SIMULATING PHARMACEUTICAL MARKETS IN THE DEVELOPING WORLD: THE PROBLEMS WITH "PULL" FUNDING MECHANISMS

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ABSTRACT

Two major trends have defined the progress of global health over the past twenty years. First, the amount of money dedicated to global health aid has increased dramatically since 1990. Second, the implementation of TRIPS within the World Trade Organization has led to a rapid harmonization of global patent law modeled after developed-world statutes. Patent laws in the developed world carry an implicit assumption that market forces will communicate consumer demand to pharmaceutical companies and will direct pharmaceutical research in

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an efficient manner, an assumption that fails in the global aid context because the developed world does not present a market large enough to exploit. Scholars have recently suggested using "pull" foreign aid programs to replicate a market in the developing world. This note will address potential problems that arise from this approach through three general case studies: (1) under-incentivization for "neglected diseases;" (2) inconsistent incentives for "Big 3 diseases;" and (3) rent-seeking inefficiencies with the Plumpy'Nut malnutrition treatment. This note will discuss the flaws present in the pull approach to simulating markets, and will propose alternatives.

I. INTRODUCTION

For several decades the international development community has sought to improve health standards across the globe.[1] Meanwhile, in 1994 the World Trade Organization (WTO) adopted the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS), mandating minimum intellectual property protection in all signatory nations.[2] Immediately, scholars raised concerns that the newly implemented patent laws might slow the progress of improving health standards in developing nations.[3] Patents on medical treatments removed the possibility of generic competition, raising prices beyond the reach of most developing-world citizens.[4] At the same time developing nations do not present markets large enough to incentivize pharmaceutical research, one of the primary goals of patent laws.[5] With little political will to reverse the trend of stronger patent laws,[6] several scholars have suggested using international donor aid as a substitute for existing markets, incentivizing the production of medicines designed for developing-world markets.[7] In theory,

[1] *See, e.g.*, U.N. Millennium Declaration, G.A. Res. 55/2, U.N. Doc. A/RES/55/2 (Sept. 18, 2000).

[2] Agreement on Trade-Related Aspects of Intellectual Property Rights, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, Apr. 15, 1994, 1869 U.N.T.S. 299.

[3] Prior to the signing of the TRIPS Agreement, "more than fifty countries did not provide patent protection on medicines." Amy Kapczynski et al., *Addressing Global Health Inequities: An Open Licensing Approach for University Innovations*, 20 BERKELEY TECH. L.J. 1031, 1043-44 (2005).

[4] *See* Kapczynksi et al., *supra* note 3, at 1033 (noting that patented ARVs in 2000 cost over $10,000 per year, while generic ARVs in 2005 cost only $168 per year). R

[5] Jean O. Lanjouw, *Intellectual Property and the Availability of Pharmaceuticals in Poor Countries*, *in* 3 INNOVATION POLICY AND THE ECONOMY 91, 97 (Adam B. Jaffe, Josh Lerner & Scott Stern eds., 2003).

[6] Recently, in fact, developed nations have sought to impose even stricter IP protection laws on developing nations through trade agreements. Kapczynski et al., *supra* note 3, at 1043. R

[7] *See, e.g.*, Michael Kremer, *Pharmaceuticals and the Developing World*, 16 J. OF ECON. PERSPECTIVES 67, 82 (2002); Aidan Hollis, An Efficient Reward System for

such "pull" mechanisms are designed to signal to pharmaceutical companies the existence of markets that can pay for the development of new medicines.[8] Using foreign aid to simulate markets suffers from its own flaw, however, since the aid organizations, rather than end-users, signal market demands to pharmaceutical companies. Such simulation could create several market inefficiencies resulting in sub-optimal levels of medical research targeted toward the interests of the developing world. This note will explore the potential for market inefficiencies through pull methods of foreign aid and then will describe potential solutions.

A. *Global Health Trends*

Two major trends have defined the progress of global health over the past twenty years. First, international aid has vastly increased with a goal of improving health conditions in the developing world.[9] Between 1996 and 1999 total donations for sub-Saharan Africa health aid increased from approximately $80 million to $865 million.[10] By 2006 the Bill and Melinda Gates Foundation alone donated $6.6 billion for global health aid, and since 2003 the President's Emergency Plan for AIDS Relief (PEPFAR) has contributed roughly $8.5 billion to supply anti-retrovirals (ARVs) to developing-world AIDS patients.[11] Meanwhile, the Organisation for Economic Co-operation and Development (OECD) increased health aid from $2.5 billion in 1990 to over $14 billion in 2006.[12] Over that same time period health aid grew from 4.6% to 13% of total overseas development assistance.[13] International health aid averaged $19 per capita in sixty-five low-income countries in 2006, an increase from $5 per capital in 1995.[14] International aid represented 20% of the total amount

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Pharmaceutical Innovation 2 (Jan. 17. 2005) (unpublished manuscript), *available at* http://econ.ucalgary.ca/fac-files/ah/drugprizes.pdf; Emmanuel Combe et al., Pharmaceutical Patents, Developing Countries and HIV/AIDS Research 14 (May 19, 2003) (unpublished manuscript), *available at* http://emmanuelcombe.org/Combe.pdf; Lanjouw, *supra* note 5, at 101. R

[8] Kremer, *supra* note 7, at 83; Hollis, *supra* note 7, at 3; Combe et al., *supra* note 7, at 14; Lanjouw, *supra* note 5, at 101. R R

[9] Laurie Garrett, *The Challenge of Global Health*, 86 FOREIGN AFF. 14, 17-21 (2007); Marwa Farag et al., *Does Funding From Donors Displace Government Spending for Health in Developing Countries?*, 28 HEALTH AFF. 1045, 1049-51 (2009); Philip Stevens, *Foreign Aid for Health: Moving Beyond Government*, THE CAMPAIGN FOR FIGHTING DISEASES 5 (discussion paper no. 4, 2008), *available at* http://www.policynetwork.net/sites/default/files/Foreign_Aid_Health_WEB.pdf.

[10] Garrett, *supra* note 9, at 17. R

[11] *Id.* at 19.

[12] Stevens, *supra* note 9, at 6. Total overseas development assistance doubled from 2000 to 2006, increasing from $59.8 billion to $119.83 billion. *Id.* at 5. R

[13] *Id.* at 6.

[14] Farag et al., *supra* note 9, at 1050. The author describes her classification of low- and middle-income countries. R

spent on healthcare in these low-income countries in 2006, an increase from 10% in 1995.[15] The upward trend in global health aid is unmistakable and should signal to pharmaceutical companies the existence of a market for new medicines.

The second major trend of the past twenty years is the implementation, through TRIPS, of substantive minimum patent protections based on developed countries' patent laws.[16] WTO membership requires acceptance of TRIPS and binds member states to its terms.[17] The WTO structure marks a significant shift in international law, establishing the Dispute Settlement Understanding and an impartial Dispute Resolution Panel, through which violations of TRIPS can be enforced.[18] One national government can "sue" another and allege that the opposing government has breached any WTO agreement.[19] If the Dispute Resolution Panel finds a violation of an agreement, the remedy is analogous to contract law where the breaching party must perform or pay damages.[20] The violating nation can choose to alter its laws or policies; if it refuses, the "victim" nation can withhold trade benefits, creating a monetary penalty.[21] The existence of concrete penalties for a TRIPS violation has a significant impact on developing nations. The implementation of TRIPS changed the substantive laws in developing countries which previously had no significant patent laws or excluded medicines from patentability.[22] Using the threat of trade sanctions, the WTO enforcement mechanism allows larger nations to coerce smaller nations into meeting their substantive legal obligations, though smaller nations lack the trade impact to coerce larger nations in an equivalent manner.[23]

After TRIPS came into effect developing nations expressed concern that implementing the substantive patent rights required by TRIPS, including patent protection for pharmaceuticals, could have significant public health consequences.[24] In response the WTO issued the Doha

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[15] *Id.*

[16] *See* Cynthia M. Ho, *Current Controversies Concerning Patent Rights and Public Health in a World of International Norms*, *in* PATENT LAW AND THEORY: A HANDBOOK OF CONTEMPORARY RESEARCH 673, 673-74. (Toshiko Takenaka ed., 2008).

[17] *Id.* at 673.

[18] *Id.* at 679.

[19] Agreement on Subsidies and Countervailing Measures, Marrakesh Agreement Establishing the World Trade Organization, Apr. 15, 1994, 1869 U.N.T.S. 3. Only national governments who are parties to the agreement can sue or be sued; private parties cannot participate.

[20] *Id*.

[21] *Id*.

[22] Ho, *supra* note 16, at 677. **R**

[23] World Trade Organization, World Trade Repot 2007, at 284, *available at* www.wto.org/english/res_e/booksp_3/anrep_e/world_trade_report07_e.pdf.

[24] Ho, *supra* note 16, at 676. **R**

Declaration in 2001, which, among other provisions, explicitly allowed developing nations to issue compulsory licenses on patented pharmaceuticals in response to a public health crisis.[25] The United States, however, has undertaken a separate campaign to curtail the Doha Declaration provisions through bilateral trade agreements with individual developing nations, referred to as "TRIPS-plus" agreements.[26] The United States also exerts tremendous pressure on developing nations that attempt to exercise their compulsory licensing rights under TRIPS to obtain less expensive medicines in the face of public health emergencies.[27] In 2001 the United States initiated a dispute resolution under the WTO procedures aimed at Brazil because Brazil's patent law allowed compulsory licensing to create generic versions of patented ARVs.[28] The United States also placed Thailand on the Special 301 watch list after Thailand issued a compulsory license for the drug Plavix.[29] The Special 301 watch list refers to an annual report prepared by the United States Trade Representative (USTR) under Section 301 of the Trade Act of 1974, identifying foreign nations that enact or fail to enact laws or policies that unfairly disadvantage American intellectual property rights holders.[30] The U.S. will push countries named on the Special 301 watch list to alter their policies, or will pursue a case in the WTO Dispute Settlement body.[31] Although the legality and ethics of such uses of the 301 watch list are debated,[32] it is reasonable to expect that the USTR will continue its policy of aggressive enforcement of TRIPS.

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[25] *See generally* World Trade Organization, Ministerial Declaration of 14 November 2001, WT/MIN(01)/DEC/2.

