

Closing the Access Gap: The Equitable Access License

Introduction

The astounding mortality rates for HIV/AIDS in the developing world,¹ despite the demonstrated life-saving capacity of antiretroviral therapies,² have focused international attention on the issue of access to medicines.³ Indeed, as of late 2003, more than ninety-eight percent of Africans affected by AIDS and more than ninety-three percent of those in “urgent need” worldwide lacked access to antiretroviral drug treatment (ARVs).⁴ But the problem is not limited to HIV/AIDS: One-third of the world’s population lacks regular access to essential medicines.⁵ The systematic inability of disease victims in many low and middle income (LMI)

¹ Approximately ninety-five percent of AIDS-related deaths occur in the developing world. *See* UNAIDS, AIDS EPIDEMIC UPDATE 5 (Dec. 2003). Sub-Saharan Africa, for example, is home to just eleven percent of the world’s population but accounts for more than two-thirds of HIV infections worldwide and eighty percent of AIDS-related deaths. *See id.* at 5, 7; WORLD HEALTH ORG., THE WORLD HEALTH REPORT 2004, at 1 (2004). While the estimated annual number of AIDS-related deaths in the United States and Western Europe has declined significantly since the mid-1990s, it has increased in developing regions. *See, e.g.*, UNAIDS, *supra*, at 13; WORLD HEALTH ORG., *supra*, at 5-7; CTRS. FOR DISEASE CONTROL & PREVENTION, HIV/AIDS SURVEILLANCE REPORT 7 (2002), <http://www.cdc.gov/hiv/stats/hasr1402/2002SurveillanceReport.pdf>; *see also* John Donnelly, *UN Says AIDS Deaths at New High*, BOSTON GLOBE, Nov. 26, 2003, at A1.

² *See, e.g.*, Frank J. Palella et al., *Declining Morbidity and Mortality Among Patients with Advanced Human Immunodeficiency Virus Infection*, 338 NEW ENG. J. MED. 853 (1998) (describing the reduction in AIDS-related mortality by more than seventy percent in Europe and the United States after the introduction of combination antiretroviral therapies); G.J. Dore et al., *Impact of Highly Active Antiretroviral Therapy on Individual AIDS-defining Illness Incidence and Survival in Australia*, 29 J. ACQUIRED IMMUNE DEFICIENCY SYNDROME 388 (2002) (providing more recent data); World Health Org., Fact Sheet 274: The 3 x 5 Initiative (Dec. 2003), at <http://www.who.int/mediacentre/factsheets/2003/fs274/en/> (citing the drop in AIDS-related mortality in Brazil following the introduction of antiretrovirals); *see also* Robert Steinbrook, *Beyond Barcelona—The Global Response to HIV*, 347 NEW ENG. J. MED. 553, 553 (2002) (describing the “striking contrast between the countries where people are dying from AIDS and the countries where they are receiving effective therapy”); Robin A. Weiss, *HIV and AIDS: Looking Ahead*, 9 NATURE MED. 887 (2003) (comparing the rapid decline in AIDS mortality in the United States following the introduction of highly active antiretroviral therapy, with the continually rising mortality rate in sub-Saharan Africa).

³ *See, e.g.*, Cecilia Oh, *The Fight for Affordable Medicines for All*, Third World Network, at <http://www.twinside.org.sg/title/twr145j.htm> (last visited May 13, 2004); *cf.* Pres. George W. Bush, State of the Union at the U.S. Capitol (Jan. 28, 2003). Although the phrase “access to medicines” is used, increasingly it is used to refer to diagnostics and disease monitoring tools, as well as therapeutics.

⁴ WORLD HEALTH ORG., *supra* note 1, at 8, 21; Agence France-Presse, *Most AIDS Sufferers in Africa Lack Access to Drugs* (Sept. 2, 2003), <http://www.aegis.com/news/afp/2003/AF030905.html>.

⁵ *See* World Health Org., Essential Drugs and Medicines Policy, at <http://www.who.int/medicines>. “Essential medicines are those that satisfy the priority health needs of the population. They are selected with due regard to public health relevance, evidence of efficacy and safety, and comparative cost-effectiveness.” *Id.*

countries⁶ to obtain essential medicines, termed the “access gap,” constitutes perhaps the most troubling humanitarian crisis of our age.

In the twenty-seven years since the World Health Organization (WHO) first identified the concept of an essential medicine,⁷ governments, intergovernmental organizations, and nongovernmental organizations have taken important steps to promote access.⁸ However, the expense and inadequate distribution of medicines remain major obstacles to access.⁹ As a result, much of the effort by activists over the last decade—spurred by the HIV/AIDS crisis, as well as by developments in U.S.-led trade policies—has focused on controlling drug prices, reforming international standards for intellectual property (IP) protections, and promoting the development and sales of generic pharmaceuticals. These efforts have, to date, achieved limited successes; a number of factors—particularly the continued growth and influence of multinational pharmaceutical companies and the strengthening of intellectual property protections

⁶ For an explanation of the World Bank’s country classification scheme, see The World Bank Group, Data and Statistics: Country Classification, at <http://www.worldbank.org/data/countryclass/countryclass.html>; for a list of countries by category, see The World Bank Group, Data and Statistics: Country Groups, at <http://www.worldbank.org/data/countryclass/classgroups.htm>.

⁷ The WHO generated its first Model List of Essential Drugs in 1977 and in 1978 declared the provision of essential drugs to be one of the eight basic elements of primary health care. Jonathan D. Quick, Editorial, *Essential Medicines Twenty-five Years On: Closing the Access Gap*, 18 HEALTH POL’Y & PLANNING 1, 1 (2003). The current list of essential drugs at <http://www.who.int/medicines> includes several ARVs for HIV/AIDS.

⁸ For example, over one hundred countries have developed national drug policies. Quick, *supra* note 7. Some governments, including Canada and Brazil, have taken steps to help populations in other countries achieve improved access to medicines. See, e.g., Keith Alcorn, *Canada Passes Law To Allow Generic HIV Drug Exports*, AIDSmap News (May 15, 2004), at <http://www.aidsmap.com/en/news/FD244B62-0D5A-474E-954D-9EF99C2BFE39.asp>; Karyn Schwarz, *Brazil: A Model Response to AIDS*, Online NewsHour, at http://www.pbs.org/newshour/health/global/generics_wto.html (last visited June 14, 2004); see also Rick Mullin, *Drug Availability*, CHEMICAL & ENGINEERING NEWS, June 2, 2003, at 11, <http://www.pubs.acs.org/cen/topstory/8122/8122notw5.html> (describing efforts by the EU to facilitate differential pricing in poor countries). Information about the efforts and achievements of intergovernmental and nongovernmental organizations are available from a host of sources. See, e.g., MÉDECINS SANS FRONTIÈRES, SURMOUNTING CHALLENGES: PROCUREMENT OF ANTIRETROVIRAL MEDICINES IN LOW- AND MIDDLE- INCOME COUNTRIES (2003) [hereinafter MSF, SURMOUNTING CHALLENGES], <http://www.accessmed-msf.org/documents/procurementreport.pdf>; Oxfam Int’l, *Cut the Cost: Impact Study* (2004) (unpublished manuscript, on file with authors).

⁹ See *infra* Section I.B. The director of the WHO’s Essential Drugs and Medicines Policy has remarked that “[p]rices for newer medicines have been of particular concern in recent years.” Quick, *supra* note 7, at 3.

internationally—have led some commentators to anticipate that the access gap will grow wider in years to come.¹⁰

The time has come to think broadly about the access problem and to consider all of the potential avenues for change—to look upon all the players in the political economy of drug development and distribution (not just the most obvious: the major pharmaceutical companies and national governments), and to consider what each might do differently. This paper focuses on the role of universities in the development and commercialization of health-related innovations and argues that universities should take collective steps to narrow the access gap by ensuring that the fruits of their research are widely available and affordable. We contend that universities are uniquely positioned to facilitate access in LMI countries through their technology transfer licensing agreements with pharmaceutical and biotech firms.¹¹

In Part I, we review the access gap and its principal causes. We also discuss the “10/90 gap”—the striking observation first made by the Committee on Health Research for Development¹² that “only 10% of the world expenditure on health R&D is spent on health conditions that represent 90% of the global [disease] burden.”¹³ Due to the paucity of

¹⁰ See, e.g., OXFAM INT’L, UNDERMINING ACCESS TO MEDICINES: COMPARISON OF FIVE US FTAs (2004), http://www.oxfamamerica.org/pdfs/fta_comparison.pdf; Mary Crewe, *Spectacular Failure—A View from the Epicenter*, 4 YALE J. HEALTH POL’Y L. & ETHICS 157 (2004).

¹¹ Another approach to this discussion would begin with the unique relationship between universities and drug development. Such a paper would argue from beliefs about the unique responsibilities and capabilities of universities (perhaps particularly in the sciences, following the Mertonian tradition)—it would be driven by concerns about the current practices of universities and a sense that changes in their drug licensing and commercialization policies would be a significant step toward the realization of public-minded ideals. Cf. DEREK BOK, *UNIVERSITIES IN THE MARKETPLACE: THE COMMERCIALIZATION OF HIGHER EDUCATION* (2003). While we discuss the normative implications of the access gap for universities at some length, *infra* Section III.A, we have chosen to start this paper by focusing on the magnitude of the access gap because it is this humanitarian crisis that fundamentally motivates our advocacy-oriented argument.

¹² COMM’N ON HEALTH RESEARCH FOR DEV., *HEALTH RESEARCH, ESSENTIAL LINK TO EQUITY IN DEVELOPMENT* (1990).

¹³ U.N. Dev. Programme, *Incentives to Reduce the 10/90 Gap* (2002), <http://www.undp.org/ods/monterrey-sideevent/incentive.pdf>; see also Global Forum for Health Research, *10/90 Report on Health Research 2003-2004* (forthcoming May 2004), <http://www.globalforumhealth.org/pages/index.asp>. The WHO’s Commission on Macroeconomics and Health has estimated that less than five percent of worldwide pharmaceutical R&D expenditures target diseases that primarily affect populations in developing countries. COMM’N. ON MACROECONOMICS & HEALTH, WORLD HEALTH ORG., *MACROECONOMICS AND HEALTH: INVESTING IN HEALTH FOR ECONOMIC DEVELOPMENT* 79, n.103 (2001),

commercial incentives, there is a striking lack of R&D—and thus treatments—for diseases that primarily affect the poor in developing countries,¹⁴ frequently termed “neglected diseases.”¹⁵ Part I concludes with a survey of current strategies to combat the access gap, and suggests that while some of these may be potentially promising, they leave considerable room for additional, novel approaches.

In Part II, we analyze the current structure of university research and technology commercialization efforts. This Part explains how a variety of patenting and regulatory practices can prevent access to health technologies derived from university inventions. These practices may impede patient access to both therapeutic and diagnostic end products, as well as inhibit the availability of research tools and technologies for scientists.

In Part III, we offer arguments to support our claim that universities can and should use licensing agreements to promote access to end products and to encourage research and development of products for neglected diseases. We maintain that this can occur at minimal financial cost to universities and their pharmaceutical firm licensees, and with substantial gains for the global poor and for universities themselves. We further suggest that this approach to licensing is not only legally and economically feasible for universities but fundamentally aligned with their institutional ethos. Finally, we include a brief summary of recent developments that lend support to the view that such change in university policy is attainable.

In Part IV, we present and explain a draft set of model licensing provisions—referred to as the Equitable Access License (EAL)—which universities can incorporate into technology

<http://www3.who.int/whosis/menu.cfm?path=whosis,cmh&language=english> (discussing a number of estimates of R&D allocation).

¹⁴ See Patrice Trouiller et al., *Drug Development for Neglected Diseases: A Deficient Market and a Public-Health Policy Failure*, 359 LANCET 2188, 2190 (2002). Only one percent of all new medications introduced between 1975 and 1999 were for the treatment of such diseases. Press Release, Médecins Sans Frontières, Drugs for Neglected Diseases Initiative: Teaming Up To Address Neglect (Mar. 12, 2003), <http://www.accessmed-msf.org/prod/publications.asp?scntid=12320031354463&contenttype=PARA&>.

¹⁵ Alternative terms include developing world diseases, Southern diseases, and tropical diseases.

transfer agreements to facilitate LMI country access to medicines.¹⁶ The EAL seeks to address access gaps that result from legal monopoly-based supply and pricing. To this end, the EAL borrows conceptually from developments in software licensing—such as the General Public License and the open source movement—in using intellectual property rights to promote nonexclusive, open market access rather than to protect exclusive market control.¹⁷ When an access gap with respect to a health product derived from university research is identified in a particular country, the EAL automatically removes patent, regulatory and production barriers for that country. This open licensing approach should enable entry of generic suppliers, catalyzing substantial price reductions.¹⁸ The EAL also applies a similar open licensing structure to facilitate research focused on neglected diseases.

Finally, we offer some preliminary recommendations for encouraging uptake and implementation of the EAL. While particularly relevant to technology transfer professionals, the EAL and the arguments in its support have important implications for a range of decision-makers including federal legislators and agencies, university administrators, intellectual property lawyers, and global health care advocates.

¹⁶ The EAL (formerly known as the Developing Country License or DCL) has been developed by an interdisciplinary working group at Yale University. Members of the working group include Sanjay Basu, Yochai Benkler, Samantha Chaifetz, Amy Kapczynski, David Scales, and Rahul Rajkumar. The group is affiliated with the Yale AIDS Network, <http://www.yale.edu/aidsnetwork>, and Universities Allied for Essential Medicines (UAEM), <http://www.essentialmedicines.org>. This paper attempts to provide context for the EAL and to articulate the arguments—complete with a review of relevant literature—that support and explain its provisions. A current draft of the EAL is included here at Appendix A.

¹⁷ Cf. The GNU General Public License: Preamble, Open Source Initiative, at <http://www.opensource.org/licenses/gpl-license.php> (“The licenses for most software are designed to take away your freedom to share and change it. By contrast, the GNU General Public License is intended to guarantee your freedom to share and change free software—to make sure the software is free for all its users.”) (last visited May 13, 2004); Creative Commons, About Us, at <http://creativecommons.org/learn/aboutus/> (“We use private rights to create public goods: creative works set free for certain uses.”) (last visited May 13, 2004). While the EAL is not truly an “open source” strategy, a term that describes software such as the Apache Web server and the Linux operating system for which source code is made freely available for experimentation and improvement by independent software developers, it mimics open source software’s approach to intellectual property rights, most explicitly by ensuring that certain research tools remain freely available under a non-exclusive, open license. EAL, App. A., Parts 2, 3(b), 5, described *infra* Part IV.

¹⁸ See discussion *infra* Part IV.

I. Inequitable Access to Research and Medicines

A. Defining the Access Gap

Millions of poor people, largely in LMI countries, die each year from preventable and treatable diseases.¹⁹ HIV/AIDS is the world's leading cause of death for those aged fifteen to fifty-nine,²⁰ killing more than three million people in 2003;²¹ other treatable diseases such as tuberculosis infections are also ravaging LMI countries.²² The public health situation is particularly dire in Africa, where life expectancy is shrinking in many countries and has fallen by as much as twenty years in some.²³

Drugs to treat life-threatening diseases in LMI countries increasingly exist—particularly for global conditions (i.e., those affecting both LMI and high-income country populations).²⁴ For example, effective ARVs for the treatment of HIV/AIDS have been available for seventeen years,²⁵ yet fewer than two percent of Africans in need of antiretroviral therapy,²⁶ and only 400,000 of the six million HIV/AIDS victims worldwide in need of antiretroviral therapy,²⁷ are

¹⁹ See Ellen F.M. 't Hoen, *The Responsibility of Research Universities to Promote Access to Essential Medicines*, 2 YALE J. HEALTH POL'Y L. & ETHICS 293, 293 (2003) (citing WORLD HEALTH ORG., THE WORLD HEALTH REPORT 2002, at 186-87 (2002)).

²⁰ WORLD HEALTH ORG., KEY FACTS FROM THE WORLD HEALTH REPORT 2004, at 1, at http://www.who.int/whr/2004/en/facts_en.pdf (last visited Aug. 28, 2004).

²¹ WORLD HEALTH ORG., *supra* note 1, at 2.

²² World Health Org., Fact Sheet 104: Tuberculosis (Mar. 2004), at <http://www.who.int/mediacentre/factsheets/fs104/en/>.

²³ WORLD HEALTH ORG., *supra* note 1, at 4-7.

²⁴ See Kevin Outterson, *Pharmaceutical Arbitrage*, 5 YALE J. HEALTH POL'Y L. & ETHICS (forthcoming 2005) (manuscript at 28, on file with authors) (defining and discussing global diseases, including AIDS); Jean O. Lanjouw, A Patent Policy Proposal for Global Diseases (June 11, 2001), [hereinafter Lanjouw, A Patent Policy Proposal], http://econ.worldbank.org/files/1733_lanjouw.pdf.

²⁵ AZT (zidovudine), the first antiretroviral medicine, became commercially available in 1987. Elizabeth Davies, *Update on Antiretroviral Therapy*, 264 PHARMACEUTICAL J. 96 (2000), <http://www.pharmj.com/Editorial/20000115/education/antiretroviral.html>.

²⁶ WORLD HEALTH ORG., *supra* note 1, at 8; see also The Henry J. Kaiser Family Found., *Number of HIV-Positive Africans on AIDS Drugs Doubled in Second Half of 2003, Accelerating Access Initiative Says*, Kaiser Daily HIV/AIDS Report (Mar. 19, 2004), at http://www.kaisernetwork.org/daily_reports/rep_hiv_recent_rep.cfm?dr_DateTime=03-19-04&show=yes#22772 (reporting that, due to a significant increase in 2003 in the number of HIV-positive Africans treated, the total has reached two percent).

²⁷ WORLD HEALTH ORG., *supra* note 1, at 8.

receiving treatment. The results of the access gap are tragic: In major southern African countries lack of widespread treatment for HIV/AIDS and opportunistic infections such as tuberculosis are expected to lead to adult population reductions of eleven to nineteen percent over the next two years.²⁸

Importantly, this is not only a problem for people living with HIV/AIDS. The access gap impacts a wide range of drugs, from cancer fighting therapies to cardiovascular medications.²⁹ The problem likewise affects those suffering from neglected diseases: While development of additional drugs targeting neglected developing world diseases is crucial to improving global health,³⁰ lack of access to existing medicines remains a major challenge.³¹

²⁸ J. S. Mukherjee et al., *Tackling HIV in Resource Poor Countries*, 327 *BMJ* 1104, 1104 (2003) (citing UNAIDS, REPORT ON THE GLOBAL HIV/AIDS EPIDEMIC (2002)) (discussing Zimbabwe, Botswana, and South Africa).

²⁹ See, e.g., Consumer Project on Technology, Gleevec/Glivac, at <http://www.cptech.org/ip/health/gleevec/index.html> (providing information on the campaign in South Korea for access to Novartis's highly effective leukemia drug). "[P]atients in developing countries are increasingly suffering from non-communicable diseases and health problems previously associated with rich countries." JENNIFER BRANT, ROBBING THE POOR TO PAY THE RICH (Oxfam Briefing Paper No. 56, Nov. 2003), http://www.oxfam.org.uk/what_we_do/issues/health/bp56_medicines.htm. The second and third most frequent causes of death in developing countries are cancer and cardiovascular disease, respectively. See WORLD HEALTH ORG., THE WORLD HEALTH REPORT 2003, at 14 (2003). Non-communicable diseases—such as diabetes, cancer, cardiovascular disease, and chronic respiratory disease—“account for some 60% of global deaths and almost half (47%) of the global disease burden.” World Health Org., Noncommunicable Diseases and Mental Health Cluster, at http://www.who.int/noncommunicable_diseases/en/. Although these conditions are associated with the developed world (and they are being treated by a large and growing array of medicines in high-income countries), LMI country residents experience the majority of death, disability, and morbidity from these conditions. *Id.*

³⁰ See discussion *infra* Section I.C. There are at least some drugs in clinical development for developing world diseases such as malaria, leishmaniasis, and tuberculosis. Cf. Trouiller et al., *supra* note 14, at 2189 (reporting that in 2001 there were six drugs in the late stages of development and another twelve projects in early development for a handful of neglected diseases).

³¹ For example, leishmaniasis currently affects approximately twelve million people—ninety percent of whom reside in five developing countries. Treatment exists; however, the branded form of the most commonly applicable treatment costs \$150 per treatment course. In African countries, where the generic form is not available, there is a severe lack of access. Médecins Sans Frontières, The Campaign: Target Diseases, Leishmaniasis, at <http://www.accessmed-msf.org/campaign/lsh01.shtm> (last visited June 14, 2004).

Human African trypanosomiasis (Sleeping Sickness)—a disease found in remote stretches of sub-Saharan Africa—is fatal if untreated; “it is a threat to 60 million people, only 7% of whom have access to diagnosis and treatment.” Médecins Sans Frontières, The Campaign: Target Diseases, Sleeping Sickness, at <http://www.accessmed-msf.org/campaign/slp01.shtm> (last visited June 14, 2004).

B. Causes of the Access Gap

What causes the access gap? Relatively high prices, inadequate health care delivery infrastructure, and lack of political will appear to be the three major contributors, often combining to make medicines unavailable and/or unaffordable to those in need.³² Of these, drug prices—particularly *retail* drug prices—present the most significant barrier to access in many LMI countries.³³

“Prohibitive drug prices are often the result of IP protection, which usually takes the form of a patent.”³⁴ Under current U.S. law, a patent provides for a twenty-year period of exclusivity during which the patent holder can exclude others from making, selling, using or importing the patented innovation.³⁵ The World Trade Organization’s (WTO) Agreement on Trade-Related Aspects of Intellectual Property (TRIPS) also establishes twenty-year patent protection as a minimum standard for member nations—to be implemented by the least developed nations by 2016.³⁶

Offering this limited or temporary monopoly is intended to reward those who have contributed, in the words of the U.S. Constitution, to the “progress of science and useful arts.”³⁷

³² A search for the most fundamental causes of the access gap would likely identify macroeconomic factors such as a country’s level of economic development, per capita wealth, and the quality of its education system. Rather than discussing approaches to reducing global poverty, this paper focuses on the more immediate, health care-related causes of the access gap, causes which appear to be addressable via targeted, domain-specific solutions.

³³ ‘t Hoen, *supra* note 19, at 294; Juan Rovira, *Trade Agreements, Intellectual Property, and the Role of the World Bank in Improving Access to Medicines in Developing Countries*, 4 YALE J. HEALTH POL’Y L. ETHICS 401, 401 (2004).

³⁴ ‘t Hoen, *supra* note 19, at 294.

³⁵ 35 U.S.C. § 154 (2000); 35 U.S.C. §§ 101-112, 271 (2000). The Patent Act of 1952 established the United States’ statutory requirements for patenting: that it be patentable subject matter, non-obvious, with utility, adequately disclosed, and precisely claimed. Act of July 19, 1952, ch. 950, 66 Stat. 792 (codified at 35 U.S.C.).

³⁶ Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, art. 27.1, Legal Instruments—Results of the Uruguay Round vol. 31, 33 I.L.M. 81 (1994) [hereinafter TRIPS Agreement]. The timeline for implementation was most recently amended by the *Doha Declaration on TRIPS and Public Health*. World Trade Org., Doha WTO Ministerial 2001, *Declaration on the TRIPS Agreement and Public Health*, WT/MIN(01)/DEC/2, at ¶ 7 (Nov. 20, 2001) [hereinafter *Doha Declaration on TRIPS and Public Health*].

³⁷ U.S. CONST. art. I., § 8, cl. 8. (“To promote the progress of science and useful arts, by securing for limited times, to . . . inventors the exclusive rights to their . . . discoveries.”)

The economic opportunity that patent-based (or regulation-based³⁸) exclusivity promises is designed to encourage private investment in innovation.³⁹ This “innovation theory of IP law”⁴⁰

³⁸ See Rovira, *supra* note 33, at 401. In the United States, there are a number of examples of regulatory-based exclusivity for pharmaceuticals. Products are given six months of exclusivity for having conducted pediatric clinical studies. 21 U.S.C. § 355a(a) (2000); see U.S. FOOD & DRUG ADMIN., THE PEDIATRIC EXCLUSIVITY PROVISION: STATUS REPORT TO CONGRESS (Jan. 2001). Drugs for orphan conditions are also granted an exclusive marketing period. 21 U.S.C. § 360aa (2000). Finally, the Hatch-Waxman Act—Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (codified as amended in scattered sections of 15, 21, 28 and 35 U.S.C.)—authorizes a period of exclusivity for the first generic to enter the market. 21 U.S.C. § 355(j) (2000). Under bilateral agreements, regulatory-exclusivity may be the result of measures that protect pharmaceutical test data. See Susan Scafidi, *The “Good Old Days” of TRIPS: The U.S. Trade Agenda and Pharmaceutical Test Data Protection*, 4 YALE J. HEALTH POL’Y L. & ETHICS 341 (2004).

