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TRIPS AND COMPULSORY LICENSING: INCREASING PARTICIPATION IN THE MEDICINES PATENT POOL IN THE WAKE OF AN HIV/AIDS TREATMENT TIMEBOMB

ABSTRACT

Significant progress has been made in recent decades to increase access to HIV/AIDS antiretroviral treatments in low- and middle-income countries. Despite all that has been done, a treatment timebomb awaits unless immediate action is taken to decrease the price of antiretroviral drugs. The treatment timebomb can be attributed in part to the increasing likelihood that HIV medicines will be patented in developing countries in compliance with the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). The Medicines Patent Pool (MPP) is a collective action mechanism designed to overcome patent barriers resulting from the implementation of TRIPS in developing countries to respond to the treatment timebomb. The MPP works directly with HIV medicines patent holders and generic manufacturers to facilitate access to new and more affordable antiretrovirals in developing countries. This Comment argues that the MPP can serve as a valuable tool to increase access to patented HIV medicines in developing countries if participation in the pool by patent holders can be increased. This Comment proposes that governments in countries hardest hit by the HIV/AIDS epidemic collectively exercise TRIPS flexibilities and issue compulsory licenses for HIV medicines to increase participation in the MPP. Such a concerted effort by low- and middle-income countries to issue compulsory licenses could make the MPP more effective at increasing access to new and more affordable HIV medicines to respond to the growing HIV/AIDS treatment crisis.

INTRODUCTION

[W]e are sitting on a treatment timebomb. We can predict many of the changing treatment needs of people living with HIV in the coming decade and they are not compatible with treatments and prices available today. Maintaining HIV treatment to keep people alive will cripple developing economies, or place unbearable strains on richer countries trying to support them. Action is needed now, to avert crisis later.

—United Kingdom All-Party Parliamentary Group on AIDS¹

In 2012, an estimated 35.3 million people worldwide were living with HIV.² That number is expected to increase five-fold by 2030.³ The magnitude of this increase is due in part to growing drug resistance,⁴ rising treatment prices,⁵ the increasing likelihood that new antiretroviral drugs will be patented in developing countries,⁶ and inadequate funding for low- and middle-income countries to purchase medicines.⁷ To respond to this so-called “treatment timebomb,”⁸ a new collective action mechanism is needed to facilitate access to patented antiretroviral drugs to produce more affordable medicines and develop improved medicines.⁹

The Medicines Patent Pool (MPP) is a new approach to managing intellectual property created to respond to the treatment timebomb and overcome patent barriers imposed by the implementation of the Agreement on

¹ UNAIDS, GLOBAL REPORT: UNAIDS REPORT ON THE GLOBAL AIDS EPIDEMIC 4 (2013) [hereinafter UNAIDS GLOBAL REPORT]. In 2009, only one-third of adults living with HIV had access to treatment. ALL-PARTY PARLIAMENTARY GROUP ON AIDS, THE TREATMENT TIMEBOMB 5 (2009) [hereinafter TREATMENT TIMEBOMB].

² UNAIDS GLOBAL REPORT, *supra* note 1.

³ *Drug Firms ‘Must Pool Patents’*, BBC NEWS, <http://news.bbc.co.uk/2/hi/health/8150457.stm> (last updated July 15, 2009). According to one estimate, approximately fifty-five million people will need access to antiretroviral treatments by 2030. TREATMENT TIMEBOMB, *supra* note 1.

⁴ TREATMENT TIMEBOMB, *supra* note 1, at 12.

⁵ *Id.* at 10.

⁶ See Ellen ‘t Hoen, Jonathan Berger, Alexandra Calmy & Suerie Moon, *Driving a Decade of Change: HIV/AIDS, Patents and Access to Medicines For All*, 14 J. INT’L AIDS SOC’Y 1, 7 (2011) [hereinafter ‘t Hoen et al., *Driving a Decade of Change*].

⁷ See *id.* at 8.

⁸ The United Kingdom All Party Parliamentary Group on AIDS coined the term “treatment timebomb” in July 2009. *Id.* at 8.

⁹ See *id.* at 1.

Trade-Related Aspects of Intellectual Property Rights (TRIPS) in 1995.¹⁰ Following the implementation of TRIPS, HIV medicines are more likely to be patented in developing countries and thus less widely available to generic manufacturers.¹¹ The MPP works with patent holders and generic manufacturers to facilitate access to patented HIV medicines in developing countries with the goal of supporting the production of affordable generic medicines, and the development of new treatments.¹² The MPP represents a promising mechanism to respond to the treatment timebomb and overcome the patent barriers described above.¹³ The MPP, however, faces its own problems in providing adequate incentives for patent holders to voluntarily license their HIV medicines patents to the pool.¹⁴

This Comment argues that the MPP can facilitate access to less expensive and more effective antiretrovirals if participation by relevant patent holders can be increased. This Comment proposes that governments in countries hardest hit by the HIV/AIDS epidemic and the least able to pay for essential antiretroviral treatments collectively issue compulsory licenses to increase participation in the MPP. Compulsory licensing can provide a legal solution under TRIPS to increase participation in the MPP and overcome the patent barriers imposed by TRIPS. A concerted effort by low- and middle-income countries to issue compulsory licenses could make the MPP more effective at increasing access to new and more affordable HIV medicines to respond to the growing HIV/AIDS treatment crisis.

Part I of this Comment introduces patent pools and the HIV/AIDS treatment timebomb, and details the creation of the MPP, including the MPP's licensing strategy and licensing successes to date. Part II reviews the incentives for patent holders to participate in the pool and examines why the current incentives are not adequate to attract enough patent holders to the pool. Part III introduces compulsory licensing and TRIPS to propose collective public action through compulsory licensing as a tool to increase participation in the MPP. Part IV concludes that the MPP is an invaluable tool for increasing access to new and affordable HIV medicines to respond to the global treatment

¹⁰ *Id.* at 8. TRIPS requires all World Trade Organization members to provide a minimum level of patent protection in all fields, including pharmaceuticals. *Id.* at 2–3. The implications of the implementation of TRIPS will be discussed briefly in Part I.A and in greater detail in Part III.B of this Comment.

¹¹ *Id.* at 2–3, 8.

¹² *Id.* at 1.

¹³ *See id.*

¹⁴ *See* REBECCA GOULDING & AMRITA PALRIWALA, RESULTS FOR DEV. INST., PATENT POOLS: ASSESSING THEIR VALUE-ADDED FOR GLOBAL HEALTH INNOVATION AND ACCESS 3, 33 (2012).

timebomb and that it can be made more effective by increasing participation in the pool through collective public action in the form of compulsory licensing.

I. THE MEDICINES PATENT POOL

This Comment argues that a patent pool for HIV medicines represents a valuable mechanism to increase access to new and more affordable antiretroviral treatments in developing countries. Part A introduces patent pools and the HIV/AIDS treatment timebomb. Part B outlines the road to creating a patent pool for HIV medicines and the MPP's mission to increase access to antiretroviral drugs. Part C examines the MPP's licensing strategy and briefly discusses licensing agreements the MPP has concluded to demonstrate that more needs to be done before the MPP can accomplish its mission to facilitate access to patented medicines in developing countries.

A. Patent Pools and the HIV/AIDS Treatment Timebomb

1. What is a Patent Pool?

A patent pool is an agreement between two or more patent holders to license their patent rights to a single entity or pool.¹⁵ Once patents are licensed to the pool, pool administrators can license the right to use the patents to third parties, such as generic manufacturers, typically upon payment of a royalty to the patent holder.¹⁶ Patent pools are created for a variety of reasons and can range in size from small, cross-licensing arrangements between two or more competitors to large, industry-wide pools including hundreds of manufacturers.¹⁷ The benefits of creating a patent pool include reduced transaction costs resulting from only having to negotiate licenses with a single entity, and the management of patents, royalties, and licensing agreements by a single pool administrator.¹⁸ Although patent pools have been used in other industries, including agriculture and aerospace engineering, since as early as 1856,¹⁹ they are relatively new in the pharmaceutical industry.²⁰

¹⁵ Michelle Childs, *Towards a Patent Pool for HIV Medicines: The Background*, 4 OPEN AIDS J. 33, 34 (2010).