[26] Kapczynski et al., *supra* note 3, at 1059-60 (discussing how the U.S. commonly negotiates bilateral agreements removing most of the TRIPS flexibilities that were designed to protect developing nations). **R**

[27] *See, e.g.*, Kevin Outterson, *Pharmaceutical Arbitrage: Balancing Access and Innovation in International Prescription Drug Markets*, 5 YALE J. HEALTH POL'Y L. & ETHICS 193, 225 (2005).

[28] *Id.* The U.S. abandoned the dispute resolution after significant international pressure.

[29] Ho, *supra* note 16, at 694-95. For a detailed discussion of the Thai compulsory license saga *see* Kevin Outterson, *Disease-Based Limitations on Compulsory Licenses Under Articles 31 and 31*bis 1-2 (Boston University School of Law Working Paper No. 09-26, 2009), *available at* http://www.bu.edu/law/faculty/scholarship/workingpapers/2009.html. **R**

[30] USTR 2011 SPECIAL 301 REP. 1 (2011).

[31] *See id.* at 15-16.

[32] *Compare* Kapczynski et al., *supra* note 3, at 1060 n.127 (noting that the U.S. Trade Representative has a Congressionally-mandated obligation to respect the Doha Declaration on TRIPS, which it arguably has exceeded in its bilateral trade negotiations), *with* Ho, *supra* note 16, at 695 (noting that Congress does not require an actual violation of international law when authorizing Special 301 investigations of foreign trade practices). **R** **R**

B. *Research Incentives*

The plight of "neglected diseases" and the general lack of research for treatments in the developing world are well-documented.[33] Increasing patent protection does not always increase research incentives for these diseases since patients in the developing world cannot afford the treatments, reducing the reward available to researchers.[34] As a result several scholars have suggested that pull funding mechanisms could simulate developing-world healthcare markets, using developed-world aid money to stand in for the consumer funds that would ordinarily attract research.[35] There are reasons to believe, however, that pull policies alone will not promote adequate levels of drug research. Identifying the most efficient use of donor funds is critically important, since initial evidence has shown that as global health aid has increased, domestic health spending by developing nation governments has decreased.[36] Thus, donor aid has assumed a much larger share of the burden even as total health spending in the developing world has increased in absolute terms.[37]

Pull policies, relying on increased patent protection coupled with increased donor aid, present opportunities for significant market distortions. The developed-world patent system assumes several market-based economic principles, including the fact that consumers will direct innovation through market choices.[38] Conforming international patent law to the developed-world model is unlikely to produce efficient results if consumers' ability to direct innovation does not exist in every country. The explosive growth of health aid means that developed-world aid organizations are increasingly interposing themselves in the normal relationship between patients as consumers and pharmaceutical companies as producers, disrupting the economic assumptions of patent law. This note will explore the possible inefficiencies that could result. Part II will outline an economic model of patent law as applied to the pharmaceutical industry. Part III will describe the three basic models of aid distribution and the role that the developed-world aid organizations assume as stand-ins for developing-world consumers. Part IV will provide three case studies to demonstrate the market distortions produced by the increase of both donor health aid and patent protection: (1) Under-Incentivization in Neglected Diseases; (2) Inconsistent Incentivization in "Big 3 Diseases;" and (3) Rent-Seeking in Malnutrition. Finally, Part V will offer some

[33] Lanjouw, *supra* note 5, at 98-99; Combe et al., *supra* note 7, at 10-12; Kremer *supra* note 7, at 68-70. R R

[34] Outterson, *supra* note 27, at 245. R

[35] *See, e.g.*, Kremer, *supra* note 7, at 83; Hollis, *supra* note 7, at 3; Combe et al., *supra* note 7, at 14; Lanjouw, *supra* note 5, at 101. R R

[36] Farag et al., *supra* note 9, at 1050. R

[37] *Id.*

[38] *See generally* WILLIAM M. LANDES & RICHARD A. POSNER, THE ECONOMIC STRUCTURE OF INTELLECTUAL PROPERTY LAW (2003).

potential solutions including the possibility of a licensing scheme adapted from a similar scheme proposed by Kapczynski, et al.[39]

II. An Economic Theory of Patent Law

While economic concerns are not the only theoretical basis for patent protection,[40] this section will focus on the economic/utilitarian justification of patent law for two reasons. First, the pharmaceutical industry closely adheres to a pure utilitarian patent law model.[41] Second, in the global health debate, the advantages of pharmaceutical patents are generally described in purely utilitarian and economic terms.[42]

In economic terms the patent law system exists to solve a public goods problem.[43] When a pharmaceutical company creates a new medicine the knowledge about how to create that medicine is a public good; the medicine is beneficial to the entire community, but the knowledge of how to make it is inherently intangible, not fixed in any physical form.[44] As a result, the knowledge itself is non-rivalrous and non-excludable.[45] The knowledge is non-rivalrous because its use by one individual does not prevent its use by another individual.[46] In the pharmaceutical context, Company A may research and develop a particular medicine. Company B can reverse engineer that medicine and learn how to make it without diminishing Company A's knowledge of how to make the medicine. Unlike a tangible piece of property, everyone can use the inventive knowledge at the same time without diminishing its quality or availability

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[39] *See* Kapczynski, et al., *supra* note 3, at 1090-93. **R**

[40] *See* Robert P. Merges, Peter S. Menell & Mark A. Lemley, Intellectual Property in the New Technological Age 2-11 (5th ed. 2010) (discussing natural rights and personhood theories of intellectual property).

[41] Rebecca S. Eisenberg, *Patents, Product Exclusivity, and Information Dissemination: How Law Directs Biopharmaceutical Research and Development*, 72 Fordham L. Rev. 477, 482 (2003-2004) (describing the unique ability of pharmaceutical companies to command true monopoly prices through their patents, as compared to other industries, and the use of price premiums to fund pharmaceutical research and development).

[42] *E.g.* Kramer, *supra* note 7, at 76-78; Combe et al., *supra* note 7, at 4-8; Peter Lee, **R**
Toward a Distributive Commons in Patent Law, 2009 Wis. L. Rev. 917, 928-31 (2009);
Lanjouw, *supra* note 5, at 100-04. **R**

[43] F. Scott Kieff, *On the Economics of Patent Law and Policy*, *in* Patent Law and Theory: A Handbook of Contemporary Research 3, 34 (Toshiko Takenaka ed., 2008).

[44] *See* Wendy Gordon, *Fair Use as Market Failure: A Structural and Economic Analysis of the* Betamax *Case and its Predecessors*, 82 Colum. L. Rev. 1600, 1610-11 (1982) (describing general characteristics of public goods).

[45] Michael S. Mireles, *An Examination of Patents, Licensing, Research Tools, and the Tragedy of the Anticommons in Biotechnology Innovation*, 38 U. Mich. J.L. Reform 141, 151 n.52 (2004-2005); Lee, *supra* note 42, at 928.

[46] Lee, *supra* note 42, at 928.

to others.[47] Likewise, such inventive knowledge is non-excludable because once the knowledge exists it is difficult to exploit without disclosure to the world.[48] Once Company A sells its medicine, the essential knowledge needed to make that medicine is sold along with the medicine itself, excluding any unique production methods that may be protected through trade secrets.

The concern with intangible inventive knowledge is the risk of free-riders; the whole world can obtain equal access to the information once it becomes public knowledge.[49] Once the knowledge underlying a particular medicine is disseminated to the public, anyone can produce that medicine at the lowest marginal cost[50] without having to consider the recovery of research costs.[51] For a pharmaceutical drug, the marginal cost to create one pill may be minuscule, but the full cost of researching and developing the medicine inside that pill may be massive. To remain competitive in the face of free-riders, the inventing company would have to lower prices, thus forfeiting any compensation for its inventive effort; otherwise it risks being pushed out of the market by undercutting competition.[52] Without a way of recovering research expenditures a pharmaceutical company will risk going out of business,[53] or it might choose to withdraw from the field in advance.[54] This worst possible outcome impedes the innovation and general scientific progress of the community.

The existence of the free-rider dilemma justifies some form of government intervention to promote the general progress of science and technology.[55] The government might choose to finance important areas of research directly.[56] In this way, every citizen is paying his share of the inventor's compensation through compulsory taxes. Although economically effective, the government is often far less efficient than the free market in properly allocating funds to the best inventive endeavor.[57] In a

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[47] LANDES & POSNER, *supra* note 38, at 14. **R**

[48] *Id.* Another approach to this problem is the use of trade secret law, which will protect information as long as the possessors of such information take reasonable steps to keep it secret. MERGES, MENELL & LEMLEY, *supra* note 40, at 36-37.

[49] Mireles, *supra* note 45, at 151.

[50] Marginal cost is the cost to produce one more copy of a given item. LANDES & POSNER, *supra* note 38, at 37-38. **R**

[51] *Id.* at 13.

[52] See *Id.*

[53] *See* Duff Wilson, *Drug Firms Face Billions in Losses in '11 as Patents End*, N.Y. TIMES, Mar. 6, 2011, *available at* http://www.nytimes.com/2011/03/07/business/07drug.html.

[54] LANDES & POSNER, *supra* note 38, at 40-41. **R**

[55] Lanjouw, *supra* note 5, at 95. **R**

[56] Michael Abramowicz, *Perfecting Patent Prizes*, 56 VAND. L. REV. 115, 119 (2003) (discussing government prizes as a replacement for market-based patent incentives in medical research).

[57] *Id.* at 121.

free-market system the public itself can influence the direction of economic activity and research through its consumer choices, directing capital flows to the industries and enterprises with the most demand.[58]

Rather than relying on inefficient government funding, the patent system attempts to solve the free-rider problem by using the law to create artificial excludability.[59] Governments institute property-like rights that patent holders can enforce against everyone else in the jurisdiction, allowing inventors to capture the positive externalities that inventions create.[60] The international patent system grants the inventor a quasi-monopoly for a limited period of time, which allows him to sell his invention at a higher than marginal rate and recover his upfront investment costs.[61] No external user can free ride because he must legally pay for any potential use of the invention.

Primarily, the international patent regime is concerned with incentivizing creation for public benefit; rewarding inventors is a secondary, though important, goal.[62] As such, the structure of patent law must be calibrated carefully to give only enough incentive as is necessary without unduly restricting public access to new and useful inventions.[63] Various doctrines address this balance, such as the limited patent term and subject matter requirements.[64] In this way patent law will protect only works that require significant investment and require the protection of patent law to encourage their production. The dual requirements of disclosure and dedication to the public domain ensure that once the patent expires the whole public can reap the benefits of the new invention.[65]

The tension between public enjoyment of an invention and the restrictions needed to compensate the inventor are enormously important in the realm of public health. Access to medicines and medical technologies is essential to saving millions of lives.[66] Public interest in free dissemination of medical knowledge is compelling, but on the other hand, pharmaceuti-

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[58] *See id.* at 121 n.24 (citing H.I. DUTTON, THE PATENT SYSTEM AND INVENTIVE ACTIVITY DURING THE INDUSTRIAL REVOLUTION 1750-1852 26 (1984)).

