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Making Intellectual Property Work for Global Health

An Article from the Symposium: Developments and Challenges in International Intellectual Property Law

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I. INTRODUCTION

Intellectual property rights (IPRs) are often conceived narrowly from the vantage point of offering incentives for private sector investment in research and development (R&D), but the legal regime of IPRs can also work to improve access to public goods for global health, particularly for those disadvantaged by destitution and disease. The WHO Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property (GSPOA), adopted by the World Health Assembly in 2008, calls for an "enhanced and sustainable basis for needs-driven, essential health research and development relevant to diseases that disproportionately affect developing countries."[1] How knowledge is generated, owned, and harnessed to support pro-poor development is at the heart of this effort. New approaches to tiering, pooling, and open-source collaboration have resulted from the struggle to deliver affordable treatments for AIDS and neglected diseases. In examining how intellectual property rights can most effectively and strategically support developing countries in implementing this ambitious and potentially catalytic agenda in enabling innovation for global health, this paper seeks to outline a coherent and strategic approach to address human development needs and to facilitate the harnessing of innovation and the sharing of knowledge for global health.

A. Asymmetry of Globalization and Intellectual Property

From bench to bedside, modern medicines[2] promise life-prolonging, if not life-saving, treatments for epidemics like AIDS,[3] tuberculosis (TB) and malaria. While the

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[1] 61st World Health Assembly, May 19–24, 2008, *Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property*, at 1, WHA61.21 (May 24, 2008), *available at* http://apps.who.int/gb/ebwha/pdf_files/A61/A61_R21-en.pdf.

[2] The United Nations Millennium Project describes medicines as "by far the most significant tool that society possesses to prevent, alleviate and cure disease." GRAHAM DUKE ET AL., UNITED NATIONS MILLENNIUM PROJECT, INTERIM REPORT OF TASK FORCE 5 WORKING GROUP ON ACCESS TO ESSENTIAL MEDICINES 9 (2004). Pharmaceuticals can comprise fifty to ninety percent of the out-of-pocket health expenditures among the poor in developing countries. World Health Org. [WHO], *WHO Medicines Strategy: Countries at the Core*, *2004-2007*, at 14, WHO Doc. WHO/EDM/2004.5 (2004). Up to eighty-six percent of the population in developing countries would fall into poverty after purchasing one of four medicines that treat asthma, diabetes, hypertension, and adult respiratory infections. *See* Lauren M. Nïens et al., *Quantifying the Impoverishing Effects of Purchasing Medicines: A Cross-Country Comparison of the Affordability of Medicines in the Developing World*, 8 PLOS MED 1, 8 (2010). This context clearly shows why the focus on access to health technologies is so central to the achievement of all Millennium Development Goals (MDGs), particularly (though certainly not limited) to MDGs 4, 5, and 6. *See generally* United Nations Millennium Declaration, G.A. Res. 55/2, U.N. Doc. A/RES/55/2 (Sept. 18, 2000); UNITED NATIONS, THE MILLENNIUM DEVELOPMENT GOALS REPORT 2010 (2010), *available at*

expectations of the benefits of such products readily cross borders in a globalizing world, the treatments themselves often lag behind, in part due to strong IPRs for these products that keep prices high and distribution low. Some consider IPR protection to be central to the package of "good" policies and institutions in developed countries along with "democracy; 'good' bureaucracy; an independent judiciary; strengthened protection of private property rights (including IPRs); and transparent and market-oriented corporate governance and financial institutions (including a politically independent central bank)."[4]

However, these policies and institutions now prescribed to developing countries are not necessarily the same policies that industrialized countries adopted to achieve the development status they have today. Rather, historical evidence suggests that these prescribed policies amount to "kicking away the ladder" to development for low- and middle-income countries,[5] and are "wholly unsuited for their economic condition."[6] Tellingly, Ha-Joon Chang documents that "Pharmaceutical products remained unpatentable until 1967 in West Germany and France, 1979 in Italy, and 1992 in Spain. Pharmaceutical products were also unpatentable in Canada into the 1990s."[7]

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http://www.un.org/millenniumgoals/pdf/MDG%20Report%202010%20En%20r15%20-low%20res%2020100615%20-.pdf#page=8 (elaborating on the Millennium Development Goals (MDG 4: Reduce child mortality. MDG 5: Improve maternal health. MDG 6: Combat HIV/AIDS, malaria, and other diseases)).

[3] Civil society mobilization, the use of flexibilities such as compulsory licensing under the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement, and generic competition have worked hand in hand in the decade-long struggle to lower the price of antiretroviral medicines in developing countries. These efforts successfully took the cost of triple-drug therapy from over US$10,000 per year to under US$100. *See* MÉDECINS SANS FRONTIÈRES, UNTANGLING THE WEB OF ANTIRETROVIRAL PRICE REDUCTIONS 6 (11th ed. 2008). At US$10,000, access to life-saving treatment was beyond the reach of the vast majority of those in developing countries, but at a few hundred dollars a year, access to such treatments became possible with support from the Global Fund, PEPFAR, and other procurement agencies. That steep difference in price revealed the gulf between the true marginal cost of producing these drugs and the high price the health care system purportedly paid for R&D.

[4] HA-JOON CHANG, KICKING AWAY THE LADDER: DEVELOPMENT STRATEGY IN HISTORICAL PERSPECTIVE 1 (2002).

[5] *Id.*

[6] Douglas Irwin, *Kicking Away the Ladder: Development Strategy in Historical Perspective*, ECONOMIC HISTORY ASSOCIATION (Apr. 25, 2004, 8:00 PM), http://eh.net/book_reviews/kicking-away-ladder-development-strategy-historical-perspective (reviewing the book of the same name by Ha-Joon Chang).

[7] Ha-Joon Chang, *Intellectual Property Rights and Economic Development: Historical Lessons and Emerging Issues*, 2 J. HUM. DEV. 287, 305–06 n.8 (2001).

The globalization of the IPR regime under the World Trade Organization's (WTO) Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement[8] has further perpetuated this asymmetry. TRIPS set a floor to intellectual property rights protection among WTO member states. Setting a floor of IPR protection places current patent owners in a knowledge-based economy at an advantage over those without such holdings.[9]

Moreover, a strong IPR regime may not be sufficient, let alone necessary, for translating scientific advances into marketable inventions. If IPRs were sufficient, or even the dominant factor, then economic gains in developing country economies should be higher for those with stronger IP protection. However, this is not the case, as economic growth in countries like China and Brazil has clearly outstripped growth in Eastern Europe. The regulation of local investments, availability of credit, and taxes and tariffs, among other factors, all play a role.

B. The Innovation Gap

Of the 1556 new chemical entities brought to market between 1975 and 2004, only one percent were for tropical disease indications.[10] Bridging this innovation gap to ensure the delivery of needed diagnostics, drugs, and vaccines to meet the public health needs is one of the key challenges besetting global health today. Tackling this market failure, product development partnerships have made substantial progress in recent years with nearly 150 products for neglected diseases in the pipeline by 2009.[11]

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[8] Agreement on Trade-Related Aspects on Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, THE LEGAL TEXTS: THE RESULTS OF THE URUGUAY ROUND OF MULTILATERAL TRADE NEGOTIATIONS 320 (1999), 1869 U.N.T.S. 299, 33 I.L.M. 1197 (1994) [hereinafter *TRIPS Agreements*].

[9] Despite the surge in domestic patenting in countries like China, the developed world holds over ninety percent of the patents granted by the patent offices in Europe, the United States, and Japan. *See* UNITED NATIONS EDUCATIONAL, SCIENTIFIC AND CULTURAL ORG. [UNESCO], UNESCO SCIENCE REPORT 2005 tbl.4 (2005), *available at* http://www.unesco.org/new/fileadmin/MULTIMEDIA/HQ/SC/pdf/sc_usr05_full_en.pdf. Because inventors seek to patent in these jurisdictions regardless of where they perform their research, this is nearly tantamount to stating that the developed world holds ninety percent of the world's patents.

[10] Pierre Chirac & Els Torreele, *Global Framework on Essential Health R&D*, 367 LANCET 1560, 1560–61 (2006).

[11] *See* INT'L AIDS VACCINE INITIATIVE INSIGHTS, POLICY BRIEF 26: INNOVATIVE PRODUCT DEVELOPMENT PARTNERSHIPS: ADVANCING GLOBAL HEALTH AND ECONOMIC DEVELOPMENT GOALS (2010), *available at* http://www.iavi.org/Lists/IAVIPublications/attachments/eb7b4247-6816-4094-9f54-9f2f2b99e95a/IAVI_Innovative_Product_Development_Partnerships_2010_ENG.pdf (citing Boston Consulting Group, Presentation to PDP Forum: PDP Support Project (July 2009)).

In 2001, the Doha Declaration on the TRIPS Agreement and Public Health recognized the role of IPRs both as an incentive for pharmaceutical R&D and for its effects on prices. While reaffirming the right of developing countries to exercise flexibilities under TRIPS,[12] the Doha Declaration also sought to deal with concerns that "WTO members with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement."[13] That same year, the United Nations Development Programme (UNDP) *Human Development Report* looked at "Making New Technologies Work for Human Development." The report examined whether the technology divide would follow the income divide and what innovative public policies might adapt global technologies to local needs,[14] concluding that "policy, not charity . . . will ultimately determine whether new technologies become a tool for human development everywhere."[15]

In 2002, the UK Commission on Intellectual Property Rights[16] picked up the thread of this emerging policy dialogue, and by 2004, the WHO created the Commission on Intellectual Property Rights, Innovation and Public Health (CIPIH). In the wake of the CIPIH report, the World Health Assembly established an intergovernmental working group in 2006 to develop a strategy and plan of action aimed at "securing an enhanced and sustainable basis for needs-driven, essential health research and development relevant to diseases that disproportionately affect developing

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[12] Special Rapporteur on the Right of Everyone to the Enjoyment of the Highest Attainable Standard of Physical and Mental Health, *Report on Promotion and Protection of All Human Rights, Civil, Political, Economic, Social and Cultural Rights, Including the Right to Development*, U.N. Doc. A/HRC/11/12 (Mar. 31, 2009) (by Anand Grover) [hereinafter Grover].

[13] World Trade Org., Ministerial Declaration on the TRIPS Agreement and Public Health, WT/MIN(01)/DEC/2, 41 I.L.M. 755 (2002).

[14] UNITED NATIONS DEVELOPMENT PROGRAMME, HUMAN DEVELOPMENT REPORT 2001: MAKING NEW TECHNOLOGIES WORK FOR HUMAN DEVELOPMENT (2001).

[15] *Id.* at 6.

[16] The Commission, which published its final report in 2002, was asked to consider how national intellectual property rights regimes could contribute to the reduction of poverty and to the benefit of poor people and developing countries. Its final report advanced a range of recommendations, including those aimed at promoting technology transfer and increasing public funding for research on health problems in developing countries. *See generally*, INTEGRATING INTELLECTUAL PROPERTY RIGHTS AND DEVELOPMENT POLICY, COMMISSION ON INTELLECTUAL PROPERTY RIGHTS (2002), *available at* http://www.iprcommission.org/papers/text/final_report/reporthtmfinal.htm.

countries."[17] The work of the Intergovernmental Working Group culminated in the eventual adoption of the GSPOA in May 2008.[18]

Although the GSPOA outlines an ambitious vision and scope of work, various actors in the public health and development field are already undertaking different aspects of this work. The GSPOA provides the means for a broad range of actors to collaborate with the WHO within a coherent and strategic framework. Narrowing the innovation gap involves shaping how knowledge is shared through the global intellectual property (IP) regime, enabling the conditions for a knowledge-based economy so that innovation meets public health needs, and monitoring milestones marking progress towards these goals.

II. SHAPING THE GLOBAL IP REGIME TO MEET INNOVATION AND GLOBAL HEALTH NEEDS

The struggle to reduce the cost of AIDS drugs has underscored the link between IP protection and public health. This relationship has attained greater significance as three trends have unfolded: (1) the global IP regime has shifted with the adoption of the TRIPS Agreement under the WTO; (2) the global burden of disease has shifted increasingly from communicable to non-communicable diseases; and (3) modern medicines have shifted from conventional drugs to more complex and expensive biologic products, including vaccines and new cancer treatments.

A. Global IP Regime

At the start of the Uruguay Round negotiations in 1986, over fifty countries did not recognize product patents on pharmaceuticals.[19] The adoption of TRIPS caused a seismic shift in the global IPR regime, raising barriers to generic entry by blocking producers from finding alternative, lower-cost means of producing the same drug. Patent protection of the end product could trump inventions over the process of manufacturing generic versions of the drug. Nowhere has this been of greater concern than in India, which came into TRIPS compliance in 2005. For low- and middle-income countries, Indian generic manufacturers supply more than eighty percent of antiretroviral drugs and nearly ninety percent of the pediatric market for such drugs.[20]

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[17] 59th World Health Assembly, May 22–27, 2006, *Public Health, Innovation, Essential Health Research and Intellectual Property Rights: Towards a Global Strategy and Plan of Action*, WHA59.24 (May 27, 2006), *available at* http://www.who.int/phi/Res59_R24-en.pdf.