³⁹ Rovira, *supra* note 33, at 401 (current intellectual property protections allow “prices to be set well above marginal and direct manufacturing costs”); John H. Barton, *TRIPS and the Global Pharmaceutical Market*, 23 HEALTH AFF. 146, 148 (2004) (“[T]he logic of the patent system is to permit an elevated price to allow recovery of research and development (R&D) costs.”); [GR. BRIT.] COMM’N ON INTELLECTUAL PROPERTY RIGHTS, INTEGRATING INTELLECTUAL PROPERTY RIGHTS AND DEVELOPMENT POLICY: REPORT OF THE COMMISSION ON INTELLECTUAL PROPERTY RIGHTS 16-17 (Sept. 2002), [hereinafter COMM’N ON IPR, INTEGRATING IPR AND DEVELOPMENT POLICY], http://www.iprcommission.org/graphic/documents/final_report.htm (describing the rationale for patents).

The United States argues that in addition to promoting investment in innovation, the intellectual property protection regime also improves the flow of information by requiring disclosure of technical details for the purposes of patent issuance. See FREDERICK M. ABBOTT, THE TRIPS AGREEMENT, ACCESS TO MEDICINES, AND THE WTO DOHA MINISTERIAL CONFERENCE 4 (Quaker U.N. Office, Occasional Paper 7, Sept. 8, 2001).

However, it is not clear that the current patent system is successful in either regard. In particular, with regard to innovation: “The most important studies of patents and innovation generally have been inconclusive regarding a correlation between patents and invention.” Abbott, *supra*, at 5 (citing a number of studies by well-respected economists). Moreover, “[t]here is ‘limited evidence on IP as an incentive for innovations’ compared to other factors.” Andrew Farlow, *Costs of Monopoly Pricing Under Patent Protection*, Presentation to Columbia University Earth Institute and Consumer Project on Technology Conference 7 (Dec. 4, 2003) (slides available at <http://www.earthinstitute.columbia.edu/cgsd/documents/farlow2.ppt>). But see COMM’N ON IPR, INTEGRATING IPR AND DEVELOPMENT POLICY, *supra*, at 13 (recognizing the importance of IP in developed countries to pharmaceutical innovation and citing empirical support).

Ultimately, it is a matter of balancing the interests of innovators (i.e., IP protections) with those of the public domain (i.e., access). As Kevin Outterson notes, “Too many restrictions on inappropriability (i.e., excessive IP rights), needlessly raises cost and restricts access to important pharmaceuticals. Too few might throttle the R&D enterprise, and society could forgo valuable qualitative improvements. It is far from clear that current policy strikes an appropriate balance.” Outterson, *supra* note 24 (manuscript at 8) (citations omitted). The pharmaceutical industry’s lack of transparency with regard to cost structure, pricing, and profitability makes it difficult to assess the appropriateness of current IP rights. See Outterson, *supra* note 24 (manuscript at 3-4). But well documented economic realities suggest that current IP rights may be excessively strong, at least in some parts of the world—the pharmaceutical industry has been one of the most profitable U.S. industries over the last decade, see, e.g., The Henry J. Kaiser Family Found., Trends and Indicators in the Changing Health Care Marketplace, 2004 Update, at 21, <http://www.kff.org/insurance/7031/ti2004-1-21.cfm> (“For every year from 1995 through 2002, the pharmaceutical industry was the most profitable industry in the U.S. In 2003, drug companies ranked as the third most profitable industry . . .”), and generics price the same products at a substantial discount, see, e.g., Standard & Poor’s, Industry Surveys: Healthcare: Pharmaceuticals 17, Dec. 11, 2003, http://www.netadvantage.standardandpoors.com/NASApp/NetAdvantage/showIndustrySurvey.do?file=/hep_1203/h ep_1203.htm (“Typically the price of a newly introduced generic drug is 25% to 50% lower than that of a brand-name version in the United States As numerous competitors enter the field for a given drug, prices of popular generic drugs drop even further. For example, a few months after [two popular drugs] lost patent protection,

has had particular currency with regard to drug development: The pharmaceutical industry touts the high cost of research and development⁴¹ and claims that exploiting the patent-protected opportunity to set prices is thus necessary to recoup R&D investments and to encourage further investment in the risky business of drug discovery.⁴² In tandem, the innovation theory and patent law serve to justify (in theory) and to protect (in practice) the artificially and sometimes prohibitively high prices of new pharmaceuticals.

While the innovation theory may be plausible in wealthy OECD⁴³ markets, it makes little sense in low income countries.⁴⁴ Simply stated, the fact that “[h]aving a monopoly on poor

generic versions in the United States were priced 80% to 90% lower than the branded products.”); CONGRESSIONAL BUDGET OFFICE, HOW INCREASED COMPETITION FROM GENERIC DRUGS HAS AFFECTED PRICES AND RETURNS IN THE PHARMACEUTICAL INDUSTRY (July 1998).

⁴⁰ Outterson, *supra* note 24 (manuscript at 5).

⁴¹ Members of the Pharmaceutical Research and Manufacturers Association (PhRMA) frequently cite Joseph DiMasi’s estimates of the high cost of drug research and development. *See, e.g.*, PhRMA, Quick Facts: Most Drugs Never Recoup the Average Cost of Development (Mar. 26, 2003), <http://www.phrma.org/publications/quickfacts/16.04.2003.717.cfm> (citing Joseph A. DiMasi et al., *The Price of Innovation: New Estimates of Drug Development Costs*, 22 J. HEALTH ECON. 151 (2003)).

DiMasi’s methods and calculations have drawn a number of critiques. *See* ROBERT YOUNG & MICHAEL SURRUSCO, RX R&D MYTHS: THE CASE AGAINST THE DRUG INDUSTRY’S “SCARE CARD” (2001) (responding to DiMasi’s original study); Richard G. Frank, Editorial, *New Estimates of Drug Development Costs*, 22 J. HEALTH ECON. 325 (2003). First, DiMasi’s calculations have been criticized for including costs that are tax-deductible: Federal tax allows for a thirty-four percent deduction of R&D costs, but DiMasi uses pre-tax dollars. Second, DiMasi figures are based on a sample set of self-originated new chemical entities: He did not include any drugs that had received financial support from the government. However, federal funding of research or clinical trials normally assists pharmaceutical companies substantially (either directly or indirectly—for example, through technology transfer from universities), *supra* note 109; Pierre Chirac et al., AIDS: Patent Rights Versus Patient’s Rights, 356 THE LANCET 502 (2000). Third, it has been argued that his study “exaggerate[s] the risks and the opportunity costs.” Philippe Demenet, *The High Cost of Living*, LE MONDE DIPLOMATIQUE, Feb. 2002 (Malcolm Greenwood trans.), <http://mondediplo.com/2002/02/04stavudine>. Finally, DiMasi has been criticized for his financial ties to PhRMA—the Tufts Centre which he runs receives sixty-five percent of its funding from the pharmaceutical industry. *Id.*

⁴² *See, e.g.*, James K. Glassman & Kevin Hassett, *Doctors Without Economics*, TECH CENTRAL STATION, Oct. 30, 2003, at <http://www.techcentralstation.com/103003C.html>. However, Professor Rebecca Eisenberg has pointed out that “[t]his standard argument loses much of its force in the case of inventions made with public funding,” where the public has taken on much of risk that the research will be fruitless. Rebecca S. Eisenberg, *Public Research and Private Development: Patents and Technology Transfer in Government-sponsored Research*, 82 VA. L. REV. 1663, 1668 (1996). *See infra* note 110 and accompanying text for further discussion of federal funding of university research.

⁴³ OECD refers to the Organization of Economic Cooperation and Development, at <http://www.oecd.org>. Because the thirty member nations are high income, developed countries, the term OECD is often used as a proxy for such markets.

⁴⁴ Members of the drug industry have argued to the contrary. *See* MICHAEL P. RYAN, KNOWLEDGE DIPLOMACY: GLOBAL COMPETITION AND THE POLITICS OF INTELLECTUAL POLICY 67-72 (1998) (discussing efforts by the pharmaceutical industry to increase IP protections in developing countries).

people offers little profit”⁴⁵ undermines the relevance of the innovation theory in low income countries. The failure of intellectual property rights in LMI countries to stimulate investment in neglected diseases is evidence of this.⁴⁶

Yet, despite the failings of innovation theory, the pharmaceutical industry has lobbied strongly and successfully for requirements that LMI countries provide patent protection for pharmaceuticals. This incongruence raises the question: Why do companies want to be able to patent in these places?⁴⁷ Admittedly, pharmaceutical companies frequently opt not to patent in very low income countries.⁴⁸ However, they often seek patents in middle income supplier

⁴⁵ Univs. Allied for Essential Medicines, Data-Driven Fact Sheet, at <http://www.essentialmedicines.org/primer.pdf> (citing G. GEREFFI, *THE PHARMACEUTICAL INDUSTRY AND DEPENDENCY IN THE THIRD WORLD* (1993)); see MÉDECINS SANS FRONTIÈRES, *DRUG PATENTS UNDER THE SPOTLIGHT 6* (2003) [hereinafter MSF, *DRUG PATENTS*], http://www.who.int/entity/3by5/en/patents_2003.pdf; Barton, *supra* note 39.

⁴⁶ See *infra* Section I.C. Critiques of Lanjouw’s *Patent Policy Proposal for Global Diseases*, which suggests that use of IP protections in LMI countries might stimulate innovation for neglected diseases, *supra* note 24, often point this out. See, e.g., Outterson, *supra* note 24 (manuscript at 24) (“Strong IP laws in low income countries are insufficient to create new markets for neglected diseases. . . . An exclusive offer to sell drugs at a loss is not valuable.”). Cf. JEAN O. LANJOUW, *INTELLECTUAL PROPERTY AND THE AVAILABILITY OF PHARMACEUTICALS IN POOR COUNTRIES* 11 (Ctr. for Global Dev’t, Working Paper No. 5, April 2002) [hereinafter LANJOUW, *IP AND AVAILABILITY*] (acknowledging that patents are insufficient to “elicit sizable investment”).

⁴⁷ An array of pharmaceutical products are, in fact, patented in low income countries. See, e.g., E-mail from Amy Kapczynski describing the various drugs patented in Tanzania—from ARVs to cancer medications, Aug. 20, 2004 (on file with authors).

⁴⁸ Amir Attaran, *How Do Patents and Economic Policies Affect Access to Essential Medicines in Developing Countries*, 23 *HEALTH AFF.* 155 (2004) (follow on to the 2001 report); Amir Attaran & Lee Gillespie-White, *Do Patents for Antiretroviral Drugs Constrain Access to AIDS Treatment in Africa?*, 286 *JAMA* 1886 (2001) (arguing that there are relatively few patents on antiretroviral drugs in sub-Saharan Africa).

The pharmaceutical industry uses this empirical work to argue that patents are not an important obstacle to access. See, e.g., Frances Williams, *Battle over Drug Prices Shifts to the WTO*, *FIN. TIMES* (London), June 20, 2001, at 12 (“‘Patents are not the problem,’ says Harvey Bale of the International Federation of Pharmaceutical Manufacturers Associations.”); see also LANJOUW, *IP AND AVAILABILITY*, *supra* note 46, at 11-12 (“[I]ndustry uses this fact [the Attaran & Gillespie-White study] to stress that patents in the poorest countries are not impeding access to drugs.”).

Many have argued in response that “this conclusion is not warranted from their data.” Outterson, *supra* note 24 (manuscript at 55-56) (providing a detailed summary of the critiques appropriately leveled at Attaran’s work); see, e.g., COMM’N ON IPR, *INTEGRATING IPR AND DEVELOPMENT POLICY*, *supra* note 39, at 23-33, 34-64 (discussing the impact of patents and responding to Attaran’s study); Connie Liu & Sanjay Basu, *Electronic Letter in Response to Attaran, Patents and Access: Another Look*, *HEALTH AFF.*, May 11, 2004, at <http://content.healthaffairs.org/cgi/eletters/23/3/15>; Consumer Project on Technology et al., *Comment on the Attaran/Gillespie-White and PhRMA Survey of Patents on Antiretroviral Drugs in Africa* (Oct. 16, 2001) (unpublished manuscript, on file with authors). Central to these criticisms is the fact that even Attaran’s work finds that drugs tend to be patented in middle income and larger low income countries—which limits the supply available to low income countries, regardless of patent status. See COMM’N ON IPR, *INTEGRATING IPR AND DEVELOPMENT POLICY*, *supra* note 39, at 41 (“The existence of patents in potential supplier countries may allow the patentee to

countries (e.g., Brazil, South Africa, India) and larger low income countries.⁴⁹ In part, the desire to hold patents in LMI countries reflects the strong interest of originator pharmaceutical firms in maintaining control and preserving their monopolies in high income markets⁵⁰—seeking to prevent any generic manufacturing out of the (unwarranted) fear that generic products may be diverted to high income markets.⁵¹ And, in part, the industry’s interest stems from the potential to generate some revenue—albeit minimal amounts—in these markets.⁵²

In seeking to strike a balance between encouraging/rewarding innovation and facilitating access, it is important to note that in LMI countries even seemingly low prices may be prohibitive.⁵³ Thus, in this context the difference between the prices of generics and patented products (even when those prices are reduced by the manufacturer) is critical.

Unlike in developed nations, where insurance companies and governments purchase over seventy percent of pharmaceuticals, in LMI countries the public sector generally fails to provide

prevent supplies being exported to another country, particularly through controls on distribution channels.”). Recent discussion of the impact of patents has focused on the role patents play in preventing the manufacture and distribution of effective fixed dose combinations (FDCs). *See, e.g.,* MSF, DRUG PATENTS *supra* note 45, at 7.

⁴⁹ *See* Attaran & Gillespie-White, *supra* note 48, at 1888 (showing patenting in South Africa).

⁵⁰ *See, e.g.,* Daryl Lindsay, *Amy and Goliath*, SALON.COM, May 1, 2001, at <http://dir.salon.com/news/feature/2001/05/01/aids/index.html?pn=1> (“The real reason the pharmaceutical industry is trying to hold the line on its AIDS patents in impoverished nations is its fear that the Third World battle is simply the thin end of the wedge and that the activists’ real goal is universal price controls on drugs—in effect, socialism justified by overpowering moral arguments.”).

⁵¹ A number of authors have noted that there is little-to-no support for the pharmaceutical industry’s concern about diversion of products from LMI to high income markets. *See* SANJAY BASU, PHARMACEUTICAL PRODUCT DIVERSION: DIVERTING ATTENTION AWAY FROM THE REAL PROBLEM? (Oxfam Briefing Paper No. 35, forthcoming) (manuscript at 3, on file with authors) (reporting that “the scope of product diversion and the difficulty of controlling it have been exaggerated by the pharmaceutical industry,” and that generic drugs have been produced in India for decades without infiltrating or undermining Western markets); Farlow, *supra* note 39, at 19. “As of 2002, both the European Commission and the pharmaceutical companies acknowledged that pharmaceutical arbitrage from poor countries into the OECD was ‘still largely theoretical.’” Outterson, *supra* note 24 (manuscript at 61) (citing DG TRADE, EUROPEAN UNION, TIERED PRICING FOR MEDICINES EXPORTED TO DEVELOPING COUNTRIES, MEASURES TO PREVENT THEIR RE-IMPORTATION INTO THE EC MARKET AND TARIFFS IN DEVELOPING COUNTRIES §3.3 (EU Working Document, Apr. 22, 2002)).

⁵² In middle income countries and even in large low income countries there are opportunities to generate revenue by selling to elites. This encourages charging particularly high prices in these markets—a practice sometimes referred to as “skimming.” *See infra* note 57. Also, as the middle and upper classes in some middle income countries are expected to grow—e.g., India—pharmaceutical companies anticipate increasing returns. *See* Outterson, *supra* note 24 (manuscript at 25) (citing Merck & Co, Inc., Form 10-K (filed with the SEC on Mar. 10, 2004) at 14).

⁵³ *See infra* notes 59, 63-65 and accompanying text.

essential medicines⁵⁴—governments lack the financial resources to purchase medicines and/or the logistical abilities to distribute medicines, particularly to rural areas. As a result, drugs are an out-of-pocket expense for most LMI country residents.⁵⁵ This reality is both important and unfortunate given the high retail prices individual purchasers in poor countries are charged—pharmaceutical prices are often the same, if not *higher*, in poor countries as in rich ones.⁵⁶ Following prolonged public outcry the major drug companies slashed prices of AIDS drugs,⁵⁷ but the same price reductions have not been provided for other types of medicines (i.e., non-AIDS drugs), and in many cases these discounts have only been made available to governments and NGOs, not individual purchasers.⁵⁸ Moreover, even those originator companies who have

⁵⁴ Rovira, *supra* note 33, at 401 (citing Quick et al., *Twenty-five Years of Essential Medicines*, 80 BULL. WORLD HEALTH ORG. 913-14 (2002)).

⁵⁵ Up to ninety percent of pharmaceutical expenditures are paid for “out-of-pocket” by LMI country residents. *Id.* at 401 (citing Quick et al., *Twenty-five Years of Essential Medicines*, 80 BULL. WORLD HEALTH ORG. 913-14 (2002)).

⁵⁶ Bas van der Heide, Drug Pricing and Access to Essential Medicines, Statement by Health Action International (HAI)-Europe for the DG Trade and Civil Society Health Issue Group Meeting (June 26, 2000) (describing “[t]he higher prices of proprietary drugs in some of the developing countries of Africa, Asia, and Latin America compared to prices in ten OECD countries”); Donald McNeil, Jr., *Prices for Medicine Are Exorbitant in Africa, Study Says*, N.Y. TIMES, June 17, 2000, at A6.

⁵⁷ Prior to 2001, pharmaceutical industry prices in LMI countries for AIDS drugs were generally close to, or in some cases exceeded, rich country levels. Companies began to offer lower prices in LMI countries—sometimes termed “differential pricing” or “tiered pricing” schemes—only after intense political and civil pressure mounted. *See, e.g., Drug Company Cuts AIDS Drug Prices in S. Africa*, REUTERS NEWMEDIA, Nov. 30, 2001, <http://www.emro.who.int/asd/WhatsNew-GlobalEvents-Reuters3011.htm>. *But see* Marleen Boelaert et al., *Letter to the Editor*, 287 JAMA 840-41 (2002) (“This impressive discount offered by the companies to developing countries was not merely due to public outcry, but mostly as a response to competition by generic drugs.”).

Some pricing modifications have only been achieved more recently. *See, e.g., Gerjo Hoffman, Firm Slashes AIDS Drug Prices*, News24.com (Apr. 28, 2003), at http://www.news24.com/News24/South_Africa/Aids_Focus/0,,2-7-659_1353020,00.html. “[U]ntil January 2003, more than three years after the need for access to medicines made world headlines at the World Trade Organization’s (WTO) Seattle conference, one pharmaceutical company was charging \$2000 a year more in Guatemala than in Switzerland for its AIDS drug. Only after months of public pressure did the price of the drug come down in Guatemala.” ‘t Hoen, *supra* note 19, at 294 (citing Associated Press, *Roche Cuts Price of AIDS Drug to Nations* (Feb. 13, 2003)).

⁵⁸ The Accelerating Access Initiative (AAI) is a partnership created in 2000 among a number of U.N. agencies and six multinational pharmaceutical companies to expand access to AIDS drugs. AAI does not impose price reductions for LMI countries; rather the initiative facilitates the negotiation of discounted prices for individual drugs between countries and the pharmaceutical companies involved. The prices negotiated through AAI are available to countries, not individuals. *See* UNAIDS & WORLD HEALTH ORG., ACCELERATING ACCESS INITIATIVE: PROGRESS REPORT 1 (June 2002) [hereinafter UNAIDS & WHO, ACCELERATING ACCESS], http://www.who.int/hiv/pub/prev_care/en/isbn9241210125.pdf; *see also* Jilian Clare Cohen, *Increasing Access to Medicines: Ghana*, Presentation at the Global Health Research Conference (May 14, 2004) (slides available at <http://icarus.med.utoronto.ca/CIHresearch/GHR2004/Cohen.pdf>) (“Prices to the patient in the private sector may be

reduced their prices continue to price their drugs above the cheapest generics available in countries where patents do not prevent generics.⁵⁹ “Despite the major reductions in ARV prices [by pharmaceutical companies], the annual cost of ARV treatment for a person living with HIV still exceeds the annual per capita gross domestic product of many least developed countries.”⁶⁰ Even in South Africa—a middle income developing country⁶¹—there are few patented drug regimens for chronic conditions, such as AIDS, that are affordable for those in need.⁶²

more [than] 32.5% higher than the AAI price.”); CARMEN PÉREZ-CASAS, MÉDECINS SANS FRONTIÈRES, HIV/AIDS MEDICINES PRICING REPORT UPDATE n.1 (Dec. 2000) [hereinafter MSF, PRICING REPORT UPDATE], <http://www.accessmed-msf.org/upload/ReportsandPublications/49200113585/Durban%20report%20update%20dec%202000.pdf> (noting the important difference between institutional prices and those charged in the private sector). To find prices (for public and private sector, branded and generic versions) for a variety of countries and medicines, see Health Action Int’l, Medicines Prices, at <http://www.haiweb.org/medicineprices>.

From the perspective of those promoting sustainable access to medicines, there are other problems with donations and so-called discounts—including the fact that both have been executed on a fairly ad hoc basis. See ‘t Hoen, *supra* note 19, at 294 (“[T]heir efforts have been neither systematic nor sufficient”); see also MÉDECINS SANS FRONTIÈRES, *EQUITABLE ACCESS: SCALING UP HIV/AIDS TREATMENT IN DEVELOPING COUNTRIES* (World AIDS Days 2002 Briefing Paper, Nov. 27, 2002) [hereinafter MSF, *EQUITABLE ACCESS*], <http://www.accessmed-msf.org/prod/publications.asp?scntid=271120021557479&contenttype=PARA&> (with the exception of Merck, pharmaceutical companies have been handling discounts on a cases by case basis leading to high variance). In an April 2004 letter to UNAIDS and the WHO, NGOs and governments complained about pricing inconsistencies and the fact that middle income countries (especially lower middle income) are not receiving adequate price discounts. Letter from Gregg Gonsalves et al. to Dr. Jong-Wook Lee, WHO, and Dr. Peter Piot, UNAIDS (Apr. 5, 2004) (posted by Richard Stern, rastern@racs.co.cr, to healthgap@listserv.critpath.org (July 30, 2004) and copy on file with authors).

For a more comprehensive critique of voluntary price reductions and donations, see Farlow, *supra* note 39, at 14-21; Udo Schuklenk, *Affordable Access to Essential Medication in Developing Countries: Conflicts Between Ethical and Economic Imperatives*, 27 J. MED. & PHILOSOPHY 179 (2001). For a discussion of the pharmaceutical industry’s perspective on differential pricing, see Outterson, *supra* note 24.

⁵⁹ See MÉDECINS SANS FRONTIÈRES, *UNTANGLING THE WEB OF PRICE REDUCTIONS: A PRICING GUIDE FOR THE PURCHASE OF ARVs FOR DEVELOPING COUNTRIES* 7 (4th ed. 2003); see also MSF, *PRICING REPORT UPDATE*, *supra* note 58, at 2 (“[E]ven if prices were reduced by 85% . . . they would still be higher than the prices currently offered by generic producers in some countries.”).

⁶⁰ UNAIDS & WHO, *ACCELERATING ACCESS*, *supra* note 58, at 2.