¹⁶ *Id.*

¹⁷ *IGWG Submission on Collective Management of Intellectual Property*, KNOWLEDGE ECOLOGY INT'L (Sept. 30, 2007), http://www.who.int/phi/public_hearings/second/contributions_section2/Section2_ManonRess-PatentPool.pdf [hereinafter *IGWG Submission*].

¹⁸ *Id.*

¹⁹ Jorge Bermudez & Ellen 't Hoen, *The UNITAID Patent Pool Initiative: Bringing Patents Together for the Common Good*, 4 OPEN AIDS J. 37, 38 (2010); see also Bradley J. Levang, *Evaluating the Use of Patent*

2. *The HIV/AIDS Treatment Timebomb*

Significant progress has been made in recent decades to increase access to HIV/AIDS antiretroviral treatments in low- and middle-income countries.²¹ The increase in access has been primarily attributed to widespread generic manufacturing of antiretrovirals, which has driven competition up and prices down.²² Despite these improvements, however, a treatment timebomb awaits, which threatens to set back the progress made unless immediate action is taken to decrease the price of antiretroviral drugs.²³ The treatment timebomb can be attributed to a number of interrelated factors that are likely to increase the cost of HIV treatment, decrease access to treatment, and heighten the need to find newer, more affordable treatments. These factors include the high likelihood that persons on antiretroviral drugs will develop resistance; inadequate funding for medicines; the lack of a commercial market for pediatric drugs; and an increase in the patenting of medicines in developing countries in compliance with TRIPS.²⁴

Pools for Biotechnology: A Refutation to the USPTO White Paper Concerning Biotechnology Patent Pools, 19 SANTA CLARA COMPUTER & HIGH TECH. L. J. 229, 236–37 (2002).

²⁰ *Medicines Patent Pool: Facilitating Access to HIV Treatment*, WIPO MAG. (June 2011), http://www.wipo.int/wipo_magazine/en/2011/03/article_0005.html [hereinafter WIPO MAGAZINE]. Historically, the pharmaceutical industry has not been seen as an appropriate forum for a patent pool model for a variety of reasons, including the importance of intellectual property in determining a pharmaceutical company's worth and the likelihood that pharmaceutical patent holders will disagree over the value of patents in the pool. COMM'N ON INTELLECTUAL PROP. RIGHTS, INNOVATION AND PUBLIC HEALTH, PUBLIC HEALTH, INNOVATION, AND INTELLECTUAL PROPERTY RIGHTS 53 (2006). Perceptions began to change in 2000 when the United States Patent and Trademark Office issued a report concluding that patent pools in biotechnology could be valuable tools to serve the interests of both public and private actors. *Id.*

²¹ See, e.g., 't Hoen et al., *Driving a Decade of Change*, supra note 6, at 7–8. Between 2003 and 2009, the number of people with access to HIV/AIDS antiretroviral treatments increased more than twelve-fold due to the increased availability of low-cost generic antiretrovirals, whose prices have dropped by over ninety-nine percent since 2000. See Ellen 't Hoen & Suerie Moon, *An Innovative Approach to Achieving Access to Medicines For All*, MEDICUS MUNDI SWITZ. (Sept. 2010), <http://www.medicusmundi.ch/mms/services/bulletin/zugang-zu-medikamenten-fur-alle/debatten-und-ansatze/24.html> [hereinafter 't Hoen & Moon, *An Innovative Approach to Achieving Access*]. The World Bank defines low-income countries as those having a Gross National Income (GNI) per capita of \$1,045 or less in 2013; middle-income countries are defined as those having a GNI per capita of more than \$1,045 but less than \$12,746. *Country and Lending Groups*, WORLD BANK, <http://data.worldbank.org/about/country-and-lending-groups> (last visited Feb. 7, 2015). The term “developing” is used to denote low- and middle-income countries. *Id.* The terms “low- and middle-income countries” and “developing countries” will be used interchangeably throughout this Comment.

²² Tina Rosenberg, *Sharing Patents to Wipe out AIDS*, N.Y. TIMES (July 21, 2011), http://opinionator.blogs.nytimes.com/2011/07/21/sharing-patents-to-wipe-out-aids/?_r=0.

²³ See 't Hoen et al., *Driving a Decade of Change*, supra note 6, at 7–8.

²⁴ *Id.* at 1, 7–8; see also TREATMENT TIMEBOMB, supra note 1, at 12.

The number of people worldwide living with HIV is expected to increase in the coming years, meaning that more people will need access to antiretroviral treatments.²⁵ Currently, the majority of people living with HIV in low- and middle-income countries are first treated with a combination of three antiretroviral drugs—Lamivudine, Stavudine, and Nevirapine—known as combination treatment.²⁶ However, merely having access to drugs does not guarantee successful treatment, as most people who have access to antiretrovirals develop resistance to the first set of drugs (first-line drugs) they take.²⁷ For these individuals, switching to a newer and more expensive set of drugs (second-line drugs) can be “a matter of life or death.”²⁸ An additional complicating factor contributing to the treatment timebomb is that second-line treatments can be up to eleven times more expensive than first-line treatments, putting them out of reach for many HIV patients in low- and middle-income countries.²⁹ The high likelihood that persons receiving treatment will develop resistance to first-line treatments over time in combination with the high cost of second-line treatments means that newer and more affordable treatments will be needed in the near future to avert a global treatment crisis.³⁰ The treatment situation is even more dire for children: only ten percent of children who need antiretroviral treatments currently have access,³¹ and many of the antiretrovirals that are currently produced are either not approved for pediatric use or are not available in pediatric formulations.³² The simple solution is to provide more pediatric antiretrovirals for children.³³ However, the lack of a commercial market for pediatric drugs means that there are few incentives for pharmaceutical companies to invest in developing pediatric antiretroviral formulations.³⁴

While antiretroviral prices have decreased in the last two decades due to increasing generic competition in low- and middle-income countries,

²⁵ See ‘t Hoen et al., *Driving a Decade of Change*, *supra* note 6, at 7–8.

²⁶ TREATMENT TIMEBOMB, *supra* note 1, at 10.

²⁷ *Id.* at 12 (noting that the “development of resistance is likely to happen to everybody over time”).

²⁸ *Id.*; see also ‘t Hoen et al., *Driving a Decade of Change*, *supra* note 6, at 7–8. It is estimated that only three percent of people receiving antiretroviral treatments in developing countries are being treated with second line drugs. TREATMENT TIMEBOMB, *supra* note 1, at 12.

²⁹ See TREATMENT TIMEBOMB, *supra* note 1, at 10.

³⁰ *Id.* at 12. Combination treatments, however, are difficult to produce because more than one person may own the patented drugs, and manufacturers must obtain permission from all patent holders before the drugs can be combined into a single pill. See *id.* at 26.

³¹ *Id.* at 6.

³² *Id.* at 25.

³³ *Id.*

³⁴ *Id.*

antiretrovirals are still too expensive for most developing countries to purchase and provide to their HIV-infected populations.³⁵ As a result, many developing countries rely on drug donation programs, funded by organizations such as the Global Fund to Fight AIDS, Tuberculosis, and Malaria, and the United States' President's Emergency Plan for AIDS Relief (PEPFAR) program, to assist them in purchasing medicines.³⁶ It is unclear how much longer this lifeline of support will be available to developing countries: the international HIV/AIDS community is facing a financial crisis, which has led to declining contributions in recent years.³⁷ If funding for drug donation programs runs out, developing countries will be left with few options to increase access to antiretrovirals on their own.

Finally, the treatment timebomb can be attributed in part to the increasing likelihood that new antiretroviral drugs will be patented in developing countries in compliance with TRIPS.³⁸ As HIV medicines are more widely patented in developing countries, it will become increasingly difficult for generic manufacturers to produce low-cost versions of the patented medicines and the cost of treatment will rise.³⁹ In addition, it will be more difficult for generic manufacturers to develop new combination or pediatric treatments if the individual HIV medicines needed to produce the treatments are patented in developing countries.⁴⁰

The increase in the patenting of medicines in developing countries is occurring in response to the adoption of TRIPS by the World Trade Organization (WTO) in 1994.⁴¹ Under TRIPS, WTO member countries must provide a minimum level of patent protection in all fields of technology, including pharmaceuticals, for twenty years.⁴² Developing countries are often required to provide patent protection exceeding the minimum requirements of TRIPS as part of trade agreements with developed countries, further restricting their ability to produce or import generic versions of patented medicines.⁴³ The

³⁵ Rosenberg, *supra* note 22.