[59] Lee, *supra* note 42, at 929.

[60] *See* LANDES & POSNER, *supra* note 38, at 12. *See also* Outterson, *supra* note 27, at 199. **R**

[61] *See* Mark A. Lemley, *The Economics of Improvement in Intellectual Property Law*, 75 TEX. L. REV. 989, 996 (1997).

[62] *See* Kieff, *supra* note 43, at 34-35. *See also* Mazer v. Stein, 347 U.S. 201, 218 (1954) ("[T]he patent statutes make[ ] reward to the owner a secondary consideration." (quoting United States v. Paramount Pictures, 334 U.S. 131, 158 (1948))).

[63] LANDES & POSNER, *supra* note 38, at 300. **R**

[64] *Id.* at 302.

[65] *See id.* at 294-95.

[66] Kremer, *supra* note 7, at 68. **R**

cal research requires massive expenditures.[67] Pharmaceutical companies develop their business models expecting that a few successful drugs will generate enough revenue to compensate the firm for its total expenditures, including vast amounts of unsuccessful research.[68] Companies therefore charge rates on drugs and medical technologies far above their marginal costs, making cutting edge technologies especially expensive and out of reach for most people in the developing world.[69] These characteristics of the pharmaceutical industry bring into sharp relief the competing goals of patent law: compensating inventors and benefiting the public. It is unlikely that most large pharmaceutical firms could survive, much less effectively research a broad array of diseases, without massive revenues from their few successful products. Such a pricing structure, however, does little to help the millions of people who need access to medical treatments they cannot afford. There is also the further concern of generational balance; freely distributing all current medicines might save millions of lives today, but at the expense of future research that could save millions more through the development of new treatments.[70]

III. The Current Model of Developing World Access to Medicines

Pharmaceutical companies ordinarily do not consider the developing world to be a readily exploitable market.[71] The costs of medicines are simply out of reach for many citizens of low-income countries.[72] While other logistical obstacles may prevent adequate medicine distribution within the developing world,[73] even if these problems were solved over-

[67] Joseph A. DiMasi et al., *The Price of Drug Innovation: New Estimates of Drug Development Costs*, 22 J. of Health Econ. 151, 180 (2003) (estimating the price of a new drug at $802 million).

[68] *See id*. at 152.

[69] In one often-cited example, the average price for an anti-retroviral regimen to treat AIDS was $10,000 per patient per year while the drugs were under patent; now that the patent has expired the same drugs cost $168 per person per year. *E.g.*, Kapczynski et al., *supra* note 3, at 1033. R

[70] *See* Lanjouw, *supra* note 5, at 95; Kremer *supra* note 7, at 75. R

[71] Kremer, *supra* note 7, at 70. In terms of pharmaceutical sales, the U.S., Europe, and Japan represented 81.1% of the global market for pharmaceuticals in 1998. *Id.* Africa specifically represented 1.1% of global pharmaceutical sales in 2002. Combe et al., *supra* note 7, at 9. R R

[72] *See* Jonathan D. Quick, Editorial, *Essential Medicines Twenty-Five Years On: Closing the Access Gap*, 18 Health Pol'y & Plan. 2 (2003).

[73] *See, e.g.*, Panos Global AIDS Programme, Antiretroviral Drugs for All? Obstacles to Access to HIV/AIDS Treatment: Lessons from Ethiopia, Haiti, India, Nepal and Zambia 7 (May 2006), http://www.panosaids.org/files/arvsforall.pdf (last visited April 3, 2011) (discussing general obstacles to effective drug distribution, such as limited infrastructure, cultural resistance, low education, failure to follow through on drug regimens); Quick, *supra* note 72, at 1 (identifying "(1)

night, pharmaceutical companies would still have little incentive to invest in treatments aimed at the developing world.

The developing world requires unique products from pharmaceutical companies. Many "local" diseases primarily infect citizens in the developing world,[74] including infectious and parasitic diseases that are common in the developing world, but incredibly rare in the developed world.[75] The World Health Organization (WHO) has produced a list of twenty diseases for which "99% of the global burden [falls] on low- and middle-income countries . . . ."[76] The most deadly of these diseases, diarrheal diseases, killed over two million people in 2000.[77] Since these diseases do not exist in significant numbers in the developed world, there are no consumers to create a market for treatments and therefore no natural incentive for pharmaceutical companies to develop medicines to treat these "local" diseases.[78]

Even for global diseases, citizens in the developing require different treatments. Global diseases cause significant numbers of deaths throughout the world, regardless of a country's income,[79] and include cancer, heart disease, and AIDS.[80] While the presence of these diseases in the developed world gives pharmaceutical companies incentives to develop treatments, the treatments are often difficult to administer in the developing world. For example, developing countries often lack a reliable power supply and require medical treatments that can be stored and transported without refrigeration, for which there is no equivalent need in the developed world.[81] Similarly, many patients in the developing world have difficulty adhering to rigorous drug schedules and would benefit from cocktail treatments that incorporate several doses into one pill.[82] Even for a global disease such as AIDS, there are unique strains

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irrational use of medicines, (2) unfair financing for healthcare, including medicines, (3) unreliable delivery systems and (4) high medicines prices" as obstacles to access to medicines).

[74] Combe et al., *supra* note 7, at 9-10. **R**

[75] The WHO in 2001 estimated that infectious and parasitic diseases represent 33% of the disease burden in low-income countries, but only 3% of the disease burden in high-income countries. Kremer, *supra* note 7, at 70. **R**

[76] Kremer, *supra* note 7, at 71. *See also* WHO, *The World Health Report 2001*, at 143-48 (2001), *available at* http://www.who.int/whr/2001/en/whr01_en.pdf. **R**

[77] WHO, *The World Health Report 2001*, at 144 (2001), *available at* http://www.who.int/whr/2001/en/whr01_en.pdf.

[78] *See* Lanjouw, *supra* note 5, at 97. **R**

[79] Kremer, *supra* note 7, at 72. **R**

[80] *Id.*; Lanjouw, *supra* note 5, at 97. **R**

[81] Lanjouw, *supra* note 5, at 97. **R**

[82] *See* Kapczynski, et al., *supra* note 3, at 1051-52. Vaccines would be even better, but so far pharmaceutical companies have shown no inclination to develop vaccines that would obviate the need for lifelong AIDS treatments in either the developing world of the developed world. Combe, et al., *supra* note 7, at 11. A single dose **R**

that exist predominantly in the developing world.[83] Moreover, the developed world has very few children who are born with AIDS, and as a result, pediatric formulations of AIDS treatments needed in the developing world are rarely researched.[84] For pharmaceutical companies to have incentives to research treatments specific to the developing world, some third party must be able to supply the money.

A. *"Push" vs. "Pull" Mechanisms*

There are two basic ways third parties can spend money to encourage development of specific medicines: (1) "push" programs subsidizing research inputs and (2) "pull" programs rewarding research outputs.[85] Push mechanisms subsidize research and development on the front end, usually through research grants or research tax credits.[86] In addition, push mechanisms can include streamlined regulatory processes that encourage and guide innovation.[87] While push mechanisms may provide economic incentives for research, they create two particular problems. First, those funding pharmaceutical research "cannot perfectly monitor" the researchers, creating a risk that the research funding may not be used optimally.[88] Second, public officials may not be the best judges of which research paths are the most promising or the most deserving of research funding.[89]

In response to these concerns, a number of scholars have suggested focusing public incentives on pull mechanisms.[90] The main advantage of a pull mechanism is that it only rewards pharmaceutical companies for

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vaccine would be far easier to administer in nations with little infrastructure when compared to daily medicine treatments. Unfortunately, not only would a vaccine produce fewer profits than a daily treatment, it would replace the profits gained from existing AIDS treatments, severely reducing income to pharmaceutical companies. *Id. See generally* Kenneth Arrow, *Economic Welfare and the Allocation of Resources for Invention*, *in* THE RATE AND DIRECTION OF INVENTIVE ACTIVITY: ECONOMIC AND SOCIAL FACTORS 609, 618-22 (Universities-National Bureau ed., 1962). This is a problem far beyond the scope of this note, but it obviously affects incentives for pharmaceutical research and deserves mentioning.

[83] Lanjouw, *supra* note 5, at 97. **R**

[84] *See* Médecins Sans Frontières, *Children Being Neglected in AIDS Fight, Says MSF*, July 13, 2004, http://www.doctorswithoutborders.org/news/article.cfm?id=712%20&cat=field-news.

[85] Kremer, *supra* note 7, at 82. **R**

[86] *Id.*

[87] Combe, et al., *supra* note 7, at 13-14. *See also* Eisenberg, *supra* note 41, at 482 **R** (describing how the Orphan Drug Act of 1983 provides regulatory benefits for drugs that treat rare diseases affecting fewer than 200,000 patients in the United States).

[88] Kremer, *supra* note 7, at 82. **R**

[89] *Id.*

[90] *See, e.g.*, Kremer, *supra* note 7, at 82; Hollis, *supra* note 7, at 3; Combe, et al., **R** *supra* note 7, at 14; Lanjouw, *supra* note 5, at 101. **R**

viable products, avoiding the risk of misdirected funds.[91] A pull mechanism also would eliminate the need for funding entities to "pick winners" at an early stage of development, and therefore will ensure that funders have the best knowledge regarding which specific products are most deserving of their funds.[92] End-product purchase commitments and drug prizes are two suggested policies employing pull mechanisms.[93] The largest suggested advantage of pull mechanisms is that they can substitute for a market, providing a large pool of money that will encourage pharmaceutical companies to invest in pharmaceutical development.[94] As Part IV, *infra*, will outline, however, the ability of pull mechanisms to simulate an adequately functional market for developing nations may be overstated. The remainder of this section describes the two kinds of third parties that might supply the funding for pull mechanisms: developing nation governments and external aid organizations.