[18] 61st World Health Assembly, *supra* note 1.

[19] CARLOS CORREA, INTEGRATING PUBLIC HEALTH CONCERNS INTO PATENT LEGISLATION IN DEVELOPING COUNTRIES 11 (2000), *available at* http://apps.who.int/medicinedocs/pdf/h2963e/h2963e.pdf.

[20] Brenda Waning et al., *A Lifeline to Treatment: The Role of Indian Generic Manufacturers in Supplying Antiretroviral Medicines to Developing Countries*, J. INT'L AIDS SOC. Sept. 14, 2010, at 1, 3.

However, since several key second- and third-line antiretroviral drugs (ARVs)[21] have recently come under patent protection in India, it is not likely that Indian generic competition will be able to reduce the global prices for ARVs at the rates seen for the first-line drugs.

The use of the TRIPS flexibilities, such as compulsory licenses, can lead to significant cost savings and increases in coverage. Thailand's compulsory license on efavirenz was expected to halve the drug price and provide an additional 20,000 patients with the drug[22] under the same budget. Generic imports of the second-line ARV, Kaletra (lopinavir/ritonavir), under compulsory license were also expected to cut the price by over eighty percent, allowing an additional 8,000 patients to access the drug.[23] A comparison of the market prices for the branded originator drugs at the time of the compulsory licenses with the prices of the imported generic equivalents demonstrate a sixty-six percent reduction in price for efavirenz and seventy percent for lopinavir/ritonavir.[24] It is expected that the prices of the cancer drugs will be between three percent and twenty-five percent of the prices for the patented drugs.[25]

See also CAMPAIGN FOR ACCESS TO ESSENTIAL MEDICINES & MÉDECINS SANS FRONTIÈRES, EXAMPLES OF THE IMPORTANCE OF INDIA AS THE "PHARMACY OF THE DEVELOPING WORLD" (2007), *available at* http://doctorswithoutborders.org/news/access/background_paper_indian_generics.pdf.

[21] ARVs are used to treat and prevent the progression of HIV and AIDS, as well as to decrease the disease's transmission rate. *See generally* WORLD HEALTH ORG., GLOBAL HEALTH SECTOR STRATEGY ON HIV/AIDS, 2011-2015 (2011), *available at* http://whqlibdoc.who.int/publications/2011/9789241501651_eng.pdf.

[22] JENNRYN WETZLER ET AL., PROGRAM IN INFO. JUSTICE AND INTELLECTUAL PROP., AM. UNIV. WASH. COLL. OF LAW, TIMELINE FOR US-THAILAND COMPULSORY LICENSE DISPUTE (3d ed. 2009), *available at* http://www.wcl.american.edu/pijip/download.cfm?downloadfile=A53BFA77-C09F-588E-975EBD9BFA42A4CE&typename=dmFile&fieldname=filename (citing MINISTRY OF PUB. HEALTH OF THAI. & NAT'L HEALTH SEC. OFFICE OF THAI., FACTS AND EVIDENCES ON THE 10 BURNING ISSUES RELATED TO THE GOVERNMENT USE OF PATENTS ON THREE PATENTED ESSENTIAL DRUGS IN THAILAND 5, 6 (2007), *available at* http://www.moph.go.th/hot/White%20Paper%20CL-EN.pdf [hereinafter THAI MINISTRY OF PUB. HEALTH]).

[23] THAI MINISTRY OF PUB. HEALTH, *supra* note 22, at 14.

[24] HEALTH INTERVENTION AND TECH. PROGRAM, THAI. MINISTRY OF PUB. HEALTH, ASSESSING THE IMPLICATIONS OF THAILAND'S GOVERNMENT USE LICENSES ISSUED IN 2006-2008 40 (2008).

[25] *Id.* Thailand also issued a compulsory license on Plavix, a drug used to treat cardiovascular disease. The Plavix compulsory license was expected to reduce the price to a tenth of what Thailand was originally paying for the medicine. THAI. MINISTRY OF PUB. HEALTH, *supra* note 22, at 15. At the time of the compulsory license, there was a ninety-eight percent reduction in price between the branded originator drug Plavix and the generic equivalent Clopidogrel. HEALTH INTERVENTION AND TECH. PROGRAM, *supra* note 24, at 40.

Yet the path-breaking efforts by Thailand and Brazil to use compulsory licensing illustrate both the benefits and the political risks of taking such a course. In 2006 and 2007, Thailand issued a total of seven compulsory licenses for a combination of ARVs and medicines used to treat cardiovascular disease and cancer, and in 2007, Brazil later followed with a single compulsory license for an HIV/AIDS drug.

Although permitted under TRIPS,[26] criticism of the compulsory licenses issued by Thailand came from various sources—the European Union (EU) Trade Commissioner,[27] United States Senators,[28] the *Wall Street Journal*,[29] and even the WHO Director-General.[30] Abbott retaliated to Thailand's compulsory license on its drug lopinavir/ritonavir (trade name Kaletra) by withdrawing seven pending applications for registration of new medicines from the Thai Food and Drug Administration. These withdrawals effectively withheld these seven drugs, which temporarily included the heat-stable version of Kaletra, from the Thai market.[31]

Brazil faced similar opposition. In 2005, Brazil announced that they were *considering* a compulsory license for tenofovir. After their announcement, Brazil was criticized by a number of US Congressmen,[32] Billy Tauzin (then the President and CEO of

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[26] WORLD HEALTH ORG., IMPROVING ACCESS TO MEDICINES IN THAILAND: THE USE OF TRIPS FLEXIBILITIES 11 (2008) (indicating that the Doha Declaration clarified each WHO member's right to decide on what grounds to issue compulsory licenses under TRIPS).

[27] ELLEN F.M. 'T HOEN, THE GLOBAL POLITICS OF PHARMACEUTICAL MONOPOLY POWER: DRUG PATENTS, ACCESS, INNOVATION AND THE APPLICATION OF THE WTO DOHA DECLARATION ON TRIPS AND PUBLIC HEALTH 49 (2009), *available at* http://www.msfaccess.org/content/global-politics-pharmaceutical-monopoly-power.

[28] WETZLER ET AL., *supra* note 22 (citing Letter from Joseph I. Lieberman et. al., U.S. Senators, to Susan Schwab, U.S. Trade Representative (Mar. 15, 2007), *available at* http://www.cptech.org/ip/health/c/thailand/).

[29] 'T HOEN, *supra* note 27, at 49–50.

[30] *Id.* at 49. The WHO Director-General later expressed regret for remarks interpreted as critical of the Thai government's issuance of compulsory licenses. In a letter to Thailand's Health Minister, she conceded that Thailand was within its rights to issue the compulsory licenses and that the WHO supported the use of such TRIPS flexibilities by developing countries. *See* Martin Khor, *Health: WHO DG Regrets Her Reported Remarks on Thai Compulsory Licenses*, TWN INFO SERVICE ON INTELLECTUAL PROPERTY ISSUES (Feb. 15 2007), http://www.twnside.org.sg/title2/intellectual_property/info.service/twn.ipr.info.020710.htm.

[31] WORLD HEALTH ORG. REG'L OFFICE FOR SOUTH-EAST ASIA & WORLD HEALTH ORG.: WEST PACIFIC REGION, BRIEFING NOTE 4: COUNTRY EXPERIENCES IN USING TRIP SAFEGUARDS 2, 2 n.4 (2008), *available at* http://www.searo.who.int/LinkFiles/IPT_Briefing_note_4_country_experiences.pdf; Khor, *supra* note 30.

[32] *See, e.g.*, JENNRYN WETZLER & ANA AYALA, PROGRAM IN INFO. JUSTICE AND INTELLECTUAL PROP., AM. UNIV. WASH. COLL. OF LAW, TIMELINE ON BRAZIL'S COMPULSORY LICENSING (2d ed. 2008), *available at*

PhRMA),[33] and even the Executive President of the Brazilian Federation of Pharmaceutical Industry.[34] Brazil's announcement sparked negotiations to lower prices, but when these failed to make adequate progress, Brazil made good on its threatened use of compulsory licensing. The compulsory license for efavirenz in 2007 faced criticism from Merck, which was "profoundly disappointed," and the US-Brazil Council, which called it "a major step backward" that would discourage investment in Brazil.[35]

Despite the Doha Declaration's confirmation of the right to use the TRIPS flexibilities, taking advantage of these flexibilities requires both the legal capacity and the political ability to resist external pressures. In many cases, rather than using these flexibilities, developing countries have instead accepted TRIPS-plus standards. Often introduced through free trade agreements (FTAs), TRIPS-plus provisions require national laws to implement stricter standards of IP protection and enforcement than required by the TRIPS Agreement, including provisions that extend the patent term, introduce data exclusivity, establish patent linkage with drug registration and approval, or create new enforcement mechanisms for IPRs. TRIPS-plus provisions can also thwart the use of flexibilities otherwise assured under TRIPS.[36]

There are concerns that TRIPS-plus provisions in general, and data exclusivity in particular, could have a negative impact on public health and access to medicines. By extending another layer of market exclusivity protection to pharmaceuticals after drug agency approval, data exclusivity precludes generic follow-on competition because firms often cannot ethically repeat trials on bioequivalent or comparable products and cannot use the originator firm's data submitted for drug registration for the period of data exclusivity. In Jordan, 103 medicines registered since 2001 have no patent protection, but nearly four out of five of these products have no generic competition

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http://www.wcl.american.edu/pijip/download.cfm?downloadfile=9C0107B5-DE2F-4E48-6CE8D03F4933FCD4&typename=dmFile&fieldname=filename (citing Mike Palmedo, *3 More Members of Congress Write USTR on Brazilian Compulsory Licensing Dispute*, IP-HEALTH (May 26, 2005, 6:37 PM), http://lists.essential.org/pipermail/ip-health/2005-May/007950.html; Letter from Joe Wilson, U.S. Congressman, to Rob Portman, U.S. Trade Representative (May 24, 2005), *available at* http://www.cptech.org/ip/health/c/brazil/wilson05242005.pdf).

[33] WETZLER & AYALA, *supra* note 32 (citing Mike Palmedo, *PhRMA Statement on Brazilian Compulsory Licensing Dispute*, IP-HEALTH (July 9, 2005, 2:01 PM), http://lists.essential.org/pipermail/ip-health/2005-July/008126.html).

[34] *See id.* (citing *Article Published in the Page "Opinion" of Jorno do Brazil by the President of the Brazilian Federation of Pharmaceutical Industry*, IP-HEALTH (Sept. 28, 2005 5:23 PM), http://lists.essential.org/pipermail/ip-health/2005-September/008335.html).

[35] Thiru Balasubramaniam, *Brazil Issues Compulsory Licence for AIDS Drug*, 11 BRIDGES WEEKLY TRADE NEWS DIGEST, no. 16, 2007, *available at* http://ictsd.org/i/news/bridgesweekly/6490/.

[36] Grover, *supra* note 12.

because of data exclusivity protections.[37] Under the IP provisions in the Central America Free Trade Agreement, generic competition for some drugs in Guatemala may not become legally available till after they go generic on the United States market.[38]

Efforts to combat counterfeit drugs have also become an instrument to advance IP enforcement. While equally concerned about stopping counterfeit drugs, civil society has vigilantly scrutinized the motivation behind activities, such as IMPACT, launched by WHO in February 2006;[39] Fondation Chirac's efforts in the Cotonou Declaration;[40] and the Anti-Counterfeiting Trade Agreement (ACTA), negotiated in secrecy and thought to risk imposing TRIPS-plus standards of IP enforcement among the United States, European Union, Switzerland, and Japan.[41] The seizure of drugs in transit through European ports, particularly from India to other developing countries, on the suspicion of IP infringement has fed these concerns.[42] The European Union

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[37] OXFAM INT'L, OXFAM BRIEFING PAPER 102: ALL COSTS, NO BENEFITS: HOW TRIPS-PLUS INTELLECTUAL PROPERTY RIGHTS IN THE US-JORDAN FTA AFFECT ACCESS TO MEDICINES 22 (2007), *available at* http://www.oxfam.org/sites/www.oxfam.org/files/all%20costs,%20no%20benefits.pdf.

[38] Ellen R. Shaffer & Joseph E. Brenner, *A Trade Agreement's Impact on Access to Generic Drugs*, 28 HEALTH AFF. 957, 957 (2009), *available at* http://content.healthaffairs.org/content/28/5/w957.full.html (published online, Aug. 25, 2009).

[39] *Frequently Asked Questions*, INT'L MEDICAL PRODUCTS ANTI-COUNTERFEITING TASKFORCE, WORLD HEALTH ORG., http://www.who.int/impact/impact_q-a/en/index.html (last visited Nov. 24 2011).