³⁶ *Id.*

³⁷ See 't Hoen et al., *Driving a Decade of Change*, *supra* note 6, at 8.

³⁸ *Id.*

³⁹ *Id.*

⁴⁰ *Id.*

⁴¹ *Id.* at 2. The World Trade Organization was established in 1995 to govern trade-related transactions between nations. *What is the WTO?*, WORLD TRADE ORG., http://www.wto.org/english/thewto_e/whatis_e/whatis_e.htm (last visited Feb. 15, 2015).

⁴² See 't Hoen et al., *Driving a Decade of Change*, *supra* note 6, at 2. In 2011, 153 countries were members of the WTO. *Id.*

⁴³ *Id.* at 8.

situation is only going to get worse: all WTO member countries must be TRIPS-compliant by 2016, at which time it will be virtually impossible for generic manufacturers to produce or import low-cost versions of patented antiretrovirals.⁴⁴

A new collective action mechanism designed to facilitate access to patented HIV medicines is needed to confront the intellectual property challenges arising from the implementation of TRIPS. The following section discusses how the MPP anticipated and can overcome these problems by working directly with patent holders and generic manufacturers to produce and develop newer and more affordable antiretroviral treatments.⁴⁵

B. Overcoming Patent Barriers by Creating a Patent Pool for HIV Medicines

Part B provides a short overview of the MPP and its mission to establish a backdrop within which to evaluate the MPP's ability to overcome patent barriers and facilitate access to patented HIV medicines.

1. The Road to Creating a Patent Pool for HIV Medicines

James Love from Knowledge Ecology International (KEI)⁴⁶ first introduced the idea for a patent pool for HIV medicines in 2002 at the International AIDS Conference in Barcelona, Spain.⁴⁷ Love, who had studied patent pools created by the United States government in 1917 to overcome patent barriers in the aircraft industry, believed that a similar concept could be used to overcome patent barriers in the HIV medicines industry.⁴⁸ The next step towards creating a patent pool for HIV medicines came in 2006 when UNITAID was created to provide "sustainable, long-term funding" for drugs and diagnostics for HIV/AIDS, tuberculosis, and malaria in developing countries.⁴⁹ Médecins Sans

⁴⁴ TREATMENT TIMEBOMB, *supra* note 1, at 20.

⁴⁵ See 't Hoen et al., *Driving a Decade of Change*, *supra* note 6, at 1, 8.

⁴⁶ KEI is a not-for-profit organization that engages in research and advocacy to manage knowledge resources in areas of intellectual property, among others. *About KEI*, KNOWLEDGE ECOLOGY INT'L, <http://keionline.org/about> (last visited Dec. 13, 2014).

⁴⁷ See 't Hoen et al., *Driving a Decade of Change*, *supra* note 6, at 8.

⁴⁸ *Id.*; see also GOULDING & PALRIWALA, *supra* note 14, at 12.

⁴⁹ Bermudez & 't Hoen, *supra* note 19, at 38. UNITAID was launched by the governments of Brazil, Chile, France, Norway, and the United Kingdom in 2006. *Id.* UNITAID is an innovative drug purchasing mechanism that obtains funding through a tax on airline tickets in participating member countries and through contributions from organizations such as the Bill and Melinda Gates Foundation and the Clinton HIV/AIDS Initiative. *Id.* As of 2010, twenty-nine countries had committed to contribute to UNITAID, the majority of

Frontières (MSF),⁵⁰ with support from KEI, submitted a proposal to create a patent pool for HIV medicines to UNITAID and the French Ministry of Foreign Affairs in June 2006.⁵¹ At that time, UNITAID was perceived as the best entity to implement the patent pool initiative because it takes a “pro-health approach to IP.”⁵² UNITAID adopted the proposal in July 2008,⁵³ and the MPP was launched as an independent entity in July 2010 with funding from UNITAID.⁵⁴ UNITAID hoped the MPP would complement other mechanisms that it utilizes to increase access to HIV medicines in developing countries such as financing and drug purchasing programs.⁵⁵

2. *The MPP as a Mechanism to Overcome Patent Barriers and Increase Access to Medicines*

The MPP was created as a direct response to the changing global intellectual property environment arising from the increased likelihood that HIV medicines would be patented in developing countries in compliance with TRIPS.⁵⁶ Under TRIPS, patented medicines are not available in generic form until the twenty-year term for patent protection expires, which means that countries hardest hit by the HIV/AIDS epidemic will have to wait a long time before more affordable medicines are made available.⁵⁷ The MPP was designed to overcome barriers imposed by patent protection for medicines in developing countries through the collective management of HIV medicines patents in a single pool with a global health goal in mind.⁵⁸

The MPP’s mission is to “reduce prices and ensure the availability of new and improved AIDS medicines” by producing generic versions of HIV antiretrovirals and developing new combination and pediatric therapies.⁵⁹

which were low- or middle-income. *Id.* UNITAID has already experienced “considerable success” in reducing drug prices through bulk purchasing agreements. TREATMENT TIMEBOMB, *supra* note 1, at 15.

⁵⁰ Médecins Sans Frontières, also known as Doctors Without Borders, is a medical humanitarian organization that provides medical care to people affected by armed conflict, natural disasters, and global epidemics, or who otherwise lack access to adequate medical care. *About MSF*, MÉDECINS SANS FRONTIÈRES, <http://www.msf.org/about-msf> (last visited Jan. 3, 2015).

⁵¹ Childs, *supra* note 15, at 34.

⁵² Bermudez & ‘t Hoen, *supra* note 19, at 38.

⁵³ *Id.*

⁵⁴ WIPO MAGAZINE, *supra* note 20; *see also* GOULDING & PALRIWALA, *supra* note 14, at 19.

⁵⁵ Bermudez & ‘t Hoen, *supra* note 19, at 38.

⁵⁶ *See* ‘t Hoen et al., *Driving a Decade of Change*, *supra* note 6, at 8.

⁵⁷ Rosenberg, *supra* note 22.

⁵⁸ Childs, *supra* note 15, at 34; *see also* ‘t Hoen et al., *Driving a Decade of Change*, *supra* note 6, at 8.

⁵⁹ *See* ‘t Hoen & Moon, *An Innovative Approach to Achieving Access*, *supra* note 21; *see also* ‘t Hoen et al., *Driving a Decade of Change*, *supra* note 6, at 1, 8.

Combination treatments are essential for simplifying and improving HIV care in developing countries; however, they are difficult to develop because more than one owner may hold the patents needed to make the combination.⁶⁰ As discussed in Part I.A, pediatric treatments are essential due to the unmet treatment need and lack of investment in developing pediatric formulations.⁶¹

The MPP pools patents held by multiple owners in a single entity to make it easier for generic manufactures to access patented medicines that otherwise would only be available to them on a license-by-license basis.⁶² Such access can lead to lower drug prices and encourage the development of new medicines, including the pediatric and combination treatments that are desperately needed in developing countries, on a shorter timeframe by simulating competition among generic manufacturers.⁶³

In order to facilitate access to patented HIV medicines, the MPP negotiates licensing agreements separately with patent holders and generic manufacturers.⁶⁴ Key to the MPP's success is that it negotiates licensing agreements from a global health rather than from a financial perspective and operates as an intermediary between patent holders and generic manufacturers.⁶⁵ The MPP's status as a non-financially-motivated intermediary is essential to its ability to negotiate licensing agreements that will increase access to more affordable patented medicines in developing countries.⁶⁶ In addition, the MPP's intermediary status is attractive to generic manufacturers, who often have difficulty negotiating favorable bilateral licensing agreements with large, financially superior pharmaceutical companies.⁶⁷

The MPP has been well received throughout the international community and seen as a positive step towards decreasing drug prices and increasing

⁶⁰ See Bermudez & 't Hoen, *supra* note 19, at 37. See *supra* note 30 and accompanying text.