B. *Developing Nation Governments*

Developing nation governments could supply funding for medical research incentives, but this solution is unrealistic for several reasons. First, governments of developing-world nations simply have little money to spend. For many of the poorest countries, government expenditure on healthcare is low, both in absolute terms and compared to private or external contributions, such as international aid.[95] Developing nations with poor populations naturally will have a much lower tax base upon which they can seek revenue to pay for general healthcare services, including payments for medicines.[96] Second, even if the money were available, many developing nations lack the infrastructure to enact public funding programs accountably and risk losing much of the money to cor-

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[91] Kremer, *supra* note 7, at 83. **R**

[92] *Id.*

[93] *Id.*; Hollis, *supra* note 7, at 3. **R**

[94] Kremer, *supra* note 7, at 85. **R**

[95] For sixty-five countries classified as "low income" by the World Bank, government spending on health averaged $37 per person in 2006, representing 38% of total health expenditures (including private payments and aid contributions). Farag et al., *supra* note 9, at 1049. By contrast, seventy-nine countries classified as "middle income" by the World Bank had government contributions of $323 per person to healthcare in 2006, representing 59% of total healthcare expenditures. *Id.* **R**

[96] Many of these countries are resource-poor, and even countries that have plentiful natural resources often fail to efficiently exploit them in a way that benefits the entire population. *See generally* Paul Collier, *Laws and Codes for the Resource Curse*, 11 YALE HUM. RTS. & DEV. L.J. 9, 11-14 (2008). Through government corruption, inefficient tax structures, and other economic defects, many poor, resource-rich nations are unable to capitalize on their natural resources in a way that significantly benefits the general public. *Id.*

ruption.[97] While programs funded by local governments would provide at least some representation for the population needing the medicines, the governments of developing countries tend to have little effective democratic representation.[98] Thus, national governments in the developing world are ineffective proxies for actual consumer demand.

C. *External Aid Organizations*

Recently, the international community has supplied an increasing amount of health aid to the developing world, representing a significant proportion of health expenditures in developing countries.[99] The WHO has stated that in low income countries approximately 50% of health expenditures are out-of-pocket (from the individual patient's personal funds),[100] while another empirical study estimated that in low-income countries approximately 20% of total health spending is contributed through external aid.[101] Governments of low-income countries contribute the remaining 30% percent of healthcare expenditures.[102]

While foreign aid contributes only 20% to total healthcare expenditures in low-income countries, money spent on medicines comes mainly from this foreign aid. The WHO estimates that a state must spend on average $35-$50 per person per year to provide basic, life-saving services.[103] Sixty-four WHO member states fail to meet this minimum average amount through government and out-of-pocket expenditures (from patients' personal funds).[104] Thirty of the lowest-spending countries do not even reach $20 per person annually in government and out-of-pocket expenditures.[105] As a result, even though low-income countries bear 80% of their healthcare costs,[106] the total health expenditures contributed by governments and local citizens funds only a minimum level of basic healthcare, covering life-saving and emergency health services. Very little money, if any, remains to pay for the relatively expensive costs

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[97] *See* Garrett, *supra* note 9, at 22 (noting that in Ghana, eighty percent of outside donor funds are diverted from their intended purpose due to corruption); Stevens, *supra* note 9, at 8 (describing the difficulty of tracking donor funds through to their intended targets). R R

[98] *See, e.g.*, The Economist Intelligence Unit, Democracy Index 2010 16 (2010), http://graphics.eiu.com/PDF/Democracy_Index_2010_web.pdf.

[99] Farag et al., *supra* note 9, at 1049. R

[100] WHO, *The World Health Report*, at xiv (2010), *available at* http://whqlibdoc.who.int/whr/2010/9789241564021_eng.pdf.

[101] Farag et al., *supra* note 9, at 1050. R

[102] Farag et al., *supra* note 9, at 1049. R

[103] WHO, Spending on Health: A Global Overview, Fact Sheet N° 319 (2007), *available at* http://www.who.int/mediacentre/factsheets/fs319.pdf.

[104] *Id.*

[105] *Id.*

[106] WHO, *The World Health Report*, at xiv (2010), *available at* http://whqlibdoc.who.int/whr/2010/9789241564021_eng.pdf; Farag et al., *supra* note 9, at 1050. R

of medicines. The money needed to purchase pharmaceutical medicines must come primarily from foreign aid.[107]

Three main groups contribute funding through international aid: multinational organizations, bilateral government programs, and non-governmental organizations (NGO's).

1. Multinational Organizations

Two multinational organizations that play large roles in distributing health aid are the WHO and the World Bank. Each organization operates differently, and the actions of each body tend to represent the interests of different constituencies within the international community. The WHO has 193 member states that operate within the World Health Assembly to decide the organization's policy through majority voting, in which every member state has an equal vote.[108] Despite the democratic structure of the World Health Assembly, the WHO has been criticized for the unwieldy nature of its Assembly and majority decision-making.[109] The WHO is funded in part through compulsory dues, the majority of which come from the developed world.[110] While the vast majority of this funding comes from developed-world governments, the WHO also receives voluntary donations from member states and other private organizations.[111]

The World Bank operates under a similar structure, but with an important difference in voting. The International Bank for Reconstruction and Development, the primary World Bank organ, has 185 member states, but voting power is proportional to the amount of money given in dues.[112] Developed nations provide the majority of the funding for the World Bank, and, therefore, the developed world controls the Bank's

[107] *See* Kremer, *supra* note 7, at 70. **R**

[108] *See generally* GIAN LUCA BURCI & CLAUDE-HENRI VIGNES, WORLD HEALTH ORGANIZATION 35-44 (2004).

[109] Devi Sridhar & Lawrence O. Gostin, *Reforming the World Health Organization*, 305 JOURNAL OF THE AMERICAN MEDICAL ASSOCIATION 1585, 1585-86 (2011).

[110] WHO Scale of Assessments 2010-2011, Feb. 16, 2010, U.N. DOC. A/63/31 (2010), *available at* http://www.who.int/about/resources_planning/scale_of_assessement_2010-2011_a63_31-en.pdf.

[111] *See* WHO ANNEX Voluntary Contributions by Fund and by Donor for the Year Ended 31 December 2010, Apr. 7, 2011, U.N. DOC. A/64/29 (2011), *available at* http://apps.who.int/gb/ebwha/pdf_files/WHA64/A64_29Add1-en.pdf.

[112] *See* IBRD Articles of Agreement art. II, § 3, Dec. 27, 1945, 59 Stat. 512, 2 U.N.T.S. 39; IBRD Articles of Agreement art. V, § 3.

functions.[113] The World Bank is often criticized for opaque decision-making and for the dominant role that the United States plays.[114]

Both the WHO and the World Bank dedicate money to pull-funding programs. The World Bank project in Nigeria is one example; the Bank committed $68 million to help Nigeria develop an effective healthcare system for procuring and distributing pharmaceuticals, which included the purchase of pharmaceuticals.[115] The WHO, likewise, spends its budget supporting health programs in member states and spent 13% of its budget on purchases of health products and medicines in 2006-2007.[116] As both the WHO and World Bank contain national governments as members, there is no role in either organization for the direct input of consumers when project funding decisions are made.

2. Bilateral Government Programs

In addition to multilateral organizations, many developed-world governments distribute health aid directly to developing nations. These governments focus heavily on pull policy programs. In the United States, for example, the United States President's Emergency Plan for AIDS Relief (PEPFAR) is a large governmental program that supplies billions of dollars to help address the AIDS epidemic worldwide.[117] Much of this money is used to purchase costly anti-retroviral drugs and distribute them to AIDS-infected patients in the developing world.[118] The Centers for Disease Control and Prevention (CDC) also had a global health budget of $319 million in FY 2010, which was used in part to both purchase and supply essential vaccines and medicines to the developing world.[119] The

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[113] *See* IBRD Articles of Agreement Schedule A.

[114] PAUL LADD, OPTIONS FOR DEMOCRATISING THE WORLD BANK AND THE IMF 4-6 (May 2003), *available at* http://www.sarpn.org/documents/d0000527/Ladd_WB_IMF.pdf.

[115] WORLD BANK, IMPLEMENTATION COMPLETION REPORT FOR THE ESSENTIAL DRUGS PROJECT IN NIGERIA, Loan 3125-UNI, Report No.: 17245 (Dec. 19, 1997), *available at* http://www-wds.worldbank.org/external/default/WDSContentServer/WDSP/IB/1997/12/19/000009265_3980203114946/Rendered/PDF/multi0page.pdf (describing a World Bank loan to Nigeria used to fund the purchase of medicines from 1990 to 1997).

[116] *See* WHO, WORKING FOR HEALTH: AN INTRODUCTION TO THE WORLD HEALTH ORGANIZATION (2007), *available at* http://www.who.int/about/brochure_en.pdf.

[117] *See* The U.S. President's Emergency Plan for AIDS Relief, *Five-Year Strategy* (2009), at 5, 11, *available at* http://www.pepfar.gov/documents/organization/133035.pdf.

[118] *Id.*

[119] DEP'T OF HEALTH AND HUMAN SERVICES, CENTERS FOR DISEASE CONTROL AND PREVENTION: JUSTIFICATION OF ESTIMATES FOR APPROPRIATION COMMITTEES 305 (2010), *available at* http://www.cdc.gov/fmo/topic/Budget%20Information/appropriations_budget_form_pdf/FY2010_CDC_CJ_Final.pdf.

United States Agency for International Development (USAID), by contrast, funds foreign governments directly for a variety of purposes including global health issues.[120] In FY 2007, USAID distributed $4.1 billion in foreign aid for the purpose of addressing global health problems.[121] The United Kingdom's Department for International Development, by contrast, spent £398 million on global health aid during FY 2010.[122]

On a structural basis the bilateral aid model is very similar to the multilateral aid model; in both cases developed-world national governments distribute domestically generated tax revenue to help finance a foreign health system. In a multilateral organization, however, the body as a whole, rather than the individual donating country, chooses how the money will be distributed. In the World Bank specifically, this distinction is minimized because weighted voting means that the member-countries that donate the most money exercise primary control over the organization's decisions.[123] To the extent that there is any political control over these bilateral aid organizations, governments representing the developed world, not the developing world, would control the use and flow of the money.

3. Non-Governmental Organizations (NGO's)

Non-governmental organizations (NGO's) represent the third model of international aid distribution. NGO's are distinct from multinational organizations in that private individuals, rather than national governments, are the constituent members. The term NGO encompasses a broad range of organizations including relatively small church-based and missionary groups that work to better health and human development in one small area of the world, as well as large-scale NGO's such as Oxfam, which focuses on global health as part of its general campaign to end poverty and injustice.[124] Newer NGO's have changed the landscape radically by offering massive sums of money through grants funding myriad global health and development projects. In the general NGO model, however, consumers have virtually no voice in how the money is spent to fund medicine purchases.

