The Medicines Patent Pool: Promoting Access and Innovation for Life-Saving Medicines Through Voluntary Licenses

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I. Introduction

In response to a crisis caused by lack of access to essential medicines in developing countries, a proposal for a patent pool emerged. Initially support stemmed primarily from two non-governmental organizations: Médecins Sans Frontières/Doctors Without Borders (MSF)[1] and Knowledge Ecology International (KEI).[2] The proposal suggested the creation of an entity that would rely on voluntary agreements by patent holders, particularly private pharmaceutical companies to license essential medicines for the benefit of patients in developing countries. Ultimately, UNITAID supported the creation of the Medicines Patent Pool (MPP) whose mission is to enable production and distribution of affordable generic versions of HIV/AIDS medicines.[3]

The MPP, a new entity, has now concluded two licensing agreements and is currently in negotiations with several

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1. MÉDECINS SANS FRONTIÈRES/DOCTORS WITHOUT BORDERS ACCESS CAMPAIGN, www.msfaccess.org/spotlight-on/patent-pool (last visited Feb. 24, 2012) www.msf.org [hereinafter MSF].

2. *See* KNOWLEDGE ECOLOGY INT'L, www.keionline.org (last visited Feb. 24, 2012) [hereinafter KEI].

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

pharmaceutical companies. Existing and future licenses will be critical to improving access to affordable HIV/AIDS medicines for patients living in the developing world. An analysis of the background to the MPP's creation, the context in which it operates, and its current licenses can help in evaluating the success of the MPP and how to improve future licenses. As one of several actors and strategies, the MPP has great potential for improving access to medicines.

Part II of this Article provides context for the access to medicines problem and background to patent pools, including examples of prior pools. Part III of this Article describes the goals and structure of the MPP. It also details and analyzes the specific provisions of the current MPP licenses, with a particular focus on the first license agreement to the MPP by a private pharmaceutical company. Part IV explores mechanisms to improve the MPP license agreements, including two specific suggestions to incentivize greater participation in voluntary licensing measures. Finally, this Article concludes that the use of all available tools—both those that currently exist as well as those being considered—should be deployed to strengthen the MPP and promote access to affordable mechanisms.

II. Patent Pools

A. Intellectual Property: Barriers to Access and Innovation

Tragically, an estimated one-third of disease-related deaths worldwide stem from lack of access to existing medical treatments.[4] HIV/AIDS reveals a particularly significant public health crisis with approximately 33.3 million persons living with HIV/AIDS by the end of 2009.[5] Access to antiretroviral medicines appears particularly bleak and, "[o]f the 12 million people living with HIV/AIDS in developing countries who will die within 3 years without immediate access to affordable antiretroviral medicines, only 4 million were receiving treatment at the end of 2008."[6] HIV/AIDS medicines are critical in saving the lives of patients, but also in preventing the spread of this disease. A study by the NIH found that "earlier initiation of

4. Brook K. Baker, *Patents, Pricing, and Access to Essential Medicines in Developing Countries*, 11 VIRTUAL MENTOR 527, 527 (2009), *available at* http://virtualmentor.ama-assn.org/2009/07/pfo41-0907.html.

5. WHO, *Global Summary of the AIDS Epidemic* (2009), http://www.who.it/hiv/data/2009_global_summary.png (last visited Feb. 24, 2012)

6. Baker, *supra* note 4.

antiretrovirals led to a 96 percent reduction in HIV transmission to the HIV-uninfected partner."[7]

For many patients in developing countries, access does not depend solely on the physical availability of the drug at a distributor, but also relies on the affordability of the drug.[8] Furthermore, because patients develop resistance to antiretroviral drugs, newer medicines, which also often have the benefit of reduced side effects, will be needed.

The World Health Organization's (WHO) Commission on Intellectual Property Rights, Innovation and Public Health (CIPIH) has notes the framework for evaluating whether public health is protected and access to medicines is made available in a meaningful manner.[9] The framework considers the availability, acceptability, effectiveness and affordability and whether the treatment is "of the lowest possible cost" to ensure access.[10] Despite the fact that the right to health has been recognized as a fundamental human right[11] and that "access to medicines is a fundamental element in achieving progressively the full realization" of this right,[12] barriers still exist and

7. U.S. Department of Health and Human Services, *Treating HIV Infected People with Antiretrovirals Significantly Reduces Transmission to Partners*, NIH NEWS, May 12, 2011, http://www.nih.gov/news/health/may2011/niaid-12.htm (last visited Feb. 2012).

8. *Id*.

9. WORLD HEALTH ORGANIZATION, PUBLIC HEALTH, INNOVATION AND INTELLECTUAL PROPERTY RIGHTS: REPORT OF THE COMMISSION ON INTELLECTUAL PROPERTY RIGHTS, INNOVATION AND PUBLIC HEALTH, (WHO Press 2006), *available at* http://www.who.int/intellectualproperty/documents/thereport/ENPublicHealthReport.pdf.

10. *Id*.

11. *See, e.g.*, International Covenant on Economic, Social and Cultural Rights (ICESCR) G.A. Res. 2200 (XXI) A—art.12, U.N. Doc. A/RES/2200(XXI), Dec. 16, 1966 ("The States Parties to the present Covenant recognize the right of everyone to the enjoyment of the highest attainable standard of physical and mental health" and States must "[create] conditions which would assure to all medical service and medical attention in the event of sickness"); *Id.* at art. 15 ("The State Parties to the present Covenant recognize the right of everyone: . . . To enjoy the benefits of scientific progress and its applications").

12. Promotion and Protection of All Human Rights, Civil, Political, Economic, Social and Cultural Rights, Including the Right to Development, Human Rights Council Res. 12/12, Rep. of the Human Rights Council, 12th Sess., Sept. 14–Oct. 2, 2009, U.N. Doc. A/HRC/12/50, at 26; International Covenant on Civil and Political Rights G.A. Res. 2200 (XXI) A, art. 6, U.N. Doc. A/RES/2200(XXI) (Dec. 16, 1966) ("Every human being has the inherent right to life. This right shall be protected by law. No one shall be arbitrarily deprived of his life."); Universal Declaration of Human Rights, G.A. Res. 217 (III) A U.N. Doc. A/RES/217 (III) art. 25 (Dec. 10, 1948) ("Everyone has the right to a standard of living adequate for the necessary social services, and the right to security in the event of unemployment, sickness, disability, widowhood, old age or other lack of livelihood in circumstances beyond his control."); Convention on the Rights of a Child art. 24, Sept. 2,

millions of persons, particularly in the developing world, are denied treatment.

Intellectual property rights often lead to monopolies and high prices, which are barriers to access to these medicines. Patents also allow rights holders to use inventions in combination with new follow-on innovations, such as fixed dose combinations or improved methods of storing or delivering the drug.

The high intellectual property barriers can create what has been called the "tragedy of the anticommons."[13] Patent thickets, arising from cases of fragmented ownership or the blocking of critical "upstream" research is patented, can also impede further development of useful new products. The result is that "multiple owners have a right to exclude others from a scarce resource and no one has an effective privilege of use. Once an anticommons emerges, collecting rights into usable private property is often brutal and slow."[14]

In order to promote the right to health, the intellectual property issues that prevent or hamper adequate access for those in the developing world must be addressed. Patent pools, operating within the existing intellectual property system, serve as one mechanism to overcome the problems of access and innovation.

B. Collective Management to Address Intellectual Property Barriers

Patent pools serve as systems of collective management of intellectual property rights, specifically for patents.[15] One definition provides that a patent pool serves as:

> An agreement between two or more patent owners to aggregate (pool) their patents and to license them to one another or third parties. Pools usually offer standard licensing terms to licensees

1990, 1577 U.N.T.S. 3 ("State Parties recognize the right of the child to the enjoyment of the highest attainable standard of health and facilities for the treatment of illness and rehabilitation of health. State Parties shall strive to ensure that no child is deprived of his or her right of access to such health care services. . . . State Parties undertake to promote and encourage international co-operation with a view to achieving progressively the full realization of the right recognized in the present article. In this regard, particular account shall be taken of the needs of developing countries.").

13. *See, e.g.*, Michael A. Heller & Rebecca S. Eisenberg, *Can Patents Deter Innovation? The Anticommons in Biomedical Research*, 280 SCI. 698, 698 (1998).

14. *Id*.

15. *See, e.g.*, *IGWG Briefing Paper on Patent Pools: Collective Management of Intellectual Property—The Use of Patent Pools to Expand Access to Essential Medical Technologies*, KNOWLEDGE ECOLOGY INTERNATIONAL, (June 3, 2007), http://keionline.org/content/view/65/1 [hereinafter *IGWG Briefing Paper*].

> and allocate a portion of the licensing fees (royalties) to patent owners according to a pre-set formula or procedure.[16]

This definition reflects the fact that patent pools can take a variety of different forms and breadth to accomplish different goals, including to address upstream research and development concerns as well as downstream access issues.[17] They have been widely used across many different sectors including for sewing machines in the nineteenth century, airplanes during World War I and, more recently, to address the necessity for common standards in technology fields.[18]

The Department of Justice and Federal Trade Commission recognized the benefits of patent pools as including: 1) clearing of blocking patents; 2) reduction in licensing transaction costs by reducing the need for multiple agreements; 3) management of multiple owners and stacking of royalties, 4) facilitation of professional management of negotiations and administration of the agreements; 5) reduction of infringement litigation costs; 6) the potential to encompass non-patent technology and know-how; and 7) the potential to facilitate technology transfer and scale up capacity building and access in developing countries.[19]

With the goal of improving access to medicines, in 2006[20] KEI[21] and MSF proposed a patent pool to UNITAID for essential medical technologies in order to lower prices, promote innovation, enhance capacity to manage legal issues, and permit larger economies of scale,

16. *Id*. (citing Robert P. Merges, *Institutions for Intellectual Property Exchange: The Case of Patent Pools*, *in* EXPANDING THE BOUNDARIES OF INTELLECTUAL PROPERTY: INNOVATION POLICY FOR THE KNOWLEDGE SOCIETY 123 (Rochelle Dreyfuss, Diane L. Zimmerman & Harry First eds., 2001)); Joel I. Klein, Address to the American Intellectual Property Law Association on the Subject of Cross-Licensing and Antitrust Law (May 2, 1997) (noting that United States v. Line Materials, 333 U.S. 287, 313 n.24 (1948) states that the term "patent pool" is not a term of art).

17. *IGWG Briefing Paper*, *supra* note 15.

