclusivity/monopoly over the production and distribution of their invention. Upon expiration of the exclusivity period, the invention enters the public domain and society as a whole is enriched. Research and development is a costly endeavor with uncertain outcomes, and no rational actor would engage in such activity if it could not exert control over the resulting product later on. Free riders kill the incentive to innovate, and only by reducing or eliminating the rents captured by free riders will we allow creators and creative enterprise to flourish.[50] Encouraging strong patent rights

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[47] Office of the High Comm'r for Human Rights, *Submission to the 5th WTO Ministerial Conference Cancun, Mexico, 10-14 September 2003: Human Rights and Trade*, at 7-8 (Sept. 2003), *available at* http://www2.ohchr.org/english/issues/globalization/trade/docs/5WTOMinisterialCancun.pdf.

[48] Oriola, *supra* note 12, at 78.

[49] *Id.* at 59-61, 90-92. *See also* Gail E. Evans, *Strategic Patent Licensing for Public Research Organizations: Deploying Restriction and Reservation Clauses to Promote Medical R&D in Developing Countries*, 34 AM. J.L. & MED. 175, 194 (citing "declining R&D productivity, rising costs of commercialization, increasing payor influence, and shorter exclusivity periods" as factors in the increasing cost to launch a new drug product).

[50] *See* Thomas F. Cotter, *Market Fundamentalism and the TRIPS Agreement*, 22 CARDOZO ARTS & ENT. L.J. 307, 323-24 (2004).

across the globe, even in developing countries, supports the protection of innovators against free riders because such encouragement eliminates the collective action problem that might lead individual countries to weaken their patent laws for short term advantage.[51] Allowing any opportunities to opt out of strong patent protection under TRIPS would lead to fewer patented inventions overall.

Complicating the research incentives question is the fact that, under the current pharmaceutical research paradigm, most drug development is financed by large, publicly traded companies; and such companies are, for the most part, the owners of the patents at issue in the access debate. As for-profit enterprises, they cannot ignore the impact of access decisions on revenues and profits, at least not if they expect to continue in business for the long term. As corporations, they are further constrained by the fiduciary duties of their managers to make decisions that benefit their shareholders.[52] So, although there may be room to balance profit maximization and access, and although the managers, officers, and directors of patent owners may desire to implement access solutions, there will always be a structural drag on their ability to do so.

When the problem is viewed through this lens, solutions should err on the side of protecting the rights of patent owners. Alan Sykes has advocated limiting compulsory licensing by narrowly construing the occurrence of a "national emergency" under TRIPS, by encouraging lengthy negotiations over licensing arrangements, and by tying the "adequate remuneration" concept of TRIPS Article 31 to actual R&D costs incurred by the patent holder (for both successful and unsuccessful research directed at the same disease).[53] After all, only if the patent owner receives the right incentives to develop drugs in the short term will it continue to devote resources to R&D in the future; and only then will we have more life-saving drugs in the long term.[54]

The patent owners are benefiting the public in the long run via continued introduction to the market of new technology, and restrictions of patent rights carry the risk of diminishing the value of such technology, maybe even to zero. Therefore, derogations of patents should be limited even as access is pursued in the short term.[55] Better to allow the patent owner to provide solutions that maintain its control over price and distribution and preserve its incentives to innovate, than to allow governments to develop their own rules for access.

Solutions that flow from this approach include donations, patient assistance programs, and negotiated low-cost sales to national governments in poor countries, all without disturbing the basic monopoly framework of patent rights. Preserving the patent system, proponents argue, presents the best hope for promoting access and alleviating public health crises, because preserving

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[51] *Id.* at 325 (citing Sykes, *supra* note 3, at 65-66).

[52] *See* Andrew Beckerman-Rodau, *Patent Law – Balancing Profit Maximization and Public Access to Technology*, 4 COLUM. SCI. & TECH. L. REV. 1, 29 (2002), *available at* http://www.stlr.org/html/volume4/beckerman.pdf.

[53] Sykes, *supra* note 3, at 67-68.

[54] *See id.* at 68.

[55] *See* Beckerman-Rodau, *supra* note 52, at 30.

the patent system also preserves the research and development that has produced the current set of essential medicines and will produce the essential medicines of the future.[56]

C. *The Political Lens*

Viewed as a political problem, access is complicated by power asymmetries among the sovereign players in the WTO[57] and by increased participation by life sciences companies in policymaking.[58] The increased macroeconomic importance of knowledge-intensive industries, such as computer technology and pharmaceuticals, has enhanced the political influence of those industries.[59] As one commentator notes, these companies are well-resourced and organized; they contribute so mightily to their states' trade balances that their interests are highly integrated with those of the state.[60]

The policies pursued by states where the pharmaceutical industry wields great influence have followed a predictable path. The United States and European Union pushed for adoption of the TRIPS agreement, establishing minimum standards of intellectual property protection (including patent protection for medicines) and enticing developing countries to abandon pro-access policies with the promise of full membership in the club of important trade partners, the World Trade Organization. The United States supplemented the carrot of WTO membership with the stick of unilateral trade sanctions in convincing developing countries to adopt the strong IP provisions of TRIPS.[61]

Post-TRIPS, the Health Flexibility Waiver notwithstanding, the owners of patented drugs have insisted upon, and gotten, even stronger intellectual property protection to the detriment of access interests. In seeking to increase access, the Waiver essentially provides a way around patent rights. But the West has insisted that a number of countries subject themselves to restrictions with respect to other types of intangible property, not squarely treated by the Waiver mechanism (so-called "TRIPS-Plus" policies).[62] For example, the United States has been aggressive in negotiating bilateral and regional free trade agreements ("FTAs") that place such heavy IP burdens on signatories as to preclude their participation in a compulsory licensing scheme, including the

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[56] *Id.*

[57] The effects of political pressure were predicted from the time of the Decision. *See* Ewelukwa, *supra* note 11, at 207 (promising "covert threats of economic sanctions" for countries who might think of using the Waiver).