[40] Int'l Ctr. for Trade and Sustainable Dev., *Chirac, African Leaders Call for Action on Fake Drugs*, 13 BRIDGES WEEKLY TRADE NEWS DIGEST, no. 35, 2009, *available at* http://ictsd.org/i/trade-and-sustainable-development-agenda/56795/; *Anti-Counterfeit Medicines Convention Foreseen in 2010*, INTELLECTUAL PROPERTY WATCH (Oct. 14, 2009), http://www.ip-watch.org/weblog/2009/10/14/anti-counterfeit-medicines-convention-foreseen-in-2010; Jacques Chirac, President of the Fondation Chirac, Speech in Cotonou Benin: The Cotonou Declaration (Oct. 12, 2009), *transcript available at* http://www.fondationchirac.eu/wp-content/uploads/2009/10/appel-anglais.pdf.

[41] *Anti-Counterfeiting Trade Agreement*, ELECTRONIC FRONTIER FOUNDATION, http://www.eff.org/issues/acta (last visited Jan. 15, 2012).

[42] In 2008, customs officials in the Netherlands made seventeen seizures, using EU regulation 1383/2003 as the legal basis for the seizures. *See* William New, *EU-India Agreement in WTO Dispute Raises Bar For EU Drug Seizures*, INTELLECTUAL PROPERTY WATCH (July 30, 2011), http://www.ip-watch.org/weblog/2011/07/30/eu-india-agreement-in-wto-dispute-raises-bar-for-eu-drug-seizures/. These seizures have been criticized by numerous civil society groups, including Oxfam and HAI Europe, on grounds that the generic shipments are legitimate under WTO rules.

finally agreed to set a higher bar before generic drugs transiting through European ports and destined for markets outside of Europe may be stopped.[43]

Adoption of TRIPS-plus provisions or the failure to exercise TRIPS flexibilities can impose real costs on the healthcare system. Partnering with other agencies, including the International Centre for Trade and Sustainable Development (ICTSD), WHO, the Pan American Health Organization (PAHO) and the World Bank, the United Nations Development Programme (UNDP) commissioned a TRIPS-plus impact assessment tool to measure the potential impact of various FTA provisions on medicine prices.[44] Preliminary findings in Peru and Colombia found that such TRIPS-plus FTA provisions would negatively impact affordable access to medicines. Merely extending the period of IP protection for an additional five years would increase medicine expenditures by approximately US$280 million in Colombia, an amount that could have been used to fund the medicine expenditures for over two million Colombians, or by US$321 million in Peru, increasing medicines prices by nineteen percent and accounting for the current medicine expenditure of over three million Peruvians.[45]

B. Global Burden of Disease

Going beyond AIDS, there has been increasing focus on the use of TRIPS flexibilities in relation to treatments for non-communicable diseases (NCDs). This mirrors the growing burden of disease in the developing world traceable to these conditions. All

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[43] *Id.*

[44] This intellectual property rights impact assessment (IPRIA) tool has thus far been used by the various collaborating partners to conduct assessments in several countries, including Colombia (2005, 2006, 2007), Guatemala (2005), Costa Rica (2005, 2008), Bolivia (2006), Dominican Republic (2008), Uruguay, Argentina, Malaysia, and Thailand (2006). *See e.g.*, WORLD HEALTH ORG., IMPACT ASSESSMENT OF TRIPS PLUS PROVISIONS ON HEALTH EXPENDITURES AND ACCESS TO MEDICINES (2007), *available at* http://203.90.70.117/PDS_DOCS/B2072.pdf. *See also* FUNDACIÓN MISIÓN SALUD, IMPACT OF THE EU-ANDEAN TRADE AGREEMENT ON ACCESS TO MEDICINES IN COLUMBIA (2009), *available at* http://www.haiweb.org/04102010/29_Mar_2010_Report_IFARMA_Impact_Study_Colombia_EN_.pdf.

[45] HEALTH ACTION INT'L EUR., IMPACT ON MEDICINES' PRICES AND CONSUMPTION FROM THE TRADE AGREEMENT BETWEEN THE EUROPEAN UNION AND TWO COUNTRIES OF THE ANDEAN COMMUNITY 7 (2009), *available at* http://www.haiweb.org/31082009/1. Non-communicable diseases already comprise over sixty percent of the deaths in low- and middle-income countries. In 2008, there were 57 million deaths worldwide, approximately 48 million of which were in low- and middle-income countries. Of those deaths, 36 million were due to NCDs, and nearly eighty percent of the NCD deaths (29 million) occurred in the developing world. WORLD HEALTH ORG., GLOBAL STATUS REPORT ON NONCOMMUNICABLE DISEASES 2010 9–10 (2011), *available at* http://whqlibdoc.who.int/publications/2011/9789240686458_eng.pdf.

together, heart disease and cancer comprise fifteen percent of the "disability-adjusted life years" lost in low- and middle-income countries—four times the burden of disease attributable to malaria.[46] Therefore, developing countries will also require affordable access to drugs for non-communicable diseases, not just the familiar list of infectious and neglected diseases.

At the September 2011 U.N. High-Level Meeting on Non-Communicable Diseases, the United States along with other industrialized countries opposed making reference to these diseases as an epidemic or public health emergency as if it would encourage developing countries to invoke TRIPS flexibilities to access generic versions of patented medicines.[47] While ultimately conceding oblique references to NCDs as a "challenge of epidemic proportions," the industrialized countries seem ready to repeat the history of AIDS.[48] Yet compulsory licenses issued by Thailand already include one for heart disease and four for the treatment of cancer. Patent opposition and litigation in India has also targeted treatments for cancer, like Gleevec, and for hepatitis C, like pegylated interferon.

IPRs as a means for mobilizing private sector investment in innovation leaves diseases endemic to developing countries—typically, Type II and III diseases—neglected.[49] The geographic distribution of these diseases determines the potential for financial returns on private investment into developing treatments for these conditions. Where

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[46] Jean O. Lanjouw, *A Patent Policy Proposal for Global Diseases,* BROOKINGS POL'Y BRIEF, no. 84, 2001 at 1, 2, *available at* http://www.brookings.edu/papers/2001/06globaleconomics_lanjouw.aspx.

[47] Sheri Fink & Rebecca Rabinowitz, *How Politics, Commerce, and Science Complicated the Fight Against an "Invisible Epidemic"*, FOREIGN AFF., Sept. 20, 2011, *available at* http://www.foreignaffairs.com/articles/68280/sheri-fink-and-rebecca-rabinowitz/the-uns-battle-with-ncds?page=show.

[48] Reminiscent of arguments made over the WHO Essential Drugs List, the claim that most non-communicable diseases in the developing world can be addressed by generic drugs raises two possible disquieting, but not mutually exclusive, conclusions. Either the pharmaceutical industry has failed to produce novel—and therefore, still patented—medicines of sufficient public health benefit to treat non-communicable diseases and merit a place alongside generic treatments (including those on the WHO Essential Drugs List), or such treatments remain so far outside of the range of affordability that they are not cost-effective enough for consideration on the WHO Essential Drugs List or for use in developing countries. Nor would this argument anticipate the future potential need for affordable, generic versions of tomorrow's medicines.

[49] Type I diseases are those found in both developing and developed countries. Type II diseases are neglected diseases, incident in both rich and poor countries, but with a substantial proportion of the cases in the poor countries. Type III diseases are the most neglected diseases and are overwhelmingly or exclusively incident in the developing countries. Intergovernmental Working Group on Public Health, Innovation and Intellectual Property, Draft Global Strategy And Plan Of Action On Public Health, Innovation And Intellectual Property, at 4,WHO Doc. A/PHI/IGWG/2/INF.DOC/6 (2007).

there is no paying market, there is no financial incentive for commercializing a life-saving treatment. Nor are there significant monopoly rents to be gained from holding patents in such markets. Where markets exist in both industrialized and developing countries, the potential of a dual market strategy is a possibility, although this can be a double-edged sword. On the one hand, the presence of a more lucrative paying market in industrialized countries might enable close-to-marginal cost pricing in the developing country markets. On the other hand, pharmaceutical firms might view large, middle-income countries, even those with sizeable poor populations, as markets with sizeable revenue potential. Firms may, therefore, wish to extract greater profits from the top of the market and refuse to adopt close-to-marginal cost pricing, denying much of the population access to the needed drugs.[50]

C. Changing Nature of Medicines

Already one in four new medicines receiving U.S. Food and Drug Administration (FDA) approval is a biologic.[51] Biologics are medicines produced from living cells, and they include vaccines as well as many of the cutting-edge therapies emerging for treating cancer, multiple sclerosis, Alzheimer's disease, and rheumatoid arthritis. By 2014, it is anticipated that biologics will make up half of the total sales of the top one hundred medicines on the U.S. market.[52]

Under the U.S. Patient Protection and Affordable Care Act, biologics receive twelve years of data exclusivity—seven more years than conventional, small-molecule drugs. Yet studies cited by the drug industry's own trade association showed little difference in the R&D costs to bring a biologic to market ($1.2 billion) compared to a conventional drug ($1.318 billion).[53] Since the complexity of biologics may entail greater clinical testing to establish bioequivalence than generic versions of conventional drugs, the barrier for follow-on biosimilars was already thought to be higher. In fact, recognizing this higher barrier to generic competition, the U.S. Federal Trade Commission recommended that biologics receive zero years of data exclusivity.[54]

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[50] *See generally* Sean Flynn et al., *An Economic Justification for Open Access to Essential Medicine Patents in Developing Countries*, 37 J. LAW MED. ETHICS 184 (2009).

[51] Asher Mullard, *2010 FDA Drug Approvals*, 10 NATURE REVIEWS DRUG DISCOVERY 82, 83 (2011), *available at* http://www.nature.com/nrd/journal/v10/n2/full/nrd3370.html.

[52] EVALUATEPHARMA, WORLD PREVIEW 2014 2 (2009), *available at* http://www.evaluatepharma.com/worldpreview2014.aspx.

[53] PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AM., PHARMACEUTICAL INDUSTRY PROFILE 2009, (2009), *available at* http://www.phrma-jp.org/archives/pdf/profile/PhRMA2009ProfileFINAL.pdf

[54] FEDERAL TRADE COMM'N, EMERGING HEALTH CARE ISSUES: FOLLOW-ON BIOLOGIC DRUG COMPETITION 69–72 (2009), *available at* www.ftc.gov/os/2009/06/P083901biologicsreport.pdf.

The market entry price of biologics in the United States is, on average, twenty-two times greater than for conventional drugs.[55] Breast cancer patients treated with Herceptin spend US$37,000 a year, and rheumatoid arthritis patients treated with Humira spend US$50,000 per year.[56] Concerns have arisen that the United States might seek to impose its approach to extended data exclusivity on other countries through regional and bilateral trade agreement negotiations, such as for the Trans-Pacific Partnership Agreement.[57] Therefore, the hurdle for differential pricing will be even greater with this next generation of medicines than it was to bring AIDS drugs to developing countries.

III. SHAPING THE GLOBAL IP REGIME

As these trends suggest, significant work with developing countries on designing policy frameworks on trade and intellectual property rights is needed to strengthen their capacity to respond. Two approaches that could help influence and shape the global IP regime include: (1) improving the transparency of the IP system and (2) ensuring the representation of the public's interest in systems of administrative and judicial review.

A. Transparency of the IP system

Transparency of the IP system is the foundation of the societal bargain in which time-limited market exclusivity is awarded to inventors in exchange for disclosure of the invention into the public domain. Transparency allows researchers and industry to build upon the inventions that receive government protection. Non-transparency of that information can hinder innovation or affordable access to health technologies. Part of the problem is rooted in asymmetry in the patent system itself, from non-transparency to the pattern of ownership and administration of patents.

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[55] LAURENCE J. KOTLIKOFF, STIMULATING INNOVATION IN THE BIOLOGICS INDUSTRY: A BALANCED APPROACH TO MARKETING EXCLUSIVITY 3 (2008), *available at* http://people.bu.edu/kotlikoff/New Kotlikoff Web Page/Kotlikoff_Innovation_in_Biologics21.pdf.

[56] Alfred B. Engelberg et al., *Balancing Innovation, Access, and Profits—Market Exclusivity for Biologics*, 361 NEW ENG. J. MED. 1917, 1918 (2009).

[57] Charles Clift, Data Protection and Data Exclusivity in Pharmaceuticals and Agrochemicals *in* INTELLECTUAL PROPERTY MANAGEMENT IN HEALTH AND AGRICULTURAL INNOVATION: A HANDBOOK OF BEST PRACTICES 431, 435 (Anatole Krattiger et al eds., 2007), *available at* http://www.iphandbook.org/handbook/resources/Publications/links/ipHandbook%20Volume%201.pdf; Ed Silverman, *Reps Seek 12 Years Data Protection in TPP Talks*, PHARMALOT, July 29, 2011, *available at* http://www.pharmalot.com/2011/07/reps-seek-12-years-data-protection-in-tpp-talks/.