18. *See* David Serafino, *Survey of Patent Pools Demonstrates Variety of Purposes and Management Structures*, KEI Research Note 2007:6 (June 4, 2007), http://keionline.org/content/view/69/1 (last visited Nov. 27, 2011).

19. *IGWG Briefing Paper*, *supra* note 15 (*citing* U.S. Department of Justice and Federal Trade Commission, Antitrust Guidelines for the Licensing of Intellectual Property (Apr. 6, 1996), *available at* http://www.usdoj.gov/atr/public/guidelines/0558.htm).

20. The existing MPP was based on the proposal in 2006 by both KEI and MSF to UNITAID. However, KEI previously proposed an "Essential Health Care Patent Pool" modeled on a patent pool that was created for the aircraft industry in WWI. The "Essential Health Care Patent Pool" was first proposed in 2002 at the International AIDS Conferences in Barcelona.

21. At the time of the 2006 proposal KEI went by the name "Consumer Project on Technology (CPTech)."

among other goals.[22] Ultimately, a proposal specifically for HIV/AIDS medicines was developed and UNITAID adopted the proposal.

III. The Medicines Patent Pool

The MPP came into existence following a UNITAID Board resolution on December 14, 2009, with the intention of "mak[ing] newer medicines available in patient-adapted form, at lower prices, for low- and middle-income countries" for HIV/AIDS patients.[23] Since its creation, it has concluded two negotiations, one with the U.S. government and one with a private pharmaceutical company.

A. Overview of the Medicines Patent Pool

Modeled after the Manufacturers Aircraft Association (MAA) patent pool,[24] the MPP seeks to overcome the intellectual property barriers to access. It is important to note that participation in the MPP exists as a purely voluntary action on the part of patent holders. As a result, the MPP must be evaluated in the appropriate context and expectations for the resulting licenses must reflect the voluntary nature of the negotiations.

The MPP focuses on encouraging licenses for HIV/AIDS medicines and operates by obtaining voluntary licenses from patent holders, then non-exclusively licensing to third parties who can create

22. *Id*.

23. Press Release, UNITAID, UNITAID Executive Board Approves Breakthrough Plan to Make AIDS Treatment More Widely Available at Lower Cost (Dec. 14, 2009), *available at* http://www.unitaid.eu/en/The-Medicines-Patent-Pool-Initiative.html; *see also* Press Release, MSF, Entry Into Medicines Patent Pool is a Welcome First Step (Sep. 30, 2010), *available at* http://www.doctorswithoutborders.org/press/release.cfm?id=4768&cat=press-release (However, this addition to the patent pool does not "clear the way for generic versions of darunavir because additional patents are held by Tibotec, owned by US firm Johnson & Johnson, undermining wider access to the drug.").

24. The Manufacturers Aircraft Association patent pool was created in 1917 in response to the U.S. government policy objectives as it drew close to entering into World War I. Those owning essential patents on airplane manufacturing components, such as the Wright brothers, charged high royalty rates and the expensive litigation resulted in stagnation in innovation for the airline industry. The United States believed it needed to increase production of aircraft for World War I and a patent pool was recommended and created in response. This pool initially held membership of eleven aircraft manufacturers and eventually grew to include nearly every manufacturer of aircrafts purchased by the U.S. government. All aircraft manufacturers were required to join the association. Royalties were lowered from $1,000 per plane to $200 per plane and in 1918 were eventually lowered further to $100 per plane.

generic versions for use in developing countries.[25] Royalties from the sale of generic versions are then paid to patent holders.[26] This model promotes generic competition, ultimately driving down prices[27] and making these essential medicines more affordable, and thus more accessible, for patients in low- and middle-income countries. The MPP is also designed to help facilitate the development of co-formulated or fixed-dose combination, thereby simplifying treatment and encouraging better compliance.[28]

In addition to the obvious benefits of negotiating licenses to promote access to generic medicines, the MPP also helps to reduce transaction costs. A generic manufacturer can sign a sublicensing agreement from the MPP rather than separately negotiating several licenses from various patent holders.[29]

25. *Frequently Asked Questions About the Medicines Patent Pool*, MEDICINESPATENTPOOL.ORG, http://www.medicinespatentpool.org/RESOURCES-PUBLICATIONS/FAQ#eztoc1012_9 (last visited Dec. 2, 2011).

26. *Id*.

27. In 1998, for example, a study by the Congressional Budget Office found that "As the number of manufacturers rises, the average prescription price of a generic drug falls. CBO's analysis shows that when one to 10 firms are manufacturing and distributing generic forms of a particular drug, the generic retail price of that drug averages about 60 percent of the brand-name price. When more than 10 manufacturers have entered the market, the average generic prescription price falls to less than half of the brand-name price." Congressional Budget Office, *How Increased Competition from Generic Drugs Has Affected Prices and Returns in the Pharmaceutical Industry*, (July 1998), *available at* http://www.cbo.gov/doc.cfm?index=655.

28. *Id*.

29. Jorge Bermudez & Ellen 't Hoen, *The UNITAID Patent Pool Initiative: Bringing Patents Together for the Common Good*, 4 THE OPEN AIDS JOURNAL 37, 38 (2010) ("In the absence of a patent pool, a company might need to obtain license from at least three different patent holders to be able to develop, produce, export and sell an ARV FDC. A very concrete example is the need for an FDC of the newly WHO-recommended first-line antiretroviral treatment for HIV/AIDS, which would consist of tenofovir (Gilead), lamivudine (GlaxoSmithKline) and either nevirapine (Boehringer-Ingelheim) or efavirenz (Bristol Mysers Squibb). An FDC of three of these drugs currently does not exist or is in limited supply. The patents on every compound in this triple-therapy are held by a different company. A generic company seeking voluntary licenses for the development and production of these FDCs would have to obtain licenses from four different patent-holders. However, if these patents could be combined in a patent pool the generic company would only have to deal with the pool, which would considerably decrease transaction costs and risk. Any qualified company that wanted to use the inventions could get a license from the pool. The patent pool would be a one-stop-shop for all parties involved—it would facilitate the legal and bureaucratic processes involve din obtaining licenses, reduce transaction costs and increase access to the intellectual property needed to make important medicines.").

B. The Medicine Patent Pool's First License: The U.S. National Institute of Health

On September 30, 2010, the MPP received its first license when the White House announced that the National Institute of Health (NIH) issued a license for NIH-owned patents on darunavir.[30] This contribution by the NIH "builds on the President's previous commitment to support humanitarian licensing policies to ensure that medications developed with U.S. taxpayer dollars are available off-patent in developing countries."[31] This license was royalty-free and non-exclusive, related to the NIH's method of treatment patents on darunavir,[32] an important protease inhibitor.[33] The geographic scope for this license was broad, encompassing all low- and middle-income countries as defined by the World Bank.[34] The field of use in this license was drawn broadly, including the "treatment and prevention of medical conditions affecting humans."[35]

Many in the public health community applauded this license, the first for the MPP.[36] The provisions making the license royalty-free and

30. NIH's patent on the method of treatment on darunavir is issued patent number 7,470,506 and listed in the FDA Orange Book with an expiration date of June 23, 2019.

31. Hillary Chen *US Government First to Share Patents with Medicines Patent Pool*, OFFICE OF SCIENCE AND TECHNOLOGY POLICY (Sept. 30, 2010) *available at* http://www.whitehouse.gov/blog/2010/09/30/us-government-first-share-patents-with-medicines-patent-pool.

32. *Public Health Service, Non-Exclusive Patent License Agreement*, NATIONAL INSTITUTE OF HEALTH LICENSE (Sept. 14, 2010), *available at* http://www.medicinespatentpool.org/content/download/214/1227/version/1/file/MPPF+Patent+License+Full+Executed+%28Sept+2010%29-NS.pdf.

33. *Id*. These patents were discovered as a class of compounds in 1998 by scientists at the NIH National Cancer Institute and the University of Illinois-Chicago as being particularly effective for patients who had developed resistance to older HIV/AIDS drugs. Eventually, one compound was developed into darunavir.

34. *Id.* at art. 3.1 ("PHS hereby grants and Licensee accepts, subject to the terms and conditions of this Agreement, a royalty-free nonexclusive license under the Licensed Patent Rights in the Licensed Territory to make, have made, and to use, but not to sell the Licensed Products and Licensed Process in the Licensed Fields of Use for the purposes of supplying the Licensed Products in low- and middle-income countries, as defined by the World Bank.").

35. *Id.* at Annex B.

36. *See, e.g.*, James Love, Director, *The NIH Patent License Agreement with the UNITAID Supported Medicines Patent Pool for Patents on Darunavir* (Sept. 30, 2011), *available at* http://keionline.org/node/956 ("The announcement today by the White House that the NIH is providing a royalty-free license for patents on darunavir to the Medicines Patent Pool is a welcome political statement that the Obama Administration recognizes the importance of a competitive supply of low cost generic medicines in the struggle to make AIDS treatment sustainable. The involvement of NIH Director Francis Collins provides a signal to other patent owners that the time is now to embrace a policy of open

non-exclusive and covering all low- and middle-income countries fit squarely into the goals of the MPP. Additionally, the fact that the U.S. government was willing to license its patents to the MPP provided political support to the new institution. NIH, as the world's largest funder of biomedical research, gave credence to the MPP as