[58] *See* Susan K. Sell, *The Quest for Global Governance in Intellectual Property and Public Health: Structural, Discursive, and Institutional Dimensions*, 77 TEMP. L. REV. 363, 364 (2004).

[59] *See id.* at 368.

[60] *See id.*

[61] *See* Brook K. Baker, *Ending Drug Registration Apartheid: Taming Data Exclusivity and Patent/Registration Linkage*, 34 AM. J.L. & MED. 303, 313 (2008) (citing use by the United States Trade Representative of its Special 301 Watch List powers under 19 U.S.C. § 2242 (2006)).

[62] *See* HESTERMEYER, *supra* note 37, at 289-90.

one created by the Waiver.[63] The anti-access provisions of these agreements fall into three categories. The first is IP protection for test data. For at least five years, a generic manufacturer may not use test data or other proprietary information that the patent owner has submitted to the relevant government for the purposes of receiving regulatory approval to market the drug.[64] In effect, this sort of restriction makes it difficult for a generic manufacturer to bring a generic version of a patented drug to market without conducting a full set of clinical trials and generating its own test data. Such an endeavor would be costly (for an industry with very thin profit margins) and lengthy (delaying the ability of patients to get access to the generic drug by years). As a practical matter, the prohibition of the use of test data erects a barrier to use of the Waiver and limits access despite the fact that relaxation of patent requirements should be access-promoting.

The second type of access-limiting provision in free trade agreements is often called a "patent/registration linkage" provision.[65] Such a provision essentially deputizes a signatory's food and drug regulatory authority as a patent infringement enforcement agent. The regulatory approval of any generic drug is delayed during the term of the relevant patent, unless authorization is obtained from the patent owner.[66] So, even if a generic meets

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[63] *Id.* at 290.

[64] *See, e.g.*, Free Trade Agreement, U.S. – Austl., art. 17.10 §1, May 18, 2004, 43 I.L.M. 1248, *available at* http://tcc.export.gov/static/AFTA.full_text.pdf [hereinafter U.S. – Austl. FTA]; Free Trade Agreement, U.S. – Bahr., art. 14.9 §1, Sept. 14, 2004, 44 I.L.M. 544, *available at* http://tcc.export.gov/static/TAA.BahrainFTAChapter14.pdf [hereinafter U.S. – Bahr. FTA]; Free Trade Agreement, U.S. – Chile, art. 17.10 §1, June 6, 2003, 42 I.L.M. 1026, *available at* http://tcc.export.gov/static/17.ipr.pdf [hereinafter U.S. – Chile FTA]; Trade Promotion Agreement, U.S. – Colom., art. 16.10 §2(a), Nov. 22, 2006, *available at* http://www.ustr.gov/webfm_send/1336 [hereinafter U.S. – Colom. FTA]; KORUS Free Trade Agreement, U.S. – S. Korea, art. 18.9 §1, Apr. 1, 2007, 46 I.L.M. 642, *available at* http://www.ustr.gov/sites/default/files/uploads/agreements/fta/korus/asset_upload_file273_12717.pdf [hereinafter KORUS FTA]; Free Trade Agreement, U.S. – Morocco, art. 15.10 §1, Jan. 1, 2006, 44 I.L.M. 544, *available at* http://tcc.export.gov/static/asset_upload_file797_3849.pdf [hereinafter U.S. – Morocco FTA]; Free Trade Agreement, U.S. – Oman, art. 15.9 §1, Jan. 19, 2006, *available at* http://www.ustr.gov/sites/default/files/uploads/agreements/fta/oman/asset_upload_file715_8809.pdf [hereinafter U.S. – Oman FTA]; Trade Promotion Agreement, U.S. – Pan., art. 15.10 §2(a), June 28, 2007, *available at* http://www.ustr.gov/sites/default/files/uploads/agreements/fta/panama/asset_upload_file131_10350.pdf [hereinafter U.S. – Pan. FTA]; Trade Promotion Agreement, U.S. – Peru, art. 16.10 §2(a), Apr. 12, 2006, *available at* http://www.ustr.gov/webfm_send/1031 [hereinafter U.S. – Peru FTA]; Free Trade Agreement, U.S. – Sing., art. 16.8 §1, May 6, 2003, 42 I.L.M. 1026, *available at* http://tcc.export.gov/static/text_final.pdf [hereinafter U.S. – Sing. FTA]; CAFTA Free Trade Agreement, art. 15.10 §1, Aug. 5, 2004, *available at* http://www.ustr.gov/sites/default/files/uploads/agreements/cafta/asset_upload_file934_3935.pdf [hereinafter CAFTA] (CAFTA includes U.S., Costa Rica, Dom. Rep., El Sal., Guat., Hond., Nicar.).

[65] Baker, *supra* note 61, at 307.

[66] *See, e.g.*, U.S. – Austl. FTA, *supra* note 64, §4; U.S. – Bahr. FTA, *supra* note 64, §2; U.S. – Chile FTA, *supra* note 64, §2; U.S. – Colom. FTA, *supra* note 64, §2(b); KORUS

the agency's approval criteria to be marketed in the relevant country, distribution of the drug could be delayed due to the existence of a patent for the drug. Although the Waiver is supposed to provide a way around patents, it does not address such linkages and thus presents an anti-access loophole for pharmaceutical companies and their governments.