⁶¹ See, e.g., Europa, *Country Overview: South Africa* (Dec. 2003), at http://europa.eu.int/comm/development/body/country/country_home_en.cfm?cid=za&lng=en&status=new; see also Achal Prabhala & Harsha Thirumurthy, *Economic Analysis of Income and Expenditure Patterns in South Africa: Implications for the Affordability of Medicines* 16 (July 23, 2003) (unpublished manuscript, on file with authors); Adam Lewinberg, *The Cost of Patents in South Africa*, at <http://individual.utoronto.ca/adamlewinberg/Access/Box7.htm> (last visited June 14, 2004).

⁶² See Prabhala & Thirumurthy, *supra* note 61; Lewinberg, *supra* note 61; see also Posting of Jamie Love, james.love@cptech.org, to ip-health@lists.essential.org (Sept. 4, 2003) (evaluating affordability of new drugs in Brazil and finding that there, as well, newer drugs are too expensive to be accessed by the majority of the population).

The improvements in access following introduction of low-cost generics in LMI countries demonstrate the importance of pricing as an impediment to access.⁶³ Studies have found that introduction of generics, which typically occurs when there is no patented product blocking market entry,⁶⁴ is critical for price reduction: “The most significant factor in lowering prices [is] the introduction of generic sources in a country.”⁶⁵ In turn, this appears to be the most effective tactic to close the access gap.⁶⁶ In addition to increasing the purchasing power of individuals in LMI countries,⁶⁷ price reductions based on generic competition (which happen more quickly and are more likely to be sustained than voluntary differential pricing by

⁶³ See, e.g., MSF, SURMOUNTING CHALLENGES, *supra* note 8 (finding that in countries where generic drugs were available, competition led to lower prices and greater accessibility); P.T. Jyothi Datta, *Government, Pharma Cos To Discuss AIDS Drugs Price-Cut Today*, HINDU BUSINESS LINE, Nov. 16 2003, <http://www.thehindubusinessline.com/2003/11/17/stories/2003111701960500.htm>.

⁶⁴ This may result from the expiration of a patent term, the government’s issuance of a compulsory license, or from a situation in which no patent exists—potentially because the country does not afford patent protection (e.g., the WTO’s least developed countries are not required to provide such protection for pharmaceuticals until 2016). See *Doha Declaration on TRIPS and Public Health*, *supra* note 35. A company may also issue a voluntary license to allow entry of one or more generic producers—the impact of generic competition is obviously strongest where it is not limited to a single seller. See, e.g., The Henry J. Kaiser Family Found., *GlaxoSmithKline Issues Voluntary License for Lamivudine, Zidovudine to South African Generic Drug Company*, Kaiser Daily HIV/AIDS Report (July 1, 2004), at http://www.kaisernetwork.org/daily_reports/rep_index.cfm?hint=1&DR_ID=24507.

⁶⁵ MSF, SURMOUNTING CHALLENGES, *supra* note 8, at 46. In May 2000 originator prices for one ARV triple combination were over U.S.\$10,000 per person per year; two years later they had dropped to approximately U.S.\$700 per person per year, but generic prices were already as low as U.S.\$210. MSF, *EQUITABLE ACCESS*, *supra* note 58, at 2 (“[Generic competition] has proven to be the most effective means of lowering drug prices.”).

See OXFAM, *PATENT INJUSTICE: HOW WORLD TRADE RULES THREATEN THE HEALTH OF POOR PEOPLE 12* (2001), http://www.oxfam.org.uk/what_we_do/issues/health/patent_injustice.htm (“In Thailand, the introduction of generic competition reduced the cost of drugs for the treatment of meningitis by a factor of 14. Generic drugs for the treatment of resistant shigella, a major cause of bloody diarrhoea, are sold in India at one-eighth of the price of patented equivalents.”); Cohen, *supra* note 58 (crediting generics with lowered prices in Ghana); van der Heide, *supra* note 56, at 1; see also *COMM’N ON IPR, INTEGRATING IPR AND DEVELOPMENT POLICY*, *supra* note 39, at 42, 45 (discussing the drop in prices brought on by generic entry but also noting that other factors, such as tariffs, may impact drug prices); JOAN-RAMON BORRELL & JAYASHREE WATAL, *IMPACT OF PATENTS ON ACCESS TO HIV/AIDS DRUGS IN DEVELOPING COUNTRIES* (CID Working Paper No. 92, May 30, 2002).

⁶⁶ MOHGA K. SMITH, *GENERIC COMPETITION, PRICE, AND ACCESS TO MEDICINES: THE CASE OF ANTIRETROVIRALS IN UGANDA* (Oxfam Briefing Paper No. 26, July 10, 2002), http://www.oxfam.ca/news/AIDS/downloads/uganda_research.pdf; see also Associated Press, *Suspension of Patents Yields Some Success in AIDS Fight* (Sept. 22, 2003), <http://lists.essential.org/pipermail/ip-health/2003-September/005306.html>.

⁶⁷ See BRANT, *supra* note 29, at 7 (“The introduction of generics is crucial to bringing down the prices in a sustainable way. . . . Access to generics, which tend to be much cheaper than branded drugs, is especially important in countries where resources devoted to healthcare are scarce, and in places where people have to pay out of their own pockets for medicines, due to an absent or nonfunctioning public healthcare system.”) (emphasis added).

originators) allow governments, as well as NGOs and intergovernmental support organizations, to be more effective providers of medical treatment. As one commentator noted, “The entry into the market of generic versions of ARVs, mainly produced by Indian manufacturers, opened the opportunity for countries to dramatically reduce the costs of AIDS treatment, in turn making it possible for countries to treat a much larger number of individuals with their available budgets.”⁶⁸ Donor programs—like the WHO’s “3 by 5 Initiative”—also depend on the availability of generic, low priced alternatives to achieve their goals.⁶⁹

Admittedly, for some LMI country residents, effective pharmaceutical treatment would remain inaccessible even if medicines were affordable. Regulators may fail to approve a product, transportation and logistics challenges may prevent product delivery to certain communities, and a lack of medical facilities and physicians may make medicines largely useless even when they reach disease victims.⁷⁰ Yet even in resource- and infrastructure-poor

⁶⁸ Rovira, *supra* note 33, 410 (discussing World Bank endorsement of developing countries purchasing of generic products). Brazil’s impressive response to HIV/AIDS is widely credited to the government’s early and aggressive reliance on generic production (and alternatively, on the threat of generic production as a bargaining tool with multinational pharmaceutical companies). *See infra* notes 76, 97. For description of how the availability of low-cost generics has facilitated recent policy developments in Uganda, see SMITH, *supra* note 66, at 6; *Uganda Begins Distributing Free Antiretrovirals*, 363 THE LANCET 2062 (2004).

⁶⁹ *See* Mamphela Ramphele & Nicholas Stern, *Generic Drugs Can Make the Money Last*, N.Y. TIMES, Mar. 1, 2003, at A19. On December 1, 2003, the WHO and UNAIDS (the Joint United Nations Programme on HIV/AIDS) launched the 3 by 5 Initiative—a plan to “treat 3 million by 2005.” UNAIDS, “Treat 3 million by 2005” (3 by 5) Initiative, at <http://www.unaids.org/en/treat+3+million+by+2005+initiative.asp> (last visited June 14, 2004) [hereinafter UNAIDS, 3 by 5 Initiative]. Like the United Nations-launched Global Fund To Fight AIDS, Tuberculosis, & Malaria, discussed *infra* note 79, the 3 by 5 Initiative has been plagued by financial constraints. *See* Crewe, *supra* note 10, at 158. Therefore, the cost-savings provided by generics has been particularly important. *See, e.g.,* Asia Russell, *The Bush Administration’s Global AIDS Promises—and Praxis*, 4 YALE J. HEALTH POL’Y L. & ETHICS 133, 138 (2004) (citing GLOBAL FUND TO FIGHT AIDS, TUBERCULOSIS, & MALARIA, GUIDELINES FOR PROPOSALS (March 2003)).

During his 2003 State of the Union Address, President Bush explained that the reduction in the costs of AIDS drugs from “\$12,000 a year to under \$300 a year . . . places a tremendous responsibility within our grasp. . . . [S]eldom has history offered a greater opportunity to do so much for so many.” Pres. George W. Bush, *supra* note 3. The price he quoted of less than \$300 per year is one that is only offered by *generic* manufacturers. *See* Russell, *supra*, at 135. Ironically, unlike the World Bank, the Global Fund, and WHO’s 3 by 5 Initiative, President Bush’s Emergency Plan for AIDS Relief (PEPFAR) has not yet embraced the use of generics. Press Release, Médecins Sans Frontières, *The Nation: Bush, AIDS, Big Pharma* (Apr. 26, 2004), <http://www.accessmed-msf.org/prod/publications.asp?scntid=13520041628468&contenttype=PARA&>.

⁷⁰ Developed country pharmaceutical firms are particularly prone to highlight this component of the access gap problem, which distracts attention from the benefits of price reductions and generic competition. *See, e.g.,* Steven Chase & Drew Fagan, *Drug Companies Balk at Ottawa’s Plan*, GLOBE & MAIL, Sept. 27, 2003, <http://www.globeandmail.com/servlet/story/RTGAM.20030927.waids0927/BNStory/Front/> (reporting the claim of

environments, drug regimens can be successfully administered,⁷¹ and compliance rates may exceed those of American patients.⁷² While systemic improvements in regulatory policy, transportation and logistics, and health care delivery infrastructure have the potential to help close the access gap,⁷³ it is unclear how much impact, if any, these changes can have if drugs remain unaffordable for many LMI country disease victims.⁷⁴

Another important factor contributing to the access gap is a lack of political will among some LMI countries to openly and fully address public health crises, particularly the HIV/AIDS epidemic. South Africa, India and China have elicited trenchant criticism in recent years for denying the scope or even existence of a serious HIV/AIDS problem in their countries.⁷⁵ Not all LMI countries have maintained willful ignorance regarding HIV/AIDS,⁷⁶ and even some of the

the Federation of International Pharmaceutical Manufacturers Associations that “the pressing need in developing countries is more cash from rich nations to fund more clinics and infrastructure to diagnose diseases” and that greater access to generic drugs is “at the bottom of the totem pole of real solutions.”).

⁷¹ See, e.g., Paul Farmer et al., *Community-Based Approaches to HIV Treatment in Resource-Poor Settings*, 358 LANCET 404 (2001).

⁷² See Donald McNeil Jr., *Africans Outdo U.S. Patients in Following AIDS Therapy*, N.Y. TIMES, Sept. 3, 2003, at A1 (summarizing surveys of AIDS patients in Botswana, Uganda, Senegal and South Africa that demonstrate medicine regimen compliance rates of approximately ninety percent, compared to seventy percent among U.S. AIDS victims).

⁷³ See Mukherjee et al., *supra* note 28; Steven Reynolds et al., *Antiretroviral Therapy Where Resources Are Limited*, 348 NEW ENG. J. MED. 1806 (2003).

⁷⁴ Abbott, *supra* note 39, at 6, 37 (“The United States and the OECD pharmaceutical industry have argued that price is only one factor in determining access to medicines in developing countries, and infrastructure and professional support must also be addressed. Yet this is hardly an argument against measures that would lower the price of patented pharmaceuticals. . . . There are, in fact, very few products for which price matters more than life-saving drugs, because price is the major obstacle to most potential consumers who otherwise have an intense demand for the product.”)

⁷⁵ See Diddier Fassin & Helen Schneider, *The Politics of AIDS in South Africa: Beyond the Controversies*, 326 BMJ 495 (2003), <http://bmj.bmjournals.com/cgi/reprint/326/7387/495>; Tina Rosenberg, *Look at Brazil*, N.Y. TIMES, Jan. 28, 2001, § 6 (Magazine), at 26 (describing South African President Thabo Mbeki’s “inexplicabl[e]” refusal to acknowledge that HIV causes AIDS as a source of the country’s lack of progress in responding to HIV/AIDS); Michael Specter, *India’s Plague*, NEW YORKER, Dec. 17, 2001, http://www.michaelspecter.com/ny/2001/2001_12_17_india.html.

⁷⁶ See, e.g., Rosenberg, *supra* note 75. Rosenberg describes Brazil’s timely and aggressive reaction to HIV/AIDS:

Since 1997, virtually every AIDS patient in Brazil for whom it is medically indicated gets, free, the same triple cocktails that keep rich Americans healthy. . . . Brazil has shredded all the excuses about why poor countries cannot treat AIDS. Health system too fragile? On the shaky foundation of its public health service, Brazil built a well-run network of AIDS clinics. Uneducated people can’t stick to the complicated regime of pills? Brazilian AIDS patients have proved just as able to take their medicine on time as patients in the United States.

more recalcitrant countries appear to be coming to terms with the disease.⁷⁷ However, as South Africa's continuing struggle to contain HIV/AIDS despite its newfound political resolve demonstrates,⁷⁸ political will is a necessary but not sufficient condition to close the access gap. Moreover, the commitment of some LMI country governments, as well as high-income donor nations, to addressing the access gap appears mercurial⁷⁹—supporting the need for a solution that harnesses market forces without requiring government intervention to supply essential medicines to LMI country residents at affordable prices.

C. The R&D Gap: Neglected Diseases

While patents and other exclusive marketing rights may encourage investment where private firms “expect later to recover in the form of extraordinary, monopoly profits,”⁸⁰ such incentives are ineffectual where it is clear that the market cannot offer such rewards. As Juan Rovira, a former Senior Health Economist at the World Bank, concluded, “[T]he patent system leads R&D toward profitable diseases and conditions, rather than towards diseases that cause the most morbidity and mortality.”⁸¹ Unfortunately, diseases principally found in developing countries offer little in terms of profit incentive—“the total market of the poorest countries . . . is

Id.

⁷⁷ For news stories following progress in South Africa over the last year, see, for example, Andrew Quinn, *S. Africa Rules Aim To Cut Drug Prices up to 70 Pct*, REUTERS NEWSMEDIA, Jan. 15, 2004, <http://www.aegis.com/news/re/2004/RE040113.html>; Lawrence K. Altman, *South Africa Says It Will Fight AIDS with a Drug Plan*, N.Y. TIMES, Aug. 9, 2003, at A1; and *Health, Treasury Team Yes' [sic] to AIDS Drugs*, BUS. DAY (S. Africa), May 7, 2003, <http://www.bday.co.za/bday/content/direct/1,3523,1340483-6079-0,00.html>. China has also made progress, see, e.g., Jim Yardley, *China Begins Giving Free HIV/AIDS Drugs to the Poor*, N.Y. TIMES, Nov. 7, 2003, at A3.

⁷⁸ See, e.g., *Drugs for the Poor Collect Dust as Council Drags Its Feet*, Health Systems Trust (Apr. 23, 2004), at <http://news.hst.org.za/view.php3?id=20040430>; *Still No News on Drug Prices*, News24.com (Apr. 21, 2004), at http://www.news24.com/News24/South_Africa/News/0,,2-7-1442_1515498,00.html.

⁷⁹ See, e.g., *id.* The absence of sustained political will on the part of many high income, developed countries—such as the United States—to adequately support the fight against these scourges has contributed to the ongoing access crisis. See MSF, *EQUITABLE ACCESS*, *supra* note 58; Crewe, *supra* note 10; Stephen Lewis, *The Precarious Promise of the Global Fund*, 4 YALE J. HEALTH POL'Y L. & ETHICS 129, 134 (2004); Associated Press, *Lack of Funding for HIV/AIDS Is Mass Murder by Complacency, Says U.N. Envoy* (Jan. 9, 2003), <http://www.worldrevolution.org/article/278>.

⁸⁰ Rovira, *supra* note 33, at 405.

⁸¹ *Id.*; see LANJOUW, *IP AND AVAILABILITY*, *supra* note 46, 1, 10 (“[P]atents will not be sufficient to attract substantial private investment because purchasing power is low.”).

on the order of 1 percent of the global pharmaceutical market.”⁸² As a result, pressing global health needs have long gone unattended⁸³—significant morbidity and mortality in low income countries is the result of diseases for which there are no effective, easy to use medicines.⁸⁴

D. Responding to the Access Gap and Neglected Diseases

The access gap and the lack of R&D investment in diseases affecting the developing world have attracted substantial attention from scholars,⁸⁵ NGOs,⁸⁶ international bodies,⁸⁷ and various national governments⁸⁸ in recent years. The increasing focus on these critical problems has led to a number of public and private sector-based ameliorative strategies, including donor financing,⁸⁹ development loans,⁹⁰ price controls,⁹¹ drug donations⁹² and negotiated price cuts for LMI countries.⁹³

⁸² Barton, *supra* note 39, 148; *see also* ‘t Hoen, *supra* note 19, at 295 (“Developing countries account for four-fifths of the world’s population, but less than ten percent of the global pharmaceutical market.”).

⁸³ *See* Carlos M. Morel, *Neglected Diseases: Under-funded Research and Inadequate Health Interventions*, 4 EMBO REP. S35 (2004); Bernard Pécoul et al., *Access to Essential Drugs in Poor Countries: A Lost Battle?*, 281 JAMA 361, 364 (1999).

⁸⁴ *See* MÉDECINS SANS FRONTIÈRES & DRUGS FOR NEGLECTED DISEASES WORKING GROUP, FATAL IMBALANCE—THE CRISIS IN RESEARCH AND DEVELOPMENT FOR DRUGS FOR NEGLECTED DISEASES (2002); Morel, *supra* note 83; Trouiller, et al., *supra* note 14. “For example, there is a growing need for new medicines to combat resistant strains of malaria and tuberculosis, to replace the ineffective and toxic drugs for sleeping sickness and Chagas disease, and to find treatments for diseases like dengue fever and Buruli ulcer that are currently almost untreatable.” ‘t Hoen, *supra* note 19, at 296.

⁸⁵ Fred Abbott, Brook Baker, John H. Barton, Carlos Correa, Patricia Danzon, Andrew Farlow, Jean O. Lanjouw, Keith E. Maskus, Jerome Reichman, and Zita Lazarrini are a few of the many established academics—primarily working in the fields of law, economics, and public health—who have made significant (and heterogeneous) contributions to the study of access to medicines.

⁸⁶ *See, e.g.*, Editorial, *The Plagues of Poverty*, N.Y. TIMES, Mar. 19, 2002, at A22 (mentioning the work of the Gates Foundation and Médecins Sans Frontières); Drugs for Neglected Disease Initiative, at <http://www.dndi.org> (last visited May 13, 2004); Health GAP: Global Access Project, at <http://www.healthgap.org/> (last visited May 13, 2004).

⁸⁷ Beginning in 2001, the WTO’s attention was turned to the access issue, leading to the adoption of the *Doha Declaration on TRIPS and Public Health*, *supra* note 35. *See* World Trade Org., TRIPS and Public Health, at http://www.wto.org/english/tratop_e/trips_e/pharmpatent_e.htm (last visited June 14, 2004). In late 2003, the WHO and UNAIDS launched the 3 by 5 Initiative. UNAIDS, 3 by 5 Initiative, *supra* note 69. The WHO and UNAIDS also developed the Accelerating Access Initiative described *infra* note 58.

⁸⁸ *See supra* note 8 (discussing efforts by national governments); U.S. Dep’t of State, The President’s Emergency Plan for AIDS Relief (PEPFAR): U.S. Five Year Global HIV/AIDS Strategy, at <http://www.state.gov/s/gac/rl/or/c11652.htm> (last visited June 14, 2004).

⁸⁹ *See, e.g.*, GLOBAL FUND TO FIGHT AIDS, TUBERCULOSIS, & MALARIA, GUIDELINES FOR PROPOSALS (March 2003), <http://www.theglobalfund.org/en/apply/proposals> (last visited July 15, 2004).

The market failure that impedes development of therapies for neglected diseases is well recognized and has led to a number of recent nonprofit initiatives⁹⁴—some of these are best described as public-private partnerships⁹⁵ or have been aided by pharmaceutical companies and research institutions in other ways.⁹⁶ Because market forces may also fail to adequately incent pharmaceutical companies to embrace differential pricing or other access-facilitating mechanisms, some countries have sought to exploit flexibilities in international intellectual

⁹⁰ See Rovira, *supra* note 33, at 407-11 (discussing World Bank financing for LMI country pharmaceutical purchasing); RAMESH GOVINDARAJ ET AL., WORLD BANK PHARMACEUTICALS (World Bank HNP Discussion Paper, Sept. 2000), http://www1.worldbank.org/hnp/Pubs_Discussion/Govindaraj%20-%20WB%20Pharmaceutical-whole.pdf.

⁹¹ See, e.g., Sanjay Kumar, *India To Extend Price Controls on Drugs*, 329 *BMJ* 368 (2004); Andrew Quinn, *supra* note 77 (South Africa). Mechanisms to control or influence the price of pharmaceuticals exist in numerous developed countries. See, e.g., Austl. Dep't of Health & Ageing, About the PBS, at <http://www.health.gov.au/pbs/general/aboutus.htm> (last modified Dec. 24, 2003) (describing the Australian Pharmaceutical Benefits Scheme); Austl. Dep't of Health & Ageing, Pharmaceutical Benefits Advisory Committee, at <http://www.health.gov.au/pbs/general/listing/committee.htm#pbac> (last updated Dec. 16, 2003); Canada, Patented Medicine Prices Review Board, at <http://www.pmprb-cepmb.gc.ca> (last visited July 15, 2004).

⁹² Drugs for the treatment of HIV/AIDS (as opposed to other diseases and conditions) have been the focus of drug donations. See, e.g., Boehringer-Ingelheim, Viramune MTCT Donation Programme, at http://www.boehringer-ingelheim.com/corporate/news/photo_mtct.htm (last visited July 15, 2004). As discussed earlier, *supra* 58, donations are not viewed as a sustainable, long-term solution by many working in the field, but do provide tax benefits to pharmaceutical companies.

⁹³ See *supra* notes 57-58; Joint Press Release, Clinton Foundation, UNICEF, Global Fund, & World Bank, New Agreements Aim To Make Lowest-cost AIDS Drugs and Diagnostics Available to Hundreds of Thousands in Developing World (Apr. 6, 2004), <http://www.unaids.org/en/in+focus/topic+areas/access+to+drugs.asp>.

⁹⁴ See, e.g., *New Generation of Non-profit Initiatives Tackles World's "Neglected Diseases,"* 82 *BULL. WORLD HEALTH ORG.* 319 (2004), <http://www.who.int/bulletin/volumes/82/5/feature0504/en>; David Perlman, *Drug Firm Seeks Cures over Cash: S.F. Nonprofit Wants To Help Poor Nations*, *S.F. CHRON.*, Aug. 19, 2002, <http://www.sfgate.com/cgi-bin/article.cgi?file=/c/a/2002/08/19/MN33767.DTL&type=printable> (describing OneWorld Health, a new nonprofit pharmaceutical firm dedicated to developing, testing and manufacturing new drugs for LMI country diseases).

⁹⁵ As Barton explains, *supra* note 39, at 151:

To respond to this problem [i.e., the lack of market incentives], a variety of nonprofit public-private partnerships, such as the International AIDS Vaccine Initiative, the Medicines for Malaria Venture, and the Global Alliance for TB Drug Development, are now in place. These efforts involve public or donor funds and often work in cooperation with the private sector. So far, they are working at the research level; when they succeed, they will face the same problem of financing production and distribution.

See also International AIDS Vaccine Initiative, at <http://www.iavi.org/>; Global Alliance for TB Drug Development, at <http://www.tballiance.org>; Medicines for Malaria Venture, at <http://www.mmv.org>.

⁹⁶ See Paul Elias, *Nonprofits Work With Drug Firms To Treat Diseases in Third World*, *L.A. TIMES*, Feb. 9, 2004, at C5 (describing transfer of some R&D programs for neglected diseases from pharmaceutical companies to nonprofits); The Henry J. Kaiser Family Found., *Johnson & Johnson To Grant License To International Partnership for Microbicides for Experimental Microbicide*, *Kaiser Daily HIV/AIDS Report* (Mar. 30, 2004), at http://www.kaisernetwork.org/daily_reports/rep_index.cfm?DR_ID=22929.

property to close the access gap. Brazil, for example, has relied on the size of its economy and the credible threat of compulsory licensing, as permitted by the TRIPS Agreement, to successfully negotiate drastic price reductions with major pharmaceutical companies.⁹⁷ Malaysia recently became the first low income country to issue a pharmaceutical compulsory license.⁹⁸ By banding together last summer, developing countries agitated for and ultimately secured passage of a WTO General Council decision enabling countries without manufacturing capacity to “make effective use of compulsory licensing under the TRIPS Agreement.”⁹⁹

Since 2001 four originator pharmaceutical companies have issued “voluntary licenses” to generic manufacturers in South Africa. Most (and perhaps all) of these issuances were attempts to preempt government issuance of compulsory licenses, which would deprive the originators of control over generic manufacturing activities. Bristol-Myers Squibb was the first firm to make a voluntary patent concession of this kind (as a result of events described in Section II.B, namely pressure from the public and particularly from Yale University).¹⁰⁰ In recent months, GlaxoSmithKline (GSK) and Boehringer Ingelheim (BI) have issued voluntary licenses, in

⁹⁷ See The Henry J. Kaiser Family Found., *Brazil's National STD/AIDS Programme Announces Largest Drug Price Reduction Deals in Five Years*, Kaiser Daily HIV/AIDS Report (Jan. 20, 2004), http://www.kaisernetwork.org/daily_reports/rep_index.cfm?hint=1&DR_ID=21751; *Brazil Reaches Deal with Firm on AIDS Drugs*, BUS. DAY (S. Africa), Sept. 3, 2001, <http://www.bday.co.za/bday/content/direct/1,3523,920202-6094-0,00.html>.