licensing of patents to the Medicines Patent Pool. There is much more the NIH can do, and much more other patent owners can do. This is the beginning of a campaign to obtain licenses voluntarily. The alternatives to the success of voluntary measures are confronting the challenges of obtaining non-voluntary licenses, or shrinking the number of persons who will receive treatment. I think everyone recognizes the stakes are very high."); Press Release, MSF, NIH Entry Into Medicines Patent Pool is a Welcome First Step (Sept. 30, 2010), *available at* http://www.doctorswithoutborders.org/press/release.cfm?id=4768&cat=press-release; Press Release, HealthGAP, Activists Applaud NIH Support for the Medicines Patent Pool But It Won't Fix President Obama's Broken AIDS Funding Promises (Sept. 30, 2011), *available at* http://www.healthgap.org/press/patent_pool_response.htm ("'Hopefully this positive step by NIH will encourage drug companies including Gilead, Abbott, and ViiV to promptly license patents on HIV medicines that they hold to the Medicines Patent Pool as well, using the same positive licensing terms as NIH,' said Brook Baker of Health GAP. 'If other rights holders share their patents with the Patent Pool alongside NIH, medicine price reductions and the creation of novel fixed-dose combination medicines will follow, which will save lives.'"); Press release, Oxfam, Oxfam welcomes breakthrough on access to HIV medicines (Sept. 30, 2011), *available at* http://reliefweb.int/node/369405 ("Oxfam today welcomed an agreement between the UNITAID-backed Medicine Patent Pool Foundation (MPPF) and the US National Institutes of Health (NIH) to license the antiretroviral drug darunavir to the patent pool. The pool was set up to reduce the cost of HIV medicines. Mogha Kamal-Yanni, Oxfam senior policy adviser, said: 'This decision could be a real breakthrough in making new HIV medicines available and affordable to poor people.'"); Press Release, Afr. Servs. Comm., African Services Committee Applauds US NIH as First to License Patents to MPP (Sept. 30, 2011), *available at* http://www.africanservices.org/index.php/Press-Room/ASC-Applauds-US-NIH-and-MPP-Partnership ("The US National Institute of Health (NIH) has become the first patent-holder to license patents to the Medicines Patent Pool (MPP), established by UNITAID this year. In so doing, the NIH and the US Government have taken a large stride forward in validating the HIV Medicines Patent Pool, and raised a leadership challenge to others within the pharmaceutical industry to follow suit. This contribution [to the MPP] marks a significant advance in the effort to provide affordable life-saving HIV medication to those in low- and middle-income countries. This move is a necessary step in meeting the goal of universal access to HIV treatment, and we hope will be an indication of the Obama Administration's ongoing commitment to putting patients right above patent rights," (quoting Kim Nichols, Co-Executive Director of the African Services Committee and UNITAID alternate board member.)); Press Release, Universities Allied for Essential Medicines, NIH Acts on Commitment to Global Access Licensing by Licensing Patents to Medicines Patent Pool (Sept. 30, 2010), *available at* http://essentialmedicine.org/story/2010/09/30/nih-acts-commitment-global-access-licensing-licensing-patents-medicines-patent-pool ("UAEM lauds the NIH for specifying all low- and middle-income countries as potential beneficiaries of the license, including countries such as Brazil, India and China where the vast majority of the world's poor still live. The NIH is sending a strong signal to universities and public institutions to improved global health. . . . Furthermore, universities should license their medicines-related patents to the Pool, and should follow the precedent set by the NIH in agreeing to equitable and transparent licensing terms.").

an institution and could also set an example for other publicly funded research institutions, universities, or patent holders to follow.[37]

While this first license from the NIH certainly represented a welcome step forward, it is important to note that these licenses did not permit the generic production of darunavir for the benefit of HIV/AIDS patients. The NIH is not the sole patent holder and the private pharmaceutical company; Tibotec/Johnson & Johnson hold other patents related to darunavir.[38] Unfortunately, Tibotec/Johnson & Johnson has not yet joined in negotiations with the MPP[39] despite the fact that three of its drugs—darunavir (DRV), etravine (ETR) and rilpivirine—are on the list of target medicines for the MPP. [40]

37. Medicines Patent Pool, *Questions and Answers: The US National Institutes of Health (NIH) License to the Medicines Patent Pool*, UNITAID.EU (Sept. 2010), http://www.unitaid.eu/images/news/patentpool/20100930_nih_license+q%26a_en.pdf (last visited Dec. 6, 2011).

38. *See* Ed Silverman, *NIH Joins AIDS Patent Pool; Where is Pharma?*, PHARMALOT, (Oct. 10, 2010), *available at* http://www.pharmalot.com/2010/10/nih-joins-aids-drugs-patent-pool-where-is-pharma/ ("Although encouraged by the NIH action, Medecins Sans Frontieres (Doctors Without Borders) says the pharmaceutical industry must now take the same step. 'This single patent isn't enough to allow a cheaper version of the medicines to be produced. We need to build on this. The onus is on the drug companies that own patents on this and other key AIDS medicines to put their patents in the pool,' says Tido von Schoen-Angerer, who runs MSF's Campaign for Access to Essential Medicines. 'If companies are genuine about wanting to boost access to newer medicines, then they must license the patents that are actually blocking generic and will make a real difference to people's lives' . . . For instance, the NIH Office of Technology Transfer has previously granted non-exclusive licenses to these patents, including to Tibotec, which is a unit of Johnson & Johnson, for darunavir, known commercially as Prezista. But von Schoen-Angerer notes this particular NIH patent will not free the way for generic versions of darunavir, because additional patents are held by Tibotec.").

39. Following a "pool party" protest outside of Johnson & Johnson's offices and pharmacies in London over Johnson & Johnson's refusal to join negotiations with the MPP, a spokesperson for the company stated "On January 31, we responded to MPPF and indicated that we generally support the MPPF and its goals, but are not starting negotiations for our antiretroviral compounds at this time." Ed Silverman, *Johnson & Johnson and Bikinis: A Patent Pool Party,* PHARMALOT.COM (Mar. 31, 2011), *available at* http://www.pharmalot.com/2011/03/johnson-johnson-and-bikinis-a-patent-pool-party/.

40. *Medicines Patent Pool, Target Medicines*, http://www.medicinespatentpool.org/WHAT-WE-DO/Target-Medicines (last visited Dec. 3, 2011). Abbott Laboratories and Merck & Co. are two other companies targeted by the MPP that have not yet entered into negotiations. Abbott Laboratories holds the patents to targeted compounds Lopinavir (LPV) and Ritonavir (r) while Merck & Co. holds the main patents to Efavirenz (EFV), Raltegravir (RAL) and Vicriviroc. The remaining seven targeted entities have either completed license agreements with the MPP (these include NIH and Gilead) or have entered formal negotiations. Those companies currently in formal negotiations and their respective target products include Boehringer-Ingelheim (holding Nevirapine or NVP), Bristol-Myers Squibb (holding Atazanavir or ATV), Roche (holding Saquinavir or SQV), Sequoia Pharmaceuticals, and Viiv Healthcare (holding Lamivudine or 3TC, Abacavir or ABC, Fosamprenavir or FSV, and Maraviroc.).

Until Johnson & Johnson enters into formal negotiations with the MPP and licenses its products to the pool, sublicensees cannot manufacture the drug for use or sale where the darunavir patents exist. Although efforts have been made to encourage Johnson & Johnson participation in the MPP, on December 19, 2011, the company issued a statement formally refusing to enter negotiations.[41]

Pharmaceutical companies should commit to the corporate social responsibility they claim to exercise[42] and ensure life-saving medicines are accessible by those living in developing countries[43] by licensing to the patent pool.

41. Ed Silverman, Just Say No: J&J Rebuffs Medicines Patent Pool, Pharmalot (Dec. 20, 2011), http://www.pharmalot.com/2011/12/johnson-johnson-rebuffs-medicines-patent-pool/; *see also* Medicines Patent Pool, Statement on Johnson & Johnson Decision on Negotiations (Jan. 31, 2012), http://www.medicinespatentpool.org/NEWS-ROOM/News-from-the-Pool/Statement-on-J-and-J.

42. Johnson and Johnson, for example, states that "As a global health care company, Johnson & Johnson has a responsibility to help create a world where people across all economic and social circumstances have access to the treatments they need." Johnson and Johnson, Access to Medicines, http://www.jnj.com/responsibility/ESG/Social/Global_Health/Access_to_Medicines (last visited Mar. 21, 2012). Merck's corporate responsibility statement on health similarly states, "As a global healthcare company, Merck believes it has a responsibility to help increase access to medicines, vaccines and quality healthcare worldwide. In this effort, we are committed to discovering smart, sustainable ways to expand access, especially in parts of the world where there is limited or no healthcare infrastructure and resources. Given the enormity of this challenge, we believe we can make the strongest contribution by working in partnership with others—governments, donors, patient organizations, healthcare professionals, nongovernmental organizations, academic institutions, multilateral organizations and others within the private sector." Merck, http://www.merckresponsibility.com/giving-at-merck/health/home.html (last visited Mar. 21, 2012).

43. Although companies have entered into their own voluntary licenses, the Medicines Patent Pool represents a more efficient process for all those involved; rather than individually negotiating licenses and terms with each developing country and generic manufacturer, a single entity can negotiate the license. Gilead, as will be discussed in greater detail below, previously issued a voluntary license for one of its drugs, but the license the MPP negotiated on the same pharmaceutical provided better terms for patients in the developing world. The medicines at issue are life-saving drugs for HIV-positive patients. More than half of the world lives on less than two dollars a day and cannot afford the high monopoly prices charged in high-income countries, nor can developing countries afford to support monopoly priced treatments. A company joining the patent pool might also benefit from the visibility and public acknowledgement that it is taking corporate responsibility seriously. It should be noted that patients in these countries cannot afford the prohibitively high prices charged by pharmaceutical companies and by licensing to the MPP, the company can receive royalty payments on the sales of generic versions of the drug that it otherwise might not receive. Due to funding shortages and the rising number of patients needing treatment, donor organizations and governments will find it increasingly difficult to meet treatment targets without generic versions of these medicines.

C. Gilead Licenses Multiple Products to Medicines Patent Pool

On July 12, 2011, the MPP and Gilead Sciences announced the first license by a private company to the patent pool.[44] This license agreement covered patents for tenofovir (TDF) and emtricitabine (FTC), as well as several pipeline drugs including elvitegravir (EVG), cobisistat (COBI) and a four-drug, fixed-dose combination of these products known as "the quad."[45] The licenses contained in the agreement specifically cover production of TDF,[46] EVG,[47] COBI,[48] and the quad,[49] as well as a covenant not to sue on FTC.[50]

The licenses also create a one-time technology transfer of know-how on the products, without any obligations of additional royalties.[51] Additionally, the agreement grants generic manufacturer licensees "NCE Exclusivity[52] or other regulatory exclusivity waivers as may be required by the applicable regulatory authorities in order to manufacture or sell Product in the Territory . . .."[53] The significant provisions of this agreement are detailed below.

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44. *Medicines Patent Pool, Medicines Patent Pool Signs Licenses to Increase Access to HIV/AIDS Medicines*, MEDICINESPATENTPOOL.ORG (July 12, 2011), http://www.medicinespatentpool.org/LICENSING/Current-Licences/Medicines-Patent-Pool-and-Gilead-Licence-Agreement/Pool-UNITAID-joint-press-release. Notably, this license achieves one of the goals of reducing transaction costs with the result being the licensing of EVG to Gilead from Japan Tobacco. A generic licensing company wishing to make the quad would have had to negotiate separately with Gilead and Japan Tobacco if the patent pool did not exist.