⁶¹ See TREATMENT TIMEBOMB, *supra* note 1, at 6, 25.

⁶² Asher Mullard, *Straight Talk With Ellen 't Hoen*, 16 NATURE MED. 1351, 1351 (2010). See 't Hoen et al., *Driving a Decade of Change*, *supra* note 6, at 8. By pooling medicines patents together, researchers can "access permission to use the component drugs from a single place, rather than having to negotiate company by company." TREATMENT TIMEBOMB, *supra* note 1, at 28.

⁶³ See IGWG Submission, *supra* note 17; 't Hoen et al., *Driving a Decade of Change*, *supra* note 6, at 6. See also Rosenberg, *supra* note 22 (noting that patent pools can make patented medicines available to generic manufacturers right away).

⁶⁴ See GOULDING & PALRIWALA, *supra* note 14, at 34.

⁶⁵ See *id.*

⁶⁶ See *id.*; Mullard, *supra* note 62, at 1351.

⁶⁷ GOULDING & PALRIWALA, *supra* note 14, at 3.

access in developing countries.⁶⁸ Since it was created, the MPP has received extensive political support from countries including the United Kingdom, the United States, Thailand, and Brazil,⁶⁹ which lends credibility and legitimacy to the institution. Organizations such as the World Health Organization, UNAIDS, the Global Fund to Fight AIDS, Tuberculosis, and Malaria, as well as the G8 and the European Union have also expressed support for the pool.⁷⁰

While the MPP currently focuses exclusively on HIV/AIDS medicines,⁷¹ it will eventually be expanded to address other diseases in developing countries, including tuberculosis and malaria.⁷² However, scaling up the MPP to address other diseases can only be justified if the MPP proves to be an effective solution to responding to the current HIV/AIDS treatment crisis.⁷³ The MPP's ability to serve as a valuable tool to increasing access to patented HIV medicines depends in large part on its licensing strategy and ability to attract key patent holders to the pool,⁷⁴ which will be discussed in the following section.

C. *Licensing in the MPP*

The MPP is a voluntary pool, meaning that patent holders must voluntarily choose to license their HIV medicines patents to the pool before the patents will be available to generic manufacturers.⁷⁵ Once patents are licensed to the pool, generic manufacturers can sublicense the right to produce and sell low-cost generic versions of the medicines in low- and middle-income countries or to combine multiple patents to develop new combination or pediatric treatments.⁷⁶ Patent holders can receive a royalty from the sale of generic versions of the patented medicines in low- and middle-income countries in exchange for licensing to the MPP.⁷⁷ The MPP then relies on market competition among generic manufacturers to bring drug prices down and increase access to treatments.⁷⁸ However, robust competition will only occur if

⁶⁸ See TREATMENT TIMEBOMB, *supra* note 1, at 28–29.

⁶⁹ See 't Hoen et al., *Driving a Decade of Change*, *supra* note 6, at 6. See also *Drug Firms 'Must Pool Patents'*, *supra* note 3; Mullard, *supra* note 62, at 1351.

⁷⁰ GOULDING & PALRIWALA, *supra* note 14, at 22.

⁷¹ Bermudez & 't Hoen, *supra* note 19, at 39.

⁷² *Id.* at 38.

⁷³ See *id.*

⁷⁴ See TREATMENT TIMEBOMB, *supra* note 1, at 28–29.

⁷⁵ Bermudez & 't Hoen, *supra* note 19, at 38.

⁷⁶ *Id.* at 38–39.

⁷⁷ *Id.* at 38.

⁷⁸ See 't Hoen et al., *Driving a Decade of Change*, *supra* note 6, at 8.

licenses for HIV medicines are available to multiple generic manufacturers in developing countries where the medicines are patented.⁷⁹

The MPP's licensing strategy is flexible⁸⁰ to attract the maximum number of patent holders to the pool, meaning that licensing terms are variable and subject to negotiation.⁸¹ However, the MPP has defined at least four principles that should guide all MPP licenses to maintain a global health-oriented approach.⁸² First, the terms and conditions of all MPP licenses must be made available to the public and all MPP licenses must be non-exclusive such that patent holders can license to other entities besides the pool.⁸³ Second, licenses must be limited to low- and middle-income countries; developed countries cannot be included within the scope of licensing agreements.⁸⁴ Third, generic manufacturers must put in place mechanisms to provide quality assurance for the generic products to accommodate the concerns of patent holders whose medicines they will be producing.⁸⁵ Fourth, the royalties that patent holders receive under licensing agreements must be adjusted based on the recipient country's HIV disease burden and ability to pay to ensure the broadest possible access to treatment.⁸⁶

The next section reviews licensing agreements concluded by the MPP since it was created and shows that the MPP needs to attract more participation by key patent holders to respond to the growing global health crisis.⁸⁷ This Comment argues that the MPP could still become an effective solution to the timebomb if participation can be increased through collective action.

1. Licensing Agreements

The MPP has experienced modest success over the past five years, signing licensing agreements for a total of twelve antiretrovirals and one drug used to

⁷⁹ *Id.* at 6 (noting that “licenses are critical because they can encourage robust competition among drug manufacturers” and competition drives down prices). *See also id.* at 8.

⁸⁰ Kelly Morris, *HIV Drug Patents in the Spotlight*, 9 LANCET 660, 661 (2009). *See also* Ellen ‘t Hoen, *Pharmaceutical Companies and the UNITAID Patent Pool*, 375 LANCET 30, 30 (2010) (“UNITAID has consulted with a wide range of stakeholders in the ongoing process of designing the Pool”).

⁸¹ WIPO MAGAZINE, *supra* note 20.

⁸² *Id.*

⁸³ *Id.*

⁸⁴ *Id.*

⁸⁵ *Id.*

⁸⁶ *Id.*

⁸⁷ GOULDING & PALRIWALA, *supra* note 14, at 21–22.

treat secondary infections in people living with HIV with six patent holders.⁸⁸ Twelve out of eighteen antiretrovirals included on the MPP's list of priority medicines have been licensed to the MPP, though one cannot be produced until another patent holder joins the pool.⁸⁹ As of October 2015, the MPP had signed fifty-nine sublicensing agreements with fourteen generic manufacturers.⁹⁰ This section will briefly discuss licensing agreements concluded by the MPP to demonstrate that more can be done to attract key patent holders and increase access to HIV medicines.

The MPP signed its first licensing agreement with the United States National Institutes of Health (NIH) in September 2010.⁹¹ The NIH license is royalty-free and permits research on a drug primarily used to treat drug-resistant HIV infections.⁹² However, the long-term practical usefulness of the license is limited until another patent holder, Tibotec, which owns patents on the drug related to manufacturing, licenses to the MPP.⁹³

In July 2011, the MPP signed its first licensing agreement with a private pharmaceutical company, Gilead Sciences.⁹⁴ A few terms of the licensing agreement are worth mentioning to better understand the challenges the MPP faces in concluding licensing agreements that will have a significant impact on

⁸⁸ *About the MPP*, MEDS. PATENT POOL, <http://www.medicinespatentpool.org/about/> (last visited Sept. 30, 2015); William New, *Medicines Patent Pool Signs 7 New Sub-Licenses for Generic HIV Drugs*, INTELL. PROP. WATCH (July 18, 2014), <http://www.ip-watch.org/2014/07/18/medicines-patent-pool-signs-7-new-sub-licenses-for-generic-hiv-drugs/>. After this Comment was written, the MPP released a report highlighting its successes over the past five years. To read more about the MPP's latest achievements in greater detail, see generally MEDS. PATENT POOL, PROGRESS AND ACHIEVEMENTS OF THE MEDICINES PATENT POOL 2010–2015 (2015), http://www.medicinespatentpool.org/wp-content/uploads/WEB_Progress_Report_2015_EN.pdf [hereinafter PROGRESS AND ACHIEVEMENTS OF THE MPP].

⁸⁹ MEDS. PATENT POOL, ANTIRETROVIRAL PRIORITIES OF THE MEDICINES PATENT POOL 11 (4th ed. 2015)

⁹⁰ See PROGRESS AND ACHIEVEMENTS OF THE MPP, *supra* note 88, at 1. As of December 2014, the MPP had signed sub-licensing agreements with ten generic manufacturers. See *Company Engagement*, MEDS. PATENT POOL, <http://www.medicinespatentpool.org/company-engagement/> (last visited Sept. 26, 2015).