⁹⁸ See KG Narendranath, *Cipla First Company To Gain from Doha Pact's Compulsory Licensing Norm*, ECON. TIMES (India), Feb. 26, 2004. In March 2004 Mozambique became the second country to issue such a license. See, e.g., Martin Khor, *Patents vs. Access to Medicines at AIDS Conference*, Daily News (Sri Lanka), Aug. 10, 2004, <http://dailynews.lk/2004/08/10/fea11.html>.

⁹⁹ World Trade Org., General Council, *Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health*, WT/L/540 (Sept. 1, 2003) [hereinafter WTO, *Paragraph 6*]. The decision makes it clear that, under limited circumstances, countries are free to export generic products for the sole benefits of countries lacking manufacturing capacity. See Alcorn, *supra* note 8 (regarding Canada's intent to export as allowed by this Declaration).

¹⁰⁰ During the summer 2001 BMS signed an “immunity from suit” agreement with Aspen Pharmacare Ltd., a South African generic company. Rachel Zimmerman et al., *Bristol-Myers Offers Not To Sue Firm Seeking to Make AIDS Drug for Africa*, WALL ST. J., July 19, 2001, at A2. Aspen finally launched the product in August 2003. See The Henry J. Kaiser Family Found., *South African Generic Drug Maker To Produce Country's First Generic Antiretroviral Drug*, Kaiser Daily HIV/AIDS Report (Aug. 7, 2003), at http://kaisernetwork.org/daily_reports/rep_index.cfm?hint=1&DR_ID=19240. By October 2003 there were two generic forms of ddI on the market. BMS also agreed not to enforce its patent on another antiretroviral, ddI (didanosine).

accordance with a settlement entered with the Treatment Action Campaign (TAC) in December 2003.¹⁰¹ The TAC had filed a complaint against GSK and BI before the South African Competition Commission alleging unfair trade practices, including excess pricing of their antiretroviral medicines, and seeking a compulsory license to produce the drugs.¹⁰² After the TAC prevailed in the initial stages, GSK and BI opted for a settlement involving voluntary licenses.¹⁰³ Last month, Merck followed suit by granting a voluntary license to its AIDS drug to the main South African generic manufacturer.¹⁰⁴ While encouraging to those concerned with closing the access gap, these voluntary arrangements have thus far only involved one or two South African generic manufacturers and have been limited to a handful of antiretrovirals. Thus their impact is limited to a single disease (HIV/AIDS) in a single country (South Africa), and because they permit a limited number of generic manufacturers they appear unlikely to reduce prices as much as open competition between generics would.

Despite the attention focused on inequitable access to research and medicines, and despite the number and variety of interventions being undertaken, we have not yet solved the

¹⁰¹ See *Competition Commission Settlement Agreements Secure Access to Affordable Life-Saving Antiretroviral Medicines*, TAC NEWSLETTER (Treatment Action Campaign), Dec. 10, 2003, http://www.tac.org.za/newsletter/2003/ns10_12_2003.htm; The Henry J. Kaiser Family Found., *GlaxoSmithKline Issues Voluntary License for Lamivudine, Zidovudine to South African Generic Drug Company*, *supra* note 64 (also discussing Boehringer Ingelheim's license to Thembalami). Earlier both GSK and BI had granted voluntary licenses on these products (known as AZT and 3TC) to Aspen Pharmacare, but only allowed the company to sell in the public sector. See, e.g., Press Release, Aspen Pharmacare Ltd., Aspen Pharmacare Receive [sic] Voluntary License from GlaxoSmithKline on Anti-Retroviral Patents in South Africa, Oct. 8, 2001, <http://www.aspenpharmacare.co.za/showarticle.php?id=135>. Following the settlement the license was extended to the private sector. See Keith Alcorn, *South African Drug Deal Bring [sic] \$140 a Year Treatment Within Reach of African Nations*, AIDSmap News (Dec. 10, 2003), at <http://www.aidsmap.com/en/news/BA7BA5B6-429F-4BE5-A615-1A392F0CFF20.asp>.

¹⁰² *Reducing the Price of Antiretroviral Medicines*, TAC NEWSLETTER (Treatment Action Campaign), Oct. 27, 2003, http://www.tac.org.za/newsletter/2003/ns28_10_2003.htm (summarizing the complaint).

¹⁰³ See *News Release from the Competition Commission*, TAC NEWSLETTER (Treatment Action Campaign), Dec. 10, 2003, http://www.tac.org.za/newsletter/2003/ns10_12_2003.htm ("The settlement agreement is the result of negotiations following the Commission's announcement in October 2003 that GSK and BI had, in its view, contravened the Competition Act of 1998. From its investigation into the complaints . . . the Commission concluded that GSK and BI had abused their dominant positions in their respective anti-retroviral (ARV) markets.").

¹⁰⁴ See Press Release, Merck & Co., Inc., Grants License for HIV/AIDS Drug Efavirenz to South African Company, Thembalami Pharmaceuticals, July 14, 2004, <http://www.pressmethod.com/releasestorage/5003645.htm>.

problem,¹⁰⁵ nor do we appear to be on the verge of doing so.¹⁰⁶ Novel and promising strategies to close the access gap thus remain very much in demand. We turn now to an entity that to date has played at most a minor role in discussions of the access gap and its solution: the American research university.¹⁰⁷

II. University Research, Technology Transfer, and the Access Gap

A. The Role of Universities in Developing Health Technologies and Pharmaceutical End Products

Universities in the United States are responsible for more than half of the country's basic research science,¹⁰⁸ and perform much of the scientific research underlying new pharmaceutical products: An estimated forty to fifty percent of the drug industry's new products rely heavily upon recent academic research.¹⁰⁹

¹⁰⁵ See, e.g., WORLD HEALTH ORG., *supra* note 1 (reporting that HIV/AIDS and other diseases continue to decimate populations in many LMI countries, particularly in Africa).

¹⁰⁶ See, e.g., 't Hoen, *supra* note 19, at 296 ("Market forces will not solve the access and R&D crisis. Therefore, the public sector, including universities and public research institutes, must step in.").

¹⁰⁷ While this paper has implications for universities in other countries (as well as for non-university non-profit research institutions both within and outside of the U.S.), we concentrate our discussion on U.S. universities, which account for a substantial share of worldwide non-profit biomedical R&D. Our empirical research to date has focused largely on the American university system, leaving us unprepared to more fully evaluate the possible impact of an EAL-like strategy in other countries and institutions at this point. Nevertheless, the strategy we advance may also be viable for universities elsewhere that play a similar role in the political economy of pharmaceutical R&D and distribution.

¹⁰⁸ NAT'L SCIENCE FOUND., SCIENCE AND ENGINEERING INDICATORS 5-5 (2004), *available at* <http://www.nsf.gov/sbe/srs/seind04/pdf/c05.pdf>.

¹⁰⁹ A study by Edward Mansfield found that that forty-four percent of the drug industry's new products and thirty-seven percent of their new development processes were developed with at least "very substantial aid from recent academic research." Edward Mansfield, *Academic Research and Industrial Innovation*, 20 RES. POL'Y 1, 2-3 (1992); see Harold W. Bremer, *The First Two Decades of the Bayh-Dole Act as Public Policy*, Presentation to National Association of State Universities and Land Grant Colleges (Nov. 11, 2001) (transcript available at http://www.nasulg.org/COTT/Bayh-Dohl/Bremer_speech.htm) (hypothesizing that although Mansfield's study is dated, the percentages are likely the same or higher today).

More generally, United States government-funded life-science-related research, most of which occurs at universities, is a major outside source of innovation for pharmaceutical companies. See Consumer Project on Technology, U.S. Government Role in Health Care R&D, at <http://www.cptech.org/ip/health/econ/govrnd.html> (last visited May 20, 2004) ("A study of the 21 drugs introduced between 1965 and 1992 that were considered by experts to have had the highest therapeutic impact on society found that public funding of research was instrumental in the development of 15 of the 21 drugs.") (citing SENATE JOINT ECONOMIC COMM., THE BENEFITS OF MEDICAL RESEARCH AND THE ROLE OF THE NIH (2000)); see also Hearing Before the S. Comm. on Governmental Affairs,

University research, primarily dependent on federal government funding,¹¹⁰ has become an increasingly important component of America's total research and development activity over the past few decades.¹¹¹ Equally dramatic has been the increase in the patenting and commercialization of academic research. Facilitated by federal policy,¹¹² including the much celebrated Bayh-Dole Act,¹¹³ and driven by generous federal funding for biomedical research,¹¹⁴

103d Cong. 71-72 (1994) (statement of James P. Love, Dir. of Econ. Studies, Ctr. for Study of Responsive Law) (of the thirty important new drugs approved by the FDA between 1987 and 1991, fifty percent of the total and more than seventy percent of those discovered in the United States benefited from substantial government funding). In a mid-1990s assessment, the National Institutes of Health (NIH) found that eighty-five percent of the basic and clinical research used to develop the top five selling drugs on the market was done by U.S. taxpayer-funded scientists and foreign universities. See ROBERT YOUNG & MICHAEL SURRESCO, *supra* note 41, at App. C (NAT'L INSTS. OF HEALTH, NIH CONTRIBUTION TO PHARMACEUTICAL DEVELOPMENT (Administrative Document, Feb. 2000)); see also Wesley M. Cohen et al., *Links and Impacts: The Influence of Public Research on Industrial R&D*, 48 MGMT. SCI. 1, 1, 8-9 (2003) (finding that over forty-one percent of the drug industry's R&D projects relied upon public research findings, twelve percent relied upon prototypes developed in public research, and more than thirty-five percent used instruments and techniques from public research—with public research defined as “contributions of university and government research labs”); Abbott, *supra* note 39, at 7 (“It is well known that U.S.-based pharmaceutical companies benefit substantially from research support by government funding, and that many important new drugs were developed with material subsidies from the government.”).

¹¹⁰ See NAT'L SCIENCE FOUND., *supra* note 108, at 5-5 (federal funds accounted for nearly sixty percent of university research over the last decade, while industry supplied .06%); David C. Mowery et al., *The Growth of Patenting and Licensing by U.S. Universities: An Assessment of the Effects of the Bayh-Dole Act of 1980*, 30 RES. POL'Y 99, 102 (2001) [hereinafter Mowery et al., *Growth of Patenting and Licensing Post Bayh-Dole*].

¹¹¹ See Mowery et al., *Growth of Patenting and Licensing Post Bayh-Dole*, *supra* note 110, at 101 (universities conducted 14.5% of all research and development in the United States in 1997, roughly double their share in 1960).

¹¹² See *id.*, at 100 (citing judicial, statutory and policy changes over the past three decades that facilitated the patenting of biomedical research results); cf. *Diamond v. Chakrabarty*, 447 U.S. 303 (1980).

¹¹³ The Bayh-Dole University and Small Business Patent Act of 1980, 35 U.S.C. §§ 200-212 (1994), allows and encourages the patenting and commercialization of discoveries made with federal research dollars. For the accepted wisdom regarding Bayh-Dole's impact, see, for example, *Innovation's Golden Goose*, THE ECONOMIST (London), Dec. 14, 2002, http://www.economist.com/science/tq/displayStory.cfm?story_id=1476653 (“Possibly the most inspired piece of legislation to be enacted in America over the past half-century was the Bayh-Dole act [sic] of 1980. . . . More than anything, this single policy measure helped to reverse America's precipitous slide into industrial irrelevance.”); see also Ashley J. Stevens, *The Enactment of Bayh-Dole*, 29 J. TECH. TRANSFER 93, 93 (2004) (“[F]oreign countries are now adopting the Bayh-Dole model, most recently Germany and, in the United Kingdom, Cambridge University . . .”).

For a less enthusiastic view, see Mowery et al., *Growth of Patenting and Licensing Post Bayh-Dole*, *supra* note 110, at 99 (concluding that Bayh-Dole was “only one of several important factors behind the rise of university patenting and licensing activity”); Jeannette Colyvas et al., *How Do University Inventions Get Into Practice?*, 48 MGMT. SCI. 61, 61-62 (2002) (finding that the rise in university patenting and licensing is the result of a “more complicated story” than simply Bayh-Dole); see also David C. Mowery et al., *Learning To Patent: Institutional Experience, Learning, and the Characteristics of U.S. University Patents After the Bayh-Dole Act, 1981-1992*, 48 MGMT. SCI. 73, 73 (2002) (noting that empirical studies of the quality of university patents post-Bayh Dole have reached varied conclusions).

¹¹⁴ See Mowery et al., *Growth of Patenting and Licensing Post Bayh-Dole*, *supra* note 110, at 100.

the number of U.S. patents granted annually to American academic institutions grew ten-fold between 1970 and 2001.¹¹⁵ Given both the quantity and quality of innovation, universities have been described in recent years as “major players in the biopharmaceutical patenting arena.”¹¹⁶ These patents have fueled substantial commercialization activity: American and Canadian universities, hospitals, and other non-profit research centers entered into approximately five thousand licensing agreements in 2002, a four-fold increase since 1991.¹¹⁷ Moreover, between 1996 and 2001 university income from licensing of their products and technologies more than doubled and the number of licenses and option agreements rose by more than half.¹¹⁸

¹¹⁵ NAT'L SCIENCE FOUND., *supra* note 108, at 5-6. Substantial growth has continued over the last decade, as the number of patents issued to U.S. universities more than doubled. ASS'N OF UNIV. TECH. MANAGERS, AUTM LICENSING SURVEY: FY 2002, at Att. B, tbl. 27 (2003), http://www.autm.net/header/frames/surveys_frame.html [hereinafter 2002 AUTM SURVEY] (also providing information about substantial increases in the number of licensing agreements); Jerry G. Thursby & Marie C. Thursby, *Who Is Selling the Ivory Tower? Sources of Growth in University Licensing*, 48 MGMT. SCI. 90, 90 (2002); Adam B. Jaffe, *The U.S. Patent System in Transition: Policy Innovation and the Innovation Process*, 29 RES. POL'Y 531, 541 (2000). In 2002, U.S. and Canadian universities, hospitals and non-profit research centers filed nearly eight thousand new United States patent applications—a fourteen percent increase over 2001. 2002 AUTM SURVEY, *supra*, at 1. The vast majority of these patents likely relate to life science applications. NAT'L SCIENCE FOUND., *supra* note 108, at 5-6.

While patenting activity among universities dates back to the early 1900s, most universities resisted direct involvement and some strongly discouraged it. Indeed, there was virtually no patenting of university medical research in the first half of the twentieth century, although universities did engage in research collaboration with industry during this period. Mowery et al., *Growth of Patenting and Licensing Post Bayh-Dole*, *supra* note 110, at 99; *see infra* note 171 and accompanying text. Even by 1970, United States universities had collectively never received even two hundred patents in a single year. *Id.* at 104; Jaffe, *supra*, at 541. Thereafter, as a result of several factors including a decline in federal funding, universities began to seek patent rents more aggressively. Mowery et al., *Growth of Patenting and Licensing Post Bayh-Dole*, *supra* note 110, at 102. In 1974 Harvard University, for example, “officially ended its stance against the patenting of medical innovations.” Harsha Thirumurthy, Yale AIDS Network, University IP Policies and Access to Medicines, Presentation at Yale Univ. (Sept. 22, 2003) (slides on file with authors). For historical analysis of technology transfer in the United States, *see*, for example, Mowery et al., *Growth of Patenting and Licensing Post Bayh-Dole*, *supra* note 110; David C. Mowery & Bhaven N. Sampat, *University Patents and Patent Policy Debates in the U.S.A., 1925-1980*, 10 INDUSTRIAL & CORP. CHANGE 781 (2001); Jaffe, *supra*; Bremer, *supra* note 109; Eisenberg, *supra* note 42 (describing the policy debates since WWII about how to treat federally funded research).

¹¹⁶ Arti K. Rai & Rebecca S. Eisenberg, *The Public Domain: Bayh-Dole Reform and the Progress of Biomedicine*, 66 L. & CONTEMP. PROBL. 289, 290 (2003).

¹¹⁷ 2002 AUTM SURVEY, *supra* note 115, at 15 (reporting that the institutions surveyed, including ninety-four of the top one hundred American research universities, executed 4673 licenses and option agreements in 2002 compared with 1278 such agreements in 1991).

¹¹⁸ NAT'L SCIENCE FOUND., *supra* note 108, at 5-6 (“Increases in licensing income and activity suggest [the] growing effort and success of university commercialization of their products and technology.”).

B. How and Why Universities Commercialize Research

Prior to 1980, inventions from federally funded research became the property of the United States government and could be licensed only on a non-exclusive basis.¹¹⁹ This intellectual property policy rested on the belief that government-funded research belonged to the public and should be freely available for public use.¹²⁰ By the late 1970s it appeared to many that this approach was failing to provide industry with sufficient incentives to commercialize federally funded research, resulting in systematic under-utilization of these discoveries.¹²¹ In 1978, Senators Birch Bayh and Bob Dole introduced legislation to spur commercialization by giving research institutions title to federally funded discoveries and allowing them to pursue exclusive licensing agreements with industry.¹²² The Bayh-Dole University and Small Business Patent Act of 1980 transformed the intellectual property regime governing federally funded research and substantially accelerated the growth of university technology transfer efforts.¹²³

¹¹⁹ Stevens, *supra* note 113, at 94 (discussing the legislative history of the Bayh-Dole Act).

¹²⁰ *Id.*

¹²¹ *Id. But cf.* Peter S. Arno & Michael H. Davis, *Why Don't We Enforce Existing Drug Price Controls? The Unrecognized and Unenforced Reasonable Pricing Requirements Imposed Upon Patents Deriving in Whole or in Part from Federally Funded Research*, 75 TUL. L. REV. 631, 640 n.46 (2001) (“The evidence marshaled to support this clam [that the government’s non-exclusive licensing policy provided insufficient incentives for industry commercialization] is elusive at best. . . . [F]igures on the utilization of government patents were hopelessly insufficient because the government did not enforce those patents . . . and thus had no way of knowing . . . how much of its patented technology was being used by others.”) (citations omitted); Eisenberg, *supra* note 42.

¹²² The stated purpose of the Bayh-Dole Act was to:

[U]se the patent system to promote the utilization of inventions arising from federally supported research or development; to encourage maximum participation of small business firms in federally supported research and development efforts; to promote collaboration between commercial concerns and nonprofit organizations, including universities; to ensure that inventions made by nonprofit organizations and small business firms are used in a manner to promote free competition and enterprise; to promote the commercialization and public availability of inventions made in the United States by United States industry and labor; to ensure that the Government obtains sufficient rights in federally supported inventions to meet the needs of the Government and protect the public against nonuse or unreasonable use of inventions; and to minimize the costs of administering policies in this area.

35 U.S.C. § 200 (1994).

¹²³ *See Innovation’s Golden Goose*, *supra* note 113; Stevens, *supra* note 113; 2002 AUTM REPORT, *supra* note 115, at 7.

Under the aegis of the Bayh-Dole Act, hundreds of universities set up technology transfer offices (TTOs) to facilitate the patenting and licensing of scientific discoveries.¹²⁴ TTOs seek to ensure the development and commercialization of university discoveries, maximize financial returns to universities, and promote local business development.¹²⁵ Of these, promoting the development and commercialization of university innovations—in order to get “university inventions into the hands of the public”¹²⁶—is frequently said to be the primary goal of university technology transfer.¹²⁷ The approach of university TTOs over the last twenty years suggests a belief that “commercializing an invention with an eye toward maximizing university revenue will also maximize the benefit the public receives from the invention.”¹²⁸

Yet in many situations, TTOs achieve results that diverge from and may conflict with the interests of the university as a whole and the public, whose funding enables the underlying discoveries.¹²⁹ TTOs typically follow a standard procedure: When researchers discover a

¹²⁴ The number of institutions engaged in technology transfer increased throughout the 1970s (prior to Bayh-Dole). See Bremer, *supra* note 109. However, since Bayh-Dole the growth has been dramatic: “There are now more than 200 universities engaged in technology transfer, eight times more than in 1980, as evidenced by the membership of AUTM.” Ass’n of Univ. Tech. Managers, Survey-Bayh-Dole Act, at http://www.autm.net/index_ie.html (last visited August 1, 2004).

¹²⁵ See, e.g., Lita Nelsen, *The Role of University Technology Transfer Operations in Assuring Access to Medicines and Vaccines in Developing Countries*, 2 YALE J. HEALTH POL’Y L. & ETHICS 301, 302 (2003); Jeannette Colyvas et al., *supra* note 113, at 68; Rebecca LeGrand, Why Do Universities Patent and License Technology? Reexamining the Goals of University Technology Transfer in the Face of a Global Health Crisis 3-4 (Sept. 11, 2003) (unpublished manuscript, on file with authors) (including discussion of Yale University’s technology transfer office’s concern for fostering a local biotechnology industry for the sake of community development and to assist with faculty recruitment).

¹²⁶ LeGrand, *supra* note 125, at 1.

¹²⁷ See, e.g., Yale Office of Cooperative Research, Yale Policy on Intellectual Property, Patents and Licensing Agreements (Feb. 11, 2002), http://www.yale.edu/ocr/indust_policies/policy2002.html. But see Colyvas et al., *supra* note 113, at 68 (finding that economic objectives are now a top priority for university patenting and licensing policies and concluding that university TTOs and patenting/patent licensing may not be the most effective way to facilitate the development and dissemination of university research); Eisenberg, *supra* note 42, at 1697, 1710 (describing the principal transfer and dissemination argument, but also acknowledging that universities increasingly “covet” licensing revenue).

¹²⁸ LeGrand, *supra* note 125, at 1.

¹²⁹ Professors Rai and Eisenberg argue that much university patenting activity is inconsistent with Bayh-Dole because universities’ “self-interest is an imperfect proxy for the overall public interest, particularly given the large role played in university decision-making by technology transfer professionals who are not themselves academics.” Rai & Eisenberg, *supra* note 116, at 304. Rai and Eisenberg further emphasize the divergent interests of scientists, who suffer when aggressive patenting prevents access to technologies that could constitute useful inputs to research, and technology transfer personnel, for whom “licensing revenues are much more salient.” *Id.* But see *infra* note 200

potentially important innovation, for example a new molecular entity with pharmacological significance, they contact their university TTO, which evaluates the invention to determine whether it has commercial potential.¹³⁰ The TTO will likely decide to patent the invention if the expected net present value of commercialization is sufficient to justify the costs of obtaining a patent;¹³¹ the patenting decision traditionally has not taken into account non-economic considerations, such as access to medicines for LMI country residents.¹³²

Before, during or after the patenting process, the TTO seeks to license the discovery to industry. Depending on the type of invention, universities will grant either a non-exclusive license—common for research and development tools—or an exclusive license—the norm for inventions likely to be further developed and (hopefully) commercialized by the licensee, such as drugs or diagnostic tests.¹³³ Universities grant a roughly equal number of exclusive and nonexclusive licenses,¹³⁴ but almost always use exclusive licenses for agreements with start-up

(discussing revenue sharing with inventors, as mandated by Bayh-Dole, which may suggest that scientists are also increasingly torn between traditional values and profits).