The third category of access-limiting provision in a typical U.S. free trade agreement is the limitation on the grounds for revoking a patent. This sort of provision limits the grounds for revocation of a patent to those grounds that could have been cited in denying the patent in the first place.[67] One interpretation of such a provision is that a patent subject to an FTA may only be revoked for fraud or for lack of novelty, utility/industrial application, or nonobviousness/inventive step. Reasons having to do with access, such as unreasonable pricing, failure to market, etc., do not seem to be available to FTA signatories.[68]

Beyond the access-limiting free trade agreements to which the U.S. has become a party, the United States Trade Representative ("USTR") has a history of threatening unilateral sanctions against nations who engage in compulsory licensing.[69] Despite USTR "side letters" that ostensibly reassure signatories that they may take steps to protect public health, potential importers and exporters under the Waiver scheme are treading carefully in the face of threats from such an important trading partner.[70] The access-limiting power dynamic between rich and poor countries has also tainted several laudable humanitarian gestures in the eyes of some observers, further complicating attempts to bridge the divide.[71] As one commentator put it, the totality of rights and obligations actually practiced by TRIPS signatories "represent the codification of political tradeoffs masquerading as positivist obligations

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FTA, *supra* note 64, §2; U.S. – Morocco FTA, *supra* note 64, §4; U.S. – Oman FTA, *supra* note 64, §2; U.S. – Pan. FTA, *supra* note 64, §2(b); U.S. – Peru FTA, *supra* note 64, §2(b); U.S. – Sing. FTA, *supra* note 64, §4; CAFTA, *supra* note 64, §2.

[67] *See, e.g.*, U.S. – Austl. FTA, *supra* note 64, art. 17.9 §5; U.S. – Bahr. FTA, *supra* note 64, art. 14.8 §4; U.S. – Chile FTA, *supra* note 64, art. 17.9 §5; U.S. – Colom. FTA, *supra* note 64, 16.9 §4; KORUS FTA, *supra* note 64, art. 18.8 §4; U.S. – Morocco FTA, *supra* note 64, art. 15.9 §5; U.S. – Oman FTA, *supra* note 64, art. 15.8 §4; U.S. – Pan. FTA, *supra* note 64, art. 15.9 §4; U.S. – Peru FTA, *supra* note 64, art. 16.9 §4; U.S. – Sing. FTA, *supra* note 64, art. 16.7 §4; CAFTA, *supra* note 64, art. 15.9 §4.

[68] *See, e.g.*, HESTERMEYER, *supra* note 37, at 290.

[69] Thailand, South Africa, Brazil, India, and Argentina have been at the receiving end of such threats. *See* Baker, *supra* note 61, at 317.

[70] *Id.* at 331-32.

[71] *See* Gathii, *supra* note 10, at 268; Michelle M. Nerozzi, *The Battle Over Life-Saving Pharmaceuticals: Are Developing Countries Being "TRIPped" by Developed Countries?*, 47 VILL. L. REV. 605, 631 nn.119-120 (citing strings attached to Pfizer's donation program for the HIV/AIDS drug Fluconazole (Diflucan)). *See also* Barbara Crossette, *AIDS Fungus Drug Offered to Poor Nations*, N.Y. TIMES, June 7, 2001, at A3; *AIDS Story: Part 2*, THE GUARDIAN (UK), Dec. 2, 2000, at 13, *available at* http://www.guardian.co.uk/world/2000/dec/02/aids.weekend7.

imposed by law."[72]

IV. RECALIBRATING THE LENSES

The views described *supra* are more often than not at odds with each other and indicate a problem that is not even simply stated, let alone solved. A view of the access problem that will ultimately lead to a solution, however, must acknowledge some shortcomings on all fronts. First, the market fundamentalist argument tends to ignore a responsibility on the part of pharmaceutical patent owners to the global human community. Given the enormous profits earned by multinational pharmaceutical companies in the developed world, some of which are financed publicly, aggressive expansion of access in the developing world, even at the cost of some of those profits, does not seem too much to ask. Pharmaceutical company profits have been described in economic terms as supra-optimal rents and should be able to absorb the cost of monitoring and enforcing an access scheme without harming innovation.[73]

The sense of responsibility should be heightened by the fact that low-access nations are not a plausible source of market-rate sales for the therapies in question.[74] So there are few, if any, lost sales attributable to humanitarian solutions. Further, for every day that the access problem is not solved, there is both a current cost in human lives and a future cost in the value of the local market. If a country is destabilized by catastrophic diseases like HIV/AIDS or malaria, its economy will never mature into a viable market for the pharmaceutical industry's chronic care therapies and lifestyle drugs. Ultimately, global growth depends on solving the access problem in the short term.

On the other hand, minimizing certain other realities of the market, as some proponents of the pure humanitarian view do, may place the long-term access effort in jeopardy. Unfortunately, access solutions that reduce control over price and supply may have a negative impact on the patent owner's long-term financial viability. For example, losing control over supply often means that a patent owner cannot prevent trade in parallel imports, or gray market goods. If medicines are diverted from a low price market to a high price market, the patent owner will lose expected sales in the high price market, and shareholder value may suffer.[75] Any sort of differential pricing creates an attractive

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[72] Ruth L.Okediji, *The International Relations of Intellectual Property: Narratives of Developing Country Participation in the Global Intellectual Property System*, 7 SING. J. INT'L & COMP. L. 315, 339 (2003).

[73] *See* Kevin Outterson, *Pharmaceutical Arbitrage: Balancing Access and Innovation in International Prescription Drug Markets*, 5 YALE J. HEALTH POL'Y L. & ETHICS 193, 223 (2005).

[74] For example, the average annual price of a first-line ARV in the United States is $7,215 per capita. One drug, Fuzeon, costs $20,000 annually. *Id.* at 251; *see also* Lanjouw, *supra* note 12, at 100, 104.