The Global Fund for AIDS, tuberculosis, and malaria is one NGO that focuses specifically on pull policy programs, giving money to fund health-

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[120] U.S. AGENCY FOR INT'L DEVELOPMENT, FISCAL YEAR 2008 ANNUAL PERFORMANCE REPORT 2-3 (2008), *available at* http://pdf.usaid.gov/pdf_docs/PDACM303.pdf.

[121] *Id.* at 26.

[122] DEPT. FOR INT'L DEVELOPMENT, DFID ANNUAL REPORT AND ACCOUNTS 2010-11 Volume 1 at 127, *available at* http://www.dfid.gov.uk/Documents/publications1/departmental-report/2011/Annual-report-2011-vol1.pdf.

[123] IBRD Articles of Agreement art. V, § 3.

[124] Oxfam International, Strategic Plan 2007-2012, *available at* http://www.oxfam.org/sites/www.oxfam.org/files/oi_strategic_plan_2007_0.pdf.

care in the developing world.[125] Since its inception in 2002, the majority of funding for the Global Fund has come from national governments.[126] The Fund contains two major structures: a board, consisting of public officials and private citizens that makes general policy and funding decisions, as well as a Secretariat of professionals that screens actual grant proposals.[127] Forty-seven percent of the Global Fund's grants have been used to procure medicines and supplies,[128] one example of which is a project that pays for the purchase of malaria medicines in developing-world countries.[129]

The Bill and Melinda Gates Foundation, another NGO that recently has provided significant amounts of money for global health projects, employs a funding strategy that uses both push and pull mechanisms.[130] Many of the research grants are paid upfront, before a viable product is developed, but there is also a review process to ensure that progress is being made toward the desired goal.[131] Unfortunately, a vast majority of the Foundation's initial projects were unsuccessful, and it has altered its project funding strategy as a result.[132] The Gates Foundation is also unique among NGO's in that it is funded through the Gates Asset Trust, meaning that soliciting donations or satisfying various donors is unnecessary.[133] The Gates Foundation is thus less publicly accountable than The Global Fund, which is funded by national governments and is, therefore, subject to at least some measure of public accountability. Private individuals make up a majority of the Gates Foundation's board and control policy decisions.[134]

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[125] *Our Activities*, THE GLOBAL FUND, http://www.theglobalfund.org/en/activities/ (last visited Jan. 12, 2012).

[126] *Donor Governments*, THE GLOBAL FUND, http://www.theglobalfund.org/en/donors/list (last visited Jan. 21, 2012).

[127] The Global Fund to Fight AIDS, Tuberculosis & Malaria, By Law As Amended 2 March 2011, Art. 7 and 8, *available at* http://www.theglobalfund.org/WorkArea/DownloadAsset.aspx?id=7100.

[128] *Procurement and Supply Management*, THE GLOBAL FUND, http://www.theglobalfund.org/en/activities/psm/ (last visited Jan. 21, 2012).

[129] *Affordable Medicines Facility – Malaria*, THE GLOBAL FUND, http://www.theglobalfund.org/en/activities/amfm/ (last visited Jan. 21, 2012).

[130] Donald G. McNeil, Jr., *Five Years In, Gauging Impact of Gates Grants*, N.Y. TIMES, Dec. 20, 2010, *available at* http://www.nytimes.com/2010/12/21/health/21gates.html.

[131] *Id.*

[132] *Id.*

[133] *About the Bill and Melinda Gates Foundation Asset Trust*, THE GATES FOUNDATION, http://www.gatesfoundation.org/about/Pages/gates-foundation-asset-trust.aspx (last visited Jan. 12, 2012).

[134] *Foundation Fact Sheet*, THE GATES FOUNDATION, http://www.gatesfoundation.org/about/Pages/foundation-fact-sheet.aspx (last visited Aug. 18, 2011).

Other NGO's have been able to secure medicines for the developing world, not through monetary efforts but by encouraging voluntary licenses or price reductions by pharmaceutical companies for their drugs.[135] While deals of this nature may enhance a company's ethical image, pharmaceutical companies are often reluctant to reduce prices without external pressure and these kinds of deals are not readily repeatable.[136] As a result, some commentators have called for a "fair use" provision for international medical patents, which would allow for the free use of medicines in the developing world since pharmaceutical companies do not expect to obtain any profits from these markets anyway.[137] However, making medicines freely available outside the developed world could cause wealthier consumers to complain about paying high prices for the same medicines that others can obtain for free, increasing arbitrage pressures.[138] Although such a dynamic already exists to some degree,[139] the public is likely to object more strenuously if medicines were completely free in the developing world. Strengthening international patent law helps to prevent arbitrage, allowing pharmaceutical companies to employ significant price discrimination among multiple countries.[140] The existing ad hoc price reductions likely will not remain permanent and will

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[135] *See, e.g.*, Kapczynski et al., *supra* note 3, at 1034-36 (describing how Médicins Sans Frontièrs pressured Bristol-Meyers Squibb into voluntarily reducing its price for AIDS medicines in South Africa). **R**

[136] *Id.*

[137] *See, e.g.*, Maureen O'Rourke, *Toward a Doctrine of Fair Use in Patent Law*, 100 COLUMB. L. REV. 1177, 1180 (2000) (advocating for a fair use doctrine in patent law where "market failures" would prevent a valuable use of a protected work simply because there was no effective way to license the patents); Kremer, *supra* note 7, at 75 (describing the market failures present in the international pharmaceutical markets). **R**

[138] Kremer, *supra* note 7, at 78. Pharmaceutical companies often charge different prices in different markets (referred to as price discrimination), based on the relative wealth of each market. Outterson, *supra* note 27, at 203-05. Consumers in a poor market therefore have an incentive to resell their drugs to a richer market, undercutting the pharmaceutical company in that market. *Id.* at 205-06. To illustrate with an example, suppose Company X sells Drug Y in a developed-world market (Country A) and a developing-world market (Country B). The price of Drug Y in Country A is $100, but it is only $10 in Country B. Profit-oriented entrepreneurs could purchase the drug in Country B for $10, then resell it in Country A for $50, undercutting Company X's price structure. Since pharmaceutical companies generally rely on profits extracted from the richest markets, arbitrage threatens the funds available to them for innovation. *Id.* **R** **R**

[139] *See, e.g.*, Daniel Gilman, *Oy Canada! Trade's Non-solution to "the Problem" of U.S. Drug Prices*, 32 AM. J.L. & MED. 247, 248-49 (2006) (describing the price differentials between U.S. and Canadian markets for the same drugs, and the political pressures this situation creates).

[140] Kremer, *supra* note 7, at 76-77. **R**

not establish predictable procedures for standardized price reductions in the future.[141]

IV. Lack of Consumer Input in Pull Policy Programs

Consumers in a market system typically communicate their demand for products through their purchase choices; demand information is transferred to producers in the form of sales and gross revenue information.[142] A firm will be successful economically only if it can supply the market with goods that consumers want to purchase. Even the pharmaceutical industry, where the government affects market incentives through research subsidies and regulation,[143] must sell its products in response to some form of consumer demand.[144]

The assumptions of consumer choice and demand communication are inherent in the international patent system, but these assumptions no longer exist in the developing world pharmaceutical market. The three models of distribution described in Part III, *supra*, all suffer from the same market defect. The parties exercising consumer choice, namely developed-world organizations and governments, do not perfectly replicate the interests of the products' end users. In the multilateral organization model, developed-world nations contribute the vast majority of the funds and significantly influence the decisions of those bodies, specifically with the World Bank's weighted voting system.[145] In the bilateral aid model, the money comes directly from developed-world governments that must consider domestic politics when making spending decisions.[146] Developed-world NGO's must satisfy their donors and organizers, who are overwhelmingly individuals from the developed world.[147] The end users of the medicines never exercise consumer choice in the prevalent international aid models. The governments of developing countries have little control as well, rendering them unable to act as intermediaries for their citizens. The strongest tool available to developing-world governments is the threat of compulsory licenses, which has sometimes com-

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[141] *See* Kapczynski et al., *supra* note 3, at 1064-66. **R**

[142] *See generally*, James D. Gwartney et al., Economics: Private and Public Choice 419-40 (12th ed. 2009) (describing the fundamentals of consumer choice and demand).

[143] *See* Eisenberg, *supra* note 41, at 477-78.

[144] *See* Kremer, *supra* note 7, at 70. **R**

[145] IBRD Articles of Agreement art. V, § 3.

[146] *See* USAID Fiscal Year 2008 Annual Performance Report 7, *supra* note 120 (describing Presidential oversight of USAID programs).

[147] *See, e.g., Financials*, Bill and Melinda Gates Foundation, http://www.gatesfoundation.org/about/Pages/financials.aspx (last visited April 4, 2011) (describing the foundation's private funding sources); *see also* Garrett, *supra* note 9, at 19 (2007). **R**

pelled pharmaceutical companies to lower prices on already-existing drugs.[148]

In the global health aid context, patent law's assumption of market communication from consumer to producer is absent. Without that essential communication, several market distortions and inefficiencies are likely to result. This section will examine these distortions through three generalized case studies: (1) under-incentivization examined through neglected diseases; (2) inconsistent incentivization examined through "Big 3 diseases": AIDS, malaria, and tuberculosis; (3) and rent-seeking examined through a recent malnutrition treatment breakthrough. In each of these cases relatively disinterested third parties are directing the funds and influencing the research and development choices of large pharmaceutical companies, producing inefficiencies and contradicting the basic assumptions of patent law theory.

A. *Under-Incentivization – Neglected Diseases*

Affecting poor populations in tropical regions of the world, neglected diseases are a category of diseases for which there are few known effective treatments.[149] Such diseases are "neglected" because they are rarely the subjects of research or public health efforts.[150] These diseases, including African Sleeping Sickness, Leprosy, Chagas Disease, and Hookworm infection, typically are caused by worms, bacteria, and protozoa.[151] Neglected diseases represent the typical example of under-incentivization in global health research.[152]

For a variety of reasons, international funding groups have little incentive or ability to direct funding to the treatment of neglected diseases. First, many of these diseases are difficult to treat,[153] and unlike diseases with substantial representation in the developed world, an added amount of upfront research is necessary because they are so poorly understood.[154] Second, most of the people infected with these diseases live in remote

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[148] *See, e.g.*, Ho, *supra* note 16, at 689-95 (discussing attempts by Brazil and Thailand to exercise their compulsory license rights under TRIPS). R

[149] Combe et al., *supra* note 7, at 9-10. R

[150] Lanjouw, *supra* note 5, at 98. R

[151] Nick Feasy, et al., *Neglected Tropical Diseases*, 93 BRITISH MEDICAL BULLETIN 179, 179-83 (2010), *available at* http://bmb.oxfordjournals.org/content/93/1/179.full.pdf+html.