¹³⁰ See Sanjay Basu, Yale AIDS Network, A Revised Framework for Global Medicine Access, Presentation at Yale Univ. (April 19, 2003) (slides on file with authors); Interview with Dr. Jon Soderstrom, Managing Director, Yale Office of Cooperative Research (OCR), in New Haven, Conn. (Dec. 4, 2003). For example, Stanford University patents approximately fifty percent of its disclosed inventions. Stanford Univ., Stanford Office of Technology Licensing (OTL), at <http://otl.stanford.edu/about/resources/otlpres.pps#9>.

¹³¹ See AMY KAPCZYNSKI, YALE UNIV. CTR. FOR INTERDISCIPLINARY RESEARCH ON AIDS, ACCESS TO ESSENTIAL MEDICINES AND UNIVERSITY RESEARCH: BUILDING BEST PRACTICES 3-4 (2003), available at http://cira.med.yale.edu/law_policy_ethics/access_ess.pdf [hereinafter WORKSHOP REPORT]. The average cost of obtaining a patent is approximately \$50,000 in the U.S., and \$12,000 to \$15,000 in an LMI country. *Id.* at 4.

¹³² See WORKSHOP REPORT, *supra* note 131, at 4.

¹³³ See YALE UNIV., OFFICE OF COOPERATIVE RESEARCH, FROM BENCH TO BEDSIDE: 1996-1998, at 5, http://www.yale.edu/ocr/images/docs/ocr_report_96-98.pdf (last visited May 17, 2004); Nelsen, *supra* note 125, at 302-03; see also Colyvas et al., *supra* note 113, at 67 (finding that exclusivity is “likely to be most important for embryonic inventions, and unimportant for inventions that are useful to industry ‘off the shelf’” and that for items licensed nonexclusively, patenting simply “allowed universities to collect revenues, but did nothing to facilitate technology transfer”). Previously, Eisenberg similarly argued that to achieve dissemination and useful application of university innovations, exclusive licensing is generally only necessary for research byproducts that are early stage and require extensive further development with little certainty of success. In many cases—as with the famed Cohen-Boyer patent for recombinant DNA technology—nonexclusive licensing is recognized as a viable way to achieve widespread adoption—but she points out that in such cases nonpatented entry into the public domain would likely be equally successful in this regard. Eisenberg, *supra* note 42, at 1700, 1710.

¹³⁴ See 2002 AUTM SURVEY, *supra* note 115, at 1 (in 2002, 53.5% of licenses for which type of exclusivity is known were non-exclusive, 46.5% were exclusive); Hall, *infra* note 165, at 14 (reporting that the majority of technology transfer licenses granted by U.C. Berkeley and Stanford are exclusive) (citing D. C. Mowery & A. A. Ziedonis, *Academic Patent Quality and Quantity Before and After the Bayh-Dole Act in the United States*, 31 RES.

companies,¹³⁵ who are likely to be the recipients of early-stage molecular discoveries with the potential to become drugs.¹³⁶ The university may receive upfront payments, milestone payments, a royalty stream, and/or equity in the licensee in return for licensing the technology.¹³⁷

Because universities engage in early stage research they are frequently well upstream with regard to drug development;¹³⁸ as a result two-thirds of university's licensing agreements are made with "newly formed or existing small companies"—in the context of the life sciences, small biotechnology or pharmaceutical companies.¹³⁹ These recipients of university discoveries are in turn involved in licensing and acquisition agreements with larger pharmaceutical firms that use these smaller companies to fill their research and development pipelines.¹⁴⁰

While university TTOs apparently do not typically patent discoveries in LMI countries due to time and budget constraints,¹⁴¹ end products based on university inventions that are particularly relevant to LMI populations may become patented in developing countries.¹⁴² The

POL'Y 399 (2002); D. C. Mowery & A. A. Ziedonis, *Numbers, Quality, and Entry: How Has the Bayh-Dole Act Affected U.S. University Patenting and Licensing?*, 1 INNOVATION POL'Y & ECON. 187 (2001))

¹³⁵ 2002 AUTM SURVEY, *supra* note 115, at 1 ("91% of licenses and options to start-ups were exclusive . . . 54% of licenses to small entities (including start-ups) were exclusive.").

¹³⁶ Interview with Jon Soderstrom, Managing Director, Yale Office of Cooperative Research, in New Haven, Conn. (Dec. 4, 2003).

¹³⁷ Bruce Berman, *From Tech Transfer to Joint Venture—Part I*, PATENT CAFE, Mar. 6, 2002, http://www.cafezine.com/index_article.asp?deptId=5&id=555&page=1; Maryann Feldman et al., *Equity and the Technology Transfer Strategies of American Research Universities*, 48 MGMT. SCI. 105 (2002) ("document[ing] the rise in university equity holdings").

¹³⁸ See, e.g., Jerry G. Thursby et al., *Objectives, Characteristics and Outcomes of University Licensing: A Survey of Major U.S. Universities*, 26 J. TECH. TRANSFER 59, 62 (2001) (finding that, at the time of licensing, forty-five percent of university inventions were at the "proof of concept" stage).

¹³⁹ ASS'N OF UNIV. TECH. MANAGERS, AUTM LICENSING SURVEY: FY 2000, at 1 (2001) [hereinafter 2001 AUTM SURVEY].

¹⁴⁰ See *Big Trouble for Big Pharma*, THE ECONOMIST (London), Dec. 4, 2003, http://www.economist.com/business/displayStory.cfm?story_id=2269456 ("Many big drug firms have begun to license more of their technology and products from outside companies, especially biotechnology start-ups."); Thursby & Thursby, *supra* note 115 (noting "increased business reliance on external R&D").

¹⁴¹ See WORKSHOP REPORT, *supra* note 131, at 4 ("It costs around \$12,000 to \$15,000 to register a patent in a developing country . . . and patent-holders must also pay annual maintenance fees and lawyer's fees."); Eisenberg, *supra* note 42, at 1666 ("[R]esource constraints prohibit patenting many discoveries that emerge from government-sponsored research.").

¹⁴² Universities, mirroring the practices of pharmaceutical companies described *supra* note 48, are more likely to patent in middle income countries. See WORKSHOP REPORT, *supra* note 131, at 4-5.

patenting of a university's innovation in an LMI country may occur either prior to licensing¹⁴³ or subsequently, at the request of the licensee.¹⁴⁴ Frequently the university's licensed patent is a critical contribution toward, but does not constitute the entirety of, the intellectual property necessary to generate the end product; the licensee may engage in and patent subsequent developments—often referred to as secondary or improvement patents.¹⁴⁵

It is clear that for some university life sciences discoveries, patenting activity in LMI countries contributes to the access gap by preventing generic competition and its attendant price reductions. The fate of a drug discovered at Yale University two decades ago offers one of the best known examples of this phenomenon to date. In 1984, Yale researchers discovered that d4t (stavudine), a reverse transcriptase inhibitor similar to AZT, was active against HIV/AIDS.¹⁴⁶ Yale filed for a patent in the United States for use of the molecule against HIV/AIDS in 1986, and then two years later entered into an exclusive worldwide licensing agreement with Bristol-Meyers Squibb (BMS).¹⁴⁷ At BMS's behest, Yale proceeded to apply for patents in South Africa and several other LMI countries (e.g., Egypt). In 1994, BMS ultimately brought d4t to market as the HIV/AIDS drug Zerit.¹⁴⁸ Zerit became part of a \$10,000+ per year anti-retroviral drug

¹⁴³ For example, the University of Minnesota patented abacavir (sold in the United States as Ziagen) in a variety of LMI countries, including Malaysia, the Philippines, Pakistan, South Africa, and Taiwan, prior to licensing it. E-mail from Adam Sitze describing the University of Minnesota's patenting activity in LMI countries in 1989 (on file with authors).

¹⁴⁴ “[T]he practice in most American universities” is for the research institution “to continue to own the patent after licensing. . . . Universities can then contract with the licensee to control in which countries the patent will be filed.” Nelsen, *supra* note 125, at 304. See, for example, the Yale and d4t examples discussed *infra* (usually licensee then pays the filing fee). Dr. Soderstrom, Yale OCR Managing Director, has argued that this practice is unlikely given the time (until patenting takes place) currently allowed by the Patent Cooperation Treaty and the length of time normally occupied negotiating a deal. Interview with Dr. Jon Soderstrom, Managing Director, Yale Office of Cooperative Research, in New Haven, Conn. (Dec. 4, 2003).

¹⁴⁵ “In the life sciences final products are general subject to multiple patents. . . . Universities are therefore often not acting alone vis-à-vis final products.” WORKSHOP REPORT, *supra* note 131, at 3; *see also* Nelsen, *supra* note 125, at 305.

¹⁴⁶ *See* John Curtis, *Hunting Down HIV*, YALE MED., Summer 1998, http://info.med.yale.edu/external/pubs/ym_su98/cover/cov_hunting11.html. D4t was first synthesized in 1966 at the Michigan Cancer Center under a grant from the National Cancer Institute. Posting of Thiru Balasubramaniam, thiru@cptech.org, to ip-health@lists.essential.org (Nov. 22, 1999).

¹⁴⁷ *See* Curtis, *supra* note 146.

¹⁴⁸ *See id.*

cocktail,¹⁴⁹ and generated \$30 to \$40 million in annual royalties for Yale.¹⁵⁰ However, the drug remained almost entirely unavailable to African HIV/AIDS victims because of Zerit's price, despite the announced willingness of an Indian pharmaceutical firm to manufacture and sell a generic version of Zerit for less than \$300 per year.¹⁵¹

In February 2001, Yale students working in conjunction with Doctors Without Borders (also known as Médecins Sans Frontières or MSF) brought pressure on the university and BMS to allow generic production and marketing of d4t in South Africa. Yale's role in exacerbating the access gap via its exclusive licensing of the drug became uncomfortably apparent.¹⁵² Within weeks—in March 2001—Yale and BMS “reached agreement . . . ‘to remove any obstacles’ on patent and price issues.”¹⁵³ BMS announced that it would not enforce its patent on d4t in South Africa and would sharply reduce prices throughout sub-Saharan Africa.¹⁵⁴ “The result was a rapid, thirty-fold reduction in the price of d4t in South Africa (from more than \$1600 to \$55 per patient per year).”¹⁵⁵ In August 2003, Aspen Pharmaceutical, a local generic manufacturer,

¹⁴⁹ See Lindsay, *supra* note 50.

¹⁵⁰ See Curtis, *supra* note 146; Julian Borger & Sarah Boseley, *Campus Revolt Challenges Yale Over \$40 Million Aids Drug Deal*, THE GUARDIAN (LONDON), Mar. 13, 2001, <http://www.commondreams.org/headlines01/0313-01.htm>. Between 1994 and 2000 d4t generated ninety percent of the university's royalty income. Demenet, *supra* note 41.

¹⁵¹ See Lindsay, *supra* note 50.

¹⁵² Articles appeared in the New York Times and other major newspapers, bringing national attention to the issue. See *id.* (discussing Yale's public relations embarrassment over the inaccessibility of d4t to African HIV/AIDS victims); Daniel Kurtz-Phelan, *Conservative Compassion: Global AIDS Activists Use Yale To Prick the Corporate Conscience*, NEW J., Apr. 20, 2001, <http://www.yale.edu/tmj/335/335compassion.htm>. Dr. William Prussoff, one of the scientists who had discovered the use of d4t to treat HIV, voiced his disapproval of the university's practices in *The New York Times*. Donald G. McNeil Jr., *Yale Pressed To Help Cut Drug Costs in Africa*, N.Y. TIMES, Mar. 12, 2001, at A3.

¹⁵³ Karen DeYoung & Bill Brubaker, *HIV Drug Price Cut for Some in Africa*, WASH. POST., Mar. 15, 2001, at A1.

¹⁵⁴ Press Release, Bristol-Myers Squibb, Bristol-Myers Squibb Announces Accelerated Effort to Fight HIV/AIDS in Africa (Mar. 14, 2001), <http://www.bms.com/landing/data/index.html>; see DeYoung & Brubaker, *supra* note 153.

¹⁵⁵ Michael Merson, *Preface to WORKSHOP REPORT*, *supra* note 131, at v. Shortly thereafter, on April 19, 2001, U.S.-based pharmaceutical companies dropped the lawsuit they had brought against South Africa, “seeking to force the government to overturn an unenforced 1997 law allowing the public health ministry to override drug patents in the event of a national health emergency.” Lindsay, *supra* note 50. Some credit the BMS d4t concession—“it had simply become too [publicly] damaging for the other companies to continue their legal battle.” *Id.*

finally “began selling generic stavudine in South Africa for up to 40% less than the reduced patented price.”¹⁵⁶

D4t is certainly not the only important drug developed by a university for which access is a problem caused in part by technology transfer policies.¹⁵⁷ To date, however, university TTOs have not proactively or systematically attempted to address access concerns in their licensing arrangements with private-sector firms. TTOs’ goals appear largely limited to protecting intellectual property, maximizing financial returns to the university, and promoting local business development.¹⁵⁸ Indeed, according to a survey of TTO professionals, they view securing royalty and licensing fees—money that serves in part to sustain and expand TTOs¹⁵⁹—as their most important objective.¹⁶⁰ Though TTO employees may not realize direct financial benefits from technology transfer agreements,¹⁶¹ they have an interest in maximizing the appearance of financial success from technology transfer activity in order to justify their

¹⁵⁶ Amy Kapczynski et al., Editorial, *Global Health and University Patents*, 30 *SCIENCE* 1629 (2003); *see supra* note 100. The national ARV program that is being rolled out in South Africa will rely upon generic versions of d4t. *See* Julian Meldrum, *South African HIV Treatment To Depend on Generic Drugs*, *AIDSmap News* (Aug. 7, 2003), at <http://www.aidsmap.com/en/news/F5E96962-F1B4-40F2-8969-624AC8A7D424.asp>.

¹⁵⁷ Other AIDS drugs developed at universities include 3TC/Epivir (Emory University), Abacavir/Ziagen (University of Minnesota), T20/Fuzeon (Duke University). *See, e.g.*, Michael Merson, *Preface to WORKSHOP REPORT*, *supra* note 131, at iv; Univs. Allied for Essential Medicines, *Data-Driven Fact Sheet*, at <http://www.essentialmedicines.org/primer.pdf>; Legrand, *supra* note 125, at 7-9. Drugs developed at universities range from chemotherapeutic agents—cysplatin and carboplatin were developed at Michigan State University—to glaucoma drugs—latanoprost/Xalatan was developed at Columbia University. Other drugs with key university input include: Epogen (University of Chicago); Erbitux (University of California at San Diego); Prilosec (University of Alabama); streptomycin (Rutgers University); penicillin (Oxford University); and insulin (University of Toronto).

¹⁵⁸ *See supra* note 127. The Association of University Technology Managers (AUTM) annual survey reports the number of patents applied for and obtained, the amount of license income received, and the number of start-up companies formed as a result of university research. 2002 AUTM SURVEY, *supra* note 115, at 11, 18, 21. While the AUTM survey briefly discusses the social impact of a handful of products developed out of university research, *id.* at 2-5, it is almost entirely focused on patenting, licensing and financial information. *See also infra* note 162.

¹⁵⁹ Thursby et al., *supra* note 138, at 61 (reporting that surveyed TTOs take an average of eleven percent of the income from licensing agreements).

¹⁶⁰ *Id.* at 65-66 (reporting that surveyed TTO personnel list generating royalties and license fees as the most important measure of TTO success, followed by the number of licenses or options signed).

¹⁶¹ *See, e.g.*, Stanford University Office of Technology Licensing, OTL and the Inventor: Roles in Technology Transfer, <http://otl.stanford.edu/inventors/resources/otlandinvent.html> (last visited May 17, 2004) (“[N]either OTL nor OTL personnel has a financial stake per se in University licenses. OTL’s budget is not based upon the amount of licensing revenue generated.”).

continued existence.¹⁶² Ironically, TTOs may often be money-losing propositions for universities.¹⁶³ Still, university TTOs are celebrated for generating income for the university and spinning out local start-up companies, while the potential contributions of technology transfer to global public health are rarely mentioned.¹⁶⁴

While the TTO serves as the primary interface between academic science and industry, its institutional ethos shares much more with the latter's desire for strong and exclusive intellectual property rights than with the former's commitment to rapid, widespread and open dissemination of discoveries for the public good. Tension between university science and industry is neither new nor avoidable: The two institutions have worked together while maintaining distinct and conflicting missions for decades.¹⁶⁵ However the current contributions of university technology transfer practices to the inequities in access to medicines and health technologies suggest that the time has come for universities to reevaluate and reorient their technology transfer activities to find a better balance.

¹⁶² TTO annual reports typically begin by proclaiming the amount of royalty income generated. See, e.g., STANFORD UNIV., OFFICE OF TECH. LICENSING, ANNUAL REPORT 2002-2003, at 8 <http://otl.stanford.edu/about/resources/otlar03.pdf> (last visited May 17, 2004) (after introductory anecdotes, the report begins with a statement of financial results: "In spite of the economic turndown, gross royalties of \$45.4M . . . More significantly, Stanford retained \$43.2M of gross royalties."); UNIV. OF CAL., OFFICE OF TECH. TRANSFER, 2002 ANNUAL REPORT 3 [hereinafter U.C. 2002 ANNUAL REPORT], <http://www.ucop.edu/ott/ars/ann02/ar02.pdf> (last visited May 17, 2004) ("In fiscal year 2002, the UC technology transfer program had another record-breaking year. Income generated by the program increased dramatically, with more than \$30 million returned to the UC system."); MASS. INST. OF TECH., TECH. LICENSING OFFICE, MIT REPORTS TO THE PRESIDENT 2000-2001, <http://web.mit.edu/communications/pres01/09.15.html> (last visited May 17, 2004) ("This was an unusually successful year financially for the Technology Licensing Office, with income of \$82.1 million, of which \$55.6 million was cash-in of equity (from two companies).").

¹⁶³ See *infra* Section III.B.

¹⁶⁴ See, e.g., Eisenberg, *supra* note 42, at 1710 (discussing view of royalties as measure of success). There are signs that TTOs' lack of concern for the implications of their decisions on LMI country health may be changing. See, e.g., Nelsen, *supra* note 125. In 2003 the AUTM held its first workshop on the health care needs of developing countries. *Id.* at 303; discussion *infra* Section III.D.

¹⁶⁵ See Bronwyn H. Hall, *University-Industry Research Partnerships in the United States*, in *RETHINKING SCIENCE SYSTEMS AND INNOVATION POLICIES* (Jean-Pierre Contzen et al. eds., forthcoming 2004), http://emlab.berkeley.edu/users/bhhall/papers/BHH04_Kansai.pdf (discussing the inherent conflict between university science's commitment to rapid publication and open dissemination and industry's reliance on strong intellectual property rights). "The traditional norms of the university have been somewhat subordinated to the desire to license discoveries." *Id.* at 14.

III. The Case for University Action

As the discussion above indicates, universities are in a unique and potentially powerful position to help close the access gap. The much-publicized story of d4t is a testament to this opportunity, although other similar “ex post” efforts by students and activists have been less successful. Advocacy initiatives at the University of Minnesota and Emory University highlight the difficulties with trying to convince university administrators to take action well after they have out-licensed their innovations.¹⁶⁶ There are significant disadvantages to reacting to an access crisis for a particular medicine, rather than incorporating access considerations from the beginning of the technology transfer process. Chief among these disadvantages is that a university’s control over the invention and subsequent product dissipates over the course of the research-development-commercialization cycle, such that the university typically has little leverage once a licensing agreement has been executed. Earlier in the cycle—for example, when deciding where to patent or how to license a discovery—universities have far greater capacity to influence the accessibility of end-products¹⁶⁷ and to facilitate research into neglected diseases.¹⁶⁸

To date, universities have done little more than acknowledge the importance of this issue.¹⁶⁹ Yet a number of ethical, economic, and legal arguments, outlined below, suggest that

¹⁶⁶ Activists’ experiences at these two universities point to the limitations of negative publicity as a tactic to force change and the complexity of trying to influence the accessibility of a final product to which a university has contributed an underlying patent. State schools, like the University of Minnesota, may be somewhat less sensitive to negative media attention than private, “brand”-conscious schools, which are more dependent on private donations and alumni generosity. Moreover, generating negative publicity is complicated and contingent, requiring a situation perceived as newsworthy (for example, it is likely to be easier to get press attention for elite, widely recognized institutions and for drugs treating high-profile diseases such as AIDS). Finally, in both cases the university held only a limited share of the total intellectual property involved. *See, e.g., Lindsay, supra* note 50.

¹⁶⁷ Lita Nelsen, the Director of M.I.T.’s Technology Licensing Office, has explained, “It is before each invention is licensed that a university can best ensure that the license will be used to advance—or at least not to hinder—efforts to meet the health care needs of developing countries.” Nelsen, *supra* note 125, at 306.

¹⁶⁸ Since university research relevant to neglected diseases often fails to attract for-profit licensees (i.e., when there is no foreseeable application in OECD markets), universities have at least begun to redirect these research projects to the emerging crop of non-profit initiatives, *supra* notes 94-96. Recent agreements involving Yale and the University of California at Santa Barbara are discussed *infra* Section III.D. But see, for example, Yale’s licensing of its antiviral suite to Achillion Pharmaceuticals, a for-profit, privately held start-up without plans to pursue neglected diseases-research. *See, e.g., Jennifer Bayot, Biomed Drugs Bring Yale Bucks, Yale Daily News, Feb. 17, 2000, <http://yaledailynews.com/article.asp?AID=4637>.*

¹⁶⁹ *See* discussion of recent developments *infra* Section III.D.

universities should exercise their latent power to meaningfully address the access gap through their technology transfer practices.

A. Institutional Principles and Public Relations Considerations

Universities' core institutional principles include the production and dissemination of knowledge, as well as a more general dedication to improving human welfare through that knowledge.¹⁷⁰ For much of the twentieth century, academic institutions were committed to allowing their discoveries to freely enter the public domain.¹⁷¹ This Mertonian tradition of open science has come under attack in the Bayh-Dole era, as universities have pursued a controlled and closed approach to research discoveries.¹⁷² Yet the unwitting and seemingly needless role of university technology transfer agreements in exacerbating the access gap¹⁷³ suggests that the pendulum has swung too far. Official university patent policies, which typically declare the

¹⁷⁰ See Jim Jackson & Jill Cowley, *Blinking Dons or Donning Blinkers: Fiduciary and Common Law Obligations of Members of Governing Boards of Australian Universities*, 6 S. CROSS U. L. REV. 8, 13 (2002) (identifying common principal function of the university as “the encouragement of the dissemination, advancement, development, and application of knowledge informed by free inquiry”); see also Eisenberg, *supra* note 42, at 22 (“By nature of their institutional mission and culture, universities may have a preference for widespread dissemination of new knowledge.”).

¹⁷¹ Archie M. Palmer, Survey of University Patent Policies: Preliminary Report (Nat’l Research Council, NAS, 1948). In 1938, Yale University’s intellectual property policy stated:

[I]t is, in general, undesirable and contrary to the best interests of medicine and the public to patent any discovery or invention applicable in the fields of public health or medicine; but if, at any time, any member of the faculty deems it necessary solely for the protection of the public, without profit to himself or the University, to control any invention or discovery by means of a patent, he shall bring the matter before the Prudential Committee.

Id.; Sahm Adrangi, *With Patent Policy, A Balance To Strike*, YALE DAILY NEWS, Mar. 22, 2001, <http://www.yaledailynews.com/article.asp?aid=15038>. At that time, Harvard University did not have a formal patent policy, but simply stated, “No patents primarily concerned with therapeutics or public health may be taken out by any member of the University, except with the consent of the President and Fellows; nor will such patents be taken out by the University itself except for dedication to the public.” Palmer, *supra*.

¹⁷² See Nannerl O. Keohane, *The Mission of the Research University*, DEADALUS, Fall 1993, at 101, 122 (“Proprietary knowledge is sometimes important for corporate success, but it is in principle antithetical to the openness in sharing knowledge that is at the heart of the university’s mission.”); Creative Commons, Projects: Proposal to Create a Science Commons, <http://creativecommons.org/projects/science/proposal> (last visited May 16, 2004); Eisenberg, *supra* note 42. Cf. ROBERT KING MERTON, *THE SOCIOLOGY OF SCIENCE: THEORETICAL AND EMPIRICAL INVESTIGATIONS* (1973).

¹⁷³ See *infra* Section III.B for discussion of the economics of technology transfer, demonstrating that access can be improved without causing financial loss to either universities or pharmaceutical companies.

ultimate purpose of technology transfer to include promotion of the public good,¹⁷⁴ are difficult to reconcile with a myopic focus on maximizing the number of patents and the amount of license and royalty revenue from university discoveries.