[75] It has also been argued that differential pricing to enhance access can lead to the expectation of lower list prices in developed markets, which would also impact the profit

arbitrage opportunity. Local prices in the importing country are low, prices in other markets (including the European Union and the United States) may be much higher, and as long as transportation and other transactions costs are sufficiently low, some entrepreneur can be expected to take advantage of the opportunity to engage in parallel trade with the drugs at issue.

The prevalence and effect of parallel trade are in dispute. The incentive to engage in gray market sales of drugs lies not with consumers, patent owners, or governments, but with other actors who interact with the distribution chain, such as local manufacturers, distributors/transport agents, or individual government officials.[76] Diversion diminishes local supply and may lead to higher local prices and decreased welfare for the consumers in need of the medicine.[77] On the other hand, documented cases of major diversion are hard to come by, minor diversion is fairly easily absorbed, and techniques exist for thwarting any attempt at large-scale diversion.[78] Whatever diversion does exist, however, potentially circumvents the industry's efforts to maintain drug quality and safety in its distribution chain.[79] So, even a small amount of diversion could lead to social welfare losses. Given the uncertainty involved, even if they don't go quite so far rhetorically, it should not be surprising for executives and managers of patent owners to reject any solution that adds volatility to a pharmaceutical company's profit calculus. Such volatility is sure to lead to access-limiting behavior on the part of managers. Any access solution that expects not to be undermined by pharmaceutical patent owners must acknowledge and deal with the risk of diversion.

The TRIPS solution to the parallel import issue focuses on the physical characteristics of the product. The August 30 Decision requires that:

> (i) only the amount necessary to meet the needs of the eligible importing Member(s) may be manufactured under the licence and the entirety of this production shall be exported to the Member(s) which has notified its needs to the Council for TRIPS;
>
> (ii) products produced under the licence shall be clearly identified as being produced under the system set out in this Decision through specific

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calculus of the patent owner. *See* Cotter, *supra* note 50, at 338.

[76] *See* Harvey E. Bale, Jr., *The Conflicts Between Parallel Trade and Product Access and Innovation: The Case of Pharmaceuticals*, 1 J. INT'L ECON. L. 637, 638 (1998).

[77] *Id.* at 648.

[78] *See* Outterson, *supra* note 73, at 261-67, (detailing the lack of documented diversion cases and distinguishing acceptable from unacceptable parallel trade); Lanjouw, *supra* note 12, at 110 (describing policy tools for dealing with diversion risk, including export controls, distribution chain monitoring, distinctive pill design, and distinctive packaging); Sloan Pearson, *Will the August 20, 2003 Decision of the WTO Provide Adequate Protection for Patent Holders Rights and is Diversion Still a Threat to the Pharmaceutical Industry?*, 5 J. HIGH TECH. L. 381, 396 (2005) (providing examples of physical differentiation between market pharmaceutical products and their donated versions).

[79] *See* Claude E. Barfield & Mark A. Groombridge, *Parallel Trade in the Pharmaceutical Industry: Implications for Innovation, Consumer Welfare, and Health Policy*, 10 FORDHAM INTELL. PROP. MEDIA & ENT. L.J. 185, 254 (1999).

labelling or marking. Suppliers should distinguish such products through special packaging and/or special colouring/shaping of the products themselves, provided that such distinction is feasible and does not have a significant impact on price; and

(iii) before shipment begins, the licensee shall post on a website the following information:

- the quantities being supplied to each destination as referred to in indent (i) above; and

- the distinguishing features of the product(s) referred to in indent (ii) above.[80]

The General Council Chairperson's Statement regarding the Decision further outlines best practices with respect to diversion; again, these best practices focus mainly on physical characteristics of the pills and packaging being produced.[81]

While rendering the products produced under the waiver easily identifiable is an important piece of the solution to the diversion problem, it is only a piece. Distinctive coloring, packaging, labeling, and other trade dress do little to dissuade traffic that is not necessarily conducted in full view of all the interested parties. A more robust set of solutions should focus on the compulsory license, and the incentives that it creates. The role of the compulsory license is often misunderstood,[82] and some discussion of its actual role and import is warranted.

Generally, in practice, compulsory licensing is very rare.[83] This is despite the existence of many laws (including Paragraph 6 of the Doha Declaration) allowing such licensing. For at least some countries, not engaging in compulsory licensing may be a matter of "face" or reputation.[84] Face-saving non-utilization of compulsory licensing validates early predictions that the Waiver system would not alone increase access, and that it was more important as a political statement than as a serviceable licensing scheme.[85] There is little guidance as to the substance of the compulsory license, that is, what it should

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[80] *Doha Declaration*, *supra* note 44, at §2(b).

[81] *See* General Council, *General Council Chairperson's Statement*, WT/GC/M/82 (Nov. 13, 2003), *available at* http://www.wto.org/english/tratop_E/TRIPS_e/gc_stat_30aug03_e.htm.

[82] *See* Arnoldo Lacayo, Comment, *Seeking a Balance: International Pharmaceutical Patent Protection, Public Health Crises, and the Emerging Threat of Bio-Terrorism*, 33 U. MIAMI INTER-AM. L. REV. 295, 317 (2002); Cotter, *supra* note 50, at 324; Marques, *supra* note 36, at 474; Christine A. Chung, Note, *A Cry for Cheap Drugs: CAFTA's Inflexible Intellectual Property Protections Create an Ominous Impact on Life-Saving Medicines*, 13 SW. J.L. & TRADE AM. 171, 182 (2006), Sykes, *supra* note 3, at 55.