45. Medicines Patent Pool License Agreement with Gilead Sciences, Inc. (July 11, 2011), http://www.medicinespatentpool.org/LICENSING/Current-Licences (follow link labeled "Main licensing agreement between the Pool and Gilead") (last visited Feb. 24. 2012) [hereinafter Main Gilead Licensing Agreement].

46. *Id.* at art. 2.3.

47. *Id.*

48. *Id.*

49. *Id.*

50. *Id.* at art. 5.3 provides "Covenant Concerning Certain Gilead Patents. Gilead covenants and agrees that it shall not, at any time during the term of this Agreement, bring any claim or proceeding of any kind or nature against MPP in relation to any of the pending and issued patents identified in Appendix 3 hereto (the "Emtricitabine Patents") to the extent that MPP remains in compliance with the terms and conditions set forth in this Agreement and each Sublicense Agreement.

51. Medicines Patent Pool, Gilead Sciences, Inc. and Generic company license [hereinafter Form Gilead Sublicense Agreement] art. 5.4, http://www.medicinespatentpool.org/content/download/482/2855/version/1/file/Form+3-way+Generic+License+%28FINAL%29+08JUL11.pdf (last visited Dec. 6, 2011).

52. Main Gilead Licensing Agreement, *supra* note 45, at 3(defined in the agreement as "five years of marketing exclusivity granted by FDA pursuant to its authority under 21 U.S.C. §§355(c)(3)(E)(ii) and 355(j)(5)(F)(ii).").

53. Form Gilead Sublicense Agreement, *supra* note 51, at art. 6.3.

1. Licensed Products

The Gilead license involves four HIV/AIDS drugs and a fixed-dose combination of these drugs. The first product, TDF, is an antiretroviral drug used in combination with other antiretrovirals for treatment of HIV and hepatitis B.[54] The World Health Organization has recommended that the use of TDF to replace an older antiretroviral, stavudine, because TDF causes fewer harmful side effects.[55] FTC is another antiretroviral that blocks enzymes used in viral replication.[56]

Significantly, the Gilead license covers drugs in the development stage, as well. COBI acts as a booster making antiretrovirals more effective at lower dosages, thus reducing their side effects.[57] EVG, another Gilead pipeline product, is an antiretroviral.[58] Gilead expects FDA approval of these drugs in the latter part of 2012 and the sublicensees will be permitted to begin preparations to market these drugs, as well as the quad, after Gilead receives regulatory approval. The inclusion of these pipeline drugs in the license agreement is highly significant because it will permit early generic competition for these products, driving down the prices for these new treatments for the benefit of those living in the covered territories. The MPP/Gilead agreement thus creates the potential for developing country patients to have earlier access to affordable new HIV/AIDS medicines.

2. Field of Use

The licensed products include a broad field of use, defined to include (or potentially include for the pipeline products) uses beyond HIV/AIDS. The agreement states:

> **"Field"** shall mean the treatment and prophylaxis of HIV infection, *provided, however*, that (a) for Product containing TDF as its sole active pharmaceutical ingredient, the Field shall include the treatment and prophylaxis of Hepatitis B Virus infection, and (b) for Product containing EVG or COBI, the Field shall include any use that is consistent with the label approved by the FDA or applicable foreign regulatory

54. Medicines Patent Pool/Gilead Licenses, Questions and Answers, MEDICINES PATENT POOL, http://www.medicinespatentpool.org/LICENSING/Current-Licences/Medicines-Patent-Pool-and-Gilead-Licence-Agreement/Q-and-A-Gilead-Licences (last visited Dec. 6, 2011) [hereinafter MPP/Gilead Q&A].

55. *Id.*

56. *Id.*

57. *Id.*

58. *Id.*

> authority for the use of such Product containing EVG or COBI.[59]

This definition allows sublicensees a wide range of uses for the products beyond HIV, including, for example, for the treatment of hepatitis B. Thus, patients afflicted by hepatitis B can also benefit from the MPP/Gilead license. Permitting sublicensees to produce these drugs to treat other diseases can increase the economies of scale leading to a reduction of price for these medicines. The expanded field of use therefore represents a positive aspect of the licensing agreement.

Contrary to some expressed concerns regarding the field of use provisions, the license does not endorse patents on new uses[60] of the drugs. The actual language of the agreement does not cover Gilead patents on new uses and does not imply endorsement of new use patents. Individual countries, in their sovereignty, continue to determine the patentability of a specific product. The field of use license determines the uses that are authorized under the existing patents. A license limited to the treatment of HIV/AIDS is useful, but broader fields of use carry even greater value because they permit generic versions of the drug to benefit patients in developing countries that suffer from diseases other than HIV/AIDS.

3. Geographic Coverage

These licenses, which cover up to 112 countries, represent the largest geographical scope of *any* voluntary license to date by a private company. In total, well over 26 million persons living with HIV/AIDS are covered by the most encompassing license, and over 25 million persons living with HIV/AIDS for the most restrictive geographic scope of these licenses.[61]

Gilead previously offered voluntary licenses on TDF in ninety-five low- and middle-income countries. The new license on TDF expands the geographic scope to cover an additional seventeen

59. Main Gilead Licensing Agreement, *supra* note 45, at art. 1 (emphasis in original).

60. "New use" patents is a mechanism where companies try to renew their monopolies by seeking a new patent over a known substance. It is a way to enjoy a longer monopoly, permitting companies to charge high prices for a longer period of time on the same product. Even though a new substance has not been created or invented, companies often seek such patents to prolong their monopolies in a process known as "evergreening."

61. James Love, *Coverage of Persons Living with HIV in Gilead MPP Licenses* (Oct. 13, 2011), KEI, http://keionline.org/node/1295 (last visited Nov. 15, 2011).

countries, for a total of 112.[62] This expansion of geographic scope over the previous licenses provides additional coverage to roughly 93,200 persons living with HIV/AIDS.[63] One hundred percent of low-income countries are included in the TDF license, which also covers approximately ninety-six percent of those living in lower middle-income countries and sixty-seven percent of those in upper middle-income countries.[64] Ultimately, the TDF license to the MPP covers approximately eighty-four percent of persons living with HIV/AIDS and ninety percent of those living in low- and middle-income countries.

The COBI license covers a slightly smaller geographic scope, including 103 countries.[65] Like the TDF license, all low-income countries are included in the license. Additionally, 92.8 percent of those living with HIV/AIDS in lower middle-income countries and 56.4 percent of upper middle-income countries are covered by the COBI license, translating to coverage of eighty percent of persons living with HIV/AIDS, eighty-five percent of those in low- and middle-income countries.[66]

62. Main Gilead Licensing Agreement, *supra* note 45 at, app. 1. The new countries included in the TDF license include: Anguilla, Armenia, Aruba, British Virgin Islands, Ecuador, El Salvador, Fiji, Georgia, Kazakhstan, Montserrat, Nauru, Palau, South Sudan, Sri Lanka, Tonga, Turkmenistan, and Turks & Caicos. It should be noted that this count includes South Sudan, a newly recognized country.

63. This figure represents the additional territories beyond the prior Gilead licenses on TDF and is based on 2009 data reported by the World Health Organization (in 2010) on the total number of persons living with HIV in these countries. Some critics of the license have cited much smaller figures (of approximately 14,000-15,000) which represent the number of persons living with HIV in these countries that are *currently* on antiretroviral treatment. The number throughout this article refer to the total number of persons that the licenses could benefit, that is, the total population covered by the licenses. There are certainly numerous people in both developed and developing countries who are not currently receiving HIV/AIDS treatment, but should be. The new countries covered by the MPP/Gilead license with significant HIV-positive patients include Ecuador (37,000), El Salvador (34,000) and Kazakhstan (13,000).

64. Although the vast majority of countries in the MPP/Gilead license are low- or middle-income countries, five high-income countries are also included in the TDF license: Aruba, Bahamas, Equatorial Guinea, Trinidad & Tobago, and Turks & Caicos. Main Gilead Licensing Agreement, *supra* note 45, at Appendix 1: Countries in the TDF Territory. Note that South Sudan was recognized as a country after the signing of these licenses. South Sudan is covered by the license, but not listed on the appendices to the license agreement originally signed between MPP and Gilead. Amendment adding South Sudan to Medicines Patent Pool Licensing Agreement with Gilead Sciences (July 15, 2011), http://www.medicinespatentpool.org/content/download/505/2987/version/1/file/Signed+amendment+adding+South+Sudan.pdf (last visited Dec. 6, 2011).

65. Main Gilead Licensing Agreement, *supra* note 45, at app. 4.

66. MPP/Gilead Q&A, *supra* note 54, at question 14.

EVG and the quad licenses include 100 countries[67] and, like the other licenses to the MPP, cover all low-income countries. The geographic scope of the EVG and quad licenses is very similar to that for COBI, but excludes three additional countries: Aruba (classified as a high-income country by the World Bank), the Dominican Republic, and Montserrat.[68] The exclusion of these three countries for EVG and the quad means that more than fifty-five percent of persons living with HIV/AIDS in upper middle-income countries are covered by these licenses.

The exclusion of a number of middle-income countries, particularly those in Asia and Latin America, represents one of the main[69] criticisms of the MPP/Gilead license. The expansion of

67. Main Gilead Licensing Agreement, *supra* note 45, at app. 4. Excluded countries from the COBI license include: Botswana, Ecuador, El Salvador, Indonesia Kazakhstan, Namibia, Sri Lanka, Thailand and Turkmenistan; *see also* Stakeholder Briefing by Gilead Sciences, New York, NY (Aug. 23, 2011). Outside of the MPP, Gilead entered into voluntary licensing agreements for COBI, EVG and the quad with four Indian generic manufacturing partners for these nine countries. These "semi-exclusive" licenses include a higher royalty rate than the MPP licenses (ten percent royalty for the quad and fifteen percent royalty for individual products while royalties on pediatric formulations are waived) and have confidential terms requiring "progress" to be shown by the four generic partners on developing pediatric formulations. During a stakeholder briefing delivered by Gilead on August 23, 2011, Gregg Alton stated that these countries were selected for the semi-exclusive license because they tend to be wealthier countries than others in the license or, for the lower income countries such as Sri Lanka, contained a small HIV prevalence.

68. *Compare* Main Gilead Licensing Agreement, *supra* note 45, Appendix 4: Countries in the COBI Territory *with* Main Gilead Licensing Agreement, *supra* note 45, Appendix 5: Countries in the EVG-Quad Territory.