As Yale's experience with d4t demonstrates, this intra-institutional tension offers advocates the opportunity to sway university behavior by publicly exposing deep inconsistencies between university policies and TTO practices.¹⁷⁵ The efforts of access advocacy organizations, combined with increased attention from the academic community,¹⁷⁶ are contributing to heightened awareness and thus greater pressure on universities. The student-led group Universities Allied for Essential Medicines (UAEM) and other organizations¹⁷⁷ are prepared to continue to publicly challenge universities' closed licensing practices. While public shaming

¹⁷⁴ See, e.g., Univ. of Pa., Penn Center for Technology Transfer, <http://www.ctt.upenn.edu/oasis/org/?d=ctt>; Yale Office of Cooperative Research, Yale University Patent Policy (Feb. 1998), http://www.yale.edu/ocr/invent_policies/patents.html; Stanford Univ., Office of Technology Licensing, OTL and the Inventor: Roles in Technology Transfer, <http://otl.stanford.edu/inventors/resources/otlandinvent.html> ("OTL is responsible for managing the intellectual property assets of the University for the public good."); Univ. of Cal., Office of the President, University of California Patent Policy (1997), <http://www.ucop.edu/ott/patentpolicy/patentpo.html> ("The following University of California Patent Policy is adopted to encourage the practical application of University research for the broad public benefit."); Mass. Inst. of Tech., Tech. Licensing Office, Mission Statement, <http://web.mit.edu/tlo/www/mission.html> ("[Our] mission . . . is to benefit the public by moving results of M.I.T. research into societal use via technology licensing.").

¹⁷⁵ In a letter to Yale requesting action with regard to d4t, MSF quoted from the university's own patent policy which states that a key objective is "the benefit of society in general." Letter from Doctors Without Borders/Médecins Sans Frontières to Yale University (Mar. 9, 2001) (on file with authors). Indeed Yale's policy elsewhere states, "The primary goal of commercializing Yale inventions is to disseminate and develop knowledge for the public good. Subsidiary goals include generating revenue for reinvestment in Yale's research and education, helping with faculty recruitment and retention, and promoting local economic development." Yale Office of Cooperative Research, Yale Policy on Intellectual Property, Patents and Licensing Agreements (Feb. 11, 2002), http://www.yale.edu/ocr/indust_policies/policy2002.html. See, e.g., Borger & Boseley, *supra* note 150 (noting this inconsistency); *supra* note 152.

¹⁷⁶ Individual scholars include Richard Nelson, John Barton, Arti Rai, and Rebecca Eisenberg. Recent editorials in *Science* have also highlighted these issues. See, e.g., Jennifer Couzin, *Report Deplores Growth in Academic Patenting*, 300 SCIENCE 406 (2003) (describing report by the United Kingdom's "premier scientific academy"); Kapczynski et al., *supra* note 156.

¹⁷⁷ Advocacy groups active in this area include MSF, HealthGap, and the Consumer Project on Technology.

may be most effective at compelling behavior modifications among some private universities,¹⁷⁸ this tactic is potentially powerful across all universities.¹⁷⁹

Where universities' normative charge to serve the public good fails to encourage action, it may be worth noting that modifying technology transfer policies to address health concerns in the developing world is a prudent course for universities seeking to avoid negative publicity and other liability risks.¹⁸⁰

B. The Economics of Technology Transfer and the Access Gap

Despite the resulting tension with core institutional values, university technology transfer activity today is largely focused on revenue generation.¹⁸¹ However, TTOs's keen interest in licensing income—as well as the substantial and well-publicized growth in the number of deals and amount of licensing revenues—belies the true economics of technology transfer.¹⁸² In a recent survey of the empirical literature, Professor Bhaven Sampat concluded, “It is likely that after taking costs into account, the majority of American research universities are losing money on their patenting and licensing activities.”¹⁸³ Johns Hopkins President William Brody has

¹⁷⁸ See *supra* note 166.

¹⁷⁹ The experiences of U.S. universities with regard to both sweatshop labor and divesture in South Africa are instructive. See Peter Dreier & Richard Appelbaum, *The Campus Anti-Sweatshop Movement*, AMER. PROSPECT, Sept.-Oct. 1999, <http://www.prospect.org/print/V10/46/dreier-p.html>.

¹⁸⁰ To the extent the behavior of their TTOs deviates from the public interest, universities may face unexpected risks. See, e.g., Peter D. Blumberg, Comment, *From “Publish or Perish” to “Profit or Perish”: Revenues from University Technology Transfer and the 501(c)(3) Tax Exemption*, 145 U. PA. L. REV. 89 (1996) (arguing that university income from technology transfer should be subject to the unrelated business income tax to the extent TTO practices stray from universities' educational and scientific mission, such as when TTOs exclusively license a technology); *Madey v. Duke Univ.*, 307 F.3d 1351 (Fed. Cir. 2002), *cert. denied*, 123 S. Ct. 2639 (2003) (narrowing the experimental use exception in patent law to deny protection to universities engaged in pure scientific research that furthers their business interests).

¹⁸¹ See *supra* notes 127, 158-162.

¹⁸² See *supra* notes 115-118 and accompanying text.

¹⁸³ Bhaven N. Sampat, *The Effects of Bayh-Dole on Technology Transfer and the Academic Enterprise: A Survey of the Empirical Literature* 12 (2004) (unpublished manuscript, on file with authors) [permission to cite requested].

similarly observed, “The dirty secret is that for many universities—perhaps most—they are not breaking even, much less making money on the proposition.”¹⁸⁴

The number of schools that make money from technology transfer is small, and those that profit tend to do so from a limited number of highly successful patents.¹⁸⁵ Columbia University, in particular, has “emerged as a patent royalty leader among . . . research institutions”¹⁸⁶—between 1993 and 2000 its annual licensing income grew from approximately \$20 million to \$143 million.¹⁸⁷ In 1999, Columbia University alone generated more than fifteen percent of all U.S. university patent income,¹⁸⁸ and did so largely as a result of a single discovery that has generated over \$400 million in revenues, making it one of the most profitable patents ever owned by a university.¹⁸⁹

Such success is in striking contrast to the vast majority of university innovations. According to data collected from TTOs, only 145 out of 20,086 active licenses—less than one percent—generated more than one million dollars in royalties in 2002.¹⁹⁰ Licensing revenues are typically equivalent to just four percent of a university’s research funds, and this figure decreases

¹⁸⁴ Johns Hopkins University President William R. Brody, *From Minds to Minefields: Negotiating the Demilitarized Zone between Industry and Academia*, Remarks at Biomedical Engineering Lecture Series (Apr. 6, 1999) (transcript available at <http://www.jhu.edu/~president/speech/biomlec.html>).

¹⁸⁵ Sampat, *supra* note 183, at 11-12 (“[A] handful of universities account for the lion’s share of licensing revenues. . . . 10% of the Carnegie research universities account for over 60% of total licensing revenues.”); *see also* 2002 AUTM SURVEY, *supra* note 115, at 19 fig. 25 (showing the distribution of total licensing income received by U.S. universities in 2002).

¹⁸⁶ Berman, *supra* note 137.

¹⁸⁷ *Id.*

¹⁸⁸ *Id.*

¹⁸⁹ Currently the validity of Columbia’s secondary patent on this technology is being questioned in court. Goldie Blumenstyk, *Company Sues Columbia U. To Invalidate Patent*, CHRON. HIGHER EDUC., May 2, 2003; Ted Agres, *Columbia Patents Under Attack*, THE SCIENTIST: DAILY NEWS, July 25, 2003, at <http://www.biomedcentral.com/news/20030725/03>. In addition, on May 10, 2004, the U.S. Patent Office granted the Public Patent Foundation’s request to reexamine Columbia’s cotransformation patent. Press Release, Public Patent Found., Patent Office Grants PUBPAT Request to Reexamine Cotransformation Patent (May 10, 2004), http://www.pubpat.org/Axel_Reexam_Granted.htm.

¹⁹⁰ 2002 AUTM SURVEY, *supra* note 115, at 20.

significantly when the costs of patent and license management, as well as the inventors' share of royalty income, are subtracted.¹⁹¹

The University of California system, one of the leaders in technology transfer,¹⁹² provides a helpful example: In 2002, the university generated \$88 million in technology transfer royalties and fees, spent \$26 million in legal fees and operating expenses, and distributed \$6 million to inventors and research partners, leaving the university system with just over \$56 million in income.¹⁹³ This represents 0.67% of the University of California's \$8.5 billion annual operating budget.¹⁹⁴ TTOs generate a similar proportion of revenue at other top universities.¹⁹⁵

¹⁹¹ See Nelsen, *supra* note 125, at 302 (2%-4%) (citing 2001 AUTM SURVEY); Richard Nelson, *Research and Technological Progress in Industry—An Analysis of the American Experience*, in INTERNATIONAL SYMPOSIUM ON ECONOMIC DEVELOPMENT THROUGH COMMERCIALIZATION OF SCIENCE AND TECHNOLOGY (2002). Cf. David C. Mowery & Bhaven Sampat, *Patenting and Licensing University Inventions: Lessons from the History of the Research Corporation*, 10 INDUSTRIAL & CORP. CHANGE 317 (2001) (finding that costly patent management made it difficult for the Research Corporation, a pre-Bayh-Dole institution, to generate positive net income).

¹⁹² See U.C. 2002 ANNUAL REPORT, *supra* note 162, at 5 (stating that “[t]he University of California leads the nation’s universities in the number of inventions reported by researchers” as well as “the number of patents granted and . . . the number of successfully commercialized inventions.”).

¹⁹³ UC 2002 ANNUAL REPORT, *supra* note 162, at 24-27.

¹⁹⁴ U.S. DEP’T OF EDUCATION, NAT’L CTR. FOR EDUCATION STATISTICS, ENROLLMENT IN POSTSECONDARY INSTITUTIONS, FALL 2001, AND FINANCIAL STATISTICS, FISCAL YEAR 2001 (2003).

¹⁹⁵ Professor Yochai Benkler has sketched a preliminary analysis of the relative size of TTO revenues to university budgets:

	2001 total revenues (millions)	2001 TTO licensing fees and royalties (millions)	% of total
All [U.S.] universities	\$227,000	\$1,270	0.56%
Columbia University*	\$2038	\$193	9.5%
		\$100-20	4.9-5.9%
Stanford University*	\$2400	\$43	1.79%
		\$36.6	1.52%
Florida State	\$2646	\$36	1.36%
University of Wisconsin-Madison	\$1696	\$32	1.89%
University of Minnesota*	\$1135	\$26.5	2.33%
Harvard University (2003)	\$2349	\$47.9	2.03%

Particularly relevant to the current discussion is the amount of revenue generated from sales in LMI countries. For both universities and pharmaceutical companies, this is exponentially less than the figures discussed above.¹⁹⁶ As an illustration of this, neither BMS nor Yale reported lost revenue as a result of the d4t patent concession in South Africa.¹⁹⁷ According to Yale University Dean Michael Merson, “This change was made at Yale without any negative consequences to the University—financial or otherwise.”¹⁹⁸ In light of these economic realities, asking TTOs to consider non-economic objectives—like increasing access—is not asking for much.

It should be noted, however, that universities often prize even limited income from technology transfer because these funds can be used for any purpose, as opposed to research grants and even donations, which typically may only be used for pre-defined purposes.¹⁹⁹ Also, a

Cal Tech (2003)*	\$531	\$26.7	5.02%
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Reprinted from Yochai Benkler, *Commons-Based Strategies to Alleviating the Problems of Patents 8* (May 2004) (unpublished manuscript, on file with authors) [hereinafter Benkler, *Commons-Based Strategies*] (format altered) (citing U.S. DEPT. OF EDUC., NAT’L CENTER FOR EDUC. STATISTICS, ENROLLMENT IN POSTSECONDARY INSTITUTIONS, FALL 2001, AND FINANCIAL STATISTICS, FISCAL YEAR 2001 (2003), TABLE F; 2002 AUTM Survey, *supra* note 115, at 18 tbl. S-12; publicly available annual reports of each university and/or its technology transfer office).

*Ambiguity in Columbia’s data “results because technology transfer office reports increased revenues for year-end 2003 as \$178M without reporting expenses; University Annual Report reports licensing revenue with all ‘revenue from other educational and research activities,’ and reports a 10% decline in this category, attributed to reduced licensing revenues from the \$133M for the previous year-end, 2002. The table reflects an assumed net contribution to university revenues between \$100-120M.” Stanford’s second TTO income data point is “[m]inus direct expenses, not including expenses for unlicensed inventions.” Minnesota’s TTO income data point is “2002, gross revenues only, University Office of Patents and Technology Marketing.” For Cal Tech’s TTO income data point, “[a]lmost half of this amount is in income from a single Initial Public Offering, and therefore does not represent a recurring source of licensing revenue.” *Id.*

¹⁹⁶ For 2002, Africa was estimated to compose 1.3% of the worldwide pharmaceutical market, and South-east Asia, China, and the Indian subcontinent combined to form only another 6.7%. IMS HEALTH, *FIVE YEAR FORECAST OF THE GLOBAL PHARMACEUTICAL MARKET, 1998-2002*, <http://www.ims-global.com/insight/report/global/report.htm>.

¹⁹⁷ See, e.g., LeGrand, *supra* note 125, at 19.

¹⁹⁸ Michael Merson, *Preface to WORKSHOP REPORT*, *supra* note 131, at v.

¹⁹⁹ See, e.g., Stanford Univ. Office of Tech. Licensing, *Why We Do It*, <http://otl.stanford.edu/about/why.html> (last visited May 17, 2004) (TTO mission includes “generating *unrestricted* income to support research and education”) (emphasis added); LeGrand, *supra* note 125, at 3 (citing Thomas A. Massaro, *Symposium on Regulation Medical Innovation: Innovation, Technology Transfer, and Patent Policy: The University Contribution*, 82 VA. L. REV. 1729, 1735 (1996)). Yale University, for example, used its royalties from d4t to build a new medical building. Demenet, *supra* note 41.

portion of technology transfer monies flow to inventors,²⁰⁰ providing potentially valuable incentives for researchers to continue working for universities rather than leaving for the private sector.

For these reasons, as well as their own dependence on licensing revenues,²⁰¹ technology transfer managers are wary of introducing any potential barriers to deal-making. As a result, even though university royalties derived from sales to LMI countries are insignificant, TTOs are generally uneasy with the idea of seeking “access provisions.” TTOs worry that they will have to settle for significantly less attractive financial terms²⁰² or, even worse, that they will be unable to close deals.²⁰³

The approach presented in Part IV—the Equitable Access License—addresses these concerns; it is designed to promote access without jeopardizing technology transfer deals. The EAL, for example, does not attempt to promote uncertain contractual provisions that would

²⁰⁰ Bayh-Dole mandates revenue sharing. 35 U.S.C. § 202(c)(7)(B). Inventors typically receive a thirty to forty percent share. *See, e.g.*, Berman, *supra* note 137 (citing Columbia’s typical distribution of forty percent to inventors); Yale Office of Cooperative Research, Yale University Patent Policy § 4(d) (Feb. 1998), http://www.yale.edu/ocr/invent_policies/patents.html (describing the distribution of net royalties); Robert L. Barchi, IP and Technology Transfer from the Academic Perspective, *at* http://www7.nationalacademies.org/step/Barchi_ppt.ppt (describing inventor’s thirty percent personal share and lab’s fifteen percent share).

²⁰¹ *See supra* note 159 and text accompanying.

²⁰² Arguably, the discussion in Section III.A of university’s institutional ethics and obligations suggests that universities should be willing to accept less attractive terms for the sake of access. At least one technology transfer director has publicly acknowledged this. *See* Nelsen, *supra* note 125, at 303. However, any substantial reduction in profitability would be an unnecessary and undesirable sacrifice given that access can be facilitated, as set forth in the Equitable Access License, *infra* Section IV.A, with minimal financial implications for pharmaceutical companies. The EAL was designed in this way to increase its feasibility and because we believe it remains desirable for income to flow back to universities, as opposed to benefiting only pharmaceutical firms. *Compare* Eisenberg, *supra* note 42, 1712 (discussing universities’ “socially valuable” utilization of licensing income) *and* Yale Office of Cooperative Research, Yale Policy on Intellectual Property, Patents and Licensing Agreements 2 (Feb. 11, 2002), http://www.yale.edu/ocr/indust_policies/policy2002.html (“Royalties that flow back to the University from licensing agreements are deployed in support of research and teaching.”) *with* Peter Jaret, *She Turns Her Pen on Drug Makers*, L.A. TIMES, Aug. 9, 2004, at F1 (“In 2002, the biggest drug companies spent only about 14% of sales on research and development and 31% on what most of them call marketing and administration. They consistently make more in profits than they spend in R&D.”).

²⁰³ For example, excess uncertainty (e.g., vague terms, concerns about potentially biased interpretations) might constitute a “deal-breaker” for licensees. According to Yale’s Office of Cooperative Research, ambiguous contractual provisions that give the university the power to make unilateral decisions to “terminate a licensing agreement” would be unacceptable. Adrangi, *supra* note 170; *see also* Nelsen, *supra* note 125, 305 (discussing limits of university’s negotiating power).

threaten a pharmaceutical company's access to high income markets, recognizing that such an approach would be untenable. Rather it relies upon provisions that are carefully constructed to affect only LMI country access,²⁰⁴ which will have little impact on the financial attractiveness of licensing agreements, given how little revenue is at stake in these countries for pharmaceutical firms.

The economics of the access gap demonstrate that the pharmaceutical industry can promote access without sacrificing significant revenues simply by allowing generics to enter essentially non-revenue generating LMI markets.²⁰⁵ The economics of technology transfer—including the pharmaceutical industry's increasing dependence on university research to fill its R&D pipelines²⁰⁶—further suggest that universities can promote access without material risk of losing deals, reducing income, or jeopardizing the viability of technology transfer operations, particularly if they act collectively.²⁰⁷ The epilogue to the Yale-d4t story offers empirical, if anecdotal, support for these arguments: “It is notable that [even] after the [events involving Yale and d4t], Pfizer invested heavily in Yale by funding a new multi-million dollar clinical trials building; it is the quality of research that appears to [principally] drive industry partnerships . . .

.,²⁰⁸

²⁰⁴ For example, the terms are carefully constructed to address the pharmaceutical industry's concerns regarding the diversion of generic products into high income markets.

²⁰⁵ See discussion *supra* note 61 and accompanying text (responding to pharmaceutical industry concerns about diversion)..

²⁰⁶ Thursby & Thursby, *supra* note 115; see Mowery et al., *Growth of Patenting and Licensing Post Bayh-Dole*, *supra* note 110, at 99, 101 (noting that prior to Bayh-Dole industry engaged in less collaboration with universities).

²⁰⁷ Pharmaceutical and biotechnology companies will almost surely resist any proposed changes to the status quo. However, if universities (or, at least, major research institutions to begin with) act together to implement new practices—thus redefining norms—pharmaceutical and biotechnology companies will have little choice. While an individual university may be dispensable to the pharmaceutical industry, universities in aggregate are not.

See Section III.E, *infra*, for discussion of the Public Sector Intellectual Property Resource for Agriculture (PIPRA)—a collective effort by public sector agricultural research institutions to ensure that IP does not impede developing world access to important ag-biotech developments. The success of PIPRA highlights what can be accomplished through access-oriented licensing terms and collective action among major research institutions.

²⁰⁸ Univs. Allied for Essential Medicines, Data-Driven Fact Sheet, at <http://www.essentialmedicines.org/primer.pdf>. Universities Allied for Essential Medicines, Data-Driven Fact Sheet, at <http://www.essentialmedicines.org/primer.pdf>.

C. Bayh-Dole Considerations

In light of the minimal economic consequences of modifying TTO licensing practices to address the access gap, federal law, particularly the Bayh-Dole Act, strongly encourages this change. The Bayh-Dole Act allows non-profit organizations to patent federally-funded research in order to, *inter alia*, “promote the utilization of inventions arising from federally supported research . . . promote the commercialization and public availability of inventions” and “ensure that the Government obtains sufficient rights in federally supported inventions to meet the needs of the Government and protect the public against nonuse or unreasonable use of inventions.”²⁰⁹ To address these public interest concerns, Bayh-Dole includes provisions reserving for the government a nonexclusive, nontransferable, irrevocable, paid-up license to practice federally-funded inventions anywhere in the world,²¹⁰ and the ability to “march-in” and force licensing of a patented invention to one or more third parties on terms “reasonable under the circumstances” to ensure the invention’s public availability.²¹¹ The government may exercise this latter right if there is inappropriate delay in achieving “practical application” of the invention,²¹² which includes making the invention available to the public on “reasonable terms,”²¹³ or if licensing is necessary “to alleviate health or safety needs which are not reasonably satisfied by the contractor, assignee, or their licensees.”²¹⁴ Thus Bayh-Dole does not envision beneficiaries exclusively pursuing their own interests in patenting and commercializing federally-funded inventions, but rather seeks to protect the public interest, including ensuring product availability at reasonable prices.²¹⁵

²⁰⁹ Bayh-Dole Act of 1980, 35 U.S.C. §§ 200-212 (1994).

²¹⁰ *Id.* §202(c)(4).

²¹¹ Bayh-Dole Act of 1980, Pub. L. No. 96-517, 94 Stat. 3015-3028, 35 USC §§ 200-211, 301-307.

²¹² *Id.* §203(a)(1).

²¹³ *Id.* §201(f).

²¹⁴ *Id.* §203(a)(2).

²¹⁵ *See* Arno & Davis, *supra* note 121, at 649-53, 659-67 (2001) (arguing that “reasonable terms” under §201(f) includes a reasonable price and that Bayh-Dole’s legislative history confirms that “the reasonable pricing

Notwithstanding the spirit and letter of the Bayh-Dole Act, the federal government has yet to enforce the statute's public interest requirements.²¹⁶ Scholars have both criticized this inaction and recommended substantial reforms to the Bayh-Dole regime, including statutory allocation of greater discretion to funding agencies to determine when federally-funded inventions should be disseminated through open access as opposed to through intellectual property rights protection,²¹⁷ and streamlining and/or more aggressive use of the Act's march-in provisions.²¹⁸

The first of these recommended changes stems from the conclusion that the intellectual property pendulum has swung too far under Bayh-Dole, and that the overall utility generated by federally-funded inventions is suboptimal due to closed/exclusive intellectual property strategies. To promote broader use of these inventions, scholars argue that Congress should reform Bayh-Dole to give funding agencies discretion to restrict and manage contractor patenting,²¹⁹ and that federal agencies should prevent or discourage academic institutions from patenting certain discoveries when open access is more appropriate for maximizing utilization.²²⁰ Professors Rai and Eisenberg, the principal proponents of this view in the academy, are primarily concerned with the retardation of scientific research resulting from protecting basic science with strong intellectual property rights. However the same argument can address the access gap effects of

requirement is an open secret"). *See also* Stevens, *supra* note 113 (discussing the legislative history of the Bayh-Dole Act).

²¹⁶ In 1989—in response to the high cost of AZT, a revolutionary AIDS drug developed primarily with NIH monies—NIH implemented a “reasonable pricing” provision in its technology transfer agreements. *See* Frequently Asked Questions About HR 626: The ‘Health Care Research and Development and Taxpayer Protection Act,’ at <http://www.cptech.org/ip/health/econ/rp-faq.html>; Legrand, *supra* note 125, at 12 (citing Hiroaki Mitsuya, Letter to the Editor, *Credit Government Scientists with Developing Anti-AIDS Drug*, N.Y. TIMES, Sept. 28, 1989, at A26). In 1995, in response to pressure from the pharmaceutical industry, the reasonable pricing requirement was withdrawn. David S. Hilzenrath, *NIH Drops Its Policy on Drug Prices; Agency Had Required ‘Reasonable’ Charge*, WASH. POST, Apr. 12, 1995, at F1.

²¹⁷ *See, e.g.*, Rai & Eisenberg, *supra* note 116.

²¹⁸ *See, e.g.*, Arno & Davis, *supra* note 121, at 647.

²¹⁹ *See, e.g.*, Rai & Eisenberg, *supra* note 116.