[152] Outterson, *supra* note 29, at 14-15.

[153] *See, e.g.*, Rick L. Tarleton, et al., *The Challenges of Chagas Disease – Grim Outlook or Glimmer of Hope?* 4 PLOS MEDICINE 1852, 1853-54 (Dec. 2007), *available at* http://www.plosmedicine.org/article/info%3Adoi%2F10.1371%2Fjournal.pmed.0040332 (discussing the challenges in treating Chagas disease, a neglected tropical disease).

[154] *See* Feasy, et al., *supra* note 151, at 180 (describing the lack of funding for researching neglected diseases).

tropical areas.[155] Such locations create additional logistical obstacles that make it difficult to transport medicines to these areas.[156] Further, the hostile climate means that many medicines cannot be stored for long periods of time without refrigeration, requiring electricity and infrastructure that is wholly absent.[157] The panoply of obstacles that must be overcome in order to treat these diseases adequately leads most aid groups to engage in a cost-benefit analysis through which they determine that they can improve more lives by directing their funding elsewhere.[158]

Generally, citizens of the developed world are unaware of these diseases despite the fact that they affect as many victims as AIDS, tuberculosis, and malaria.[159] Such ignorance influences the decisions of aid organizations in two ways. First, organizations relying on private donors will be able to gain more donations by focusing on diseases already in the public consciousness.[160] Second, the lack of general public awareness will affect the decisions of government officials, who are in charge of distributing funds in the context of bilateral or multilateral aid. Governments ordinarily will respond to the concerns of their populations, but if most of the public is unaware of the particular harms of neglected diseases, politicians will gain no benefit by spending money on treatments for these diseases.[161] In sum, despite the presence of some consumer demand for these neglected disease treatments,[162] developed-world aid organizations must consider other factors when making their funding decisions. Pharmaceutical companies thus have little incentive to research treatments for neglected diseases because they are unable to internalize the benefits of the medicines they would produce. In the case of neglected diseases, pull-funding mechanisms would be ineffective because the interests of aid organizations make it unlikely that they will supply a sufficient amount of money to entice adequate research expenditures.

B. *Inconsistent Incentivization – "Big 3 Diseases"*

"Big 3 diseases" (AIDS, tuberculosis, and malaria) account for the majority of international funding for medicines.[163] Treatments for these three diseases exist in varying forms, but much more research is needed to develop forms in which medicines can be transported and stored with-

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155 *Id.*

156 *Id.*

157 *Id.*

158 *See id.*

159 PETER J. HOTEZ, FORGOTTEN PEOPLE, FORGOTTEN DISEASES: THE NEGLECTED TROPICAL DISEASES AND THEIR IMPACT ON GLOBAL HEALTH AND DEVELOPMENT 4 (2008).

160 *See id.* at 2-3.

161 *See id.*

162 *Id.* at 4.

163 Outterson, *supra* note 29, at 6, 10-11.

out electricity.[164] None of these diseases have a completely effective vaccine, and tuberculosis, in particular, requires new research to overcome recently mutated antibiotic-resistant strains.[165] Although these diseases receive significant attention and funding, the particular needs of patients in the developing world are not being met for many of the same reasons described in the discussion of neglected diseases, *supra* Part IV.A.[166] In particular, research into stable forms of medicines that can be stored without refrigeration is not a top priority for aid organizations because such treatments would only benefit part of the overall population requiring medicines.[167] Further, aid organizations may find it more cost effective to treat a larger population with existing, less expensive medicines, than to treat a smaller population with newer, more effective, yet more expensive medicines.[168] Just as in neglected diseases, the cost-benefit decisions that aid organizations would make are not necessarily the same as those that the consuming population would make.

There is also the further risk that, despite the large sums of money dedicated to "Big 3 diseases," inconsistent funding will result in suboptimal levels of research. To take one example, at the beginning of his presidency President Obama announced a desire to focus more attention on malaria and tuberculosis treatments, which could save more lives when compared to funding AIDS treatments alone, but he accomplished this goal by reducing funding for AIDS treatments.[169] The United States is also likely to curtail its global aid spending in the face of the financial crisis of the late 2000's.[170] As the economy and personal fortunes naturally fluctuate over time, the foreign aid system will experience instability in its funding, creating a risk that pharmaceutical companies will be unable to predict confidently how much money will be available for new medicines designed to treat the "Big 3 diseases." Pharmaceutical companies base profit projections on the lifetime of the patent (twenty years), and when the lead time for research is taken into account, they project revenues and expenses out for a period of at least twenty-five years or

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[164] Lanjouw, *supra* note 5, at 97. **R**

[165] *See* Jun Liu, *New Vaccine Against Tuberculosis: Current Developments and Future Challenges*, 17(2) SCIENCE FOUNDATION IN CHINA 50, 50-52 (2009).

[166] *See* Outterson, *supra* note 29, at 15.

[167] *Id.*

[168] Combe et al., *supra* note 7, at 11. **R**

[169] *See* U.S. Agency for Int'l Dev., *Lantos-Hyde United States Government Malaria Strategy* 5 (2010); Donald G. McNeil, Jr., *Obama is Criticized on AIDS Program*, N.Y. TIMES, Dec. 9, 2009, http://query.nytimes.com/gst/fullpage.html?res=9403E3DD103AF93AA35751C1A96F9C8B63.

[170] *See* Josh Rogin, *Obama Cuts Foreign Assistance to Several Countries in New Budget Request*, FOREIGN POLICY (Feb. 14, 2011, 1:08 PM), http://thecable.foreignpolicy.com/posts/2011/02/14/obama_cuts_foreign_assistance_to_several_countries_in_new_budget_request.

longer.[171] Profits become incredibly difficult to project when the actual amount of money available to purchase these medicines is likely to fluctuate over time, especially with the U.S. government shifting significant amounts of money among policy goals depending on the particular policy goals of each administration. Although the infected populations remain constant or increase over time,[172] the shifting of government attention from one disease to another will not communicate a constant economic incentive to pharmaceutical companies, risking sub-optimal research into treatments for "Big 3 diseases."

C. *Rent-Seeking Inefficiencies – Malnutrition*

The example of the malnutrition treatment Plumpy'Nut, as will be described in detail, *infra*, demonstrates that even when the existing patent system produces an affordable treatment for developing-world health conditions, the existing foreign aid model risks producing rent-seeking inefficiencies. Economic rent is defined as a payment above the minimal amount needed to allow a producer to sell its goods (taking into account resource and production costs), or in other words, a payment above the amount that the goods "could command in their next best alternative use."[173] Rents are an inevitable part of the patent system, as patents create artificial monopolies which allow producers to seek profits above those which are required to keep them in business.[174] In the foreign aid model, however, aid organizations are an independent source of rents and companies rationally might conclude that the profits they can obtain from foreign aid would be higher than their profits from selling directly to developing-world patients.

While the availability of such rents is not inherently undesirable, their existence will encourage producers to expend resources to obtain the artificial rents.[175] Such behavior is termed "rent-seeking," defined as actions taken, and societal costs incurred, by producers solely to obtain artificial profits, i.e. profits available because of government action.[176] The classic

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171 Henry Grabowski & John Vernon, *A New Look at the Returns and Risks to Pharmaceutical R&D*, 36 MANAGEMENT SCIENCE 804, 809 (1990) (estimating that a patented drug has a product life cycle of 25 years on average).

172 WHO, Global health sector strategy on HIV/AIDS 2011-2015, at 4 (2011), *available at* http://whqlibdoc.who.int/publications/2011/9789241501651_eng.pdf (global HIV/AIDS infections are still increasing); WHO, World Malaria Report 2010, at xii (2010) (listing 233 million cases of malaria in 2000, 244 million cases in 2005, and 225 million cases in 2009); WHO, Global Tuberculosis Control 2011, at 1 (2011) (tuberculosis cases have been falling slowly since 2002, but still infected 8.8 million people in 2010).

173 Robert D. Tollison, *Rent Seeking: A Survey*, 35 KYKLOS 575, 577 (1982).

174 *Id.* at 576-77.

175 *Id.*

176 *Id.* at 578.

example of rent-seeking in a patent context is lobbying by companies for increased patent protection; the lobbying costs do not benefit society but are spent solely to obtain additional rents from the government.[177] More broadly, however, rent-seeking can encompass any behavior that imposes social costs in search of government rents,[178] and such behavior is apparent in the recent case of Plumpy'Nut, a breakthrough treatment for malnutrition.[179]

Malnutrition is a pervasive health condition that afflicts a large percentage of children in the developing world.[180] Until recently, efforts to develop foods or treatments to treat malnutrition effectively have had mixed success at best.[181] In 1997 French scientist André Briend developed a breakthrough new treatment based on peanut butter that proved remarkably effective at treating some forms of malnutrition.[182] Plumpy'nut could be administered at home with no hospitalization, could be packaged and used with minimal water, and would remain unspoiled for two years.[183] In the few locations where Plumpy'nut was administered on a trial basis, the results were extraordinary when compared to prior treatments.[184]

The patent to Plumpy'nut is owned by Briend's employer, Nutriset, a French company that was created to research and develop new treatments for malnutrition.[185] This new breakthrough maintained Nutriset's dominance in the field of malnutrition, as they had patented the previous

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177 *Id.* at 577-78.

178 *See id.* at 583.

179 *See generally* Sasha S. Rao, *Improving Access to Patented Humanitarian Products via TRIPS: A Study of the Plumpy'nut Problem*, 15 MICH. ST. U. J. MED. & L. 111; Andrew Rice, *The Peanut Solution*, N.Y. TIMES, Sept. 2, 2010, http://www.nytimes.com/2010/09/05/magazine/05Plumpy-t.html?sq=plumpy%20nut&st=cse&scp=1&pagewanted=all.