69. The geographic scope and exclusion of certain countries is a section that was almost universally criticized by civil society. Oxfam welcomes Gilead's historic decision to make HIV drugs accessible to poor, Oxfam (July 12, 2011), http://www.oxfam.org.uk/applications/blogs/pressoffice/2011/07/12/oxfam-welcomes-gilead%E2%80%99s-historic-decision-to-make-hiv-drugs-accessible-to-poor/?v=media; Gilead license expands access, but several countries left out, MSF (July 12, 2011), http://msf.org/msf/articles/2011/07/gilead-licence-expands-access-but-several-countries-left-out.cfm; KEI Comment on the Medicines Patent Pool license with Gilead, KEI (July 12, 2011), http://keionline.org/node/1184; International Treatment Preparedness Coalition (ITPC) and Initiative for Medicines, Access and Knowledge (I-MAK), *The Implications of the Medicines Patent Pool and Gilead Licenses on Access to Treatment: Briefing Paper* (July 25, 2011), *available at* http://www.i-mak.org/storage/ITPC%20I-MAK%20-%20The%20Broader%20Implications%20of%20the%20MPP%20and%20Gilead%20Licenses%20on%20Access%20-%20FINAL%2025-7-2011.pdf.; Brook Baker, Inside Views: Corporate Self-Interest and Strategic Choices: Gilead Licenses to the Medicines Patent Pool, IP WATCH (July 21, 2011), http://www.ip-watch.org/2011/07/21/corporate-self-interest-and-strategic-choices-gilead-licenses-to-medicines-patent-pool/; Open Letter from Thai Civil Soc'y (July 21, 2011), http://www.patentes.org.br/sulsul/media/file/Open%20Letter%20from%20

geographic scope in future licenses would be a welcome improvement and is an area where progress can be clearly measured and monitored.

In sum, for all the products covered by the MPP/Gilead licenses, all low-income countries and nearly all lower middle-income countries are included. Although room for improvement with respect to geographic coverage exists, the majority of low and middle-income countries are covered. In terms of persons living with HIV/AIDS, approximately twenty-five million persons directly benefit from the licenses, representing a significant portion of the HIV-positive population; half a million persons living in developing countries are excluded from the licensed territory.

Negotiations, particularly ones entered into voluntarily, involve a balancing between competing objectives and improvements in one area may result in less favorable provisions in other sections of the agreement. To expand the geographic scope, it may be necessary to consider changes in other terms of the license or new incentives for companies to provide more extensive geographic coverage.[70]

4. Sourcing of active pharmaceutical ingredients

One of the limitations of the license permits sourcing of active pharmaceutical ingredients (API) exclusively from India.[71] The agreement defines "Licensed API Supplier" as "an entity (other than the applicable Sublicensee) that is licensed by Gilead or sublicensed by MPFF under a sublicense Agreement, to manufacture and sell API to third parties in the Field in India."[72] The licensing agreement between the MPP and Gilead states:

Article 2.1 Sublicense Agreements. The parties intend that MPP will identify potential manufacturers of generic pharmaceutical products located in India (collectively "Manufacturers") and, once identified, MPP shall have the right to execute (together with Gilead) a sublicense agreement with each such Manufacturer pursuant to which MPP shall grant such Manufacturer a sublicense under the

Thai%20organizations.pdf (last visited Feb. 24, 2012); Open Letter from the Latin-American Civil Soc'y Grps. (July 20, 2011).

70. Other concessions may also be involved in order to improve some areas of the agreement, such as the expansion of the geographic coverage.

71. *See* Main Gilead Licensing Agreement, *supra* note 45, at art. 2.1.

72. *Id.* at art. 1: Definitions.

rights granted to MPP in Sections 2.2 and 2.3 according to the Form Sublicense Agreement.[73]

The terms of the agreement thus restricts the sourcing of API and the manufacture of the licensed products to India. The agreement does not permit the sale of API to non-licensees.

The limitation on API sourcing and manufacture of the licensed products is another area with room for improvement and has been widely criticized by public health groups. Although the Gilead/MPP agreement offers a non-exclusive license within India, it restricts competition to one country and prohibits domestic manufacture.[74] While Gilead has indicated a willingness to consider modifications to the agreement, for example, to permit the manufacturer of products in a particular country outside of India, it has generally not accepted proposals to permit manufacturing in any country and this area remains controversial.

5. Royalties

The license agreement currently requires sublicensees to pay royalties to Gilead in the amount of three percent of its sales of generic TDF produced under the agreement.[75] For COBI, EVG and the quad, a five-percent royalty applies.[76] Gilead has waived its royalties on pediatric formulations of the licensed product.[77]

73. *Id.* at art. 2.1.

74. Permitting domestic manufacture could help strengthen development and encourage local capacity building. The Declaration on the Right to Development art. 8, A/RES/41/128 (Dec. 4, 1986) ("States should undertake at the national level, all necessary measures for the realization of the right to development and shall ensure, inter alia, equality of opportunity for all in their access to basic resources, education, health services, food, housing, employment and distribution of income. Effective measures should be undertaken to ensure that women have an active role in the development process. Appropriate economic and social reforms should be carried out with a view to eradicating all social injustices.").

75. Form Gilead Sublicense Agreement, *supra* note 51, at art. 4.1(a)-(c). The royalties are currently set at three percent. However, should TDF receive patent protection in India, those royalties will be increased to five percent. The patent landscape of TDF in India is murky at the moment. No patent on TDF currently exists in India, however Gilead has appealed the rejection of this patent and is pursuing patent protection for this drug.

76. *Id*. at art. 4.1(d)-(g).

77. *Id.* at art. 4.1(h) and 6.2(3)(i)-(ii). Sublicensees have the right to develop pediatric formulations for patients under the age of twelve. It should be noted that for EVG and EVG combination products, Gilead's prior written consent is necessary for the development of pediatric formulations, such consent "not to be unreasonably withheld."

The license restricts the manufacture of the products to India and, as a result, royalties must be paid in the licensed territories, even when the products are exported to a licensed territory for which no patents exist for the drugs, a result that has been widely criticized by health groups.[78] While many of Gilead's products do not receive patent protection in the majority of the territories covered by the MPP agreement, the patent status of these products in the country of sale or use represents only half of the equation; patents in the country of manufacture represents the other consideration. By applying for patents in India and limiting API sourcing and production to India, Gilead effectively created a system requiring the payment of royalties because patents exist or remain pending in the country of manufacture and export.

Of the royalties owed to Gilead, the agreement reserves a small brokers fee for the MPP.[79] Gilead has agreed to pay the MPP five percent of all sublicense revenue received, up to a maximum of $1 million per calendar year.[80] This figure translates to between 0.15 and 0.25 percent of the total sale revenues, a marginal amount.[81]

6. Termination Provisions

Under the MPP/Gilead license, sublicensees can terminate the licenses at any time. The licenses on the products are severable or "unbundled," meaning that sublicensees have the ability to take a license on all products or just some. Sections 10.4[82] and 10.5 of the

78. International Treatment Preparedness Coalition, *Concerns About the Process, Principles of the Medicines Patent Pool and the License*, PETITIONBUZZ.COM (Oct. 10, 2011), https://www.petitionbuzz.com/petitions/mppunitaid (last visited Dec. 6, 2011).

79. Main Gilead Licensing Agreement, *supra* note 45, at art. 3.1.

80. *Id*.

81. Despite the fact that the MPP estimates that these revenues will only amount to approximately $10,000 over the next four years, which represents less than one percent of the MPP's operating budget, some concerns have been raised as to whether this broker's fee presents a conflict of interest. It is the opinion of the Author that such a small broker's fee does not, inherently, present a conflict of interest. Furthermore, as a matter of practicality, as well as being a directive from the UNITAID Board, the MPP should consider avenues for financial sustainability beyond dependency on UNITAID. Due to controversies raised about the potential for, or the appearance of, conflicts of interest, however, the MPP has stated that it would consider waiving its broker's fee. *See Response to Questions & Comments to Medicines Patent Pool-Gilead Licenses*, MEDICINES PATENT POOL, http://www.medicinespatentpool.org/LICENSING/Current-Licences/Medicines-Patent-Pool-and-Gilead-Licence-Agreement/Response-to-Feedback (last visited Dec. 6, 2011).

82. Form Gilead Sublicense Agreement, *supra* note 51, at art. 10.4 provides that licensees have the right to terminate the agreement in its entirety upon thirty days prior

MPP/Gilead license agreement explicitly provide that sublicensees have the right "at its sole discretion, to terminate the licenses . . . with respect to any particular API, at any time."[83] The termination becomes effective immediately upon the receipt of written notice from the sublicensee to Gilead and the MPP.[84] Termination of the license on one product does not affect the license for any other API or product.[85]

The unbundling provisions represent a significant flexibility for sublicensees to select only the products they wish to produce or the ones where they believe patents stand as a barrier to the manufacture and sale of the drug. Thus, where the patent landscape is not clear or where it appears that a patent does not exist or will not be granted, such as for Gilead's drug TDF, sublicensees are free to terminate the license on that product.

In fact, when the MPP announced that two Indian generic manufacturing companies had signed sublicense agreements, one company, Aurobindo, elected to only take licenses on COBI, EVG, FTC,[86] and the quad.[87] Immediately upon signing its sublicense,

written notice to both Gilead and MPP. Article 10.5 governs the termination of licenses on an API basis.

83. *Id.* at art.10.5. I note that some criticisms have pointed out that sublicensees must sign the license in its entirety, then terminate its licenses on the specific API for which it does not wish to take a license. These critics suggest that a better model for the license would be create four individual licenses and sublicensees could then select the licenses to sign, rather than the licenses to terminate. As a practical matter, however, this distinction does not carry a difference and the effect will likely be that generic companies will elect to terminate the TDF license while retaining their licenses on the other products unless India grants Gilead's application for a patent on TDF.

84. *Id.* at art. 10.5.

85. *Id.* at art. 10.5(c).