If patent holders make legal claims that are not justified by their filings, the consequences may result in inappropriate claims of infringement; R&D efforts blocked or wasted on unnecessary work-arounds; undeserved licensing revenues; or blocked generic entry. A case in point, GlaxoWellcome moved to halt the importation into Ghana of Duovir from Cipla, an Indian generic firm. In a communication to Cipla, Glaxo alleged that any exports the generic firm made to Ghana would be illegal, as they would violate four patents held by the company there on Combivir, a two-drug combination of lamivudine and zidovudine. Rather than contest the claim in court, Cipla discontinued imports of Duovir into Ghana.[58] It turned out that Glaxo's claims were not justified.[59] Even though the patent claims of Glaxo officials were questionable and would not likely have prevailed in litigation, they effectively barred Cipla from exporting the generic Duovir to Ghana.

To minimize the problems of IP non-transparency, two steps would be of significant value as developing country governments often do not know what patents are valid in their patent offices: (1) the creation of searchable patent databases that identify IP for health technology products and (2) the training of developing country pharmaceutical firms and procurement agencies on assessing the validity of IP claims.

Initial steps to examine the potential for developing a pharmaceutical patent database arose from an October 2008 technical consultation, *Transparency in the Patent System: Meeting Patent Information Needs of Developing Countries*, organized by the UNDP, WHO, and the European Patent Office (EPO). The meeting discussed the feasibility of a patent search methodology, which uses the patent listings in the U.S. FDA Orange Book and Canada's Patent Registry as a starting point to identify the patents relevant to specific pharmaceutical products.[60] The methodology could provide a means for quickly obtaining preliminary information on the patent status of medicines from publicly-available sources on the Internet. Next steps could test and implement this methodology as a tool to provide information to guide pharmaceutical procurement in developing countries.

Further work will need to be undertaken to compile the necessary patent information into a searchable patent database. While the patent methodology may provide the

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[58] Amrita Nair-Ghaswalla, *MNCs Allege Cipla's African 'Aid' Violates Patent*, THE TIMES OF INDIA, Feb. 10, 2001.

[59] Three of the company's alleged four patents were invalid in Ghana. At the time the patents were granted, Ghana did not issue patent protection for pharmaceuticals. Ghana had actually affirmatively rejected the three patents. The fourth patent at issue covered one specific formulation of Duovir, but Cipla stated that this patent did not pertain to the product it manufactured. Mark Schoofs, *Glaxo Enters Fight in Ghana on AIDS Drug*, WALL ST. J., Dec. 1, 2000, at A3, *available at* http://www.aegis.com/news/wsj/2000/WJ001202.html.

[60] *See generally* Barbara Milani & Cecilia Oh, *Searching for Patents on Essential Medicines in Developing Countries: A Methodology*, 4 INT'L J. INTELLECTUAL PROP. MGMT. 191 (2011).

initial base of information, the maintenance and updating requirements of a searchable database require further consideration. The usefulness of such a database is also manifest in the Medicines Patent Pool's efforts to provide such an inventory of patent registration on AIDS drugs in low- and middle-income countries.[61]

IP transparency has been emphasized in recent initiatives, such as the World Intellectual Property Organization's (WIPO's) recent *Project on Developing Tools for Access to Patent Information*, which is aimed at achieving related goals. This project addresses several recommendations in the WIPO Development Agenda by improving understanding of patent information and key trends in technology by developing countries. Its main outputs include accessible Patent Landscaping Reports on a range of subjects, e-learning tutorials providing training on the use of patent information, and regional conferences to exchange best practices and develop skills.[62]

B. Systems of Administrative and Judicial Review

Transparency may be a necessary, but not sufficient, condition to redress the lack of balance in the present IP system, as transparency must be accompanied by the capacity to act on these findings. While the number of new chemical entities has trended downwards since the mid-1990s, the number of patents applied and granted for pharmaceutical products has increased. There is a need not only to track trends in pharmaceutical patenting, but also to monitor growing concerns that patenting strategies are becoming obstacles to innovation. The IP system must therefore enable the opportunity for expedient administrative and judicial review at strategic points of intervention, and there also must be trained individuals to take advantage of that opportunity.

Adhering to patentability criteria requires expertise and capacity in a country's patent office. The assessment of whether a gene sequence, a secondary indication for an existing drug, or a follow-on biologic is patentable can have significant implications not only for potential commercialization but also for affordable access. Since the scope of patent claims is determined at the country level, the prosecution of patent applications typically resides with the local patent office.

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[61] The Medicines Patent Pool has compiled the patent registration status of selected drugs to treat HIV/AIDS across many low- and middle-income countries. *See The Patent Status Database for Selected HIV Medicines*, MEDICINES PATENT POOL (Oct. 2011), http://www.medicinespatentpool.org/LICENSING/Patent-Status-of-ARVs. Even with this focus on AIDS medicines and with the legal expertise and resources of the Medicines Patent Pool, the patent database is incomplete in some countries.

[62] WIPO Comm. on Dev. and Intellectual Prop., Project on Developing Tools for Access to Patent Information (Recommendations 19, 30, and 31), WIPO Doc. CDIP/4/6 (Sept. 25, 2009), *available at* http://www.wipo.int/edocs/mdocs/mdocs/en/cdip_4/cdip_4_6.pdf.

However, an interesting alternative model of such review had been offered by the Brazilian National Health Surveillance Agency (ANVISA). Established in 1999, ANVISA is an independent regulatory agency, linked to the Ministry of Health. Among its functions are review and prior approval of patents on pharmaceutical products and processes granted by the National Institute of Industrial Property (INPI). Over the years, ANVISA has declined to approve or returned for reexamination multiple patents for lack of novelty, lack of inventive step, and other reasons. Until the Brazilian Attorney General limited the agency's role in reviewing pharmaceutical patents early in 2011,[63] ANVISA also provided an important exemplar of an institutional check on patenting when it might affect public health.

IV. ENABLING INNOVATION FOR KNOWLEDGE-BASED ECONOMIES

Between 2002 and 2007, investment in science in developing countries grew at three times the rate of that in industrialized countries.[64] While R&D spending rose by a third in developed countries during this period, developing countries doubled their R&D expenditures over the same period, from US$135 to US$274 billion.[65] Despite these gains, the fifty least developed countries (LDCs) still only account for 0.5 percent of the world's researchers, and spending on R&D in the developing world totaled only 1 percent of GDP in 2007 compared to 2.3 percent in the developed world.[66] Within health, such R&D investment—both in developing countries and for diseases endemic in these countries—helps to shape the priorities for innovating health technologies. By engaging researchers in disease-endemic countries in such R&D, it might better reflect on-the-ground realities of implementing and delivering such technologies in resource-limited settings. By investing in such R&D, developing country governments too can signal their commitment to meeting these public health challenges.

In times like these, calling for greater investment in R&D may seem counter-cyclical.[67] The global financial crisis has slashed donor funding for research. The Swedish aid

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[63] Roy Zwahlen, *Brazilian Attorney General of the Union Restricts ANVISA's Role in Pharmaceutical Patent Review*, PATENTLY BIOTECH (Jan. 31, 2011), http://www.biotech-now.org/public-policy/patently-biotech/2011/01/brazilian-attorney-general-of-the-union-restricts-anvisas-role-in-pharmaceutical-patent-review.

[64] Ochieng' Ogodo, *Poor Countries Spending More on Science*, SCI. & DEV. NETWORK (Oct. 7, 2009), http://www.scidev.net/en/news/poor-countries-spending-more-on-science-.html.

[65] *Id.*

[66] *Id.*

[67] It should be noted though that a study examining whether economic recessions result in diminished development assistance for health failed to find any statistically significant association in the short or long run. David Stuckler et al., *Does Recession Reduce Global Health Aid? Evidence from Fifteen High-Income Countries, 1975–2007*, 89 BULL. WORLD HEALTH ORG. 252, 252 (2011). In addition, development assistance for health climbed significantly from

agency (SIDA) cut its 2010 research cooperation budget by almost twenty-five percent, or approximately US$36 million, while Wellcome Trust reduced its 2008/2009 grant giving by US$49 million.[68]

Even with strong IP protection, non-paying markets do not assure firms of returns on investment. Private markets will consistently undersupply public goods. Apart from insufficient incentives for private sector investment, there remains a shortfall of public funding. The mismatch between public health priorities and market-driven incentives for pharmaceutical R&D compounds this problem further. Given the failure of private markets to fill these gaps, public-private partnerships have focused on bringing otherwise neglected health technologies to market.

These product development partnerships seek to combine public financing and private sector expertise to bring to market novel diagnostics, drugs, and vaccines for neglected diseases. The number of these product development partnerships has proliferated in recent years, from 63 neglected disease projects by the end of 2004 to an estimated 150 in the pipeline of product development partnerships by 2009.[69] Multinational corporations have conducted half of these projects, invariably on a "no profit-no loss" basis. Of note, the balance of these projects were undertaken by small-scale businesses, such as small and medium sized Western firms, developing country firms, and academic institutions, for which these projects represented commercial opportunities. Unlike multinational corporations, they found the opportunity costs of pursuing projects on neglected diseases to be potentially profitable. To find ways of sustainably producing these public goods, this insight may be key. Reviewing more closely the case study of drugs like praziquantel, a treatment for schistosomiasis, one finds that modest public funding can sometimes seed the sustainable production of a public good.

US$5.6 billion in 1990 to US$21.8 billion in 2007, much of this channeled through public-private partnerships like the Global Fund for AIDS, Tuberculosis and Malaria and the Global Alliance for Vaccines and Immunization as well as NGOs. Nirmala Ravishankar et al., *Financing of Global Health: Tracking Development Assistance for Health from 1990 to 2007*, 373 LANCET 2113, 2113–24 (2009). However, these findings still may not reflect the picture for near-term cuts in donor funding for research.

[68] Linda Nordling, *Sweden Slashes Research Aid Budget*, SCI. & DEV. NETWORK (Sept. 1, 2009), http://www.scidev.net/en/news/sweden-slashes-research-aid-budget.html. At this time, recalling the words of the Commission on Health Research for Development in 1990 might be prudent: "One view considers that research must wait until current health service priorities have been met and financial resources are less constrained. . . . [O]n the contrary, research is essential today because the results are needed now to empower those who must accomplish more with fewer resources." COMM'N ON HEALTH RESEARCH FOR DEV., HEALTH RESEARCH: ESSENTIAL LINK TO EQUITY IN DEVELOPMENT xvii (1990).

[69] *See* Mary Moran, *A Breakthrough in R&D for Neglected Diseases: New Ways to Get the Drugs We Need*, 2 PLOS MED. 828, 828–30 (2005); *Innovative Product Development Partnerships*, *supra* note 11.

In the 1970s, clinical trials found that praziquantel effectively treated a widely prevalent disease of parasitic worms, schistosomiasis. Bayer and E. Merck registered the patent for praziquantel in thirty-eight countries.[70] Responding initially to a domestic need (praziquantel also treats *Clonorchis sinensis*, the liver fluke, in Korea), a South Korean firm—Shin Poong Pharmaceutical Company—developed an alternative production process for praziquantel. This alternative process yielded significant cost-savings, and Shin Poong obtained a process patent in Korea to protect it.[71] Receiving five years of government protection from competition in 1983, Shin Poong competed with Bayer in a legal duopoly on the Korean market. By setting its price significantly below Bayer's, Shin Poong both pushed Bayer's prices down and captured most of the domestic market. In the early 1980's, Bayer had an effective monopoly on praziquantel in Korea, but their market share dropped to ten percent by the early 1990s, as Shin Poong's share climbed to ninety percent.[72] At the same time, the price of praziquantel would decrease by over ninety percent between 1990 and 2004.[73] The increased access to praziquantel contributed significantly to the decline in rates of parasitic infections from schistosomiasis in endemic countries and of liver fluke in Korea.[74]

By the early 1990s, Shin Poong had become the world's single largest producer of praziquantel. The company filed for patent rights to the production process in twelve additional countries, but also pursued licensing arrangements with firms in other countries.[75] For Bayer, praziquantel represented 0.001 percent of its total worldwide pharmaceutical sales in 1994 and only 0.2 percent of its total sales to all developing countries. Its production costs resulted in a price fifty percent higher than that of other world market suppliers. By contrast, Shin Poong had a less costly production process and fewer products competing for use of its manufacturing facilities and therefore gave praziquantel high priority. The opportunity costs for this developing country firm were quite different.[76] But until the early 1990s when the original product patents expired, it could only compete in markets that did not recognize product patents. [77] In a TRIPS or TRIPS-Plus world, how will a Shin Poong develop a drug at an affordable price for neglected diseases afflicting those in developing countries?

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[70] Alan Fenwick & Howard Thompson, *Praziquantel: Access to Medicines*, *in* ACCESS: HOW DO GOOD HEALTH TECHNOLOGIES GET TO POOR PEOPLE IN POOR COUNTRIES 39, 41–42 (Laura J. Frost & Michael R. Reich eds., 2009).