⁹¹ WIPO MAGAZINE, *supra* note 20.

⁹² Krista Cox, *The Medicines Patent Pool: Promoting Access and Innovation for Life-Saving Medicines Through Voluntary Licenses*, 4 HASTINGS SCI. & TECH. L. J. 293, 300 (2012); see also WIPO MAGAZINE, *supra* note 20; Kaitlin Mara, *The Medicines Patent Pool: Improving Access to ARVs and Stimulating Innovation for New Medicines*, AFR. HEALTH, Jan. 2012, at 20–21.

⁹³ Cox, *supra* note 92, at 301 (noting that Tibotec has so far declined to negotiate with the MPP).

⁹⁴ *Id.* at 304. The Gilead license covered production of the drugs tenofovir (TDF), elvitegravir (EVG) and cobicistat (COBI), as well as a fixed-dose combination of the four drugs called the Quad; the license contains a covenant not to sue on emtricitabine (FTC). *Id.*; see also *Licenses in the MPP*, MEDS. PATENT POOL, <http://www.medicinespatentpool.org/current-licences/> (last visited Sept. 26, 2015).

increasing access to patented medicines in developing countries.⁹⁵ For example, the license covers generic production of three drugs, including two pipeline drugs, used to treat HIV infections, as well as a four-drug combination product called the Quad;⁹⁶ the license permits the generic products to be sold in 112 low- and middle-income countries;⁹⁷ and Gilead receives a three to five percent royalty on sales of generic products.⁹⁸ Most strikingly and the subject of criticism, the Gilead license excluded a number of middle-income countries, in particular in Asia and Latin America.⁹⁹ In addition, the license restricted the sourcing of active pharmaceutical ingredients and generic manufacturing of the licensed drugs to India.¹⁰⁰ The MPP signed a second licensing agreement with Gilead in 2014,¹⁰¹ which again excluded a number of middle-income countries such as Argentina, Brazil, China, and the Philippines.¹⁰²

Since concluding the initial licensing agreement with Gilead, the MPP has signed licensing agreements with Bristol-Myers Squibb in 2013,¹⁰³ ViiV Healthcare in April 2014,¹⁰⁴ and with AbbVie in 2014.¹⁰⁵ In addition, the MPP signed a Memorandum of Understanding with ViiV Healthcare in 2013 for

⁹⁵ See *infra* Part II.A for a detailed discussion of the incentives to participate in the MPP. See *infra* Part II.B for a discussion of the problems the MPP must overcome before it can attract patent holders and effectively respond to the global health crisis.

⁹⁶ Cox, *supra* note 92, at 304; see also Morris, *supra* note 80, at 660.

⁹⁷ Cox, *supra* note 92, at 306, 308.

⁹⁸ *Id.* at 308.

⁹⁹ *Id.* at 306 (noting that “[t]he exclusion of a number of middle-income countries, particularly those in Asia and Latin America, represents one of the main criticisms of the MPP/Gilead license”).

¹⁰⁰ *Id.* at 309.

¹⁰¹ *Licenses in the MPP*, *supra* note 94. The agreement was amended in June 2015 to cover generic production of EVG in China and South Africa and to include a license to manufacture a combination of TDF/FTC with efavirenz (EFV). *Id.*

¹⁰² Catherine Saez, *New Medicines Patent Pool-Gilead Agreement for New HIV Drug in 112 Countries*, INTELL. PROP. WATCH (July 24, 2014), <http://www.ip-watch.org/2014/07/24/new-medicines-patent-pool-gilead-agreement-for-new-hiv-drug-in-112-countries/>.

¹⁰³ *Licenses in the MPP*, *supra* note 94. The MPP signed a licensing agreement with Bristol-Myers Squibb in 2013 for a key HIV medicine, which covers 110 low- and middle-income countries. *Id.*

¹⁰⁴ *Id.* The MPP signed two licensing agreements with ViiV Healthcare covering adult and pediatric use of a new drug, dolutegravir (DTG), used to treat HIV in 2014. *Id.* ViiV Healthcare is a collaboration between GlaxoSmithKline, Pfizer, and Shionogi. *Id.* The agreement has since been expanded to cover 127 countries for adult use and 121 countries for pediatric use. PROGRESS AND ACHIEVEMENTS OF THE MPP, *supra* note 88, at 4.

¹⁰⁵ *Licenses in the MPP*, *supra* note 94. In November 2014, the MPP signed a licensing agreement with AbbVie for two HIV drugs for children. *The Medicines Patent Pool (MPP) Signs Licensing Agreement with AbbVie for HIV Paediatric Formulations of Lopinavir and Ritonavir*, MEDS. PATENT POOL (Dec. 1, 2014), <http://www.medicinespatentpool.org/mpp-signs-licensing-agreement-with-AbbVie-for-HIV-paediatric-formulations-of-lopinavir-and-ritonavir/> [hereinafter *MPP Signs Licensing Agreement*]. The AbbVie licensing agreement covers 102 countries. *Id.*

pediatric antiretrovirals,¹⁰⁶ and a price agreement with Roche in 2013 for a drug used to treat a secondary infection in people living with HIV.¹⁰⁷ The MPP signed a licensing agreement with Merck Sharp & Dohme (MSD) for pediatric use of a third-line HIV drug in February 2015.¹⁰⁸

The MPP received support from numerous pharmaceutical companies, including Johnson & Johnson's subsidiary company Tibotec, Abbott, Boehringer-Ingelheim, Merck, Gilead, ViiV Healthcare, Roche, and Bristol-Myers Squibb, when it was created.¹⁰⁹ The MPP has signed licensing agreements with many of these pharmaceutical companies.¹¹⁰ However, several key pharmaceutical companies have declined to participate in the MPP at all¹¹¹ or have failed to conclude licensing agreements with the MPP after several years of negotiations.¹¹² For example, Tibotec and Abbott have declined to negotiate despite the fact that three patented drugs held by Tibotec are included on the MPP's list of targeted medicines.¹¹³ All key patent holders need to participate and the geographic scope of licenses needs to be expanded if the MPP is to achieve its mission to increase access to HIV medicines in low- and middle-income countries.

¹⁰⁶ *Licenses in the MPP*, *supra* note 94. The Memorandum of Understanding included a binding agreement to license a drug for pediatric use in 118 countries. In addition, ViiV Healthcare agreed to license a pediatric HIV drug currently in development for use in 118 countries once approved by regulatory authorities. The Memorandum of Understanding was converted into a licensing agreement in April 2014. *Id.*

¹⁰⁷ *Id.* The price agreement will reduce the price of the drug by ninety percent in 138 developing countries. *Id.*

¹⁰⁸ *Id.*

¹⁰⁹ Mullard, *supra* note 62.

¹¹⁰ See GOULDING & PALRIWALA, *supra* note 14, at 21–22; *Company Engagement*, *supra* note 90.

¹¹¹ As of October 2015, the MPP had not signed any licensing agreements or entered into negotiations with Tibotec and Abbott. *Medicines Patent Pool Announces Negotiations with Two Additional Pharmaceutical Companies*, MEDS. PATENT POOL (July 18, 2011), <http://www.medicinespatentpool.org/medicines-patent-pool-announces-negotiations-with-two-additional-pharmaceutical-companies/>.

¹¹² The MPP has been negotiating with Boehringer Ingelheim since 2011 but as of October 2015 still had not concluded a licensing agreement. *Company Engagement*, *supra* note 90.

¹¹³ *Target Medicines*, MEDS. PATENT POOL, <http://www.medicinespatentpool.org/licensing/target-medicines/> (last visited Feb. 13, 2015). In 2015, Johnson & Johnson began working with the MPP to support the Paediatric HIV Treatment Initiative (PHTI), a collaboration between the MPP, UNITAID, the Drugs for Neglected Diseases *initiative* (DNDi), and the Clinton Health Access Initiative, which was launched in May 2014 to “speed the development of better-adapted HIV medicines for children living in resource-limited countries.” See *The Medicines Patent Pool on Janssen’s Extension of its Access Policy for Paediatric Medicine Darunavir (Statement)*, MEDS. PATENT POOL, <http://www.medicinespatentpool.org/the-medicines-patent-pool-mpp-statement-on-janssens-extension-of-its-access-policy-for-paediatric-medicine-darunavir-to-support-the-work-of-the-paediatric-hiv-treatment-initiative-phti/> (last visited Sept. 18, 2015); *Company Engagement*, *supra* note 90.