86. One criticism of the MPP/Gilead license suggests that termination of the TDF license also terminates a sublicensee's ability to produce FTC, as well. However, as evidenced by Aurobindo's actions, termination of TDF does not impact rights granted under the license with regard to FTC. The severability of the license on one API leaves the remainder of the license intact. Article 5.3 of the MPP/Gilead license's covenant not to sue states that "Gilead covenants and agrees that it shall not, at any time during the term of this Agreement, bring any claim or proceeding of any kind or nature against MPP in relation to any of the pending and issued patents identified in Appendix 3 hereto (the "Emtricitabine Patents") to the extent that MPP remains in compliance with the terms and conditions set forth in this Agreement and each Sublicense Agreement." Nothing in the agreement ties the covenant not to sue on FTC to the TDF license. The MPP/Gilead license should still permit a sublicensee with a valid agreement on other products, such as COBI, EVG or the quad, to produce FTC. Because of this perceived ambiguity and complaint by civil society organizations, on November 14, 2011, Gilead and the MPP amended the license agreement to clarify that where a licensee terminates its TDF license, Gilead "shall not during the term of this Agreement, bring a claim or proceeding of any

Aurobindo took advantage of the unbundling provision and notified Gilead of its intent to terminate the license for TDF.[88] As a result, Aurobindo can sell TDF to countries outside of the territory without paying royalties, provided that patent barriers do not exist in those countries.[89]

Many of the criticisms surrounding the MPP/Gilead license are aimed at the TDF license. One criticism is the fact that TDF does not currently receive patent protection in India. As a practical matter, however, the fact that the licenses are unbundled makes many of the criticisms[90] moot. For example, because TDF does not receive patent protection in the vast majority of countries in the licensed territory and is also not currently patented in India, sublicensees terminating

kind against Licensee in relation to the Emtricitabine Patents with respect to Licensee's manufacture, use or sale of Products that incorporate TDF and FTC as active pharmaceutical ingredients (such Products, "TDF/FTC Products") in the TDF Territory. For clarity, upon a TDF Termination, nothing set forth in this Section 7.5 shall be interpreted to prevent Gilead from enforcing any right, title or interest in any of its proprietary rights covering TDF (including the TDF Patents) against Licensee with respect to its activities related to TDF/FTC Products in the TDF Territory, or from enforcing any right, title or interest in any of its proprietary rights covering FTC (including the Emtricitabine Patents) against Licensee with respect to its activities related to TDF/FTC Products outside the TDF Territory." Second Amendment to Gilead License Agreement, MEDICINES PATENT POOL, (Nov. 14, 2011), http://www.medicinespatentpool.org/content/download/597/3420/version/1/file/MPP+Second+Amendment+%28fully+executed%29.pdf [hereinafter Second Amendment to Gilead License Agreement].

87. *Generic Companies Join the Medicines Patent Pool: Aurobindo signs on to increase access to medicines around the world*, MEDICINES PATENT POOL (Oct 11, 2011), http://www.medicinespatentpool.org/NEWS-ROOM/News-from-the-Pool/Generics-Join-the-Pool.

88. Letter from Aurobindo to Gilead, Sub: Termination Notice for Tenofovir (Sep. 20, 2011), *available at* http://editor.ne16.com/medicines_patent_pool/aurobindo_fully_executed2.pdf. As Gilead clarified in the amended license, termination of the TDF license does not affect Aurobindo's (or other sublicensees') ability to produce FTC and the TDF/FTC combination. *See infra* note 89 and accompanying notes.

89. According to the MPP's patent status database, *The Patent Status Database for Selected HIV Medicines*, MEDICINESPATENTPOOL, http://www.medicinespatentpool.org/LICENSING/Patent-Status-of-ARVs, several countries may purchase TDF from Aurobindo as patents on this drug do not exist in: Argentina, Brazil, Chile, Colombia, Malaysia, Peru, Philippines, Ukraine, and Uruguay.

90. Such as the assertion that the MPP/Gilead license introduces a "global patent system" and permits Gilead to receive royalties on TDF "until every possible legal avenue is exhausted." International Treatment Preparedness Coalition (ITPC) and Initiative for Medicines, Access and Knowledge (I-MAK), *The Implications of the Medicines Patent Pool and Gilead Licenses on Access to Treatment: Briefing Paper* (July 25, 2011), *available at* http://www.i-mak.org/storage/ITPC%20IMAK%20%20The%20Broader%20Implications%20of%20the%20MPP%20and%20Gilead%20Licenses%20on%20Access%20-%20FINAL%2025-7-2011.pdf [hereinafter ITPC/I-MAK Briefing Paper].

the TDF license can manufacture and export to those countries without royalties.

7. Ability to Supply to Countries Outside the Licensed Territory

Although a number of middle-income countries were excluded from the licensed territory, the agreement explicitly permits sublicensees to produce the licensed products for use in excluded countries that have issued a compulsory license. Section 10.3(d) of the agreement states:

> For further clarity, and notwithstanding anything to the contrary in this Agreement, it shall not be deemed to be a breach of the Agreement for Licensee to supply an API or Product outside the Territory into a county where (i) the government of such country has issued a compulsory license relating to such API or Product allowing for the importation of such API or Product into such country, provided Licensee's supply of Product or API into such country is solely within the scope and geographic range of such compulsory license and only for the duration that such compulsory license is in effect and/or (ii) the Government of India has issued a compulsory license allowing for the export of any API or Product from India and into such country, provided that (Y) there are no patents controlled by Gilead that contain a valid claim covering the use, import offer for sale or sale of such API or such Product issued in such country or a compulsory license has also been issued by the relevant authorities of such country and (Z) Licensee's supply of Product or API into such country is solely within the scope and geographic range of the compulsory license issued by the Government of India and only for the duration that such compulsory license is in effect.[91]

91. Second Amendment to Gilead License Agreement, *supra* note 86. The original license contained different language for the final clause (Z) and previously read "(Z) Licensee and Gilead are in agreement (with such agreement not to be unreasonably withheld) regarding the existence, scope and content of such compulsory license." Clause Z had initially operated as a notification requirement, requiring the Licensee to notify Gilead that a compulsory license existed. Although it was a notification requirement and did not give Gilead the right to veto or approve of the existence of such a compulsory license—states, in their sovereignty have the right to issue compulsory licenses, an important TRIPS flexibility that can be used to protect the public health—some civil society groups criticized this portion of the license and argued that Gilead must give its permission for Licensees to operate under a compulsory license. *See* ITPC/I-MAK Briefing Paper, *supra* note 90. It does not appear that the intention of the parties was for Gilead to have veto power over a compulsory license and on November 14, 2011, Gilead and the MPP amended the license to clarify the rights regarding compulsory licenses. Clause (Z) now removes any mention of Gilead and simply clarifies that supplying under a compulsory license must be within the scope and geographic range of the compulsory license and during the time such license is in effect.

This provision thus permits sublicensees to export to countries outside of the licensed territory using the following two mechanisms.

First, under 10.3(d)(i) of the compulsory licensing provision, sublicensees may export the licensed products to a country excluded from the territories of this license where a patent exists in that country and the government issues a compulsory license. An export license from India does not appear to be required in such cases.

Second, where patents do not exist in a particular country of import or use for the licensed products, the government may issue a notification to India for import of the products and the Government of India could then issue a compulsory license allowing for the export of the product, through an application of 10.3(d)(ii). This second outcome—which, from a survey of the current patent landscape for Gilead's patents seems to be the mechanism that will be used with greater frequency—is made possible through Section 92A of the Indian Patents Act[92] which provides for compulsory licenses for export to countries with insufficient or non-existent manufacturing capacity. The plain language of section 92A requires the Controller to grant a compulsory license for export upon notification by a country of insufficient manufacturing capacity.[93] Countries excluded from the MPP/Gilead license are therefore still able to benefit from the licenses.

As will be discussed in further detail in Part IV.B, *infra*, the compulsory licensing provision of the MPP/Gilead license is an important one and countries should take advantage of this flexibility

92. The Patents Act, No. 39, Section 92A (as amended by Patents (Amdt.) Act. 2005) ("(1) Compulsory license shall be available for manufacture and export of patented pharmaceutical products to any country having insufficient or no manufacturing capacity in the pharmaceutical sector for the concerned product to address public health problems, provided compulsory license has been granted by such country or such country has, by notification or otherwise, allowed importation of the patented pharmaceutical products from India. (2) The Controller shall, on receipt of an application in the prescribed manner, grant a compulsory license solely for manufacture and export of the concerned pharmaceutical product to such country under such terms and conditions as may be specified and published by him. (3) The provisions of sub-sections (1) and (2) shall be without prejudice to the extent to which pharmaceutical products produced under a compulsory license can be exported under any other provision of this Act. Explanation—For the purposes of this section, "pharmaceutical products" means any patented product, or product manufactured through a patented process, of the pharmaceutical sector needed to address public health problems and shall be inclusive of ingredients necessary for their manufacture and diagnostic kits required for their use.").

93. No binding precedent has interpreted Section 92A of the Indian Patents Act. Accordingly, it is unclear whether 92A would require the notification requirements under the Paragraph 6 mechanism of the Doha Declaration and the August 30 TRIPS Decision.

to protect their patients and to place additional pressure on private pharmaceutical companies to expand the licensed territories.

8. Grant Back Provisions

Article 2.3 of the agreement requires licensees to grant back improvements related to the licensed technology:

> License Grant to Gilead. Licensee hereby grants to Gilead a nonexclusive, royalty-free, worldwide, sublicensable license to all improvements, methods, modifications and other know-how developed by or on behalf of Licensee and relating to API or a Product ("Improvements"), subject to the restrictions on further transfer of Licensee's technology by Gilead as set forth in Section 5.2.[94]

This grant-back is non-exclusive, meaning that the sublicensee is free to license its improvements to other manufacturers. Additionally, the improvements subject to the grant-back provision are limited to those made prior to any termination of a license on the product and the transfer of know-how would be completed at Gilead's expense.[95]

Here, Gilead has obtained a freedom to operate with respect to improvements related to the products it licensed to the MPP. It is important to note that Gilead did not receive a right to ownership of any the improvements, but rather, negotiated only a right for its own use. Only the developer of the improvement would have the right to license or share the improvements with third parties or to patent the improvements.[96]

Three main categories of grant-back provisions exist:[97] non-exclusive grant-backs,[98] "assignment" provisions,[99] and exclusive[100]

94. Form Gilead Sublicense Agreement, *supra* note 51, at art. 2.3.

95. *Id.* at art. 5.2.

96. *See id.* at art. 5.2 governing reporting requirements of improvements and stating that "Licensee shall provide Gilead with an annual report, in writing and in reasonable detail that sets forth any Improvements, *including any patent applications claiming Improvements*." (emphasis added).