[71] Michael R. Reich & Ramesh Govindaraj, *Dilemmas in Drug Development for Tropical Diseases: Experiences with Praziquantel*, 44 HEALTH POL'Y 1, 3–4 (1998).

[72] *Id.* at 4.

[73] Fenwick & Thompson, *supra* note 70, at 51.

[74] Reich & Govindaraj, *supra* note 71, at 4.

[75] *Id.*

[76] *Id.* at 7.

[77] *Id.* at 10.

As seen in this example, opportunity costs for pharmaceutical companies in developing countries may differ from those of large multinational companies. In those markets, some firms may also be more interested in producing and marketing treatments for diseases endemic in their countries. These factors can lead to innovation and R&D investments, including in lower-cost processes and delivery mechanisms, that are targeted to the public health needs of their populations. As the pool of researchers and scientists in developing countries grows, there is a greater justification for promoting and facilitating innovation in these settings.

The challenge is to shape an environment that will enable innovation in developing countries. The sharing of knowledge is critical for ensuring the participation of those in developing countries in the innovation process. For technology transfer or sharing of knowledge to occur, both ends of the exchange must be positioned and prepared to participate. On the receiving end, the R&D infrastructure, human capital, and financial resources must be in place.

The global and national IP regime also has a key role in shaping whether or how this technology transfer takes place. This knowledge may be codified in what is disclosed in patent applications, but it also often involves tacit know how. This distinction points to the layers of innovation necessary to apply knowledge for developing health technology products, from access to scientific publications, data and material sharing to patenting and licensing of inventions. To understand the science behind journal articles, one may require access to the underlying data. To make the most use of proprietary compound libraries, one may need access to the associated annotation. Complicating access to this knowledge, the IP regime may limit or condition its use. Each layer of innovation thus poses its own challenges to open scientific exchange and sharing of knowledge. Powerful norms govern the scientific exchange within these layers of innovation, some shaped by the IP regime and others by funder requirements, government regulations, and professional standards. Characterizing the norms, obstacles, and opportunities at each stage can help point the way to solution paths that lower the barriers to sharing knowledge and improve the scientific community's ability to respond to the challenges of global health.

A. Scientific Publications

Traditional journal publications rely on reader subscriptions as a key revenue source. Subscription prices may place access to research out of reach, not just for institutions in the developing world, but also among patients in the developed world. By posing barriers to non-subscribers, patients and their families may be unable to access literature that might inform them of the latest scientific advances, even when such research is publicly funded.

As subscription fees have outpaced library budgets, many have begun to question whether a model of open access to scientific publications might offer a superior alternative. Open access advocates have laid out two pathways—a "green road" and a

"gold road." The green road involves authors self-archiving their own peer-reviewed journal articles and making them free in on-line open access repositories, such as might be hosted on their university server.[78] Authors may retain copyright or a non-exclusive license to their own work. The challenges to the green road are how to signal quality and make it easy for users to find such quality research in these institutional archives. Complementing the green road, the gold road involves publishing in open access journals. Such publications have adopted a different business model than traditional journals. Rather than rely on subscriber fees, the journal supports its operations through other revenue sources. These can include institutional subsidies, membership dues, advertising, endowments, upfront submission or publication fees, or, of course, voluntarism. In fact, most open-access journals do not charge any publication fees.[79] Regardless of the source of journal support, the published article in such journals becomes freely available for viewing, without copyright licensing fees. This arrangement not only permits broader dissemination of the research, but also greater opportunities for "remix." The transaction costs of assembling a specialized collection of open-access journal articles (e.g., approaches to improve rational use of antibiotics in resource-limited settings or diagnostic strategies for evaluating fever in children in malaria-endemic countries) are low when compared to doing the same with non-open-access articles, each with reprint rights to be negotiated.

B. Data Sharing and Material Transfers

Barriers to sharing of data and materials for research present another problem for innovation and research for developing countries. Delays in fulfilling material transfer

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[78] In 2008, the faculty at Harvard University adopted a policy encouraging voluntary deposit of completed research articles in an institutional repository that will eventually be accessible worldwide on the Internet. *Harvard University Unanimously Votes 'Yes' for Open Access*, BERKMAN CENTER FOR INTERNET AND SOCIETY AT HARVARD UNIVERSITY (Feb. 19, 2008), http://cyber.law.harvard.edu/node/3927. Harvard Law School, Harvard Kennedy School of Government, the Stanford University School of Education, Boston University, and the Massachusetts Institute of Technology have followed suit with similar open access initiatives of their own. *See* Art Jahnke & Jessica Ullian, *University Council Approves Open Access Plan*, BU TODAY (Feb. 17, 2009), *available at* http://www.bu.edu/today/node/8320; Peter Suber, *OA Mandate at the Stanford School of Ed*, OPEN ACCESS NEWS (June 26, 2008, 12:57 PM), http://www.earlham.edu/~peters/fos/2008/06/oa-mandate-at-stanford-school-of-ed.html; Marisa Taylor, *MIT Moves Toward Open Access*, WALL ST. J. BLOGS (Mar. 25, 2009, 8:46 PM), http://blogs.wsj.com/digits/2009/03/25/mit-moves-toward-open-access/; Press Release, Harvard Kennedy School, Harvard Kennedy School Faculty Votes for Open Access for Scholarly Articles (May 16, 2009), *available at* http://www.hks.harvard.edu/news-events/news/press-releases/open-access-vote.

[79] Peter Suber, *No-Fee Open Access Journals*, SPARC OPEN ACCESS NEWSLETTER, NO. 103 (Scholarly Publishing and Academic Resources Coalition, Wash, D.C.), Nov. 2, 2006, *available at* http://www.earlham.edu/~peters/fos/newsletter/11-02-06.htm#nofee.

requests may significantly hold back projects by more than a month for one out of six biomedical researchers, even for those in non-profit or government research institutions.[80] Denial of material transfer requests may prompt them to abandon lines of research altogether. In a study of genetics researchers, nearly half reported that at least one of their requests for information, data, or materials related to published research were denied over the previous three years.[81] The most frequent reasons given for denying requests included the high costs of producing materials or information, the need to protect their own or their colleagues' ability to publish, and the commercial value of the data or material.

The need for sound and equitable means to share data and materials has been most recently illustrated by the handling of avian flu wild virus samples in the WHO's Global Influenza Surveillance and Response System (GISRS). Largely Northern vaccine manufacturers need the wild virus samples to seed their vaccine development. Though these samples come largely from developing countries, Indonesia and others complain that no benefit sharing—in the form of revenues, affordable vaccines, or guaranteed vaccine stocks—flows back to them despite the fact that the disease disproportionately afflicts their populations.[82] Protracted inter-governmental negotiations finally led to a standard material transfer agreement—one for those within the GISRS and one for outside groups including pharmaceutical firms—that would govern the sharing of the virus samples.[83] For those outside of GISRS, recipients of virus samples would have to commit to benefit sharing, such as in a set-aside of ten percent of vaccine production for WHO stockpiles, provision of the antiviral treatment at a concessionary price for developing countries, or offering royalty-free licenses for use by developing country manufacturers.

C. Patenting and Licensing of Inventions

Three types of IP obstacles deserve mention—patent thickets, patent holdouts, and temporal lag. While patent thickets and patent holdouts are relatively well known in the legal literature,[84] temporal lag is less often characterized, and occurs when rapidly

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[80] John P. Walsh et al., *View from the Bench: Patents and Material Transfers*, 309 SCI. 2002, 2002–03 (2005).

[81] Eric G. Campbell et al., *Data Withholding in Academic Genetics: Evidence from a National Survey*, 287 J. AM. MED. ASS'N 473, 477 (2002).

[82] Kaitlin Mara, *WHO Members Fail to Finish Pandemic Flu Preparations*, INTELLECTUAL PROP. WATCH (May 18, 2009), http://www.ip-watch.org/weblog/2009/05/18/who-members-fail-to-finish-pandemic-flu-preparations/.

[83] Catherine Saez, *WHO Members on Verge of New Framework for Pandemic Flu Response*, INTELLECTUAL PROP. WATCH (May 23, 2011, 3:33 PM), http://www.ip-watch.org/weblog/2011/05/23/who-members-on-verge-of-new-framework-for-pandemic-flu-response/.

[84] The proliferation of patents on a technology landscape can lead to thickets, where innovators face significant transaction costs or unresolvable uncertainty over what patent

emerging epidemics outpace the speed of prosecuting applications at the patent office. As a consequence, firms face uncertainty in their IP holdings in the development of novel pharmaceutical products—diagnostics, drugs, or vaccines—but face pressure to move forward in any case. By blocking valuable upstream research or blocking the downstream usage of existing technologies, these IP obstacles can create barriers to access. The complexity of biologics and the need for fixed-dose combination medicines to treat diseases like AIDS heightens these concerns.

A patent landscape study offers a case in point. Of the top ten antigens for malaria, the landscape found 167 patent families filed by 75 different organizations. These 167 families were narrowed down to 39 moderate- to high- priority patents. By the time the patent landscape was conducted, nearly half of these priority patents were no longer available for licensing.[85] Unlike the tragedy of the commons, Heller and Eisenberg have described this as the tragedy of the anti-commons where "multiple owners each have a right to exclude others from a scarce resource and no one has an effective privilege of use."[86]

Several key observations might be made of the malaria vaccine patent landscape. Many of these patents (nearly seventy percent) were originally held by publicly funded organizations. This suggests that any effective solution to patent thickets requires the participation of universities and public research institutions, not just private corporations. Figure 1 illustrates the shift in availability of priority patents under license for a malaria vaccine.

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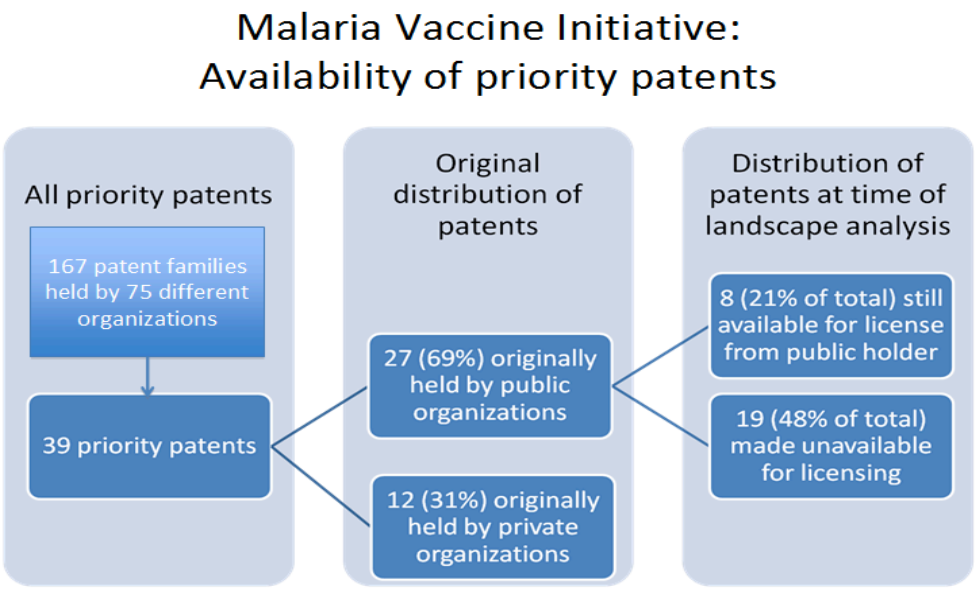
claims require a license in order to secure the freedom to operate in this space. Patent holdouts result when the IP owner refuses to license a technology, either to block competitors or to ensure exclusivity over the market for one's own firm.

[85] The 167 patent families were ranked in terms of priority based on a number of factors: "patent status (pending, issued, lapsed, or expired), length of estimated patent life, territory, and overlap between claims and vaccine-candidate attributes." This analysis resulted in the classification of 39 families (twenty-three percent of the 167 total families) as moderate- to high- priority. Sandra L. Shotwell, *Patent Consolidation and Equitable Access: PATH's Malaria Vaccines*, *in* INTELLECTUAL PROPERTY MANAGEMENT IN HEALTH AND AGRICULTURAL INNOVATION: A HANDBOOK OF BEST PRACTICES 1789, 1791 (2007), *available at* http://www.iphandbook.org/handbook/ch17/p21/.

[86] Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 SCI. 698 (1998).

Figure 1: Malaria Vaccine Patent Landscape



Created from data presented in Sandra L. Shotwell, *Patent Consolidation and Equitable Access: PATH's Malaria Vaccines*, *in* **Intellectual Property Management in Health and Agricultural Innovation: A Handbook of Best Practices** 1789 (Anatole Krattiger, Richard T. Mahoney, Lita Nelsen, et al., eds., 2007).