²²⁰ *See* Rai & Eisenberg, *supra* note 116, at 302 (in the case of the NF-kb cell-signaling pathway – the subject of a patent recently granted to three nonprofit institutions – “as in many others, upstream patents issued to academic institutions serve as a tax on innovation, diluting rather than fortifying incentives for product development.”)

current TTO practices: Bayh-Dole was not intended to and should not allow universities to ignore the public interest by pursuing closed licensing strategies for those federally-funded inventions with potential to narrow the access gap if managed through an open licensing approach.

The second proposal asserts that federal agencies should enforce Bayh-Dole's march-in provision whenever products based on federally-funded inventions are not made available at reasonable prices. Related to this goal, scholars advocate streamlining Bayh-Dole's march-in provision so federal agencies can more easily compel licensing without first exhausting administrative and judicial review procedures.²²¹ Bayh-Dole's march-in provision lay dormant until 1997, when CellPro, a small biotechnology firm, unsuccessfully petitioned the government to exercise its march-in rights.²²² Then, in early 2004, the non-profit organization Essential Inventions brought Bayh-Dole march-in petitions to facilitate access to Pfizer's \$1 billion glaucoma drug Xalatan (latanoprost)—invented in NIH-funded research at Columbia—and AIDS-blockbuster Norvir (ritonavir)—invented in NIH-funded research at Abbott.²²³ The petitions attracted some press attention²²⁴ but failed to spur government action. On July 29, 2004, Dr. Elias Zerhouni, Director of the NIH, announced that the government would not exercise its march-in rights.²²⁵

Although government agencies (and NIH specifically) may be best situated to ensure that universities license their technologies in a socially responsible manner, as Rai and Eisenberg

²²¹ *Id.* at 311; see also Barbara M. McGarey & Annette C. Levey, *Patents, Products, and Public Health: An Analysis of the CellPro March-In Petition*, 14 BERKELEY TECH. L.J. 1095, 1009-10 (1999) (describing the “unwieldy nature of the [Bayh-Dole] march-in administrative process”).

²²² McGarey & Levey, *supra* note 221.

²²³ For the march-in petitions and other related documents, see Essential Inventions, Ritonavir (Norvir), at <http://www.essentialinventions.org/drug/ritonavir.html>; Essential Inventions, Latanoprost (Xalatan), at <http://www.essentialinventions.org/drug/latanoprost.html>.

²²⁴ Norvir, which had been the subject of a 400% price hike over the previous year, was the subject of considerable press. *E.g.*, Gardiner Harris, *Price of AIDS Drug Intensifies Debate on Legal Imports*, N.Y. TIMES, Apr. 14, 2004, at A1; *Debate over Ritonavir Price Increase Gains Momentum*, 363 THE LANCET 1369 (2004).

²²⁵ Nat'l Inst. of Health, Office of the Director, Opinion in the Case of Norvir (Jul. 29, 2004), http://www.autm.net/announcements/NIH_March-InDecision.pdf.

suggest,²²⁶ the federal government seems unlikely to take action. Yet, it is increasingly apparent that current commercialization practices for federally-funded inventions are often inconsistent with Bayh-Dole. Bayh-Dole beneficiaries, primarily universities, have a duty to respect the public interest purposes of Bayh-Dole. University TTOs should therefore strive to ensure that patenting and licensing agreements for federally-funded inventions promote “public availability,” “practical application” on “reasonable terms”, and the “alleviat[ion of] health or safety needs.”²²⁷ Bayh-Dole thus strongly encourages—even if it does not currently compel—universities to address the access gap via TTO policy.

D. Recent Developments

In a 2003 article entitled *The Role of University Technology Transfer Operations in Assuring Access to Medicines and Vaccines in Developing Countries*, Lita Nelsen, Director of M.I.T.’s Office of Technology Licensing, wrote: “The first task is to raise awareness of these issues in the university community as a whole.”²²⁸ The very fact that a technology transfer director authored such a piece signals some of the important changes that have taken place since the March 2001 BMS/Yale d4t patent concession.

There are a number of indications that the technology transfer community is willing to consider steps to address health concerns of the developing world. In December 2003 the Association of University Technology Managers (AUTM) formed a special interest group to examine global health issues,²²⁹ and the 2003 and 2004 AUTM annual meetings included several relevant poster presentations and workshops.²³⁰ The Centre for Management of IP in Health

²²⁶ Rai & Eisenberg, *supra* note 116, at 313.

²²⁷ *Id.* § 203(a)(1)-(2), (f).

²²⁸ Nelsen, *supra* note 125, at 303.

²²⁹ *New AUTM Special Interest Group Announced: Technology Transfer Professionals for Global Health*, AUTM NEWSLETTER (Ass’n of Univ. Tech. Managers), November/December 2003, at 9.

²³⁰ *See* Nelsen, *supra* note 125, at 303 (mentioning workshop held at the 2003 annual AUTM meeting). Workshops at the 2004 conference included “Tech Mangers for Global Health.” Posters included “Global Health and the University: Exploration of Resources and Strategies for Licensing and Developing University Inventions that Address ‘Neglected Diseases’ and Other Afflictions Prevalent in Low-Income Countries.” ASS’N OF UNIV. TECH. MANAGERS, AUTM 2004 ANNUAL MEETING (2004), http://www.autm.net/meetings/autm2004/AUTM_04_FP.pdf.

R&D (MIHR), a U.K.-based organization that generally supports strong intellectual property rights,²³¹ has recently released a handbook of best practices for technology transfer managers that includes a reprint of Nelsen's article and outlines other "practices to protect the interests of the public sector."²³²

With regard to neglected disease research, several universities have moved beyond rhetoric. Last summer, Yale University and the University of Washington granted OneWorld Health an exclusive license to a novel class of high potency compounds, potentially effective against parasitic diseases common in the developing world.²³³ The license allows OneWorld Health to develop the compounds for use against neglected diseases, while Yale and the University of Washington are free "to pursue a pharmaceutical partner to develop the same compounds for fungal infections in industrialized countries."²³⁴ Early in 2004, University of California at Santa Barbara "donated the patent rights to [a] class of cardiovascular medicines [for] their novel use as a potential treatment for schistosomiasis, a parasitic scourge."²³⁵

It is clear that significant change in technology transfer policies will require collective action among universities.²³⁶ The recently-created Public Intellectual Property Resource for

²³¹ MIHR, at <http://www.mihr.org>. MIHR initially received funding from the Rockefeller Foundation. Press Release, Rockefeller Found., IP Management Organization for Health R&D To Address Needs of Poor People (Jan. 22, 2002).

²³² CTR. FOR MGMT. OF IP IN HEALTH R&D, MIHR: HANDBOOK OF BEST PRACTICES FOR MANAGEMENT OF INTELLECTUAL PROPERTY IN HEALTH RESEARCH AND DEVELOPMENT 66-71, 73-78, 81-91 (Richard T. Mahoney ed., 2004).

²³³ Press Release, Yale University, Institute for OneWorld Health Licenses Potent Therapy from Yale and University of Washington To Treat Chagas, One of the Largest Parasitic Diseases in the World (July 8, 2003), <http://www.yale.edu/opa/newsr/03-07-08-01.all.html>.

²³⁴ *Id.*

²³⁵ Associated Press, *UC Santa Barbara Patent Give To Aid Parasitic Fight* (Feb. 23, 2004), http://www.mercurynews.com/mld/mercurynews/news/local/states/california/northern_california/8031289.htm.

²³⁶ Given the perceived risks of seeking access-promoting provisions, *supra* Section III.B, individual universities are unlikely to act alone. *See supra* note 207; WORKSHOP REPORT, *supra* note 131, at iii, 12 (reporting that one of the central conclusions from a conference on university technology transfer policies was that "[c]hanges in university practice will require collective action"). *Cf.* Rai & Eisenberg, *supra* note 116, at 306 (noting the need for collective action but expressing concern that universities will not be able to achieve it).

Agriculture (PIPRA)²³⁷ illustrates the promise of this approach. Faced with substantial fragmentation—as well as exclusive public-to-private licensing—of intellectual property rights, several public sector agricultural research institutions founded PIPRA in 2003 to improve management of intellectual property resources.²³⁸ The association’s members share intellectual property with each other and work collaboratively to facilitate access to agricultural technologies in order to advance development and distribution of crops.²³⁹ As a public sector consortium, PIPRA can marshal substantial negotiating power in dealings with industry,²⁴⁰ bolstering the effectiveness of projects such as the development of best practices provisions for public sector intellectual property licensing agreements.²⁴¹

There are other examples of successful collective action by universities—from the campus anti-sweatshop movement²⁴² to the recent refusal of universities to impose secrecy clauses on the results of academic research²⁴³—that demonstrate that even a few elite institutions working together can facilitate change in behavioral norms. In the case of biomedical research,

²³⁷ PIPRA was established following an editorial in *Science* in January 2003 which implored research institutions to “adopt policies regarding IP that make the results of research available for use in developing countries.” Roger N. Beachy, IP Policies and Serving the Public, 299 *SCIENCE* 473 (2003). The author, Roger Beachy, President of the Danforth Plant Science Center, described the obstacles to accessing Vitamin A rich genetically-engineered rice in the developing world. Beachy noted that the Danforth Plant Science Center had successfully introduced a broad access provision into its licensing agreements with private sector firms. *Id.*

²³⁸ Public Intellectual Property Resource for Agriculture, Background, at <http://www.pipra.org/background.php> (last visited Sept. 2, 2004).

²³⁹ Public Intellectual Property Resource for Agriculture, Purpose, at <http://www.pipra.org/purpose.php> (last visited Sept. 1, 2004).

²⁴⁰ See Benkler, Commons-Based Strategies, *supra* note 195, at 4.

²⁴¹ Public Intellectual Property Resource for Agriculture, Activities, at <http://www.pipra.org/activities.php> (last visited Sept. 1, 2004).

²⁴² See, e.g., Dreier & Appelbaum, *supra* note 179. Despite strong initial resistance, today 125 universities have joined the Workers’ Rights Consortium—a monitoring group born of the campus anti-sweatshop movement. EMI MACLEAN ET AL., *EQUITABLE ACCESS LICENSE ORGANIZING MANUAL*, v1.0, at 3 (David Tannenbaum et al. eds., 2004).

²⁴³ See WORKSHOP REPORT, *supra* note 131, at 12.

Companies wanted universities to agree to certain limits on publication of research done with grants. In response, a group of elite universities worked together, refusing such secrecy clauses. It soon became easier for other universities to do so, and companies now generally accept the fact that they cannot require such conditions since it conflicts with the basic mission of the university to disseminate knowledge.

Id.

the top ten NIH-funded institutions receive the bulk of federal funding and secure the majority of technology transfer deals. In light of the power of these top institutions to affect the behavior of others and the strength of groups like the AUTM, collective action among universities appears to be an attainable goal.

IV. What Universities Can Do

Even after universities come to see that their patenting and licensing practices can help close the access gap, and that doing so is consistent with their mission and in their best interest, they must implement an intellectual property strategy to achieve this goal.²⁴⁴ To the extent TTOs have thus far done little to advance the health concerns of LMI country populations, it may be because they are simply unsure of what to do.

Since mid-2002, the Yale AIDS Network (YAN) and the subsequently created UAEM have been focused on the question of how universities can best promote equitable access to medicines. In order to answer this complicated question in a way that will address the concerns of universities and industry, as well as serve the needs of LMI populations, members of YAN and UAEM have pursued a multi-pronged approach: They have met with university administrators and officials, consulted with academics and IP lawyers, sought feedback from industry contacts, and worked extensively with global health advocates.

Below, in Section IV.B, we present and explain the product of these efforts—the Equitable Access License (EAL)—a set of model licensing provisions developed by UAEM²⁴⁵

²⁴⁴ Michael Merson, *Preface to WORKSHOP REPORT*, *supra* note 131, at iv. In September 2002 the Yale AIDS Network and the Center for Interdisciplinary Research on AIDS gathered a distinguished group to discuss “what universities as intellectual property holders can do to promote access to essential medicines and medical technologies in developing countries.” *WORKSHOP REPORT*, *supra* note 131, at iii. Participants included university officials, technology transfer managers, academics, treatment access advocates, and representatives of foreign government drug development programs. For a full list, see *id.*, at 18 app. B. While the participants did not reach consensus on most issues, they found “significant common ground” including agreement that universities have an important role to play. *Id.* at iii.

²⁴⁵ *Supra* note 16.

and intended to be incorporated into any license a university²⁴⁶ enters with a company for any technology that may produce a health-related end product.²⁴⁷ In Section IV.C we then discuss strategies for achieving widespread implementation of the EAL. But, first, we briefly describe the process by which the EAL's approach was devised and set forth the relative strengths of this strategy.

A. Background to the Equitable Access License: Identifying a Workable Approach

Prior to creating the Equitable Access License, UAEM evaluated a variety of intellectual property strategies to address the access gap, including 1) encouraging universities to refrain from patenting innovations in LMI countries,²⁴⁸ and 2) designing contractual provisions that would require licensees to make end products available at reasonable prices in LMI countries. However, these approaches proved to be unsatisfactory for a number of reasons.

Asking universities to refrain from patenting health-related innovations in LMI countries was found to be both unattractive to universities²⁴⁹ and likely to be ineffective in ensuring access in poor countries. Since universities rarely hold *all* of the intellectual property rights necessary to make a generic form of an end product,²⁵⁰ licensees are likely to own additional patents and may have other exclusive rights—such as rights to clinical trial data—that could impede generic production of a drug or technology.²⁵¹ Thus, a non-patenting strategy may not prevent private

²⁴⁶ The EAL can of course also be used by other non-profit drug development institutions, or even by well-intentioned private sector firms.

²⁴⁷ As described earlier, universities typically grant worldwide exclusive licenses for inventions that have promise as new therapies or diagnostics. In return for the exclusive right to use the university's invention in the countries where patents are held, the university is promised certain sums (such as a royalty on sales of the end product) and assurances that the licensee (the company) will diligently develop and commercialized the university invention. Once incorporated, the EAL provisions then constitute an additional form of consideration granted to the university in exchange for the exclusive rights granted to its invention.

²⁴⁸ See, e.g., Kapczynski et al., *supra* note 156.

²⁴⁹ E.g., Interview with Dr. Jon Soderstrom, Managing Director, Yale Office of Cooperative Research (OCR), in New Haven, Conn. (Dec. 4, 2003)

²⁵⁰ See *supra* notes 145, 166.

²⁵¹ UAEM Working Group, The Equitable Access License: Explanatory Document 4 (2004) (unpublished manuscript, on file with authors). For example, the United States did not patent ddI in Thailand, but Bristol-Myers Squibb later secured patents there (and in other countries where the U.S. had not patented) on further developments. See WORKSHOP REPORT, *supra* note 131, at 9.

sector firms from securing monopolies in LMI countries. Arguably, without a patent, the university lacks the leverage to influence ultimate access.²⁵²

Similarly, asking universities to include a fair pricing requirement in their licenses will likely meet strong resistance from universities and pharmaceutical companies—and produce suboptimal results for LMI populations—for a number of reasons. First, the economics of drug pricing are far from straightforward—the task of defining fair or reasonable prices is daunting, requiring information that is often unavailable or difficult to gather from credible sources.²⁵³ Moreover, research indicates that price reductions by originators are a far less reliable way to approach “lowest price” than generic competition.²⁵⁴ For example, although BMS claimed it was selling d4t below cost in Africa, generic companies have been able to undercut its price by up to forty percent while still turning a profit.²⁵⁵

Second, requiring reasonable pricing in LMI countries also forces universities to confront the pharmaceutical industry’s apprehensions about differential pricing. Drug firms are likely to be concerned that by selling their products for significantly less in an LMI country they may be effectively lowering the price in the many high income markets that rely on reference pricing systems, a form of “virtual arbitrage.”²⁵⁶

Finally, this type of contractual provision places an affirmative burden on the pharmaceutical company licensee, which in turn requires monitoring and potentially enforcement by the university (or another non-profit organization). Universities and non-profits generally

²⁵² See *id.* (“[P]atents might provide universities control or leverage to encourage companies to lower prices [or take other action].”).

²⁵³ Reasonable pricing is arguably a function of both the supplier’s economics (marginal cost of production, potentially plus a reasonable profit) and the consumers’ economics (capacity to pay). In UAEM’s experience, gathering information for either category that both advocates and pharmaceutical firms will perceive as unbiased is quite challenging. See, e.g., Outterson, *supra* note 24 (manuscript at 50) (discussing lack of transparency in the pharmaceutical industry with regard to marginal cost); see also discussion *supra* note 39.

²⁵⁴ See discussion *supra* Section I.B notes 65-66 and text accompanying.

²⁵⁵ See Meldrum, *supra* note 156.

²⁵⁶ Outterson, *supra* note 24 (manuscript at 44, 78); see Farlow, *supra* note 39, at 19; Lana Kraus, Note, *Medication Misadventures: The Interaction of International Reference Pricing and Parallel Trade in the Pharmaceutical Industry*, 37 VAND. J. TRANSNAT’L L. 527, 536 (discussing the pervasiveness of reference pricing in Europe in particular and in developed countries generally).

lack the resources this would require.²⁵⁷ Even if universities were able to set forth a seemingly clear and sustainable formula for determining “reasonable price,”²⁵⁸ and thus were able to persuade licensees to agree to such a term, enforcing a fair pricing provision would require “a robust willingness to risk legal disputes with companies.”²⁵⁹ From the perspective of access advocacy, it is undesirable to have universities assume this enforcement role, given their need to maintain ongoing relationships with pharmaceutical companies and their attendant proclivity for appeasing licensees on matters perceived as non-material to the university.

The shortcomings of these strategies—non-patenting and reasonable pricing clauses—have led UAEM to embrace an alternative approach: contractual provisions that ensure open licensing,²⁶⁰ thus facilitating market entry by generics, in LMI countries. Under this approach, all patent and data rights necessary for the production of any end product covered by these provisions are made available in LMI countries (in exchange for a reasonable royalty rate). In sharp contrast to a non-patenting agenda, this strategy does not limit a university’s influence to end products resulting exclusively from its own inventions. By contractual arrangement, the university’s access-facilitating provisions reach any end product that relies, even in part, on a patented university innovation.

In addition to effectively lower prices, facilitating generic entry and competition promises to yield improved access to fixed dose combinations and other improvements (e.g.,

²⁵⁷ See UAEM Working Group, *The Equitable Access License: Explanatory Document*, *supra* note 251, at 3 (“A system of price controls could easily require significant administrative expense.”). Given the economics of technology transfer, discussed in Section III.B, it is apparent that TTOs do not have the capacity to take on such this additional burden.

²⁵⁸ Based on UAEM’s efforts—particularly those of Achal Prabhala and Harsha Thirumurthy—the working group determined that this was doubtful.

²⁵⁹ See UAEM Working Group, *The Equitable Access License: Explanatory Document*, *supra* note 251, at 3.

²⁶⁰ The EAL defines “open licensing” as non-exclusive licensing of all of the typical rights associated with a patent (use, import, export, sale, manufacture). EAL, App. A, Part 1(a). Because of the non-exclusive nature of open licensing, there is no limit to the number of generics companies (or other entities) that can take advantage of these terms.

reformulations).²⁶¹ Pharmaceutical companies may argue that generics afforded market entry by the EAL will reduce their profits and thereby undermine research incentives. However, we have seen that the scale of pharmaceutical sales and company revenues in LMI countries belies this claim. Plans to facilitate generic entry that call for the payment of reasonable royalties to originator companies further rebut these objections.²⁶²

By using generics—rather than differentially priced patented products—to achieve lower prices, this approach should avoid industry concerns regarding effects on reference pricing systems in high income markets.²⁶³ Still, pharmaceutical companies may express anxiety about the diversion of generics into wealthy markets—i.e., low-priced generics produced under the EAL “find[ing] their way into the black market in developed countries.”²⁶⁴ This concern finds little empirical support,²⁶⁵ and can be addressed in the same manner that the WTO has elected to treat the issue: requiring use of different packaging, pill color, and shape in different countries to facilitate identification of illegal importations.²⁶⁶

Perhaps most importantly, UAEM’s open access approach does not place any ongoing demands on universities or pharmaceutical companies. Instead, it introduces a third set of players—generics companies (or other alternative suppliers, such as NGOs)—with market incentives to narrow the access gap by offering low-priced products. By making the transfer of

²⁶¹ See UAEM Working Group, *The Equitable Access License: Explanatory Document*, *supra* note 251, at 3. Price controls, on the other hand, cannot facilitate FDCs, as the exclusive rights held by different manufacturers prevent production.

²⁶² Both the TRIPS Agreement’s compulsory licensing provisions and the EAL’s open licensing structure incorporate reasonable royalties, *infra* notes 287-288. The recent TAC Settlement also provides for the payment of royalties to the originator firms. See *Competition Commission Settlement Agreements Secure Access to Affordable Life-Saving Antiretroviral Medicines*, *supra* note 101.

²⁶³ Reference pricing schemes for on-patent drugs should not incorporate the prices of generics. See generally Patricia M. Danzon, *Reference Pricing: Theory and Evidence* 3, 6 (May 22, 2001) (unpublished manuscript, on file with authors).

²⁶⁴ UAEM Working Group, *The Equitable Access License: Explanatory Document*, *supra* note 251, at 6.

²⁶⁵ See *supra* note 51. “There have been no recorded cases of this happening.” MACLEAN ET AL., *supra* note 242, at 6.

²⁶⁶ See WTO, *Paragraph 6*, *supra* note 99. Access advocates have also suggested that “developed countries can take responsibility for preventing illegal importation into their own countries instead of putting the onus and blame on poorer ones.” MACLEAN ET AL., *supra* note 242, at 6.

rights to generics companies “automatic,” once certain basic requirements have been met, the administrative costs for universities and their licensees can be minimized.

While this approach—set forth in the Equitable Access License—is viable no matter where the university or licensee hold patents, it requires the existence of one or more patents to form the basis for the licensing agreement. This approach thus follows the remarkably successful open source and free software movements, which recognize that intellectual property rights can be used to promote open as well as closed access, to protect the commons as well as private property.²⁶⁷ There appears to be a growing array of projects, like the EAL, that seek to use commons-based intellectual property strategies to better address global health needs.²⁶⁸ As these initiatives expand and multiply, their shared approach will attract greater attention and increased acceptance, facilitating the widespread adoption of the EAL.

B. The Equitable Access License

i. Enabling Competition To Reduce the Access Gap

The EAL seeks to improve access to biomedical products in LMI countries by removing barriers to competition. Any end product²⁶⁹ that relies upon a university patent that has been out-licensed under the EAL is subject to open licensing.²⁷⁰ Neither the fact that the university’s

²⁶⁷ See *supra* note 17 and accompanying text; MACLEAN ET AL., *supra* note 242, at 5 (discussing strategies that “mobilize intellectual property rights to protect a robust public domain, rather than to protect monopoly interests of either the university or licensee.”).

²⁶⁸ See, e.g., Stephen M Maurer, Arti Rai and Andrej Sali, *Finding Cures for Tropical Diseases: Is Open Source an Answer?*, in BIOTECHNOLOGY: ESSAYS FROM ITS HEARTLAND 33 (Lynn Yarris ed., 2004) (advancing a proposal for “open source drug discovery”); Benkler, Commons-Based Strategies, *supra* note 195 (discussing a number of these projects, including PIPRA, the Ensemble Genome Browser, and the Public Library of Science).

²⁶⁹ Part 1(c) of the EAL defines “end products” as any “product developed by the licensee that is relevant to the protection of enhancement of health which requires the use of the technology herein licensed . . . for its production.” EAL, App. A., Part 1(c).