97. David J. Dykeman, Licensing Technology: When Licensing Out Patents, Make Sure Improvements Are Granted Back (Mar. 6, 2006), http://www.masshightech.com/stories/2006/03/06/focus2-When-licensing-out-patents-make-sure-improvements-are-granted-back.html.

98. *Id*. (Non-exclusive grant backs "allow the licensor to practice the improvement, while the licensee retains title and all other rights. Non-exclusive grant backs may be with or without royalty. A royalty-free, fully paid up, non-exclusive license grant back protects against a licensee filing improvement patents on its own.").

99. *Id*. (Assignment grant backs require the licensee to assign any improvements back to the licensor. As Dykeman notes, "Assignment grant back provisions are unpopular with

grant-backs.[101] The first category, non-exclusive grant backs, such as the one contained in the MPP/Gilead licensing agreement, represent the "most common approach because it is acceptable to licensees and is generally legally permissible."[102] Ultimately, this clause protects Gilead's interests while still promoting competition, unlike the other two categories of grant-backs.

9. Licensees free to challenge patents

Significantly, the MPP/Gilead agreement leaves space to utilize other strategies, in conjunction with the existing licenses, to improve access to medicines. The licensing agreement does not contain "no challenge" provisions, meaning that sublicensees are free to challenge the patent validity of Gilead's patents. The agreement does not block any system of pre- or post-grant opposition, nor does it create any legal barriers to challenging spurious patents. Like many of the provisions detailed, *supra*, the absence of a "no-challenge clause" provides licensees with significant and positive flexibilities.

D. Evaluation of the Medicines Patent Pool on the Basis of Current Licenses

Any evaluation of the resulting licenses must take into consideration the fact that companies negotiating with the MPP do so voluntarily. Thus, a private pharmaceutical company is free to walk away from the negotiating table without issuing any licenses on its life-saving medicines. In any negotiation, unless one party has all the bargaining power while the other side has none, common sense dictates that the terms will involve trade-offs with each side giving up the terms it wants in some areas, while achieving the outcomes it has sought in others. This reality is magnified in a situation, such as here, where the negotiations occur through pure voluntary actions.

licensees and may require a lower royalty on the original license in exchange for the licensee relinquishing ownership of its future improvements.").

100. *Id*. (These provisions "provide the licensor an exclusive right to use or sublicense any patented improvements, while the licensee retains only a non-exclusive right to practice the patented improvements.").

101. *Id*. ("Legal concerns of grant backs: Antitrust concerns have been raised about assignment or exclusive grant backs as being anticompetitive for inhibiting innovation. For this reason, grant back provisions have often met resistance within the pharmaceutical industry, particularly with discoveries made using research tools. The stronger argument is that grant backs foster competition by allowing the licensor and licensee to share the risks and rewards of innovation. Non-exclusive grant backs are virtually always competitive and unlikely to raise antitrust concerns.").

102. *Id.*

With these dynamics in mind, several considerations exist for evaluating the success of the MPP and the effectiveness of the licenses it has negotiated. Although public health activists may have ideal licensing terms in mind, realistically the MPP will not be able to achieve the "perfect" license without a change in structure providing the MPP with additional leverage in the negotiations. An all or nothing mentality with regard to these licenses[103] will likely result in nothing and the impacts on the millions of persons living with HIV/AIDS must be considered before rejecting the licenses in their entirety.[104]

When evaluating the licenses, critics should consider the geographic scope and number or percentage of persons covered by the agreement, particularly as compared to other voluntary licensing agreements.[105] As noted in Part III.C, *supra*, the MPP/Gilead license has the largest geographic scope of any voluntary license to date and is clearly an improvement on this basis. The expanded TDF license covers an additional estimated 93,200 additional persons living with HIV/AIDS as compared with the previous Gilead license on TDF. While room for improvement exists with regard to geographic scope, the current MPP/Gilead license already represents an improvement over the prior TDF license.

In addition to the expanded number of patients covered by the MPP licenses, new provisions exist explicitly permitting generic drug companies receiving the MPP licenses to operate outside of the voluntary license, under compulsory licenses, without breaching the voluntary license. The language on compulsory licenses contained within the MPP license ensures that countries excluded from the geographic scope of the voluntary license can still benefit through threats of, or actually granting, compulsory licenses and importing the products from sublicensees of the voluntary licenses. This possibility did not exist in the prior TDF licenses.

103. For example, suggesting that the MPP reject the license unless *all* low- and middle-income countries are included.

104. One analogy presented during the civil-society pre-meeting in advance of the UNITAID 3rd Consultative Forum is whether a starving person begging for a full loaf of bread who is then offered only a half a loaf should reject the half loaf in its entirety or accept it, then return and ask for more.

105. Unfortunately, other voluntary licensing agreements are often kept secret with regard to their terms. It is difficult to evaluate the MPP licenses against other voluntary license agreements because, while the MPP takes steps forward to improve transparency by posting their final licenses on their website, other voluntary licenses have not been made public.

In addition to the expanded geographic coverage on TDF, Gilead also provided licenses for its pipeline products. This portion of the agreement represents a strong step forward for public health because patients in developing countries often do not have early access to newer medicines.

Additionally, the MPP/Gilead license supports innovation for pediatric formulations by waiving any royalties on such products. While access to affordable medicines is certainly an important aspect in promoting public health, innovations for new treatments, such as fixed dose combinations and pediatric formulations, are also critical. Any evaluation of the MPP/Gilead license should acknowledge this provision as a positive outcome of the negotiations.

IV. Carrots and Sticks: Using All Available Tools to Enhance Voluntary Licensing Agreements

In order to rectify the identified problems and enhance voluntary licenses through expansions of both product coverage and geographic scope, it will be helpful to find ways that provide the MPP additional leverage during current and future negotiations. Such leverage may be offered by providing private industry with additional incentives to license its products to the MPP, or through evidence that excluding particular countries from the agreements would not serve the interests of the company.

A. Donor Prize Fund

One of the biggest critiques of the MPP license with Gilead centers around the middle-income countries left out of the agreement.[106] Although the MPP/Gilead license represents the largest geographic scope of any voluntary license to date, a number of

106. *See* Médecins Sans Frontières Access, *MSF Review of the July 2011 Gilead Licences to the Medicines Patent Pool*, MSFACCESS.ORG, 8 (Dec. 2011), http://www.msfaccess.org/sites/default/files/MSF_assets/HIV_AIDS/Docs/AIDS_Briefing_GileadLicenceReview_ENG_2011.pdf ("The exclusion of some lower middle- and middle-income countries (including China, Thailand, Argentina, Peru, Egypt, and Ukraine) disappointed patient groups in these countries, who were hopeful that these VL negotiations would bring an end to their struggle to increase access to Gilead's products . . . ."); Thai Network of People living with HIV/AIDS (TNP+), *Open Letter from Thai Civil Society -21/07/2011*, PATENTES.ORG.BR, 1, http://www.patentes.org.br/sulsul/media/file/Open%20Letter%20from%20Thai%20organizations.pdf ("bad news for millions of people living with HIV in the low and middle income countries excluded from the benefits of the Patent Pool"); MPP/Gilead Q&A, *supra* note 54, at question 14 ("The Pool acknowledges that the geographical scope of the license is a critical area where it needs to be improved."); *see also* note 67, *supra* and accompanying notes.

middle-income countries, particularly those that are upper middle-income were not included in the license. In these countries, the licensed products are unavailable unless the government issued a compulsory license. In order to expand geographic coverage and induce new licenses with better terms, additional incentives (aside from the marginal public relations boost in media a company might receive) are necessary. Although a broad range of incentives may improve the landscape for the MPP, one particular proposal put forth by the governments of Bangladesh, Barbados, Bolivia and Suriname in 2009[107] to the World Health Organization[108] deserves consideration as a compliment to the MPP.[109] This proposal, titled "Prize Fund to Support Innovation and Access for Donor Supported Markets for HIV/AIDS" (hereinafter "Donor Prize Fund"), would create a model that would support an innovation agenda while also de-linking product prices from the cost of innovation through a prize system.

The Donor[110] Prize Fund would create a reward system for research and development that would be linked to voluntary licenses

107. The 2009 proposal was based on an earlier proposal presented by the Bolivian government in March 2008 during the WHO Intergovernmental Working Group on Public Health, Innovation and Intellectual Property. *See* Proposal By Bolivia: Plan of Action IGWG II (bis) (Mar. 2008), http://www.who.int/entity/phi/submissions/ENBoliviaConf Paper1.pdf.

108. *Proposal by Barbados, Bolivia, Suriname and Bangladesh, a Prize Fund to Support Innovation and Access for Donor Supported Markets: Linking Rewards for Innovation to the Competitive Supply of Products for HIV-AIDS, TB, Malaria and Other Diseases for Humanitarian Use* (Apr. 15, 2009), http://www.who.int/entity/phi/Bangladesh_ Barbados_Bolivia_Suriname_DonorPrize.pdf [hereinafter Donor Prize Fund Proposal].

109. One of the recommendations that emerged from the UNITAID 3rd Consultative Expert Working Group was that UNITAID should "[c]onduct a study of all possible options that would expand geographic scope and increase product coverage for the Medicines Patent Pool including, but not limited to, the Bangladesh, Barbados, Bolivia and Suriname donor prize fund proposal, a submission being considered by the WHO CEWG and WIPO's Development Agenda project on open collaborative models. UNITAID should evaluate and identify ways to incentivize participation in the Medicines Patent Pool." Intellectual Property Workshop Recommendations, UNITAID 3rd Consultative Forum, slide 6 (Oct.5, 2011) *available at* http://www.unitaid.eu/images/ CFinfo/CF11/presentations/ip-workshop-recommendations.pdf.

110. Donors, such as the Global Fund, UNITAID, PEPFAR and others play a critical role in supporting access to life-saving medications, but their support depends on low treatment costs in order to adequately serve the millions of persons living with diseases such as HIV/AIDS. Because drug developers often refuse to license their patents to generic competitors and charge high monopoly prices for their products, the costs of these treatments could prove unsustainable in the long-run. Even domestically in the United States, the cost of HIV/AIDS drugs is so high that many state AIDS Drug Assistance Programs (ADAPs) are in crisis, with thousands of persons on waitlists for treatment. Globally, the rise of donor funding has, in some cases, encouraged greater patenting of products in developing countries, resulting in higher prices and reduced ability to provide

on the resulting products.[111] Funding would come from a fraction of donor drug purchasing budgets, such as from the Global Fund, UNITAID or the U.S.-supported PEPFAR program, and used to reward the voluntary licensing of products to the MPP.[112] Innovators could apply for a share of the fund, but the Donor Prize Fund would condition any reward on the patent holder providing an open license in all developing countries, permitting generic competition.[113] Requiring the inclusion of all developing countries ensures a sufficiently large market for generic products, allowing for economies of scale that can ultimately lead to lower costs for essential medicines.[114]

The Donor Prize Fund would divide rewards between the eligible patent holders based on "the relative impact of the products on health outcomes."[115] Applicants would qualify on the basis of clinical evidence demonstrating the efficacy of the new product as compared to prior existing treatment options.[116] The share of the reward would be proportional to its impact on improving health treatments, thus rewarding more important products that truly represent an improvement. The Donor Prize Fund would only award prizes for the showing of a successful patent or product.