[83] *See* Attaran, *supra* note 8, at 746-47 & n.7 (arguing that for most of the decade preceding 2003, almost no country compulsorily licensed "finished medicines on an extensive scale").

[84] *Id.* at 750.

[85] *See* Scott Lucyk, *Patents, Politics and Public Health: Access to Essential Medicines Under the TRIPS Agreement*, 38 OTTAWA L. REV. 191, 194 (2006-07).

actually say. Uncertainty about license terms, including what constitutes "adequate remuneration," may be a hindrance to compulsory licenses in general, not only under the Waiver scheme.[86] In the face of diversion and arbitrage risk, it is dismaying, but not surprising, that IP-exporting countries have imposed TRIPS-plus provisions that discourage use of the Waiver. There is no assurance that any licenses coming out of the Waiver scheme would approximate anything that an IP owner would want out of a licensing arrangement.[87] There remains too much opportunity for strategic behavior on the part of others (governments, third parties) and not enough recourse to de-incentivize such behavior. The main use of compulsory licensing laws and schemes seems to be as a lever to influence price negotiations on patented drugs. Brazil has been so successful at this negotiating tactic that other countries are adopting it as an access tool.[88]

Several commentators have examined the license, mainly by focusing on streamlining the process, rather than adopting particular substantive terms. Amir Attaran proposes a "non-justiciability" solution to the access problem, excusing manufacture under compulsory license under certain conditions.[89] The manufacturing country would be shielded from WTO dispute resolution proceedings under the Attaran proposal, provided the parties to the license meet any of three criteria: (1) the importing country has a per capita income of $2,935 or less, (2) the importing country has "an adult HIV seroprevalence of one percent or greater," or (3) the importing country faces an "acute public health emergency."[90] As the actual use of compulsory licenses is circumscribed in the first place, Attaran argues that non-justiciability based on objective criteria highlights the limited downside of Paragraph 6 and makes it more palatable to patent owners and their governments.[91]

Frederick Abbott and Jerome Reichman have advocated a "pooled" licensing approach to address the unresolved public action problem at the heart of the access issue.[92] Under such a scheme, a number of countries could pool compulsory licenses in order to promote economies of scale in manufacturing and procurement, decreasing costs and increasing purchasing power/leverage

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[86] *See* Antony Taubman, *Rethinking TRIPS: 'Adequate Remuneration' for Non-Voluntary Patent Licensing*, 11 J. INT'L ECON. L. 927, 932 (2008).

[87] In a negotiated, market-driven license, key terms might include term/duration of license; defined royalty or royalty calculation; scope of licensed technology and of territory; requirements regarding sales and royalty records, reporting, and inspection; default, termination, and acceleration provisions; and representations and warranties of the parties.

[88] *See* Robert Bird & Daniel R. Cahoy, *The Impact of Compulsory Licensing on Foreign Direct Investment: A Collective Bargaining Approach*, 45 AM. BUS. L.J. 283, 316 (2008).

[89] Attaran, *supra* note 8, at 769.

[90] *Id.* at 760-64.

[91] *See id.* at 743-44.

[92] 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, 921-22 (2007).

with both originator drug companies and generic producers.[93]

Amir Khoury proffers an enhanced compulsory licensing model, calling for retroactive compensation for patent owners, avoiding production slowdowns and enabling exporting and importing nations to act quickly.[94] Royalties would be paid to patent owners only if it was proved ex post that the compulsory license was employed without justification under TRIPS. Further, if the importing state made no profit on the distribution of the drug, no royalty would be owed. The term of the license would be limited, the World Health Organization would participate in the settlement of disputes, and data exclusivity provisions of TRIPS-plus agreements would be relaxed.[95] Robert Bird and Daniel Cahoy suggest a regionally coordinated license akin to the pooled license strategy discussed *supra*. Regional trade associations, rather than individual nations, could issue the license and bargain collectively over its terms. The incentive to launch such a scheme is greatly diminished by the TRIPS-plus tactics of the West, as Bird and Cahoy observe.[96]

V. A MODEL FOR A CO-OP LICENSING SCHEME

Although the debate is not often framed in these terms, the access conundrum stems in part from the desire of multiple interdependent actors to maximize their welfare, all the while taking into account the likely actions of competing wealth-maximizers in the same system. Game theory represents a useful tool for analyzing the parties' incentives and ways in which re-alignment of such incentives may yield more socially desirable outcomes.[97] Problems of intellectual property, international trade, and international relations have proven amenable to game theoretic treatment; and the access problem, which combines elements of all three disciplines, is ripe for such analysis.[98]

This Article is particularly interested in applications of non-cooperative game theory, in which the player's only concern is maximizing its own individual payoffs within the parameters of the game.[99] Behavior that could be

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[93] *See id.* at 973-74.

[94] Amir H. Khoury, *The "Public Health" of the Conventional International Patent Regime & the Ethics of "Ethicals:" Access to Patented Medicines*, 26 CARDOZO ARTS & ENT. L.J. 25, 59 (2008).

[95] *See id.* at 58-63.

[96] *See* Bird & Cahoy, *supra* note 88, at 328.

[97] Game theory has been described as seeking to "explore how people make decisions if their actions and fates depend on the actions of others." Note, *Finding Strategic Corporate Citizenship: A New Game Theoretic View*, 117 Harv. L. Rev. 1957, 1959 (2004) (quoting PETER C. ORDESHOOK, GAME THEORY AND POLITICAL THEORY: AN INTRODUCTION xii (1986)).

[98] *See, e.g.*, Bird & Cahoy, *supra* note 88, at 321-28; Chris J. Katopis, *Perfect Happiness?: Game Theory as a Tool for Enhancing Patent Quality*, 10 YALE J.L. & TECH. 360 (2007-08); Horace E. Anderson, Jr., *The Privacy Gambit: Toward a Game Theoretic Approach to International Data Protection*, 9 VAND. J. ENT. & TECH. L. 1, 28 (2006).