²⁷⁰ Whether or not an end product “relies” on a university’s patent can be understood in the following way: If the end product could not lawfully be produced without a license to the university’s patent, then it relies, at least in part, on that patent. Universities are adept at evaluating whether a product relies on one of its patents, a skill typically used to determine when the university is owed royalties. See, e.g., Lynda Richardson, *At University, Dreams of Billions and Billions*, N.Y. TIMES, May 13, 2000. It is worth noting that the EAL does not require that products discovered with the help of a university research tool (e.g., a cell line or reagent) be openly licensed in LMI countries.

patent is “just one component of an end product that is covered by many [patents],”²⁷¹ nor the fact that the university’s patent may have been sub-licensed by the licensee to another entity impede the efficacy of the EAL.²⁷²

If a generic supplier (or other entity, such as a ministry of health or an NGO) wishes to compete with a university’s licensee in an LMI country to make or market a given product that is covered by the EAL,²⁷³ the generic supplier (the “Notifier”²⁷⁴) has only to write a letter to the university and the licensee, expressing this intent to invoke the EAL in the LMI country.²⁷⁵

This notification triggers the EAL’s open licensing provisions,²⁷⁶ automatically lifting patent, regulatory, and manufacturing barriers.²⁷⁷ Intellectual property and regulatory hurdles are immediately removed through the open licensing of any patented technologies and proprietary data, respectively, in a given LMI country (the “Notified Country”);²⁷⁸ these tactics are intended to secure conditions conducive to low prices. Open licensing the right to manufacture in any

²⁷¹ UAEM Working Group, The Equitable Access License: Explanatory Document, *supra* note 251, at 8.

²⁷² EAL, App. A., Part 5 (applying terms to any sub-licensees).

²⁷³ The third party, of course, would not have to invoke the EAL provisions if there were no barriers to generic entry in that LMI country. This description presumes either that the university, its licensee, or a sublicensee hold relevant patents or other exclusive rights in the LMI country.

²⁷⁴ EAL, App. A., Part 1(g)(ii).

²⁷⁵ EAL, App. A., Part 3(a).

²⁷⁶ EAL, App. A., Part 3.

²⁷⁷ In a straightforward and unambiguous manner, the EAL ensures that any patents that might exist are non-exclusively licensed upon notification to the university and licensee.

UAEM had initially adopted a more complicated approach, seeking to objectively define an “access gap,” and requiring that a supplier demonstrate that such a gap existed in a particular LMI country before open licensing conditions would apply in that country. Specifically, UAEM proposed that an access gap would exist wherever a worker earning GDP per capita purchasing power parity would have to pay more than a certain percentage of his income for a typical course of treatment of an End Product. However, efforts to collect the data needed to measure an access gap in this way revealed that this data is neither readily accessible nor sufficiently reliable.

The EAL therefore relies upon a simple rule: In all LMI countries, if someone wishes to compete with the licensee to supply the end product, they must notify the university and licensee, and they will then be deemed to have permission to make, sell, export, or import the End Product from the time of notification and for the duration of the life of the relevant patents.

UAEM Working Group, The Equitable Access License: Explanatory Document, *supra* note 251, at 9.

²⁷⁸ EAL, App. A., Part 3(b)(i)-(ii).

country allows suppliers to export generic medicines to the LMI country in question.²⁷⁹ Even where there are no patents in place—as is frequently the case in the poorest countries²⁸⁰—there is a significant need for these provisions of the EAL. The inability to use existing proprietary data (e.g., clinical trial results)²⁸¹ and a lack of manufacturing capacity in the notified country²⁸² can constitute significant obstacles to generic production.

Since the Notifier is automatically provided with the necessary license(s),²⁸³ it may immediately begin, lawfully, to sell the end product in the specified LMI country without infringing upon any rights held by the licensee or sub-licensee.²⁸⁴ The EAL itself aims to afford legal protection to any entity wishing to make use of its provisions.²⁸⁵ There is no need for the

²⁷⁹ EAL, App. A., Part 3(b)(iii) (“so long as the manufacture is ‘for the sole purpose of distribution in the notified country’”).

²⁸⁰ See *supra* notes 48, 141.

²⁸¹ In light of recent trade agreements that have increasingly used pharmaceutical test data as a source of additional market protections, see Scafidi, *supra* note 38, the EAL specifies that all such data possessed by the university or licensee can be used by companies wishing to register generic versions. By granting an open license to such data, the EAL ensures that the notified country’s regulatory agency will be free to rely upon clinical trial and other data (which will generally have already been submitted to the U.S. F.D.A., and other regulatory agencies) in demonstrating the safety and efficacy of the generic alternative. The generic producer will still have to demonstrate bioequivalence, and meet other regulatory requirements related to manufacturing standards, to the extent that these requirements exist in the notified country.

²⁸² See WTO, *Paragraph 6*, *supra* note 99. The WTO’s process for exporting generics to a developing country under a compulsory license has been described as burdensome. Editorial, *WTO Takes a First Step*, 362 THE LANCET 753 (2003). In contrast, under the EAL, companies that care to export will be able to avoid the August 30 process by taking advantage of the EAL’s grant of voluntary permission to produce for the purpose of exporting to LMI countries. To preempt complaints about diversion risks, the EAL, like the WTO, requires that end products manufactured by alternative suppliers under the EAL be distinguishable from the end product sold by the licensee/sub-licensee. EAL, App. A., Part 3(b)(iii)(1).

²⁸³ The EAL provides the university with a limited license (a “grant back”) to any subsequent improvements by the licensees or sub-licensees; this allows the university to non-exclusively sublicense these improvements to Notifiers. See EAL, App. A., Part 2. Relatedly, any third party that receives an open license must “grant back” its improvements to the university. This ensures that subsequent developments by a generic producer are also available in LMI countries under the open licensing terms of the EAL. See EAL, App. A., Part 3(b)(i). The “grant back” structure was adopted to maintain privity among the parties. EAL, App. A., Part 1(d) (defining licensee improvements to include subsequent patents or proprietary rights).

²⁸⁴ UAEM Working Group, *The Equitable Access License: Explanatory Document*, *supra* note 251 (“While there is no need for the university to formally “grant” the open license—the existence of the EAL alone is sufficient to protect parties operating under its terms from legal consequences—nothing in the EAL prevents a university from also issuing a voluntary license upon request.”)

²⁸⁵ It is critical that generic manufacturers and other potential Notifiers (i.e., alternative suppliers/producers) feel comfortable with the EAL’s legal mechanism and confident that they will be adequately protected. Thus far communications with executives at generics companies suggest that the EAL would be well-received.

university to examine the appropriateness of a generic's market entry, to monitor prices, or to assume any other administrative burden. If the licensee or the university wishes to contest the applicability of the license to the product or patents included in the notification, they may inform the notifying party and take legal action if needed. It is likely that the primary venue will be the jurisdiction in which the alleged violation is occurring or has occurred (i.e. the Notified Country, and/or the Exporting Country).²⁸⁶

The EAL, like the compulsory licensing provision of TRIPS,²⁸⁷ envisions payment "in consideration of the open licenses."²⁸⁸ For middle income countries, the structure set forth in the EAL calculates royalties as a GNP-determined percentage of the U.S. sale price.²⁸⁹ For low income countries the EAL sets the royalty rate at one percent.²⁹⁰ By creating a sliding scale

²⁸⁶ UAEM Working Group, The Equitable Access License: Explanatory Document, *supra* note 251, at 10 ("It is also possible that the generic producer could be sued in other countries where it has assets, but jurisdictional doctrines such as *forum non conveniens* may limit the willingness of courts in such countries to hear such cases. A notifying party risks infringement liability if the license does not apply, for example, because it does not cover the patents or products claimed.").

²⁸⁷ See TRIPS Agreement *supra* note 36.

²⁸⁸ EAL, App. A, Part 3(c). This royalty provision only applies to compensate for sales that would otherwise constitute patent infringement; the subsequent provisions for research do not entail royalties.

²⁸⁹ EAL, App. A., Part 1(g)(i). The following example serves to illustrate the EAL's royalty provision:

If the annual per person U.S. sale price of d4t were \$3800, to determine the royalty in a middle income country one would multiply the sale price by 10% (the percentage of a sale price that goes back into R&D in the average pharmaceutical company) and then multiply the product by the middle income country's GNP, expressed as a percentage of the U.S. GNP. Consider hypothetical scenarios for three middle income countries:

- Korea (GNP 29% of the U.S. GNP): annual per person royalty would be $\$3800 \times 0.10 \times 0.29 =$ approximately \$110
- Mexico (GNP 13% of the U.S. GNP): annual per person royalty would be approximately \$50
- Russia (GNP 8% of the U.S. GNP): annual per person royalty would be approximately \$30

Compare these to a flat rate of 4% of lowest world generic price: at current lowest world prices for d4t, a 4% royalty rate in any LMI country would generate only \$1.20 per year. However, using the royalty scheme proposed here, Korea would pay much more—nearly 100% of the generic price, in the case of d4t—than Uganda.

UAEM Working Group, The Equitable Access License: Explanatory Document, *supra* note 251, at 10 n.19 (based on the work of James Love, Director of the Consumer Project on Technology).

²⁹⁰ EAL, App. A., Part 1(g)(ii). Maintaining some royalty for low income countries is necessary to allow generic companies to benefit from the safe harbor provision, which provides that the university or licensee's acceptance of a royalty is deemed an agreement that the EAL applies to the patents in question. EAL, App. A., Part 3(c).

royalty structure, the cost of R&D is distributed in accordance with ability to pay, thus higher income countries pay for a higher share of R&D.²⁹¹ The EAL provides that this royalty should be distributed evenly between the university and the licensee. Acceptance of the royalty payment essentially represents a covenant not to sue, thus guaranteeing the Notifier additional legal protection from any later claims that the patents and products notified for are not covered by the EAL.²⁹²

ii. Facilitating Neglected Disease Research and other Research in LMI Countries

A secondary objective of the EAL is to encourage research and development, particularly research activities conducted in LMI countries²⁹³ and into neglected diseases. The EAL gives researchers in LMI countries access to university technologies, and derivative technologies developed by licensees, for any and all research purposes. The EAL also allows researchers in non-LMI countries to use such technologies for research targeting neglected diseases.

Under the EAL, scientists in LMI countries are free to engage in research using university patents or licensee improvements; any patents resulting from this research would then be subject to the EAL's open access provisions.²⁹⁴ This allows them to work on introducing product improvements that can result in significant clinical benefits for patients, but are often neglected or delayed by the multinational pharmaceutical companies—including pediatric formulations, fixed dose combinations, and extended release formulations.²⁹⁵ A patented

²⁹¹ See Tim Hubbard, Alternatives to the Price System, Presentation at Columbia University (Dec. 4, 2003); James Love, A New Trade Framework for Global Healthcare R&D, Presentation at Columbia University (Dec. 4, 2003); James Love, From TRIPS to RIPS: A Better Trade Framework to Support Innovation in Medical Technologies, Workshop on Economic Issues Related to Access to HIV/AIDS Care in Developing Countries (May 27, 2003).

²⁹² EAL, App. A., Part 3(c) (safe harbor provision).

²⁹³ This would serve one of the principal, traditional functions of technology transfer: enabling technology capacity-building outside the United States.

²⁹⁴ EAL, App. A., Part 4(b).

²⁹⁵ "For example, pediatric formulations for HIV/AIDS drugs are currently inadequate because there is little market for them in rich countries. Patent-holding drug companies often defer research into improvements such as once-a-day dosing or extended release versions of a drug, conducting this research only towards the end of the drug's patent life so that they can secure a new patent on the improvement after the initial patent expires." UAEM Working Group, The Equitable Access License: Explanatory Document, *supra* note 251, at 5.

improvement or innovation yielded by these research efforts would then be openly licensed, according to the terms of the EAL, in LMI countries; if patented in high income countries, working the patent would require negotiating a cross-license with the licensee (in order to secure use of the underlying patents). For example, if University (“U”) licensed a patented molecule (“M”) to Company (“C”), researchers in an LMI country could freely complete research involving M. If this research produced a new patented product (“M+”), M+ would be available to for open licensing according to the EAL’s procedure in LMI countries. However, producing M+ in a high income country would require use of the patent for M and this would require negotiating a cross-license with C.

The EAL also includes a “humanitarian research” clause to encourage research on neglected diseases²⁹⁶ in all countries.²⁹⁷ This clause is not limited in geographical scope; it allows any entity to complete research using the university’s patent innovation and any licensee improvements to it, without paying a royalty,²⁹⁸ if the research targets a neglected disease.²⁹⁹ The EAL then applies an open licensing structure, similar to that available for third party Notifiers (alternative suppliers of end products to LMI countries). Any party that wishes to engage in research for a neglected disease must notify the university and licensee of this intent; they are then automatically granted an open license to the technologies covered by the EAL (that is, the originally licensed technology and related technologies that qualify as “licensee improvements”). In turn, the provisions of the EAL apply to any resulting end products.³⁰⁰ As

²⁹⁶ EAL, App. A., Part 1(b) (defining neglected research).

²⁹⁷ EAL, App. A., Part 4(b)(i).

²⁹⁸ EAL, App. A., Part 4(b)(iii). Royalties are not required for humanitarian research, but the EAL’s royalty provisions would apply to the sales of any resulting products.

²⁹⁹ The EAL adopts the definition from the U.S. Orphan Drug Statute because the key determinant of whether research for a particular disease is “neglected” is whether it occurs (and therefore has a market) in rich countries. A neglected disease is therefore any with a U.S. incidence of less than 200,000. 21 U.S.C. §§ 360aa-360ee (2004).

³⁰⁰ EAL, App. A., Part 4(b)(ii).

in the scenario described above, negotiating a cross-license in high income countries is required.³⁰¹

While pharmaceutical companies may express concern that creating essentially a worldwide research exemption—both for the underlying university patent and any licensee or sublicense improvements—for *neglected diseases* will actually lead to scientists using these technologies to pursue research into non-neglected diseases. However, such conduct is not protected or permitted by the EAL—it is simply “no more legal under the EAL than in its absence. Such use would constitute infringement and be actionable in a judicial proceeding.”³⁰² Moreover, an infringing lab that sought to benefit financially from its research would likely be exposed: There would be no way to register a patent without revealing that the lab had, in the process of its research, made use of the university and company patent (without permission). Of course, early-stage research may produce results applicable toward a variety of indications, including non-neglected diseases. The EAL does not prevent a researcher from negotiating cross-licenses in order to be able to make use of such an innovation.

iii. Encouraging Transparency

The EAL has been purposefully designed so that a university is not responsible for monitoring access conditions and does not need to take any other steps to facilitate access. Instead, the EAL enlists third parties, namely generics companies, and offers them a series of

³⁰¹ UAEM Working Group, *The Equitable Access License: Explanatory Document*, *supra* note 251, at 6.

The EAL cannot, by itself, solve the problem of lack of funding for neglected research. But since it is desirable to stimulate this research as much as possible, the EAL allows researchers to seek to capture related revenues in high income countries. Note, for example, that some orphan diseases can provide sizeable profits in the U.S.; for example, a new anti-malarial or tuberculosis agent, or an extended release version of an ARV, would likely be profitable in wealthy countries. The EAL does not, however, force the university and licensee to sublicense their technology for use in rich country markets. The parties will instead have to negotiate cross-licenses.

While the EAL requires open licensing in LMI countries, it also sets a reasonable royalty rate, which may allow the innovator to recover some of his investment, even in the absence of high income markets. It is important to note that most research on neglected diseases and applications is currently funded by governments, universities, and philanthropic foundations, and is not driven by market concerns. Open licensing requirements should therefore generally not inhibit research funded in this way.

Id.

³⁰² *Id.* at 7.

legal protections in order to facilitate their market participation. Thus, it is imperative that third parties be able to discover the existence of the EAL's application to a particular technology. The final part of the EAL³⁰³ seeks to facilitate transparency, such that the existence and applicability of the agreement can, with reasonable efforts, be known. We have also required that any applications for improvement patents filed by the licensee or other improvers include a sentence indicating that the innovation is covered by the EAL.

C. Conclusion: Promoting Implementation of the EAL

The current political economy of medical research, product development, and distribution presents an opportunity for U.S. universities to efficiently and powerfully address global health needs through their technology transfer activities. Yet these institutions largely continue to promulgate the exclusive-licensing, limited-access status quo, despite its questionable economic logic and tension with their institutional principles. The flowering of commons- and access-promoting intellectual property strategies, as well as rumblings among advocates, scholars, and even some technology transfer offices, suggest that university technology transfer may be ready for change.

This paper is primarily intended to serve as a resource for (potential) advocates. By describing the critical health needs of many LMI country populations, we hope to encourage participation in a campaign for improved access to medicines and increased research into neglected diseases. By analyzing the institutional and economic context for technology transfer and articulating a range of arguments in support of university efforts to address the access and R&D gaps, we hope to provide the tools to understand and, in turn promote, the EAL. The next big step will be to push for implementation of the EAL. It is clear that collective action among top universities will be a critical component of this effort.

The seminal BMS-Yale-d4t patent concession suggests that a multi-level communication and education strategy is necessary—working to cultivate an informed movement among

³⁰³ EAL, App. A., Part 6.

students and other activists, while reaching out to sympathetic academics and high-ranking university administrators. The d4t experience also reminds us that, when all else fails, the media is a powerful ally.

Other strategies for advancing EAL implementation may include encouraging universities to restructure the performance metrics on which TTOs and their employees are evaluated, to systematically introduce concern for global health needs and provide incentives for negotiating licensing agreements with access-facilitating provisions; and reforming the Bayh-Dole regime, either administratively, legislatively, or judicially, to help refocus technology transfer activity on advancing the public interest.

APPENDIX A:

MODEL PROVISIONS FOR AN “EQUITABLE ACCESS LICENSE”

1. Definitions

- a. **“Open License”** means a non-exclusive license granting the user the right to manufacture, use, sell, import, or export, the technology in question in the country in question, in exchange for a Fair Royalty.
- b. **“Neglected Research”** means any use of the Technology or Licensee Improvements in an effort to develop treatments, prophylaxis, or devices for a neglected disease.
 - i. **“Neglected Disease”** is any disease or condition that, as of the date of notification, (A) affects less than 200,000 persons in the United States, or that (B) affects more than 200,000 persons in the United States, but there is no reasonable expectation that the cost of developing and making available in the United States a drug for the disease or condition will be recovered from sales in the United States of such drug.
- c. **“End Product”** means product [or a reformulation or repackaging thereof] that is developed by the Licensee and relevant to the protection or enhancement of health which requires the use of the Technology herein licensed [and/or Licensee Improvements] for its production.
 - i. “End Product” may include, but is not limited to: (a) any Compound, (b) any products which contain one or more of the Compounds as Active Ingredients, (c) any products which contain one or more Active Ingredients which are manufactured using a Compound as an intermediate, (d) any products which contain one or more Active Ingredients which are manufactured by a process covered by a Valid Claim, or (e) any product whose use is covered by a Valid Claim relating to such use.

1. “Active Ingredient” means any ingredient contained in a Product that has a therapeutic, monitoring, or diagnostic activity for at least one use of such Product that is indicated on approved labeling.
 2. “Valid Claim” means either (a) a claim in a pending patent application included with the Patent Rights, or (b) a claim of an issued and unexpired patent included within the Patent Rights, which has not been held unenforceable, unpatentable, or invalid.
- d. **“Licensee Improvements”** means all data, information, know-how, methods, procedures and processes, that are the subject of a patent or other exclusive right which are (a) possessed by Licensee as of the effective date of this agreement or (b) which are invented, developed or acquired by Licensee (other than from University) during the term of this Agreement and which (i) relate to the manufacture, use or sale of an End Product and (ii) Licensee owns or otherwise has the right to grant to the University, including but not limited to biological, chemical, biochemical, toxicological, pharmacological, metabolic, formulation, clinical, analytical and stability information and data.
- e. **“Eligible Country”** means any country that is defined by the World Bank as a “low income” or “middle income” country at the time that Notification is made.³⁰⁴
- f. **“Notified Country”** means a country in which a party has notified that it intends to produce and/or distribute.
- g. **“Fair Royalty”**

³⁰⁴ This language could be modified if these categories changed, and because the status is established as of notification, there should be no difficulties if and when definitions change and/or countries move into or out of categories.

- i. For all “Low Income” countries, according to the World Bank classifications at the time of the signing of this license, the Fair Royalty shall be 1% of [net sales revenue].
- ii. For all “Middle Income” countries, according to the World Bank classifications at the time of the signing of this license, the annual royalty shall be either:
 1. if the End Product is sold in the United States, a sum equal to ten percent of the annual U.S. sale price³⁰⁵ for the End Product multiplied by the GNP of that country expressed as a percentage of the GNP of the United States, or
 2. if the End Product is not sold in the United States, 5% of the [net sales revenue] of the End Product by the Notifier in the country in question.

2. Licensee Grant Back: The Licensee grants, in consideration for this license, a limited license to all present or future Licensee Improvements to the University, for the sole purpose of making effective the sublicensing of these Improvements under an open license upon receipt of notification of intent to supply or conduct humanitarian research. The licensee also agrees to include, in any patent application for a Licensee Improvement, a sentence reading: “This patent is subject to the provisions of the Equitable Access License.”

3. Notification of Intent To Supply

³⁰⁵ This would also need to be defined, but should be significantly easier with the U.S. than with most other countries. It might be possible to define the annual U.S. sale price as the price paid by federal veteran’s or Medicaid benefits.

- a. **Notification:** Any party wishing to make use of the technology licensed herein and any Licensee Improvements for any purpose (including research on or commercial production of an End Product) in an Eligible Country shall, by letter, announce its intention to make use of the terms of this license and notify both the University and Licensee of the country/countries that the Notifier wishes to supply or conduct research in. There is no limitation to the number of parties that may notify.
- b. **Open Licensing:** Notification will be deemed to grant the Notifier an open license of all the Technology, and an open sub-license of all the Licensee Improvements granted to the University herein, within the specified country/countries for the duration of the patent or other exclusive right [for the sole purpose of meeting the goals of this license], subject to the following conditions:
 - i. **Notifier Grant Back:** Any Improvements made by a Notifier under the terms of the open license will be deemed licensed to the University for the sole purpose of licensing the use of those rights under the terms provided herein. A Notifier Improver must also include, in any patent application for an Improvement, a sentence reading: “This patent is subject to the provisions of the Equitable Access License.”
 - ii. **Notifier Sub-Licensing:** A Notifier may grant sub-licenses to the Technology and Licensee Improvements under the same terms as the open license.
 - iii. **Open Manufacture:** The open license granted to a Notifier includes the right to manufacture the End Product in, and export the End Product from, any country for the sole purpose of meeting the goals of this license.
 1. Notifiers should distinguish such products from the End Product sold by the Licensee through special packaging and/or special

coloring/shaping of the End Product, provided that such distinction is feasible and does not have a significant impact on price.³⁰⁶

- c. **Fair Royalties:** In consideration of the open licenses granted by University, any entity that makes use of such open licenses to facilitate sale of End Product in a Notified Country will pay or cause to be paid to University and Licensee a Fair Royalty, that royalty to be shared evenly between the University and Licensee. Fair Royalties shall be paid only upon sales of End Products, and only where the sale of such Product in the Notified Country would, but for the open license, infringe an issued Patent held by University or Licensee in the Notified Country. Acceptance of payment by the University and Licensee shall constitute their waiver of any claims that the license granted under Sub-Section 3(b) is invalid.

4. **Notification for Humanitarian Research**

- a. **Notification:** Any party wishing to take advantage of the terms of this license to undertake Humanitarian Research in any country shall, by letter, notify both the University and Licensee of the Neglected Disease that they intend to research. There is no limitation to the number of parties that may notify.
 - b. **Open Licensing:** Notification will be deemed to grant the Notifier an open license of all the Technology, and an open sub-license of all the Licensee Improvements granted to the University herein, for the duration of the [university's / improver's] patent or other exclusive right [for the sole purpose of meeting the goals of this license], provided that:

³⁰⁶ This language is taken almost verbatim from the August 30 WTO text on conditions for export under paragraph 31 of TRIPS.

- i. In all high income countries, the open license shall only grant the Notifier permission to use the University technology and Licensee Improvements to undertake Neglected Research.
- ii. Any Improvements made by a Notifier under the terms of the open license will be deemed licensed to the University for the sole purpose of licensing the use of those rights under the terms provided herein, except that all Fair Royalties accrued will be divided evenly between the Notifier Improver, the University, and the Licensee.
- iii. Notifier Improver must include, in any patent application for an Improvement, a sentence reading: “This patent is subject to the provisions of the Equitable Access License.”
- iv. No royalty shall be due to either the University or the Licensee for the use of University or Licensee technologies for the sole purpose of conducting Neglected Research.

5. Assurance of Freedom To Operate: Any sub-licenses or other grants of right that relate to the Technology or End Product granted by either the University or Licensee shall incorporate the terms of this license, in order to meet the goals of this license.

6. Transparency: Notwithstanding any provisions in this agreement to the contrary, either party may publicize the fact that the technology, Licensee Improvements, or End Product are subject to a license that includes the EAL.