Patent holdouts also can result in delay or denial. In a study of 132 U.S. laboratory directors conducting genetic testing, twenty-five percent stopped performing a genetic test, and fifty-three percent did not develop one or more genetic tests because of a patent or license.[87] The development of a new DNA recombinant hepatitis B vaccine, based on a different production process, was stifled until the originator patent was overturned by the UK House of Lords.[88]

For rapidly moving epidemics like SARS, the time lag between the emerging infectious disease and the much slower prosecution of patents can introduce uncertainty over the underlying IP needed to manufacture a diagnostic or treatment. Responding to these concerns, leading research centers involved in identifying coronavirus as the cause of SARS considered pooling their IP.[89] In the end, the

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[87] Mildred K. Cho et al., *Effects of Patents and Licenses on the Provision of Clinical Genetic Testing Services*, 5 J. OF MOLECULAR DIAGNOSTICS 3, 3–8 (2003).

[88] Julie Milstien & Miloud Kaddar, *Managing the Effect of TRIPS on Availability of Priority Vaccines*, 84 BULL. WORLD HEALTH ORG. 360, 362 (2006).

[89] James H. M. Simon et al., *Managing Severe Acute Respiratory Syndrome (SARS) Intellectual Property Rights: The Possible Role of Patent Pooling*, 83 BULL. WORLD HEALTH ORG. 707, 707–10 (2005).

epidemic subsided faster than the evaluation of the patent claims among these parties could be resolved.

V. CREATING AN ENABLING ENVIRONMENT FOR SHARING KNOWLEDGE

The value chain of R&D represents the inputs and outputs at each stage from discovery to delivery of a health technology. The sharing of knowledge constitutes a key input all throughout this value chain. Across the layers of innovation, IP and other proprietary rights over knowledge can complicate the process of sharing. In these instances, the value chain of R&D may require re-engineering, paving the way for alternative models of innovation that can better meet the public health needs of the poor. A number of approaches have evolved to overcome limitations to the sharing of knowledge. Three approaches worthy of consideration include tiering, pooling, and open-source collaboration.

A. Tiering

Many are familiar with the use of tiering, where preferential, lower drug prices are given to developing countries while industrialized countries pay the full price. Under tiering arrangements, the market is segmented between those receiving preferential treatment and those not receiving such treatment. The tiering is often structured along some measure of resource availability, such as income or the UNDP's Human Development Index.

Tiering does not have to be just over price: it can be applied at different points in the value chain between benchtop and bedside, by granting royalty-free licenses or use of a resource like a compound library for R&D on neglected diseases in developing countries. There are, however, challenging issues to resolve over tiering practices. Selecting which countries belong to which tier is a key consideration. The tension over how to treat middle-income countries in tiered pricing schemes has surfaced repeatedly in recent years. The Pan American Health Organization's (PAHO's) efforts to secure discount pricing for vaccines in Latin America have come into conflict with the Global Alliance for Vaccines and Immunizations' (GAVI) efforts to obtain the lowest possible price for LDCs. Since PAHO covers a region with only one LDC—Haiti—its procurement requirement that they must receive the lowest available price on a vaccine has put it at odds with vaccine suppliers seeking to offer GAVI a better price for LDCs.[90]

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[90] PAHO has a "most-favored nation" (MFN) clause in its contracts that requires suppliers to provide PAHO the lowest price given to any purchaser from that supplier. *See* PAUL WILSON, OXFAM & MÉDECINS SANS FRONTIÈRES, GIVING DEVELOPING COUNTRIES THE BEST SHOT: AN OVERVIEW OF VACCINE ACCESS AND R&D 10 (2010), *available at*

B. Pooling

On the demand side, pooling the markets of LDCs with middle-income countries may be key to achieving the economies of scale necessary to bring products to market. The WTO General Council's August 30, 2003 decision recognized the need to harness economies of scale to ensure sufficient group purchasing power and to facilitate local production of pharmaceutical products.[91] The decision allowed the use of compulsory licenses by LDCs to be extended to a regional economic bloc when that bloc is subject to a regional trade agreement and when LDCs comprise the majority of that bloc. The Rockefeller Foundation's *Charting a Fairer Course for Intellectual Property Rights* program supported efforts to study both how to seed regional pooled procurement in sub-Saharan Africa and also how to exercise TRIPS flexibilities as a regional economic bloc.[92] In the same vein, efforts by the UNDP and WHO have rekindled interest in regional pooled procurement in the East African Community (where only Kenya is a non-LDC) to improve medicine supply. As the WHO began to work on harmonizing regulatory systems in this regional bloc, the UNDP focused on the task of harmonizing IP laws to facilitate regional trade. A UNDP regional consultation in November 2007 led to a report, accepted by the East African Community and its Secretariat, on harmonizing IP laws in the region.[93]

While pooled procurement initiatives organize demand to allow for higher volume purchases of drugs or vaccines, pooling can also be done upstream in the R&D pipeline where there might be fewer complications of IP rights over the building blocks of knowledge. Such pools will allow for research inputs, such as research tools and compound libraries, to be assembled and bundled in ways that lower the transaction costs of accessing them.

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http://www.oxfam.org/sites/www.oxfam.org/files/giving-developing-countries-best-shot-vaccines-2010-05.pdf.

[91] Decision of the General Counsel of 30 August 2003, *Implementation of Paragraph 6 of the Doha Declarations on the TRIPS Agreement and Public Health*, ¶ 6, WT/L/540 & Corr.1 (Aug. 30, 2003), *available at* http://www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm.

[92] Management Sciences for Health conducted an analysis of the potential for regional pooled procurement in Sub-Saharan Africa. *See Conferences: Rockefeller Pooled Procurement Technical Meeting*, MGMT SCI. FOR HEALTH, http://www.msh.org/seam/3.3.1.2.htm#rockefeller (Anthony So helped to co-found *Charting a Fairer Course for Intellectual Property Rights* as a Rockefeller Foundation program officer). The South Centre study examined the use of TRIPS flexibilities by regional economic blocs. *See* Sisule F. Musungu et al., *Utilizing TRIPS Flexibilities for Public Health Protection Through South-South Regional Frameworks*, SOUTH PERSPECTIVES, Apr. 2004, *available at* http://www.southcentre.org/index.php?option=com_content&task=view&id=72&Itemid=67.

[93] *See* Cailin Morrison, Intellectual Property Law, Pooled Procurement and Access to Antiretroviral Therapy in the East African Community (Dec. 2007) (unpublished study commissioned by the UNDP) (on file with the author).

Although there have been pools established to provide access to patents comprising MPEG-2, DVD, and other standards in the electronics industry, pools in the biomedical field are fewer. A number of recent efforts, however, have renewed interest in this approach.

Combining pooling with tiering, GlaxoSmithKline announced plans for a patent pool for neglected diseases in 2009.[94] Initially, the pool addressed neglected diseases corresponding to those covered under FDA Priority Review Voucher program, which excludes Chagas disease and AIDS. The starting conditions of the tiered access under the Pool only provided an initial commitment that IP licensed from the Pool could apply to products commercialized for use in LDCs.[95] The pool is now administered by BIO Ventures for Global Health (BVGH), reframed as *The Pool for Open Innovation Against Neglected Tropical Diseases*.[96] The Pool currently includes seven contributors and six users.[97] From the beginning, licenses for patents were to be royalty-free in LDCs, but users could negotiate with pool contributors for rights outside of the LDCs on a case-by-case basis.[98] The presence of South African organizations among the pool users suggests that the Pool may already be working to extend rights outside the LDCs, at least on a limited basis.[99] The Pool will need to demonstrate its value added

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[94] Andrew Witty, Chief Executive Officer, GlaxoSmithKline, Speech to Harvard Medical School: Big Pharma as a Catalyst for Change (Feb. 13, 2009), *available at* http://www.hcp.med.harvard.edu/files/Big%20pharma%20as%20a%20catalyst%20for%20change_EMBARGOED%20until%2013_02_09%2014%2000%20EST.pdf (summary).

[95] *Id.* (noting that "any benefits from the pool must go in full and solely to LDCs"). However, nearly eighty percent of the eighty-two patent families originally made available by GSK in the Pool had no current or prospective filings in LDCs. Thus the value of offering to license such patents would have largely benefited those seeking to commercialize the IP by manufacturing outside LDCs for use in LDCs. However, the advantage for some of these groups to license from the Pool as opposed to directly from the company remains to be seen.

[96] *BIO Ventures for Global Health Chosen to Administer the GSK and Alnylam Intellectual Property Pool*, BIO VENTURES FOR GLOBAL HEALTH (Jan. 20, 2010), *available at* http://www.bvgh.org/News/BVGH-News/Press-Releases/Article-January-20-2010.aspx.

[97] The contributors are GSK, Alnylam, MMV, the Massachusetts Institute of Technology, the University of California-Berkeley, the California Institute of Technology, and Stanford University. The users are the Emory Institute for Drug Discovery, iThemba Pharmaceuticals, the South Africa Technology Innovation Agency, the University of California-San Francisco Sandler Center for Drug Discovery, Stanford University, and the University of Cape Town. *About the Pool*, POOL FOR OPEN INNOVATION, http://ntdpool.org/news/partners (last visited Nov. 25, 2011).

[98] BIO VENTURES FOR GLOBAL HEALTH, POOL FOR OPEN INNOVATION AGAINST NEGLECTED TROPICAL DISEASES: CORE PRINCIPLES 1, *available at* http://www.bvgh.org/LinkClick.aspx?fileticket=BOLmqvC-QGM%3d&tabid=164.

[99] *See* Press Release, BIO Ventures for Global Health, South Africa Becomes First Government to Use the Pool for Open Innovation to Stimulate Neglected Disease Drug Research and Development (May 5, 2010), *available at* http://ntdpool.org/news/releases/south-africa-becomes-first-government-use-pool-ope

to the field by lowering the transaction costs associated with locating and licensing multiple patents for potential users. However, the Pool does not appear to grant routinely blanket or boilerplate licenses to its users: it requires case-by-case (and patent-by-patent) assessment, at least partially defeating the rationale for pooling arrangements in the first place.

BVGH has also partnered with the World Intellectual Property Organization (WIPO) in its recent launch of Re:Search.[100] As a database, WIPO Re:Search is a resource where intellectual property—not only patents, but also research tools, compounds, and annotated data—is shared under royalty-free licenses for neglected diseases in LDCs. Re:Search brings together contributions from eight pharmaceutical companies and a dozen non-profit research institutions and broadens the definition of neglected diseases, from FDA's Priority Voucher Program to WHO's definition, most notably including Chagas disease. Regrettably, the inclusion of Chagas disease may mean little since the burden of this disease overwhelmingly falls outside of those countries classified as least developed.[101] The sharing of data could potentially shave years off R&D into neglected disease treatments, but like for Pool for Open Innovation Against Neglected Tropical Diseases, it remains to be seen whether and what value WIPO Re:Search will add for the neglected disease research community: whether transaction costs are really lowered absent a licensing template, and whether patents contributed to this pooled resource had been registered in LDCs in the first place. Not all contributors to WIPO Re:Search necessarily will subscribe to the lowest common denominator of only ensuring royalty-free access in least developed countries. Therefore, a simple step that WIPO could take to better serve the public interest would be to make the licensing conditions of contributors to Re:Search transparent in the database.

Also in 2009, UNITAID had proposed a patent pool that would lower the prices of AIDS drugs in developing countries and facilitate the development of improved

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("The assistance from the pool will help South Africa to meet its twin goals of addressing major health needs, and growing its economy." (quoting Melinda Moree, Chief Executive Officer, BIO Ventures for Global Health)).

[100] *See generally Re:Search: Sharing Innovation in the Fight Against Neglected Tropical Diseases*, WORLD INTELLECTUAL PROP. ORG., http://www.wipo.int/research/en/ (last visited Jan. 9, 2012).

[101] Médecins sans Frontières remarked that by anchoring the WIPO Re:Search initiative to focus only on least developed countries, "WIPO is taking an unacceptable step in the wrong direction by setting the bar for access too low . . ." *Drugmakers Pool Ideas to Battle Tropical Diseases*, REUTERS, Oct. 26, 2011, http://www.reuters.com/article/2011/10/26/us-tropical-diseases-idUSTRE79P7KK20111026. *See also* Hannah Waters, *Patent-Sharing Scheme for Neglected Diseases May Have Catch*, 17 NATURE MED. 1529 (2011).

formulations.[102] By pooling voluntary licenses to component AIDS drugs, the pool would enable generic manufacture of much needed pediatric formulations and novel fixed-dose combinations providing second- and third-line treatment for AIDS.[103] UNITAID subsequently spun off the Medicines Patent Pool to achieve these objectives.[104] From the beginning, the primary point of contention has been the treatment of middle-income countries in the pool's licensing arrangements. When the pool obtained its first license in 2010 from the National Institutes of Health (NIH), that license allowed pool users to use the NIH's patents on an antiretroviral called darunavir "on a world-wide basis and to sell products covered therein in low and middle-income countries."[105] However, the NIH license in and of itself was not sufficient for manufacturing darunavir.[106] The next and most recent license obtained by the pool—in 2011, from Gilead Sciences—was less expansive in its geographical scope, excluding a number of middle-income countries, such as China and Brazil, and limited licensees and manufacturers of the active pharmaceutical ingredients to Indian companies.[107]

A number of useful lessons that may be applicable in other pooling initiatives may be derived from observing such pools develop over time. Should pooling focus more like traditional patent pools on strategically bundling IP for specific target products or broader access to building blocks of knowledge for a research commons? Such decisions will influence whether significant patent holdouts and antitrust issues arise. Complementary strategies such as pooled procurement may also play an important role in determining the demand for these new formulations and ultimately the value added of such initiatives.