[99] *See* DAVID M. KREPS, GAME THEORY AND ECONOMIC MODELLING 9 (1990).

labeled "cooperative" or "collaborative" generally comes about under such a regime if the behavior serves the best individual interests of the actors.[100] A primary tool in analyzing non-cooperative situations is the normal form, or strategic form game. One version of the normal form game is the well-known Prisoner's Dilemma. In the normal form game, the players move simultaneously and without knowledge of the other player's choice of move. Three key elements make up the normal form game: (1) the players, (2) the strategies available to them, and (3) the payoff to each player for each combination of player strategies.[101]

David Kreps illustrates a typical embodiment of a normal form game in matrix format using the children's game Rock-Paper-Scissors to outline strategies and payoffs. Assuming two children, Alan and Beth, each with a strategy set (Throw Rock, Throw Paper, or Throw Scissors), and each standing to win a point if favored by the combination, lose a point if disfavored by the combination, or stand pat if the combination is a draw. The payoffs from a Rock-Paper-Scissors game can be modeled as follows (in each set of payoffs, Alan's payoff appears before the comma, and Beth's payoff appears after the comma):[102]

Figure A

		Beth		
		Rock	Paper	Scissors
Alan	Rock	0,0	-1,1	1,-1
	Paper	1,-1	0,0	-1,1
	Scissors	-1,1	1,-1	0,0

A game may be "solved" by deducing which strategies players are likely to adopt, given the potential payoff to the player and given what that player knows about the other player's goals, available strategies, and payoffs.[103] The players can be expected to gravitate toward strategies that deliver them higher payoffs, and the solution concepts of non-cooperative game theory proceed under that assumption.[104]

A normal form game model of the Health Flexibility Waiver system might include three players, a Patent Owner ("PO"), a country taking advantage of the Waiver ("Waiver Country" or "WC"), and a Distributor/Diverter ("D"). For purposes of this model, we assume that the players' available strategies are

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[100] *Id.*

[101] *See* DOUGLAS G. BAIRD, ROBERT GERTNER & RANDAL PICKER, GAME THEORY AND THE LAW 8 (1994).

[102] *See* KREPS, *supra* note 99, at 10-11.

[103] *See id.*

[104] Although much has been made of the failure of the rationality assumption in economic theory, this Article assumes that, regardless of whether possession of dollars or widgets is important to a particular person, that person has some capacity for making decisions that are consistent with his tastes and goals.

as follows: WC may choose License or Forego, that is, issue a compulsory license under the Waiver or forego issuance of a compulsory license, relying on the market and the largesse of PO to meet its people's needs. D may choose Divert or Refrain, either choosing to divert medicines manufactured under the license to the gray market or leaving the distribution chain undisturbed. Although PO does not play in the first iteration of this game, its strategy choices in a later iteration will be Introduce or Withhold, that is, either introduce its drug in WC's local market, or decline to do so.

Precise payoffs for each of the strategies in the game are difficult to calculate, but we can posit the components of each player's expected result. WC's payoff in the License/Forego strategy decision will depend on current revenues from the license (either direct revenues or taxes on the revenues of the compulsory licensee), current cost of licensing (including royalties paid to PO), current costs of manufacturing and distribution, current costs of local innovation (adaptive know-how associated with optimizing formulation and delivery systems for local conditions), future public health and development gains from stabilizing the situation with regard to the relevant disease, and potential cost of retaliation by PO (or its government) in the event of diversion or other disrespect of PO's patent rights.

The payoff from D's strategy choice of Divert versus Refrain will depend on potential current revenues from diversion to the gray market, any current direct costs associated with the diversion (including transportation and other transaction costs), the opportunity cost of engaging in pharmaceutical diversion rather than other economic activity, the cost incurred if its activities are detected (including fines or imprisonment, depending on local law), and the likelihood of detection (including the inclination of WC toward detection and the resources available for detection-related activities).

Although PO does not play in this game's first iteration, we will describe here the components of its payoff, because it will receive payoffs based on the moves of the other two players even if it does not move. PO's payoff might be comprised of current revenues (from regular sales or from royalties relating to a licensee's manufacture of PO's drug under compulsory license), lost sales in the event of diversion (in the instant market and in foreign markets), current cost savings from reduction or elimination of its own local supply chain, future revenues in the local market, and future benefits of local innovation (adaptive know-how associated with optimizing formulation and delivery systems for local conditions).

For purposes of this game, in the event of a License decision, we posit current revenues for WC of 10, a licensing cost (including royalty paid) of 3, manufacturing and distribution cost (including the cost of innovating to optimize manufacturing and distribution for local conditions) of 3, and some future gain from improvements in public health, the present value of which is at least as much as current income from compulsory licensing, or 4.[105] WC's

[105] It should be noted that the values used in this model are stylized for simplification purposes, but they attempt to reflect rough orders of magnitude with regard to actual factors. *See* IMS, Global Pharmaceutical Sales 2000 – 2007, http://www.imshealth.com/

total payoff from licensing should then be 10-3-3+4, or 8. If WC licenses and D diverts, say, 50% of the licensee's stock, WC's revenues fall to 5, its costs remain unchanged, and its future gains are erased as treatment does not reach a critical mass of its populace. In this event, WC's total payoff falls to -1.