II. EVALUATING PARTICIPATION IN THE MPP

This Comment argues that the MPP has not attracted enough participation from key patent holders or concluded licensing agreements that are likely to have a significant impact on increasing access to treatment to effectively respond to the global HIV/AIDS crisis in the post-TRIPS era. Part A reviews the current incentives for patent holders to voluntarily participate in the MPP. Part B discusses why the current incentives are inadequate to elicit sufficient patent holder participation to be an effective patent-oriented solution to the global health crisis. Part II lays the foundation for Part III in which a proposal to increase participation in the MPP through compulsory licensing in compliance with TRIPS will be evaluated.

A. Incentives to Participate in the MPP

Most major pharmaceutical companies have enacted their own programs to increase access to HIV medicines in developing countries, including tiered pricing systems for developed, middle-income, and developing countries, or bilateral voluntary licensing agreements with generic manufacturers for low or no royalties.¹¹⁴ However, these internal mechanisms are insufficient to tackle the multifaceted nature of the treatment timebomb.¹¹⁵ For example, bilateral licensing agreements between a patent holder and a generic manufacturer are unlikely to enable the development or production of combination treatments, which often requires bringing together more than one patent holder.¹¹⁶ In addition, the impact of bilateral agreements on reducing prices of existing antiretrovirals is limited where only a few generic manufacturers are allowed to produce generic versions of the patented medicines.¹¹⁷ A patent-oriented solution that can bring together multiple patent holders and generic manufacturers is needed to facilitate increased access to patented antiretrovirals.

The MPP provides a benefit over patent holders' existing mechanisms to increase access to antiretrovirals in developing countries because it facilitates access to numerous HIV patents.¹¹⁸ By pooling together multiple patents in a single pool, generic manufacturers can produce more affordable antiretrovirals

¹¹⁴ See TREATMENT TIMEBOMB, *supra* note 1, at 15; GOULDING & PALRIWALA, *supra* note 14, at 29.

¹¹⁵ TREATMENT TIMEBOMB, *supra* note 1, at 29.

¹¹⁶ *Id.*

¹¹⁷ *Id.* at 19.

¹¹⁸ See 't Hoen et al., *Driving a Decade of Change*, *supra* note 6, at 1.

and develop new combination and pediatric medicines.¹¹⁹ A key determinant of the MPP's success will be its ability to provide a range of incentives for patent holders to participate in the pool that outweigh the incentives for patent holders to rely on their own internal mechanisms to increase access to antiretrovirals.¹²⁰ The MPP provides a range of incentives for HIV medicines patent holders to participate in the pool, including but not limited to compensation in the form of royalties for licenses granted to generic manufacturers; positive press and a boost in reputation from licensing; the possibility of avoiding the risk of compulsory licensing; and reduced transaction costs.¹²¹

Patent holders will be compensated when they license products to the MPP.¹²² Patent holders licensing to the MPP can receive royalties when generic versions of the patented medicines are sold in low- and middle-income countries included within the scope of the agreement.¹²³ In addition, patent holders that license to the MPP will receive positive press and a boost in reputation for taking action to improve access to HIV medicines in developing countries.¹²⁴ Many patent holders want to contribute to global health; licensing to the MPP provides patent holders with a definite and visible way of doing so¹²⁵ while at the same time giving them access to developing country markets that they otherwise may not supply.¹²⁶

Further, patent holders may choose to license to the MPP in order to avoid the possibility that their patents will be used in developing countries without their consent.¹²⁷ Under TRIPS, countries are permitted to issue compulsory licenses for patented medicines under certain conditions, including if there is a national or public health emergency.¹²⁸ By voluntarily licensing their HIV medicines patents to the MPP, pharmaceutical companies can avoid the risk

¹¹⁹ *See id.*

¹²⁰ Bermudez & 't Hoen, *supra* note 19, at 39.

¹²¹ *Id.*

¹²² Mullard, *supra* note 62.

¹²³ Bermudez & 't Hoen, *supra* note 19, at 39; *see also* Mara, *supra* note 92.

¹²⁴ Bermudez & 't Hoen, *supra* note 19, at 39; *see also* Mara, *supra* note 92.

¹²⁵ Mullard, *supra* note 62.

¹²⁶ *See* Bermudez & 't Hoen, *supra* note 19, at 39.

¹²⁷ *Id.* This incentive will be addressed in greater detail in Part III.B.

¹²⁸ *See, e.g.,* Sara Germano, *Compulsory Licensing of Pharmaceuticals in Southeast Asia: Paving the Way for Greater Use of the TRIPS Flexibility in Low- and Middle-Income Countries*, 76 UMKC L. REV. 273, 280-81 (2007). Compulsory licensing and TRIPS will be discussed in greater detail in Parts III.A and B.

that countries will issue compulsory licenses for their patented medicines.¹²⁹ Finally, patent holders only have to negotiate a single license with the MPP before their medicines will be made available to generic manufacturers.¹³⁰ As a result, by voluntarily licensing to the MPP, patent holders can reduce the transaction costs and uncertainty associated with negotiating licenses with generic manufacturers on a case-by-case or drug-by-drug basis.¹³¹

Although the MPP provides a range of incentives for patent holders to license to or negotiate with the pool, the MPP faces hurdles in reaching the level of participation needed to become an effective solution to increasing access to HIV medicines in developing countries. These hurdles are outlined in Part B to establish a framework within which to evaluate a proposal to increase participation in the MPP through compulsory licensing.

B. Roadblocks to Increasing Participation in the MPP

The MPP must overcome at least four roadblocks in order to serve as a valuable tool for facilitating access to new and more affordable antiretrovirals to respond to the treatment timebomb: (1) minimal financial incentives for patent holders to participate; (2) imbalance of bargaining power in licensing negotiations; (3) slow pace of licensing negotiations and production of generic medicines; and (4) insufficient consequences for patent holders that choose not to participate in the pool. Part III suggests that collective action through compulsory licensing can be an effective solution to increase participation in the MPP and overcome these hurdles.¹³²

First, the MPP's ability to attract key HIV medicines patent holders is limited because there are minimal financial incentives for patent holders to voluntarily participate in the pool.¹³³ The lack of sufficient financial incentives for patent holders to participate in the MPP comes in many forms, including limited royalties from licensing agreements and the risk of parallel importing.¹³⁴

¹²⁹ Bermudez & 't Hoen, *supra* note 19, at 39. This incentive will be addressed in greater detail in Part III.B.

¹³⁰ *See id.*

¹³¹ *Id.*

¹³² The roadblocks discussed in Part II.B are meant to be an inclusive but not exhaustive list—the MPP may face additional roadblocks in achieving its mission of increasing access to newer and more affordable HIV medicines that are beyond the scope of this Comment.

¹³³ *See* GOULDING & PALRIWALA, *supra* note 14, at 33.

¹³⁴ *See id.* at 4, 30.

Currently, patent holders who contribute to the MPP can receive royalties when generic manufacturers license the right to use their patents to produce and sell low-cost versions of the patented medicines in developing countries.¹³⁵ However, the royalties patent holders receive under licensing agreements with the MPP offer little to no advantage over those patent holders can receive from bilateral licensing agreements with generic manufacturers.¹³⁶ For example, Gilead receives royalties between three and five percent under its licensing agreement with the MPP.¹³⁷ In comparison, Tibotec, the Johnson & Johnson subsidiary that has declined to participate in the MPP, receives royalties between two and five percent under a bilateral licensing agreement it negotiated with a generic manufacturer to produce an HIV drug.¹³⁸ Further, patent holders may be reluctant to license to the MPP due to the risk of parallel importing, whereby generic medicines produced in developing countries leak into developed country markets and erode the patent holders' profit margin.¹³⁹ To be an effective part of the solution to increasing access to antiretrovirals, the MPP must provide greater financial incentives for patent holders to participate in the pool rather than rely on their own internal mechanisms to increase access to patented antiretrovirals.¹⁴⁰

Second, patent holders have greater bargaining power than generic manufacturers and pool administrators in negotiating licensing agreements.¹⁴¹ Patent holders have greater bargaining power than generic manufacturers because they can exclude middle-income countries from licensing

¹³⁵ Bermudez & 't Hoen, *supra* note 19, at 39. See also 't Hoen et al., *Driving a Decade of Change*, *supra* note 6, at 8.