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[102] *See generally UNITAID Moves Toward a Patent Pool for Medicines*, UNITAID (July 9, 2008), http://www.unitaid.eu/en/resources/news/113-unitaid-moves-towards-a-patent-pool-for-medicines.html.

[103] *See id.*

[104] *See The Medicines Patent Pool Is Moving*, UNITAID (Nov. 1, 2010), http://www.unitaid.eu/en/resources/news/301-the-medicines-patent-pool-is-moving.html.

[105] MEDICINES PATENT POOL, PUBLIC HEALTH SERVICE: NON-EXCLUSIVE PATENT LICENSE AGREEMENT 1 (2010), *available at* http://www.medicinespatentpool.org/content/download/214/1227/version/1/file/MPPF+Patent+License+Full+Executed+(Sept+2010)-NS.pdf.

[106] MEDICINES PATENT POOL, QUESTIONS AND ANSWERS: THE US NATIONAL INSTITUTES OF HEALTH (NIH) LICENSE TO THE MEDICINES PATENT POOL 1 (2010), *available at* http://www.unitaid.eu/images/news/patentpool/20100930_nih_license_q%26a_en.pdf.

[107] *The Medicines Patent Pool/Gilead Licenses: Questions and Answers*, MEDICINES PATENT POOL, http://www.medicinespatentpool.org/LICENSING/Current-Licences/Medicines-Patent-Pool-and-Gilead-Licence-Agreement/Q-and-A-Gilead-Licences (last visited Jan. 9, 2011).

VI. OPEN-SOURCE COLLABORATION

A number of initiatives have begun to influence current intellectual property rights norms and build on open science and innovation models as a means of enhancing R&D processes in developing countries. As it becomes increasingly clear that ownership of knowledge can impede access to that knowledge and increase the transaction costs of undertaking R&D, better understanding of these impediments has led to approaches that seek to increase access through collaborative research and achieve lower transaction costs through collective management of the ownership of knowledge. These models of collaboration have the potential to lay the foundations for the infrastructure of a knowledge-based economy that is able to meet public health needs in the developing world. A number of these models also highlight the value of South-South collaboration[108] that enhances local ownership and participation in these projects. While some of these efforts may emerge spontaneously from the scientific community, others may require strategic political support and public investment.

A. Open Science

Building on the norms of open science, efforts to bring the tools and philosophy of the free software movement into the wet lab science of drug discovery deserve closer attention. The Open Source Drug Discovery (OSDD) initiative, organized by India's Council of Scientific and Industrial Research, seeks to provide a platform for collaborative research to produce low-cost drugs.[109] Tuberculosis is the first target of the OSDD project. Launched in September 2008, activity has rapidly ramped up on the site, with over 4800 registered participants from 130 countries.[110]

The OSDD approach is to build an open science and innovation model, providing access to the building blocks of knowledge and promoting collaboration among researchers. Its web portal provides a single platform with drug discovery resources, a wiki collaboration system, and a place for sharing molecular research findings.[111] A click-wrap license ensures that findings belong to the OSDD community and that modification and additions are granted back. Though still early-stage, the plans are to license generated knowledge royalty-free to pharmaceutical companies in exchange

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[108] "South-South collaboration" refers to situations in which "collaboration [occurs] between the developing countries themselves." David Dickson, *South-South Collaboration Picks up Steam*, SCIDEV.NET, Nov. 17, 2003, *available at* http://www.scidev.net/en/editorials/southsouth-collaboration-picks-up-steam.html.

[109] *What is OSDD*, OPEN SOURCE DRUG DISCOVERY, http://www.osdd.net/about-us (last visited Nov. 25, 2011).

[110] *Id.*

[111] *See generally Community Developed Network Resources*, OPEN SOURCE DRUG DISCOVERY, http://www.osdd.net/ (last visited Nov. 25, 2011).

for producing these products at the lowest possible prices.[112] Unlike other open source innovation efforts, OSDD does not rely on voluntarism alone, but is backed by Indian government funding (US$46 million).[113] It also taps into a network of over thirty Indian universities and other collaborators, from which voluntary contributions have come. In fact, efforts to compile and re-annotate the TB genome recruited hundreds of volunteers, resulting in completion of the task in four months.[114]

B. Regional Innovation Platforms

In the developing world, emerging economies like China, India, and Brazil have exceptional promise to contribute to pharmaceutical innovation to meet the needs of the world's poor. Many LDCs though lack such infrastructure, trained workers, or capital for R&D. A regional innovation platform could concentrate expert resources and infrastructure, harness the intellectual capital of more than one country, and ensure accountability to multiple governments. Regional cooperation can enable information sharing, networking, and economies of scale.[115] Importantly, regional innovation platforms encourage not only R&D *for* diseases endemic in developing countries, but also *by* those in disease-endemic countries.

On the one hand, if a single laboratory facility were built, then locating that facility in any one country might limit regional buy-in and support for the institution. On the other, a regional innovation platform need not consist of just one facility, but might engage a network of them. Regional ties make repeated interactions more likely, and this may be the foundation for greater cooperation over time. To assess how a regional innovation platform might work, it would be useful to review existing exemplars, from biomedicine and other fields, based in developing countries.

C. Models for a Regional Platform for Innovation

In the 2007 Noordwijk Medicines Agenda, many participants in the Organisation for Economic Co-operation and Development (OECD) High-Level Forum on Medicines for Neglected and Emerging Infectious Disease

> voiced strong support for a more open innovation system that might involve one or multiple virtual networks of researchers from both developed and

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[112] *See What is OSDD*, *supra* note 109.

[113] *See id.*

[114] R. Prasad, *How the Young Brigade Mapped the TB Genome*, THE HINDU, Apr. 15, 2010, http://www.thehindu.com/sci-tech/article397395.ece.

[115] Björn Hettne & Fredrik Söderbaum, *Regional Cooperation: A Tool for Addressing Regional and Global Challenges, in* INTERNATIONAL TASK FORCE ON GLOBAL PUBLIC GOODS, ACHIEVING GLOBAL PUBLIC GOODS 179, 230 (2006).

> developing countries. Networks which encouraged common infrastructures and shared knowledge bases might yield economies of scale. The success of existing initiatives (*e.g.* WHO/TDR, and Product Development Partnerships) suggests how a model of open innovation might be broadened to address multiple infectious diseases, and indeed any market which is small, fragmented or deemed commercially 'unprofitable.'[116]

Initiatives such as the International Center for Diarrheal Disease Research in Bangladesh (ICDDR,B) and the International Vaccine Initiative provide examples of cross-country research collaboration. A world leader in diarrheal disease research,[117] ICDDR,B has contributed to the development of oral rehydration therapy[118] and demonstrated the limits of injectable cholera vaccine and the effective use of the oral vaccine.[119] Though ninety-five percent of its staff are Bangladeshi nationals, the Center has trained over twenty thousand health professionals from seventy-eight countries since its establishment in 1978.[120] ICDDR,B also assists with technology transfer to the developing world and serves as a resource for others. For example, ICDDR,B scientists were called upon to help manage the cholera outbreak among Rwandan refugees a few years ago.[121]

Based in South Korea, the International Vaccine Institute (IVI) was also established at the initiative of UNDP in 1997.[122] Over the following decade, IVI has become an international center for vaccine research and training and focuses on diseases of the

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[116] ORG. ECON. COOPERATION & DEV., NOORDWIJK MEDICINES AGENDA: CHANGING THE FACE OF INNOVATION FOR NEGLECTED AND EMERGING INFECTIOUS DISEASES 4 (2007), *available at* http://www.oecd.org/sti/biotechnology/NMA.

[117] *About Us*, INT'L CTR. FOR DIARRHEAL DISEASE CONTROL IN BANGLADESH, http://www.icddrb.org/who-we-are (last visited Nov. 25, 2011).

[118] INT'L CTR. FOR DIARRHEAL DISEASE CONTROL IN BANGLADESH, STRATEGIC PLAN TO THE YEAR 2010 10 (2003), *available at* http://www.icddrb.org/what-we-do/publications/cat_view/52-publications/10043-icddrb-documents/10059-strategic-plan/10136-strategic-plan-2010.

[119] *See 50 Years of Cholera Research—Continuing to Save Lives*, INT'L CTR. FOR DIARRHEAL DISEASE CONTROL IN BANGLADESH, http://www.supportforlife.org/media-centre/news/2143-50-years-of-cholera-research-continuing-to-save-lives (last visited Nov. 25, 2011).

[120] *Achievements*, INT'L CTR. FOR DIARRHEAL DISEASE CONTROL IN BANGLADESH, http://www.icddrb.org/who-we-are/achievements (last visited Nov. 25, 2011).

[121] *Id.*

[122] *Milestones*, INT'L VACCINE INITIATIVE, http://www.ivi.int/about_us/historycal_landmarks.html (last visited Nov. 25, 2011).

most impoverished, such as typhoid, cholera, and shigella.[123] IVI also spawned the Pediatric Dengue Vaccine Initiative[124] and manages a technical assistance and technology transfer program[125] (e.g., transfer of oral killed whole-cell cholera vaccine to a company in Indonesia and India for manufacture).

IQSensato, a Geneva-based think tank, elaborated further on the idea of a regional platform.[126] Several potential functions for such a platform might include:

> - Establish a searchable interactive database of scientists, centers and services to facilitate information sharing and communications among partners;
>
> - Mobilize academia/scientists with complementary disciplines to work together in priority R&D areas; to attract better funding opportunities;
>
> - Promote establishment of centres of excellence and encourage formal and informal networks among scientists;
>
> - Promote instruments that stimulate sustainable investments through governments and other funding institutions. [127]

Another exemplar, described by the International Task Force on Global Public Goods as "perhaps overdue to be applied to health research,"[128] is the Consultative

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[123] *See Partners*, VI-BASED VACCINES FOR ASIA INITIATIVE, http://viva.ivi.int/Tools/partners.html (last visited Nov. 25, 2011).

[124] *See Milestones*, *supra* note 122.

[125] *Introduction*, INT'L VACCINE INITIATIVE, http://www.ivi.int/about_us/introduction.html (last visited Nov. 25, 2011).

[126] Huda Gashut & Nicoletta Dentico, *The WHO Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property: Taking Leadership in the Eastern Mediterranean Region (EMR)*, 3 IQSENSATO IN FOCUS: EXPERT COMMENTARY & OPINION 1 (2009), *available at* http://www.iqsensato.org/pdf/in-focus-vol-3-no-2.pdf.

[127] *Id.* at 10.

[128] UMA LELE ET AL., HEALTH SYSTEM CAPACITIES IN DEVELOPING COUNTRIES AND GLOBAL HEALTH INITIATIVES ON COMMUNICABLE DISEASES ¶ 152 (2006), *available at* www.umalele.org/publications/health_system_capacities.pdf. The World Economic Forum Task Force on Low-Carbon Prosperity also proposed using the CGIAR model in developing a global network of centers for energy research, in what they call the Consultative Group on International Energy Research (CGIER). Ola Al-Ghazaway, *Task Force Proposes Regional Hubs for Energy Research*, SCIDEV NET, Sept. 29, 2009, http://www.scidev.net/en/news/task-force-proposes-regional-hubs-for-energy-research-1.html.

Group for International Agriculture Research (CGIAR). CGIAR is a global network of fifteen research centers with broad priority areas on research, capacity building, poverty reduction, and policy support, among others. A more recent initiative, supported by TDR (Special Programme for Research & Training in Tropical Diseases), is the African Network for Drugs and Diagnostic Innovation (ANDI).[129] Through partnership among African institutions, ANDI seeks to "creat[e] a sustainable platform for R&D innovation in Africa to address Africa's own health needs."[130]

D. Consultative Group on International Agricultural Research ("CGIAR")

Executed on a global scale, the network of research centers in CGIAR may also inform a regional platform model. The centers each operate independently and have different research priorities, but collectively, the fifteen centers also have the ability to work together and pool resources on a broader scale.[131] In this way, the advantages of each Center on a regional level—to bring economies of scale in pooling resources and capacities or to focus on needs-driven research—can be targeted to specific areas of the world or to specific problems.