If WC foregoes, it earns no revenues from licensing, and it incurs no costs associated with manufacturing or distribution. WC misses out on the future gains from stabilization of the public health situation, but it may receive other gains from this strategy. If WC forgoes, it is likely to be in compliance with the expectations of PO and its government under the relevant free trade agreement or bilateral trade agreement. If PO and its government are satisfied with WC's performance, then drug donations and favorable trade treatment may follow. We assume that such favorable treatment is worth 3 to WC. If WC forgoes and D diverts, WC will earn no licensing revenues, incur no costs, and receive a perhaps slightly diminished gain from PO (e.g., if diversionary activity affects donated drugs or any market rate drugs in circulation). WC's total payoff in this event is 2.

D faces a strategy choice of Divert vs. Refrain. Assuming that D's direct costs of diversion (transportation, mainly), opportunity costs of diversion (from not pursuing other economic activity), likelihood of detection, and cost of being detected remain low, Divert is a profitable strategy for D, allowing him to reap all or most of the revenue from diverting the product. Diverting 50% of production in the event of a License decision by WC will lead to a payoff for D of 5. Even if WC foregoes, there will still be a positive payoff to be had by D, by siphoning of some of the other gains that WC receives for foregoing (Donated and/or market rate medicines can be diverted as readily as compulsorily licensed ones). The gain from diversion is greater under (License, Divert) than it is under (Forego, Divert), because there are more drugs in the stream of commerce under the former combination of strategies.[106] D's total payoff falls to 2 under (Forego, Divert).

PO's full (worldwide) revenues are assumed to be 100. In the event of a Refrain strategy being employed by D, PO earns its full revenues. If there is diversion, PO is assumed to suffer a 20% reduction in revenues in high price markets, to 80. If WC licenses, PO will receive some benefit in future periods from WC's local innovation. Some portion of such innovation could become

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deployedfiles/imshealth/Global/Content/StaticFile/Top_Line_Data/GlobalSales.pdf (global pharmaceutical sales were approximately $700B in 2007) (last visited June 7, 2010); About Phrma, http://www.phrma.org/about_phrma/ (global pharmaceutical research and development spending was approximately $65B in 2009) (last visited June 7, 2010); DAVID R. SUGDEN, GRAY MARKETS: PREVENTION, DETECTION, AND LITIGATION 24 (2009) (revenues lost to the gray market annually of approximately $10B); Medicines Australia, Global Pharmaceutical Industry – Facts at a Glance, http://www.medicinesaustralia.com.au/pages/images/Global%20-%20facts%20at%20a%20glance.pdf (market share in the developed vs. developing world: North America: 45%, Europe: 20%, Japan: 10%, United Kingdom: 3%, Australia: 1%, Rest of World, including many of the markets that are potential Waiver Countries: 21%) (last visited June 7, 2010).

[106] (Donated Drugs + Market Rate Drugs + Licensed Drugs) vs. (Donated Drugs + Market Rate Drugs).

part of PO's overall store of know-how, and could feed product development in other markets. We assume for simplicity that PO's gain from local innovation is equivalent to WC's local innovation expenditure of 3. A License strategy by WC also increases PO's revenues in future periods (due to the economic stabilization that should flow from public health stabilization). We will assume that the present value of such increased revenues is equivalent to 5% of PO's current worldwide revenues. If WC foregoes, PO receives no benefit from local innovation, and its revenues are flat in future periods. The payoffs of all three players are given in the table below for each combination of strategies by WC and D. In each cell, WC's payoff is given first, D's payoff second, and PO's payoff third.

Figure B

		D	
		Refrain	Divert
WC	License	8, 0, 108	-1, 5, 88
	Forego	3, 0, 100	2, 2, 80

In this game, D's Divert strategy is strictly dominant.[107] No matter which strategy WC chooses, D is better off choosing Divert and may be expected always to do so. Given that D will always choose Divert, WC's best strategy is Forego. Choosing Forego saves WC the costs associated with licensing and delivers some benefit in the way of largesse from PO. Licensing in the face of D's Divert strategy is a recipe for a negative payoff. This outcome of the game produces equilibrium without producing an access solution. The players maximize their payoffs in understandable but access-limiting ways.

It should be noted that the foregone access opportunity is not necessarily a win for PO. PO reaps potential benefits from a License decision in the form of local innovation gains and increased future revenues, but under a Forego strategy those benefits never materialize. Only alterations to the players' expected payoffs, and commitment by the players' to actions that will deliver such payoffs, will increase the likelihood of PO (and humanity in general) reaping the benefits of the License strategy.

How might the players' payoffs be altered? First, D's likelihood and cost of detection must be increased. One approach to such an increase would be for PO to commit to funding detection activities to be carried out on the ground by WC. PO is probably better positioned to provide the resources to bolster the investigatory apparatus, but WC controls the investigatory apparatus and knows the local players. Deployment of the resources is better left in WC's hands. As a further incentive to actively detect, the royalty rate owed by WC and/or its licensee to PO could be on a sliding scale and tied to the level of diversionary activity. The lower the amount of diversion, the smaller the

[107] A strictly dominant strategy is one that is always the player's best choice, regardless of the other player's strategy choice. *See* BAIRD, *supra* note 101, at 11; KREPS, *supra* note 99, at 26.

royalty that WC or the licensee would owe to PO. The combination of cheaper detection (because of direct funding by PO) and cheaper licensing (because of the lower royalty rate tied to reduced diversion) can increase WC's incentive to choose a License strategy.

A second approach to altering the player's payoffs would be to reduce the cost of local innovation and increase the benefit for local innovation, from WC's perspective. Direct investment by PO is one clear way of reducing WC's outlays for adaptive R&D, thus reducing the cost of the License strategy. Increasing incentives to License can also be accomplished by enhancing WC's gain from licensing. Allowing WC to participate in PO's worldwide gains from exploitation of locally-developed know-how might achieve such an enhancement. Importantly, both PO and WC gain from a commitment by PO to partner with WC in pursuing local innovation, because if License is never chosen, and local innovation never occurs, PO misses out on long term revenue opportunities.