¹³⁶ See GOULDING & PALRIWALA, *supra* note 14, at 35.

¹³⁷ Cox, *supra* note 92, at 308.

¹³⁸ *Tibotec Signs Multiple Agreements with Generic Manufacturers to Provide Access to New HIV Treatment*, JOHNSON & JOHNSON (Jan. 27, 2011), <http://www.investor.jnj.com/releasedetail.cfm?ReleaseID=545920>.

¹³⁹ See GOULDING & PALRIWALA, *supra* note 14, at 30 (noting that patent holders are hesitant to voluntarily license their medicines because of the potential for "unsanctioned reimportation of generic products from lower- or lower-middle-income markets into middle- or high-income markets"). See also Josh Ruxin, *AIDS Drugs-For Profit or Not?*, FORBES (Nov. 11, 2010), <http://www.forbes.com/sites/sciencebiz/2010/11/11/aids-drugs-%C3%A2%C2%80%C2%93-for-profit-or-not/>; *What's Behind U.S. Drug Companies' Response to the AIDS Crisis Abroad?*, WHARTON (Apr. 11, 2001), <http://knowledge.wharton.upenn.edu/article/whats-behind-u-s-drug-companies-response-to-the-aids-crisis-abroad/>.

¹⁴⁰ See Nikhil Kumar, *Big Pharma and the Business of HIV/AIDS*, INDEPENDENT (Dec. 1, 2010), <http://www.independent.co.uk/news/business/analysis-and-features/big-pharma-and-the-business-of-hiv-aids-2147987.html>; Daniel Costello, *HIV Treatment Becomes Profitable*, L.A. TIMES (Feb. 21, 2008), <http://articles.latimes.com/print/2008/feb/21/business/fi-hiv21>.

¹⁴¹ See Morris, *supra* note 80, at 660. Gilead Sciences, for example, the patent owner of tenofovir disoproxil fumarate (TDF), has control over generic manufacturers in negotiating its license agreements. *Id.*

agreements.¹⁴² Patent holders prefer to restrict generic sales in middle-income countries where they can already make a profit from the sale of patented HIV medicines.¹⁴³ In contrast, generic manufacturers prefer to include middle-income countries in licensing agreements so that they can reach economies of scale faster and maximize profits.¹⁴⁴ Patent holders also have greater bargaining power than MPP administrators. For example, under the initial licensing agreement with Gilead, Gilead had to give a small portion of the royalties it received to the MPP as a broker's fee.¹⁴⁵ One year later, however, Gilead amended the agreements to remove any royalty payments due to the MPP.¹⁴⁶ The MPP and generic manufacturers need additional bargaining tools to negotiate licensing agreements with patent holders that are designed to facilitate broader access to new and more affordable antiretrovirals, with limited or no restrictions.¹⁴⁷

Third, the pace of negotiating licensing agreements and distributing generic medicines is too slow to keep up with the urgency underlying the treatment timebomb.¹⁴⁸ As discussed in Part I.A, one of the advantages of creating a patent pool to facilitate access to patented medicines is that patent pools can make the patented medicines available to generic manufacturers right away.¹⁴⁹ When the MPP was created, pool administrators hoped that there would be a time lag of only one to two years between concluding a licensing agreement and producing and distributing generic drugs.¹⁵⁰ However, over the past five years, the MPP has only produced and distributed one drug, Tenofovir (TDF), in developing countries.¹⁵¹ While generic production of the drug has decreased

¹⁴² See *id.* at 661; Cox, *supra* note 92, at 306–07. The inclusion of middle-income countries in the scope of MPP licenses was one of the most contentious issues when the MPP was created. Childs, *supra* note 15, at 35.

¹⁴³ Morris, *supra* note 80, at 661.

¹⁴⁴ *Id.*

¹⁴⁵ Cox, *supra* note 92, at 311.

¹⁴⁶ *Licenses in the MPP*, *supra* note 94.

¹⁴⁷ Cox, *supra* note 92, at 309 (noting that negotiations with patent holders involve competing interests and that it may be necessary for the MPP to change certain terms of the licenses or create new incentives in order to achieve more favorable provisions); see also Bermudez & 't Hoen, *supra* note 19, at 38 (noting that licenses need to cover both low and middle-income countries in order to attract multiple generic manufacturers and stimulate the level of competition needed to lower drug prices).

¹⁴⁸ See GOULDING & PALRIWALA, *supra* note 14, at 3, 30 (noting that to be effective, the MPP needs to make it faster and easier for patent holders and generic manufacturers to license patented medicines).

¹⁴⁹ See *supra* note 63 and accompanying text.

¹⁵⁰ Mullard, *supra* note 62.

¹⁵¹ See Saez, *supra* note 102; PROGRESS AND ACHIEVEMENTS OF THE MPP, *supra* note 88, at 1. Tenofovir was licensed to the MPP in 2011 by Gilead Sciences. *Licenses in the MPP*, *supra* note 94. The MPP has also

prices and increased access,¹⁵² the long-term impact of the MPP will be limited until more generic antiretrovirals are produced and savings are realized.¹⁵³ In addition, MPP administrators hoped that licensing agreements with patent holders would be concluded within one year.¹⁵⁴ However, most MPP licenses have taken well over one year to be finalized.¹⁵⁵ Immediate action is needed to decrease the price of antiretroviral drugs and increase access to treatment.¹⁵⁶ To accomplish this task, the MPP needs to be able to license and produce generic medicines on a shorter timeframe.

Lastly, there are insufficient consequences for patent holders that choose not to participate in the MPP.¹⁵⁷ Since the MPP was created, there have been numerous calls from governments and social activists for pharmaceutical companies to license to the MPP.¹⁵⁸ Despite these calls, several prominent pharmaceutical companies, including Merck and Tibotec—the Johnson & Johnson subsidiary—have been reluctant to negotiate with the MPP,¹⁵⁹ expressing a preference to rely on their own internal mechanisms to reduce prices and increase access to HIV drugs.¹⁶⁰ Other patent holders have outright

distributed TDF combination drugs in 115 countries. PROGRESS AND ACHIEVEMENTS OF THE MPP, *supra* note 88, at 10.

¹⁵² Saez, *supra* note 102 (“The price of TDF has dropped 45%-87% in the past two years and the MPP’s generic partners have distributed three million TDF treatments in the same time period.”).

¹⁵³ See PROGRESS AND ACHIEVEMENTS OF THE MPP, *supra* note 88, at 11 (noting that “for new ARVs, savings are likely to start three-four years after the MPP license is signed”).

¹⁵⁴ Mullard, *supra* note 62.

¹⁵⁵ See *Company Engagement*, *supra* note 90.

¹⁵⁶ See ‘t Hoen et al., *Driving a Decade of Change*, *supra* note 6, at 7–8.

¹⁵⁷ See Cox, *supra* note 92, at 319, 323 (noting that there is a need for an additional “stick” to place pressure on and encourage patent holders to participate in the MPP).

¹⁵⁸ See Hannah Semigran, *Altruism and Profit: The Changing Role of Pharmaceutical Companies in Global Health*, HARV. C. GLOBAL HEALTH REV. (Feb. 1, 2012), <http://www.hcs.harvard.edu/hghr/print/spring-2011/altruism-profit-pharma/>. See also Philippe Douste-Blazy & Jorge Bermudez, *GSK: Please Extend Patent Pool to AIDS Drugs*, 373 LANCET 1339, 1339 (2009); *Drug Firms ‘Must Pool Patents’*, *supra* note 3.

¹⁵⁹ Semigran, *supra* note 158. See also Cox, *supra* note 92, at 301. Merck only began negotiating with the MPP in the second quarter of 2014. *Company Engagement*, *supra* note 90.