In addition to distributing prizes for final products, the Donor Prize Fund proposal includes an open source dividend of up to five percent of prize fund payments for the knowledge or materials used to ultimately create the successful products, provided that these materials were licensed on a "royalty free basis for a field of use and geographic region that is consistent with the field of use and geographic region covered by the Prize Fund rewards."[117] The right

sufficient treatment to HIV/AIDS patients. As noted in the Donor Prize Fund Proposal, *supra* note 108 at 2, "For example, patents were reportedly sought in 38 African countries, including several least developed countries (LDCs) for the one second generation HIV-AIDS drug, while an earlier product, developed by the same company before the creation of the Global Fund or PEPFAR, was patented in zero African countries." This increase in patenting and resulting higher monopoly prices reduces the value for dollar for donors.

111. *Id.* at 1.

112. *Id.* The proposal notes that a suggested amount to create the fund would take ten-percent of all drug purchasing budgets because ten percent would likely create a sizeable product fund sufficiently large enough to create strong incentives for drug companies.

113. *Id.*

114. *See, e.g.*, UNITAID, Cost Benefit Analysis for UNITAID Patent Pool, UNITAID/EB8/2008/11/1 (June 2008).

115. Donor Prize Fund Proposal, *supra* note 108,.at 3.

116. *Id.*

117. *Id.* at 4.

owners to peer-reviewed articles who make the full text of supporting publications available for free from the moment of publication would also be eligible for a share of the open source dividend, up to ten percent of the total dividend.[118]

This system would work in tandem with the MPP by providing an incentive for companies to voluntarily license their products[119] to the MPP in return for a portion of the prize fund. Here, unlike the existing structure, a "carrot" is offered to private industry, in the form of a monetary reward, in exchange for an open license for all developing countries. Not only would the donor prize fund potentially provide adequate incentive for a company to include all low- and middle-income countries in its geographic scope, but could also encourage more and better drugs to be licensed to the MPP. Additional conditions could be placed on receiving a prize from the fund, such as permitting sublicensees to be located in the developing world outside of India.

Private companies may be inclined to participate in the prize fund for a variety of reasons, including the fact that some products may have limited patent coverage in developing countries and the prize could represent a source of revenue the companies might not otherwise receive. Furthermore, depending on the size of the prize, the reward through the prize fund may be greater than the profit from sale of the product in the developing country itself where the patents are subject to compulsory licenses and the innovator may receive only a reasonable royalty. The patent holder would not have to spend time or resources to apply for or enforce its patents. Companies making early contributions to the MPP and early applications for a share of the prize fund would likely benefit from a smaller number of competing entries and thus a larger portion of the fund.

Ultimately, the donor prize fund would provide an incentive for industry to join the medicines patent pool and to create new medications or tools that would particularly benefit those living in developing countries. As a result of the award mechanism, which requires evidence of an improvement over existing treatments, heat

118. *Id.* at 4–5. Additional information, as well as the specific requirements set forth, on both the open source dividend and open access publishing is available from the full proposal submitted by Bangladesh, Barbados, Bolivia and Suriname.

119. *See id.* at 3. The license would permit the production of the product, include a waiver of any exclusive rights to data protection of the product, and a provide technology transfer of know-how.

stable formulations or fixed dose combinations may be eligible for a larger reward.

Recently, proposals have been made to modify the donor prize fund to a more general HIV/AIDS prize fund. Such modification would include contributions from governments that fund their own HIV/AIDS treatment programs.

B. Compulsory Licenses

In addition to a system of rewards to incentivize companies to join the MPP and expand product and geographic coverage, it will be important for individual governments, particularly those countries left out of the MPP/Gilead license, to also place pressure on patent holders. Governments have a number of tools available and the coordinated use of all mechanisms is necessary to more fully promote the right to health.

First, governments should work to enact appropriate TRIPS-compliant flexibilities and reject pressures to enact TRIPS-plus measures, such as those faced through bilateral and plurilateral free trade agreements with developed countries such as the U.S. or E.U.[120] States must preserve their rights to use TRIPS flexibilities, but beyond that, must actually evidence a willingness to exercise these rights.

One particularly important TRIPS-flexibility for developing country governments to use, is the issuance of compulsory licenses to access medicines, including those subject to the MPP. Under the MPP/Gilead license, sublicensees can supply to countries that have

120. The U.S. and E.U. both seek TRIPS-plus measures in free trade agreements. Aside from existing trade agreements, the U.S. is currently negotiating a large plurilateral free trade agreement, known as the Trans-Pacific Partnership Agreement (TPPA), with eight other countries of widely differing development levels: Australia, Brunei, Chile, Malaysia, New Zealand, Peru, Singapore, and Vietnam. Several other countries have also expressed interest in joining the TPPA, with Canada, Japan and Mexico making formal approaches. The TPPA is reportedly eventually expected to encompass the entire APEC region. Leaked copies of U.S. proposals for the intellectual property chapter, available at http://keionline.org/tpp, illustrate the numerous TRIPS-plus measures proposed. Also of great concern is the currently negotiated E.U-India free trade agreement, with reports that the E.U. is seeking TRIPS-plus measures in India that would impact the ability of generic manufacturers in India to supply generic versions of medicines to the developing world. *See, e.g.*, Sarah Boseley, *Does EU/India free trade agreement spell the end of cheap drugs for poor countries?* Sarah Boseley's Global Health Blog, THE GUARDIAN (Feb. 10, 2012), http://www.guardian.co.uk/society/sarah-boseley-global-health/2012/feb/10/hiv-infection-pharmaceuticals-industry. Both agreements are being negotiated in secret making it extremely difficult for the general public to know and understand how these agreements will affect them.

issued a compulsory license for the licensed products, or where the importing country requests the Government of India to issue an export license permitting the sale of the drugs to those countries. This provision is a significant concession in the MPP/Gilead license and, to the extent governments elect to exercise this right, will result in an expansion of the current territories.

More generally, developing countries have to demonstrate a willingness to grant compulsory licenses for patents on any product that is not licensed voluntarily to the MPP. The possibility of a government granting a compulsory licenses is an important "stick" to encourage private pharmaceutical companies to expand geographic coverage of its products and license additional products to the MPP.

V. Conclusion

The MPP has the potential to improve access to patented life-saving medicines for the millions of patients suffering from HIV/AIDS by negotiating licensing agreements with private companies to permit generic production of these drugs. However, the MPP is one of many actors in the public health field and all parties must become more involved in order to maximize the utility of the current licenses and improve future licenses.

As discussed in the preceding section, individual country governments must play an active role in protecting its citizens and residents and ensure access to affordable life-saving treatments. Under the existing MPP/Gilead license, governments can access the Gilead licensed products by issuing a compulsory license for those drugs. By doing so, countries that do issue a compulsory license will send a strong signal to other pharmaceutical companies that these countries should be included in the license agreements. Implementing and using these TRIPS flexibilities will be important to improving the public health and country governments must resist TRIPS-plus measures that developed countries, such as the United States or the European Union, often pressure countries to adopt through free trade agreements[121] or other mechanisms. The use of TRIPS flexibilities such as compulsory licenses will likely encourage the expansion of the geographic scope for future licenses as companies may prefer the certainty of the royalty payments negotiated with the MPP than the royalty paid on compulsory licenses.

121. *Id. See also* Sanya Reid Smith, *"TRIPS Plus" Bilateral Agreements – A Threat to Public Health*, THIRD WORLD RESURGENCE, December 2006, *available at* http://twnside.org.sg/title2/twr196.htm.

Civil society can also play a significant part in improving MPP licenses. In addition to voicing concerns about the existing licenses, civil society should move to putting additional pressure on pharmaceutical companies, including Gilead. Civil society can pressure Gilead in the hopes of expanding the geographic scope or persuading the company that permitting manufacture outside of India would be beneficial. Additionally, civil society should pressure companies currently in negotiations with the MPP to conclude negotiations and license their products to the pool, while pressuring companies that are not currently negotiating, to join the pool.[122]

In addition to the measures that available in the existing landscape, new mechanisms and incentives should be explored to encourage companies to enter into voluntary licensing agreements with the MPP. The donor prize fund presents one potential incentive mechanism that could encourage pharmaceutical companies to license its products to the MPP for use in all developing countries. Any other incentive mechanisms should also be considered and, where appropriate, developed for use in tandem with the MPP.

All available tools, both those currently in existence and proposals for new mechanisms, must be used and considered to protect the public health. While the MPP certainly has a significant role to play, as evidenced by the recent license with Gilead covering between 100 and 112 low- and middle-income countries, it is not the only mechanism to improve access to medicines. Failure to take advantage of other tools relies too heavily on a voluntary mechanism without providing any additional leverage to improve upon the current licenses, potentially setting unrealistic expectations for the MPP. While the Gilead licenses should represent a floor, not a ceiling for the MPP, building on the existing license requires governments and civil society to coordinate their efforts and place additional pressures to improve the public health. Patent pools, such as the MPP, may represent one mechanism to promote access to medicines, but they must be coupled with other strategies and alternatives to maximize success.

122. For example, activists have participated in "pool parties" to encourage companies such as Merck or Johnson & Johnson to join negotiations with the MPP. Armaghan N. Behlum, *Student 'Pool Party' Protests Merck: Global Health Groups Urge Big Pharma to Give Poor Countries Discounts*, HARVARD CRIMSON (Oct. 23, 2011), http://www.thecrimson.com/article/2011/10/23/medical-students-protest-merck/; Ed Silverman, *Johnson & Johnson And Bikinis: A Patent Pool Party*, PHARMALOT (Mar. 31 2011), http://www.pharmalot.com/2011/03/johnson-johnson-and-bikinis-a-patent-pool-party/.

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