A third approach to payoff alteration involves increasing the opportunity cost of D's decision to Divert. Again, direct investment by PO can play a role. PO may invest directly in local distributors, providing handsome benefits for local firms who respect the supply chain, and exacting penalties or terminating relationships when breaches are detected. Similarly, PO may elect to share a small portion of its gains from local innovation with D, subject to supply chain integrity maintenance. The upshot of such an approach is to make it profitable for D to allow the product to reach its intended destination, and very expensive to deviate from PO's and WC's access goals. Creating a lucrative and legitimate role for D gives D something to lose in choosing Divert.

Figure C

		D	
		Refrain	Divert
WC	License	12, 3, 106	5, 0, 86
	Forego	3, 0, 100	2, 0, 80

A goal for the local market might be the payoff set depicted in Figure C above. In this scheme, a (License, Refrain) combination leads to WC earning current revenues of 10, as before, but having distribution costs absorbed by PO, gaining 4 from stabilization, and receiving 1/3 of PO's local innovation gain of 3. WC's payoff is thus 10-3+4+1=12. D receives legitimate distribution revenue of 2, and a local innovation gain equal to WC's, for a total payoff of 3. In the event of a Divert decision by D, the penalties imposed by PO erase any payoff for D and reduce WC's payoff by doubling its royalty rate and eliminating its innovation gain share. As we assume diversion also eliminates WC's stabilization gain, WC's payoff drops to 10-6=4, in the event of a (License, Divert) combination. In any scenario where WC Foregoes, we assume that its payoffs are unchanged from the former iteration. D's payoff is assumed to always fall to 0 if it chooses Divert.

Although Figure C points us in the direction of a pro-access result that

benefits PO, WC, D, and WC's citizens, achieving this result will be more difficult than the normal form model indicates. The interactions among these players will be dynamic and iterative.[108] Such interactions are often modeled using extensive form games.[109] Such a model is beyond the scope of this Article, and further research is needed in order to define the precise form that the players' interactions would take in such a game. Future work on these issues could also go farther in positing the precise license terms that would create the final alignment of incentives represented by Figure C.

VI. MOVING FORWARD ON ACCESS

This Article has explored an alternative to common thinking regarding compulsory licensing. In a traditional all-or-nothing, zero-sum conception of patents and compulsory licensing, the parties have little incentive to engage in strategies that increase access to medicines for ordinary people. Patent owners assume, rationally, that some parties are prepared to divert their product from low income markets to high income markets. They pressure their governments to pressure the governments of countries that might otherwise be interested in issuing compulsory licenses. Fearing retaliation, potential Waiver countries do not issue licenses because all of the distributors' incentives point toward a decision to divert products to the gray market. Rather than incur the trade wrath of developed countries, Waiver country governments choose the access-limiting strategy of foregoing compulsory licensing.

What is needed is a view of compulsory licensing that gives multiple actors a stake in the development of local know-how regarding the medicines and a strong economic interest in protecting the integrity of the supply chain. Investment by patent owners (and their governments) in the local innovation infrastructures and anti-diversion apparatuses of countries interested in utilizing the Waiver could go a long way toward decreasing the cost of licensing and increasing the gains from such a strategy. Local players have the ground-level knowledge to greatly enhance the value of the patent owner's asset. The patent owner actually has the resources to put that knowledge to use. By emphasizing a long term relationship (with repeatable wins and losses for countries, their licensees, and distributors, depending on their level of cooperation), and by being willing to share gains from innovation (which on a percentage basis would probably have a significant impact on local player payoffs), patent owners can help move the access debate away from old thinking.

The co-op licensing model discussed here is influenced by the scholarly and popular movement in intellectual property away from an absolute property rights paradigm, concerned only with some mythic individual inventor's incentive to innovate and need for a monopoly in order to innovate. Innovation and technology policy can be used to serve both individual goals

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[108] *See, e.g.*, Anderson, *supra* note 98, at 33.

[109] *See id.*

and broader societal goals such as economic development.[110] User innovation, local innovation, and collaborative innovation, can enhance the value of a patent owner's intellectual property and improve welfare for users at the same time.[111] In fact, successful deployment of a technology in a given market may depend on some form of user innovation or local knowledge.[112] Ultimately, the TRIPS access scheme will work only with local support, investment in local capabilities, and local development leading to organic adoption of intellectual property recognition, once more pressing issues of public health, safety, and welfare are addressed.[113]

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[110] *See generally, e.g.*, Peter K. Yu, *Building Intellectual Property Coalitions for Development*, *in* IMPLEMENTING THE WORLD INTELLECTUAL PROPERTY ORGANIZATION'S DEVELOPMENT AGENDA 79 (Jeremy de Beer ed., 2009), *available at* http://www.idrc.ca/openebooks/454-3/.

[111] *See* Rochelle Cooper Dreyfuss, *TRIPS and Essential Medicines: Must One Size Fit All? Making the WTO Responsive to the Global Health Crisis*, *in* INCENTIVES FOR GLOBAL PUBLIC HEALTH: PATENT LAW AND ACCESS TO ESSENTIAL MEDICINES 51, 58-60 (Thomas Pogge, Matthew Rimmer & Kim Rubenstien, eds., forthcoming 2010) *available at* http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1443248; Katherine J. Strandburg, *Evolving Innovation Paradigms and the Global Intellectual Property Regime*, 41 CONN. L. REV. 861, 871 (2009).

[112] *See* Strandburg, *supra* note 111, at 876-78.

[113] *See generally* Lanjouw, *supra* note 12.