180 Jennifer Bryce, et al., *Maternal and Child Undernutrition: Effective Action at National Level*, THE LANCET 4 (Maternal and Child Undernutrition Series), 65 (2008), *available at* http://www.who.int/nutrition/topics/Lancetseries_Undernutrition4.pdf.

181 Rice, *supra* note 179.

182 *Id.*

183 *Id.*; Rao, *supra* note 179, at 114.

184 *See, e.g.,* El Hadji Issakha Diop et al., *Comparison of the Efficacy of a Solid Ready-to-Use Food and a Liquid, Milk-Based Diet for the Rehabilitation of Severely Malnourished Children: A Randomized Trial*, 78 AM. J. OF CLINICAL NUTRITION 302, 304-05 (2003); Rachel E. Amthor et al., *The Use of Home-Based Therapy with Ready-to-Use Therapeutic Food to Treat Malnutrition in a Rural Area During a Food Crisis*, 109 J. OF THE AM. DIETETIC ASS'N 464, 466-67 (2009); Milton Tectonidis, *Crisis in Niger – Outpatient Care for Severe Acute Malnutrition*, 354 NEW ENG. J. MED. 224, 225 (2006).

185 *History and Values*, NUTRISET, http://www.nutriset.fr/en/about-nutriset/history-and-values.html (last visited Jan. 12, 2012).

standard for malnutrition treatment in 1993.[186] When Plumpy'nut was first developed, however, Nutriset had very little manufacturing capacity.[187] Although Nutriset has slowly expanded its factories, its growth is limited as a small private company, with revenue of $80 million and profit of $8 million in 2008.[188] Nutriset's most recent expansion, in 2009, allows it to produce 33,000 tons of Plumpy'Nut per year, but global demand reached 50,000 tons in 2011.[189] Médicins Sans Frontièrs hopes to vastly expand Plumpy'Nut distribution, aiming to treat 20 million children annually in Africa and South Asia, which would overwhelm Nutriset's current production capacity.[190]

Nutriset and Plumpy'nut differed from the normal pharmaceutical company/drug model in two ways that should have allowed for more rapid production and dissemination of this treatment. First, as a small company, Nutriset has a similarly small overall research and development budget.[191] The success of its F-100 and F-75 malnutrition treatments meant that Nutriset enjoyed a steady profit, and Plumpy'nut was discovered nearly accidentally, without the decades of research and millions of dollars usually necessary for such a discovery at a large pharmaceutical company.[192] Thus, Nutriset did not have an institutional need to seek excessive returns on its Plumpy'nut patent.

Second, Plumpy'nut is the rare kind of medical treatment that is nearly affordable for people living in poverty. A daily regimen costs twenty dollars per month on average, even taking into account the higher marginal price from the patent protection.[193] Despite the fact that some developing-world citizens and governments potentially could afford Plumpy'nut without the intervention of developed-world aid organizations, Nutriset greatly restricted its licenses, and manufactured most of the products at its own, low-capacity facility.[194] Further, because of its broad patent,[195]

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[186] *See* WHO, Management of Severe Malnutrition: A Manual for Physicians and Other Senior Health Workers, at 21 (1999), *available at* http://whqlibdoc.who.int/hq/1999/a57361.pdf (describing F-75 and F-100 formula as the standard treatment for malnutrition in 1999 (before Plumpy'nut was shown to be effective)); *see also Product Range*, NUTRISET, http://www.nutriset.fr/en/product-range/nutriset-product-range.html (last visited Jan. 21, 2012) (identifying F-75 and F-100 as Nutriset products).

[187] Rice, *supra* note 179.

[188] Rao, *supra* note 179, at 116.

[189] *Id.* at 114.

[190] *Id.* at 115.

[191] *Id.* at 116.

[192] Rice, *supra* note 179.

[193] Brandon Gast, *Plumpy'nut: A Tool for Malnutrition*, GLOBAL ENVISION (Dec. 14, 2007), http://www.globalenvision.org/library/9/1825.

[194] Rao, *supra* note 179, at 116.

[195] *Id.* at 119.

Nutriset sought to prevent others from producing similar and cheaper versions of Plumpy'Nut.[196]

As the virtues of Plumpy'nut were published between 2006 and 2009, Nutriset maintained strict control over its patent and restricted licenses,[197] seeking to obtain significant profits from the international aid community, rather than licensing broadly and selling directly to consumers or developing-world governments.[198] However, Nutriset soon faced uncontrollable patent violations and suits challenging the Plumpy'nut patent in court.[199] In response Nutriset and Médicins Sans Frontièrs reached an agreement in late 2010, whereby Nutriset would publish its Plumpy'Nut patent and allow others to develop and produce similar formulas that treat malnutrition in the same way.[200] Presumably, this will allow multiple manufacturers to begin producing Plumpy'nut copies and provide the required supply to patients.

Nutriset's initial reaction of maintaining tight controls over licenses and production can be explained as a form of rent-seeking behavior. A product like Plumpy'nut, which is both inexpensive and effective, is attractive to many international aid organizations, which are willing to spend their funds on such a proven treatment. Although Nutriset could have sold Plumpy'Nut to developing-world consumers for an adequate profit, the company reasonably believed that it could obtain greater profits by selling to international aid organizations.[201] Thus, Nutriset expended resources, by forgoing broad licenses and restricting production capacity, to seek and obtain the rent offered by the aid organizations. Such inefficient rent-seeking would not have been an option but for the availability of international aid money that was divorced from consumer spending.[202]

V. Potential Solutions and Intractable Issues

The current trend of harmonizing patent law throughout the world is likely to continue for the foreseeable future. Thus, the legal and international aid communities must work together to ensure that the expansion

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196 Hugh Schofield, *Legal fight over Plumpy'Nut, the hunger wonder-product*, BBC News, April 8, 2010, http://news.bbc.co.uk/2/hi/europe/8610427.stm.

197 Rao, *supra* note 179, at 115.

198 *Id.* at 116. Nutriset has stated that its primary goal is developing its in-house franchise production model, rather than licensing its patent for broader production. *Id.* at 117.

199 In 2010 in Haiti two manufacturers produced products similar to Plumpy'Nut, ignoring Nutriset's patent. Rice, *supra* note 179. In early 2010 two American nonprofits sued to invalidate Nutriset's patent on Plumpy'Nut. Schofield, *supra* note 196.

200 *Malnutrition: The Plumpy'nut Patent Now Accessible Online*, Nutriset, *available at* http://www.nutriset.fr/en/news-media/press-releases/malnutrition-the-plumpynut®-patent-now-accessible-on-line.html (last visited Jan. 12, 2012).

201 Rao, *supra* note 179, at 117.

202 Tollison, *supra* note 173, at 578.

of developed-world patent laws increases, rather than decreases, global social welfare. Legal commentators have noted flaws in the push funding mechanisms which, when paired with strong patent laws, fail to maximize research incentives for developing-world medicines.[203] While these commentators have suggested pull funding mechanisms as an adequate solution, this note has suggested that pull mechanisms are likely to suffer from their own incentive problems. Pharmaceutical companies do not have enough monetary incentive to research medicines for diseases primarily affecting the developing world.[204] Further, when pharmaceutical companies do create effective treatments for developing-world diseases, they have incentives to extract excessive compensation from international aid funding sources.[205] Ultimately, additional empirical research is necessary to determine the complete extent of the problems underlying both push and pull funding mechanisms as more medicines are developed under new international patent regimes.[206] This section will suggest solutions that could successfully combine push and pull mechanisms, as well as identify potentially intractable problems.

A. *Combining Push and Pull Mechanisms*

Considering the deficiencies in push-only and pull-only funding mechanisms, it may be possible to pursue a combination push/pull approach in a way that amplifies the benefits and decreases the inefficiencies inherent in each funding method. The discussion in Part III.C.3., *supra*, describes how the Gates Foundation has attempted to combine push and pull mechanisms in its funding through performance-based grants aimed at specific diseases.[207] As the funding model is modified over the next few years,[208] the Gates Foundation may prove effective at directing funding toward developing-world treatments, and further observations of its work may provide a basis for future empirical analysis.

One commentator, in addressing the problems of neglected diseases in particular, has suggested a kind of prize system to encourage more research in specific areas, which would combine push and pull funding mechanisms.[209] The prize would be dedicated to a specific medicine or disease, pushing research in that direction, but the prize would only be given upon creation of a viable product, representing the pull element,

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[203] *See supra* note 6.

[204] *See supra* Parts IV.A. and IV.B.

[205] *See supra* Part IV.C. (discussing Nutriset's vigorous exploitation of its Plumpy'Nut patent in an attempt to seek rents from the international aid community).

[206] By one measure it takes nearly eight years on average for a new drug to be clinically tested and approved. Editorial, *New Estimates of Drug Development Costs*, 22 J. OF HEALTH ECON. 325, 326 (2003).

[207] McNeil, *supra* note 130.

[208] *Id.*

[209] Hollis, *supra* note 7. **R**

and mimicking consumer markets which reward inventors only for finished products.[210] Congress recently enacted a law that would grant expedited review and other incentives for medicines that treat neglected diseases, which could function similarly to a prize system.[211] A prize system may still be subject to the core criticisms of push funding mechanisms, however. The prize creators might focus on specific diseases, directing funds toward their desired goals and ignoring the needs of the developing-world population.[212] Indeed, the criticism that "advocacy, the whims of foundations, and the particular concerns of wealthy individuals and governments drive practically the entire global public health effort" would still be credible,[213] with developed-world scientists, aid organizations, and governments providing the money and setting the terms of the prizes. Ultimately, the concerns associated with push funding mechanisms are likely to be retained with prizes despite the inclusion of pull funding characteristics.

Another solution can be adapted from the open licensing approach advocated by Amy Kapczynski, et al., termed the Equitable Access License.[214] That article sought a global solution to the complex problems that exist in the medical research process, including patent thickets that stifle innovation and the inability to provide medicines to the developing world at near-marginal prices.[215] The authors noted that basic upstream research[216] for new medicines often is conducted at large research universities utilizing government funding, and that fundamental discoveries from this research are utilized in a wide variety of medicines.[217] Due to of the importance of research universities in the pharmaceutical development process,[218] the authors called for universities to use their patent leverage to create open licenses that would allow for greater research freedom and would reduce costs and increase competition, thus lowering prices in the developing world.[219] Universities can take advantage of the

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[210] *Id.*

[211] Food and Drug Administration Amendments Act of 2007, Pub. L. No. 110-85, 121 Sta. 823 (codified in scattered sections of 21 U.S.C. (2007)).