There are several other characteristics of CGIAR that make it an innovation platform. With more than two thousand scientists among its fifteen international Centers, it has the technical expertise,[132] and with over US$500 million invested annually into research, it has the necessary funding base.[133] Possessing large global gene banks, it also crucially has the technological base. Eleven of the fifteen CGIAR Centers are

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[129] *African Network for Drugs and Diagnostics Innovation (ANDI): New Network Launched in Abuja, Nigeria*, TDR (Nov. 2008), http://apps.who.int/tdr/svc/publications/tdrnews/issue-81/african-network.

[130] *ANDI*, AFRICAN NETWORK FOR DRUGS AND DIAGNOSTICS INNOVATION, http://www.andi-africa.org/home-front-page/about-andi (last visited Nov. 25, 2011).

[131] As one example, three CGIAR Centers focus on rice – the International Rice Research Institute in the Philippines, the African Rice Center in Benin, and the Centro Internacional de Agricultura Tropical in Colombia. While these three Centers are located in different regions of the world and each face problems for their specific climate and regional needs, they collaborate to accomplish shared goals. This collaboration created the New Rices for Africa (NERICAs) program, which combines the high productivity of Asian rice species with the hardiness of African rice species. NERICAs are now planted on an estimated 100,000 hectares in Africa, and in Guinea alone, NERICAs have saved the country approximately US$13 million in rice imports. *See Research & Impact: Areas of Research: Rice*, CONSULTING GROUP ON INT'L AGRIC., RESEARCH, http://cgiar.org/impact/research/rice.html (last visited Nov. 25, 2011); *Research & Impact: Snapshot of CGIAR Impacts*, CONSULTING GROUP ON INT'L AGRIC. RESEARCH, http://cgiar.org/impact/snapshots_impacts.html (last visited Nov. 25, 2011).

[132] ALLIANCE OF THE CGIAR CENTERS, WHAT IS THE ALLIANCE? 1 (2008), *available at* www.cgiar.org/pdf/alliance_What%20is%20the%20alliance.pdf.

[133] *Id.*

tasked with maintaining the CGIAR gene banks, which hold 650,000 accessions of wild and domesticated crops in the public domain.[134] CGIAR is committed to making this information available "as global public goods,"[135] and it uses standard Material Transfer Agreements to keep it that way.[136] Gleaning best practices from the CGIAR, this may serve as a model to support an international platform for health research.

E. African Network for Drugs and Diagnostics Innovation (ANDI)

ANDI is "a platform to help support African institutions to participate in discovering, developing and manufacturing the health products they need the most."[137] ANDI represents an effort to strengthen national capacity in developing countries to address local health needs, by promoting and sustaining African-led R&D innovation through the discovery, development, and delivery of affordable new tools, including those based on traditional medicines.[138] An analysis of health R&D capacity in Africa—as measured by research articles and clinical trials—suggests that "diseases disproportionately affecting Africa are under-prioritized."[139] Coordinated by an African-based secretariat, ANDI is intended to harness systematically the available research capacity in the region by providing an institutional framework that will source, manage, and grant funding to support network activities, while proactively establishing sustainable funding mechanisms for its operations.[140]

The expectation is that ANDI will be able to provide a robust collaborative structure to expand and extend the African-led research, such as that at the National Institute for Pharmaceutical Research and Development in Nigeria and the Kenya Medical Research Institute, which has led to the development of a natural-products-based formulation for the treatment of sickle-cell anemia and diagnostic kits for hepatitis B

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[134] *Research & Impact: Genebanks & Databases*, CONSULTING GROUP ON INT'L AGRIC. RESEARCH, http://cgiar.org/impact/genebanksdatabases.html (last visited Nov. 25, 2011).

[135] *Id.*

[136] The seed collections are available to all researchers and have facilitated agricultural development in countries recovering from conflict (Afghanistan, Somalia) or natural disasters (Honduras, Nicaragua). *Id.* The CGIAR gene banks serve as the jumping-off point for crop improvement, and over eighty percent of the seed samples distributed in the past decade have gone to universities and national agricultural research systems for this purpose. *Id.*

[137] Marc Twagirumukiza, *Drugs and Diagnostic Innovation in the Developing World: A Review and Call for Debate*, THE SCI. ADVISORY BOARD, http://www.scienceboard.net/community/perspectives.231.html.

[138] *See ANDI*, *supra* note 130.

[139] Solomon Nwaka et al., *Developing ANDI: A Novel Approach to Health Product R&D in Africa*, 7 PLOS MED, June 2010, at e1000293, 2 fig. 1 (2010), *available at* http://www.plosmedicine.org/article/info%3Adoi%2F10.1371%2Fjournal.pmed.1000293.

[140] *See ANDI*, *supra* note 130.

and HIV.[141] Although still in its early stage of development, the WHO Department of Public Health, Innovation and Intellectual Property has singled out ANDI as an example of the collaboration needed for GSPOA implementation.[142]

VII. CONCLUSION: ENSURING ACCOUNTABILITY IN MAKING IP WORK FOR GLOBAL HEALTH

Technologies, particularly those that offer innovations for health, can help achieve the Millennium Development Goals. Reduced malaria incidence as a result of disease control programs has contributed to higher household incomes in endemic areas.[143] In Vietnam the sixty percent decline in malaria in the 1990s translated into a US$180 million annual economic benefit.[144] Ensuring access to simple health innovations, such as a de-worming treatment program based out of a primary school, not only improved childhood health but also reduced school absenteeism by one-quarter and was less costly than other ways of boosting school participation.[145] Oral rehydration therapy has prevented deaths from diarrhea, but an affordable rotavirus vaccine could be more cost effective, prevent childhood mortality, and improve school attendance.[146] In environments where women otherwise lack control over the use of barrier contraception that might prevent sexually transmitted disease or pregnancy, a microbicide gel can protect them from infection, providing them a means of control and empowerment.[147]

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[141] Tom Mboya-Okeyo et al., *The African Network for Drugs and Diagnostics Innovation*, 373 LANCET 1507, 1507–08 (2009).

[142] *See* WORLD HEALTH ORG., REPORT: PLANNING MEETING WITH REGIONAL ADVISERS ON MEDICINES FOR THE IMPLEMENTATION OF THE GLOBAL STRATEGY AND PLAN OF ACTION ON PUBLIC HEALTH, INNOVATION AND INTELLECTUAL PROPERTY (26-27 AUGUST 2009) 3 (2009), *available at* http://www.who.int/phi/documents/PlanningMeetingwithRegionalAdvisersonMedicinesfortheImplementationoftheGSPOA.pdf.

[143] Jürg Utzinger et al., *The Economic Payoffs of Integrated Malaria Control in the Zambian Copperbelt Between 1930 and 1950*, 7 TROPICAL MED. & INT'L HEALTH 657, 657 (2002).

[144] Ramanan Laxminarayan, *Does Reducing Malaria Improve Household Living Standards?*, 9 TROPICAL MED. & INT'L HEALTH 267, 271 (2004).

[145] *See generally* Edward Miguel & Michael Kremer, *Worms: Identifying Impacts on Education and Health in the Presence of Treatment Externalities*, 72 ECONOMETRICA 159 (2004).

[146] *See generally* Deborah Atherly et al., *Rotavirus Vaccination: Cost-Effectiveness and Impact on Child Mortality in Developing Countries*, 200 J. INFECTIOUS DISEASES S28 (2009), *available at* http://jid.oxfordjournals.org/content/200/Supplement_1/S28.long; Atanacio Valencia-Mendoza et al., *Cost-Effectiveness of Introducing a Rotavirus Vaccine in Developing Countries: The Case of Mexico*, 8 BMC INFECTIOUS DISEASES 103 (2008), *available at* http://www.biomedcentral.com/1471-2334/8/103.

[147] GLOBAL CAMPAIGN FOR MICROBICIDES, GIVING WOMEN POWER OVER AIDS (2010).

Expanding access to these innovations will be equally important. By taking measure of innovation, perhaps greater progress might be made towards these twin goals of innovation and access as well as towards prioritizing efforts to diagnose, prevent, and treat those in disease-endemic countries. There are several existing indices that measure innovation, but they may not be adapted specifically for measuring factors specific to non-paying markets for neglected diseases, nor do they adequately capture the root causes of poverty, such as a country's ability to innovate to address its own problems. In other innovation indices that are created for use in developed countries, attention has often been focused on the capacity to innovate and on the input factors, such as R&D investment, human capital, resources invested in R&D, and diffusion of old or new technologies. Such inputs are then typically correlated to intermediate outputs, such as patent counts or royalty receipts, and outcomes such as GDP per capita. They fail to focus on either the environment for innovation or the actual progress towards innovation.[148]

Though not specific to health technologies, TRIPS Article 66.2 sets down important reciprocal obligations upon WTO member states: "Developed country Members shall provide incentives . . . for the purpose of promoting and encouraging technology transfer to least-developed country Members in order to enable them to create a sound and viable technological base."[149] More focused on public health concerns, such obligations are echoed in paragraph 7 of the Doha Declaration: "We reaffirm the commitment of developed-country Members to provide incentives to their enterprises

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[148] For example, the UNCTAD Innovation Capability Index (UNICI) is comprised of the Technological Activity Index (R&D personnel, patents granted and scientific publications per million population) and the Human Capital Index (literacy rate as percent of population, secondary school as percent of population, and tertiary enrollment as percent of age group). While perhaps useful as a global gestalt of innovation capability, such an index is likely to be insensitive to a host of indicators of pharmaceutical innovation in emerging economies—open science collaboration, conduct of clinical trials in-country, collaborative research signified by co-authored papers between North and South, and generic manufacturing capacity. For a discussion of some of these factors, see generally Solomon Nwaka et al., *supra* note 139. The shortcomings in developing an innovation index not only come from data limitations, but also, as Francis Gurry, Director-General of the World Intellectual Property Organization noted in introducing *The Global Innovation Index 2011*, "there is no clear understanding of which factors interact in specific country settings and how to influence innovation. Many factors—say, the number of science PhDs—may not operate in an identical manner across different countries." As he acknowledges, "Even less is known about how new products and processes come about in developing countries, how innovation diffuses, and what its impacts are." Francis Gurry, *Foreword* to INSEAD, THE GLOBAL INNOVATION INDEX 2011: ACCELERATING GROWTH AND DEVELOPMENT, at xi (Soumitra Dutta ed. 2011) (forward entitled *Why Innovation is Important*).

[149] *TRIPS Agreements*, *supra* note 8, art. 66.2.

and institutions to promote and encourage technology transfer to least-developed country Members pursuant to Article 66.2."[150]

While systems like the U.S. Trade Representative's Special 301 Report[151] monitor compliance with TRIPS or TRIPS-Plus IP provisions, similar monitoring for compliance with TRIPS Article 66.2 is lacking. A study examining such compliance found both failure of developed countries to report their technology transfer activities and failure to carry out programs that would qualify as technology transfer to LDCs.[152] Of the 292 programs reported, thirty-one percent target WTO members that are LDCs, but only twenty-two percent of the 292 programs reporting would qualify as technology transfer to WTO LDCs.[153]

Narrowing the health gap between industrialized and developing countries will be challenging, and new threats to this goal continue to emerge.[154] The strategic use of intellectual property rights, particularly by the public and philanthropic sectors, can play a significant role. While tiering and pooling approaches address how the inputs and outputs of research are organized, open source approaches focus more on the means of knowledge production, both lowering barriers to collaboration and engaging end-users. Building regional innovation platforms can also bolster local capacity to respond to these public health challenges and to enable those in disease-endemic countries to participate in innovation. In meeting the twin goals of innovation and access, these approaches show how policymakers might make IP work for global health.

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[150] *Doha Declaration on the TRIPS Agreement and Public Health*, ¶ 7, WT/MIN(01)/DEC/W/2 (Nov. 14, 2001).

[151] This report is an "annual review of the global state of intellectual property rights (IPR) protection and enforcement" and "identifies a wide range of concerns, including… ongoing, systemic IPR enforcement issues presented in many trading partners around the world." RONALD KIRK, OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE, 2011 SPECIAL 301 REPORT 1 (2011), *available at* http://www.ustr.gov/webfm_send/2841.

[152] SUERIE MOON, INTERNATIONAL CENTRE FOR TRADE AND DEVELOPMENT, POLICY BRIEF NUMBER 2: DOES TRIPS ART. 66.2 ENCOURAGE TECHNOLOGY TRANSFER TO LDCS? (2008), *available at* http://www.unctad.org/en/docs/iprs_pb20092_en.pdf.

[153] *Id.* at 5–6.

[154] On multiple fronts, efforts are afoot that risk placing commercial interests over public health in applying IPRs. The Trans-Pacific Partnership Agreement negotiations, the Novartis lawsuit in India over Section 3(d) of the India Amended Patents Act (2005), and the European Union-India free trade agreement negotiations each raise concerns that threaten the achievement of the goal of applying IPRs strategically for public health. *See* Brook K. Baker, *Novartis, Big Pharma, and Their US and EU Surrogates Throw a Triple Punch at Indian Generics*, ACT UP-BASEL (Feb. 10, 2012), http://actupbasel.org/actupbasel/?Novartis-Big-Pharma-and-their-US.