[212] *See* Garrett, *supra* note 9, at 22-23 (critiquing this practice as "stovepiping" of international aid). **R**

[213] *Id.* at 23.

[214] Kapczynski, et al., *supra* note 3, at 1090-93. **R**

[215] *Id.* at 1039.

[216] Upstream research focuses on basic, fundamental discoveries that "advance scientific understanding and . . . develop the tools of the research field . . . ." *Id.* at 1078.

[217] *Id.* at 1078-79.

[218] *See generally* Ashley J. Stevens, et al., *The Role of Public-Sector Research in the Discovery of Drugs and Vaccines*, 364(6) NEW ENG. J. MED. 535 (2011) (describing the increased role that universities play in creating end-market pharmaceutical products).

[219] *Id.* at 1090-93.

patents on their research results, and the subsequent downstream need for licensing these discoveries, to incorporate license terms that foster, rather than inhibit, free access.[220] This work has led to the creation of Universities Allied for Essential Medicines (UAEM), a student-led organization that advocates for using university licensing to increase drug access utilizing the Equitable Access License Framework.[221] UAEM's suggestions have gained some traction thus far, as a number of large research universities have recognized the need to recognize non-monetary social goals when constructing their patent licensing policies.[222]

This licensing model can be adapted to address the challenges presented by the inefficiencies of push and pull funding mechanisms. Licenses of the type advocated by UAEM can be adapted to incorporate the most useful benefits of push and pull funding to direct research toward medicines for the developing world. Universities, when licensing their upstream patents, can include a requirement that a small percentage of the profits derived from a given patent must be dedicated to developing medicines that will be sold exclusively in the developing world. As previously stated, universities are a primary source of upstream research and have tremendous leverage to negotiate licensing terms.[223] In recent years, since the passage of the Bayh-Dole Act in 1980, universities have patented their discoveries at an increasing rate.[224] Further, research universities are governed by policies that favor scientific inquiry and dissemination of knowledge, rather than profits from patent licenses.[225] Because

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[220] *Id.*

[221] For a discussion of the role of Universities Allied for Essential Medicines in promoting the Equitable Access License, including critiques of the model, *see e.g.* Dave A. Chokshi & Rahul Rajkumar, *Leveraging University Research to Advance Global Health*, 298 JAMA 1934 (2007); Beirne Roose-Snyder & Megan K. Doyle, *The Global Health Licensing Program: A New Model for Humanitarian Licensing at the University Level*, 35 AM. J.L. & MED. 281, 296-98 (2009); Katherine M. Nolan-Stevaux, *Open Source Biology: A Means to Address the Access & Research Gaps?*, 23 SANTA CLARA COMPUTER & HIGH TECH. L.J. 271 (2007); April E. Effort & Ashley J. Stevens, *Using Academic License Agreements to Promote Global Social Responsibility*, 43 LES NOUVELLES: J. LICENSING EXECUTIVES SOC'Y 85 (2008); Rebecca Goulding, et al., *Alternative Intellectual Property for Genomics and the Activity of Technology Transfer Offices: Emerging Directions in Research*, 16 B.U. J. SCI. & TECH. L. 194, 219-20 (2010).

[222] Goulding, et al., *supra* note 221, at 220-21.

[223] Kapczynski, et al., *supra* note 3, at 1078-79; Risa L. Lieberwitz, *Confronting the Privatization and Commercialization of Academic Research: An Analysis of Social Implication at the Local, National and Global Levels*, 12 IND. J. GLOBAL LEGAL STUD. 109, 149-50 (2005). R

[224] Lieberwitz, *supra* note 223, at 110 (describing the increase in the number of patents filed by U.S. universities over time: 264 patents in 1979, 2,436 in 1997, and 8,534 in 2000).

[225] Lieberwitz, *supra* note 223, at 110.

university research is often funded by the federal government,[226] the use of these license terms could also be required as a condition for federal grant funding.[227] This licensing model would retain the essential character of the current international aid model: developed-world citizens would be subsidizing the research costs for the developing world. Instead of taking this money through taxes and charitable donations, however, the money paid to pharmaceutical companies for medicines in the developed world would be the source of funding.

The license itself would function as the push mechanism, requiring pharmaceutical companies to dedicate research to developing-world diseases and treatments. Two common pitfalls of push mechanisms, adverse selection and moral hazard,[228] would be avoided under this model. Adverse selection occurs when outside organizations direct funding toward specific research paths, despite the fact that researchers are more likely to know which research paths are the most promising.[229] The licensing model would avoid this problem because no outside organization would be dictating the direction of research, and pharmaceutical companies would be able to select the research paths they find most promising. Moral hazard arises when funding organizations cannot monitor the use of their funds perfectly, increasing the likelihood that the money will be used to research other products.[230] The moral hazard concern would be mitigated by the requirement that the pharmaceutical company develop products that must be sold exclusively in the developing world. Monitoring costs could be reduced further by utilizing the newly implemented radiofrequency identification tags mandated by the Food and Drug Administration to combat drug counterfeiting by tracking individual packages of drugs from production to retail sale.[231] Thus, for drugs sold in the United States, data will exist to show exactly where each package is sold, confirming that the pharmaceutical companies are living

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[226] Kapczynski, et al., *supra* note 3, at 1078. **R**

[227] This would not be a completely radical provision, as the Bayh-Dole Act allows the government to mandate licenses of patents to ensure their practical application when the patented inventions were developed with government-funded research. 18 U.S.C. § 203. *See generally* 18 U.S.C. §§ 200-212. The government has never exercised its "march-in" rights in this way, however. James DeGiulio, Comment, *The Genomic Research and Accessibility Act: More Science Fiction than Fact*, 8 Nw. J. Tech. & Intell. Prop. 292, 304 (2010).

[228] Kremer, *supra* note 7, at 82. **R**

[229] *Id.*

[230] *Id.*

[231] Barnaby J. Feder, *F.D.A. Imposes Long-Delayed Rule to Require Tracking of Prescription Drugs*, N.Y. TIMES, June 10, 2006, *available at* http://www.nytimes.com/2006/06/10/business/10drug.html?pagewanted=print. *See generally* FOOD AND DRUG ADMINISTRATION, COMBATING COUNTERFEIT DRUGS (Feb. 18, 2004), *available at* http://counterfeiting.unicri.it/docs/FDA%20combating%20ctf%20drugs.pdf.

up to their licensing obligations and selling certain medicines in the developing world.

Such a licensing model could also reduce the inefficiencies inherent in pull funding mechanisms. As long as the pharmaceutical company keeps profiting from the developed-world products it manufactures under the license, the amount of money available for researching developing-world treatments will be relatively constant and predictable, reducing risks of under-incentivization from the inability of pharmaceutical companies to predict the level of donor aid available in the future.[232] Likewise, because the license would require research to develop medicines sold exclusively in the developing world, the actual potential of developing-world markets can be examined on their own merits, as opposed to in comparison to the developed world. That is, the market for developing-world treatments will always be miniscule in comparison to the market in the developed world as long as the drastic wealth disparity exists between the two groups of countries.[233] If pharmaceutical companies are required to develop medicines specifically for the developing world, they can examine the market potential for those medicines without reference to the market size of the developed world. Thus, the most needed medicines would offer the greatest potential market (in comparison to less-needed medicines in the developing world). Research would be directed more efficiently as a result, and the risks of under-incentiviziation with current pull models would be lessened.[234] Finally, a licensing model would prevent the risks of rent-seeking.[235] Pharmaceutical companies would produce medicines for the developing world because they are required to under the licensing agreement, not because they are seeking excessive rents from international aid organizations. Thus, truly revolutionary treatments could be distributed more liberally and at a lower price.

B. *Intractable Problems*

Ultimately, exporting the developed-world model of pharmaceutical development to the developing world will create its own set of market inefficiencies that must be recognized. In the developed world, insurers and doctors, rather than patients, generally decide the cost of medicines, as well as which medicines should be prescribed, interfering with the normal consumer-producer market interaction.[236] Consumers ultimately have reduced control over product choices.[237] Further, pharmaceutical companies have incentives to create medicines that gain little in terms of

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[232] *See supra* Part IV.B.
[233] *See supra* note 64.
[234] *See supra* Part IV.A.
[235] *See supra* Part IV.C.
[236] Hollis, *supra* note 7, at 3. **R**
[237] *Id.* at 5.

therapeutic value, but can generate profits through strategic marketing.[238] Indeed, one significant market distortion in the developed-world pharmaceutical industry is caused by excessive marketing. Pharmaceutical companies spend more on marketing than on drug development because marketing cheaply developed drugs is a surer path to profits.[239] The federal government attempts to mitigate this problem by investigating pharmaceutical companies under the False Claims Act for providing kickbacks to doctors that encourage them to prescribe specific drugs.[240] Exporting the developed-world pharmaceutical patent model to the developing world risks exporting these market inefficiencies as well, and it must be recognized that even in the developed world consumers do not communicate unfiltered demand to pharmaceutical companies.

VI. CONCLUSION

The growth of international health aid is a welcome development and seems likely to continue in the near future. The dominance of an international patent system based on developed-world economic principles also seems inevitable at this point, despite potential criticisms. However, the intersection of these two developments has introduced significant market distortions by granting economic consumer choice to aid organizations rather than the end-users of these medicines. The obstacles to creating robust markets for medicines in the developing world are already substantial, but these market distortions prevent pharmaceutical companies from responding to normal consumer demand in the developing world. As long as the patent law and global health aid models exist in their current forms, it seems unlikely that legitimate markets will ever exist in the developing world, and the interests of developing-world consumers will continue to be underrepresented in pharmaceutical research. Combining push and pull funding mechanisms may provide the best possible solution. Building on the ideas put forth by Kapczynski, et al., and UAEM universities could license their patents with a requirement that pharmaceutical companies take the profits earned from products utilizing those patents and devote a percentage of the profits to research developing-world medicines. This solution would capture the respective benefits of push and pull funding mechanisms while minimizing their inefficiencies.

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238 *Id.* at 6.

239 *Id.* at 9.

240 *See generally* U.S. DEPT. OF HEALTH AND HUMAN SERVICES, OFFICE OF THE INSPECTOR GENERAL, COMPLIANCE PROGRAM GUIDANCE FOR PHARMACEUTICAL MANUFACTURERS (2003), *available at* http://oig.hhs.gov/fraud/docs/complianceguidance/042803pharmacymfgnonfr.pdf.