¹⁶⁰ Elizabeth Sukkar, *Patent Pools: An Idea Whose Time Has Come*, 338 BRIT. MED. J. 974, 975 (2009). As one official from Glaxo-Smith Kline put it:

For HIV, we believe that extensive research is already underway, and thus it is not a neglected disease. Millions of dollars are ploughed into research into HIV every year by the pharmaceutical industry. To improve access, we already have an extensive voluntary licensing programme for HIV across Sub Saharan Africa, involving eight licensees. These licensees are free to develop FDCs and paediatric versions and we believe this is a much simpler approach than the creation of a patent pool. . . . [a]ll our ARVs are also available at not-for-profit prices in all Least Developed Countries and Sub Saharan Africa. We therefore do not see the need to include our HIV patents in any pool.

declined to negotiate with the MPP.¹⁶¹ The primary consequences facing patent holders that decline to participate in the MPP are criticism from governments and social activists and possible reputational damage.¹⁶² While criticism and reputational damage are significant consequences, having additional consequences for patent holders that choose not to participate would go a long way towards increasing participation in and the effectiveness of the MPP.

III. A PROPOSAL TO INCREASE PARTICIPATION IN THE MPP THROUGH COMPULSORY LICENSING

As a new approach to managing intellectual property created in response to the implementation of TRIPS,¹⁶³ the MPP has the potential to reduce prices and increase access to new and more affordable antiretrovirals if it can overcome the four roadblocks discussed above.¹⁶⁴ However, in order to accomplish its mission, the MPP must find a way to increase participation in the pool by key HIV medicines' patent holders and conclude licensing agreements that are favorable from a global health perspective with few or no restrictions.

Part A provides background information on compulsory licensing and outlines the provisions of TRIPS and subsequent declarations that permit compulsory licensing under certain conditions. Part A is intended to lay the foundation for Part B, which illustrates how collective action by low- and middle-income countries through compulsory licensing could be utilized to increase participation in the MPP. Part C discusses how developing countries can overcome the hurdles outlined in Part II.B through a concerted effort to

TREATMENT TIMEBOMB, *supra* note 1, at 28–29.

¹⁶¹ Semigran, *supra* note 158. In 2011, Tibotec issued a formal statement refusing to enter into negotiations with the MPP for darunavir and several of its other HIV drugs. Cox, *supra* note 92, at 301.

¹⁶² See GOULDING & PALRIWALA, *supra* note 14, at 4–5. The potential to avoid compulsory licensing was listed as an incentive for patent holders to participate in the MPP when it was created in 2010. Bermudez & 't Hoen, *supra* note 19, at 39. However, since the MPP was created, few countries have taken steps to issue compulsory licenses for HIV medicines patents. See Catherine Saez, *Ecuador Grants First Compulsory License for HIV/AIDS Drug*, INTELL. PROP. WATCH (Apr. 22, 2014), <http://www.ip-watch.org/2010/04/22/ecuador-grants-first-compulsory-licence-for-hiv-aids-drug/> (noting that Ecuador issued a compulsory license for an antiretroviral drug owned by Abbott in 2010); Peter Maybarduk, *US Government Special 301 "Watchlist" and Developing Country Use of Compulsory Licenses for Healthcare*, INFOJUSTICE (May 2, 2013), <http://infojustice.org/archives/29493> (noting that Thailand renewed its compulsory license for two antiretrovirals in 2010). This Comment argues that a more concerted effort by developing countries to issue compulsory licenses for HIV medicines is needed to provide a sufficient incentive for patent holders to voluntarily join the MPP. See *infra* Part III.C.

¹⁶³ See 't Hoen et al., *Driving a Decade of Change*, *supra* note 6, at 8.

¹⁶⁴ See *supra* Part II.B.

issue compulsory licenses for patented HIV medicines; Part C also discusses several obstacles developing countries may face in issuing compulsory licenses in connection with the MPP and how these obstacles can be addressed.

A. An Introduction to Compulsory Licensing and TRIPS

1. What is a Compulsory License?

A compulsory license is an “authorization by the government to itself or to a third party to use the patent without the permission of the patent holder.”¹⁶⁵ A compulsory license allows a government to override a patent holder’s rights when it is in the state’s interest to do so.¹⁶⁶ Compulsory licenses may be issued, for example, when a patent holder fails to offer the patent product on the market, or offers the product at a price that is too high for potential buyers in the market to afford.¹⁶⁷ The concept of compulsory licensing has been around for almost as long as patent law itself and the laws of many countries, including the United States, permit some form of compulsory licensing.¹⁶⁸

2. Compulsory Licensing Under Article 31 of TRIPS

Prior to the adoption of TRIPS, patent protection for pharmaceuticals differed among countries.¹⁶⁹ Many developing countries, including India, provided little to no patent protection for medicines.¹⁷⁰ With the adoption of TRIPS by the WTO in 1994, however, all WTO member countries became required to provide a minimum level of patent protection in all fields of technology, including pharmaceuticals, for twenty years.¹⁷¹ Within the twenty years of patent protection, generic companies are not permitted to develop or manufacture generic versions of the patented medicines without a license from the patent holder.¹⁷²

¹⁶⁵ Germano, *supra* note 128, at 279–80 (citing FREDERICK ABBOTT ET AL., INTERNATIONAL INTELLECTUAL PROPERTY IN AN INTEGRATED WORLD ECONOMY 55 (2007)).

¹⁶⁶ GOULDING & PALRIWALA, *supra* note 14, at 15.

¹⁶⁷ *HIV/AIDS, TRIPS, and Second-Line Therapy*, AVERT, <http://www.avert.org/hiv-drugs-patents-legislation.htm> (last visited Feb. 12, 2015).

¹⁶⁸ See Germano, *supra* note 128, at 279; see also KARIN TIMMERMANS & TOGI HUTADJULU, INDON. MINISTRY HEALTH, THE TRIPS AGREEMENT AND PHARMACEUTICALS 32 (2000).

¹⁶⁹ Germano, *supra* note 128, at 277.

¹⁷⁰ See ‘t Hoen et al., *Driving a Decade of Change*, *supra* note 6, at 2. India began providing patent protection for pharmaceuticals in 2005. *Id.* at 4.

¹⁷¹ *Id.* at 2.

¹⁷² TREATMENT TIMEBOMB, *supra* note 1, at 21.

As discussed in Part I.A, the implementation of TRIPS has led to the increased patenting of medicines in developing countries, making it more difficult to develop new antiretrovirals and manufacture generic versions of patented HIV medicines.¹⁷³ The least developed countries were given a grace period to comply with the provisions of TRIPS.¹⁷⁴ However, all WTO member countries are required to be in compliance with TRIPS by 2016, after which it will be virtually impossible to produce generic antiretrovirals without permission from the patent holder.¹⁷⁵ Despite increasing patent protection, all hope is not lost. TRIPS includes provisions, known as TRIPS flexibilities, which legally permit countries to overcome the patent barriers imposed by TRIPS by producing or importing generic versions of antiretrovirals under certain conditions.¹⁷⁶

TRIPS flexibilities are found in Article 31, which permits “other use without authorization of the right holder,” including the use of a patent by the government or third parties authorized by the government without the patent holder’s consent.¹⁷⁷ Article 31 has been interpreted to authorize WTO member countries to issue compulsory licenses for patented medicines provided that certain conditions are met.¹⁷⁸ Several points about Article 31 are worth mentioning.

TRIPS flexibilities are only available to those countries wherein domestic law permits some form of compulsory licensing.¹⁷⁹ Thus, a country wishing to issue a compulsory license under Article 31 must already have in place or must put in place laws authorizing compulsory licensing.¹⁸⁰ Under Article 31, governments wishing to use patents without the patent holder’s permission must have made prior unsuccessful attempts to gain the patent holder’s authorization “on reasonable commercial terms and conditions.”¹⁸¹ Countries are permitted to bypass the authorization provision and issue a compulsory license without first attempting to obtain the patent holder’s consent if there is

¹⁷³ See *supra* Part I.A.

¹⁷⁴ TREATMENT TIMEBOMB, *supra* note 1, at 19.

¹⁷⁵ *Id.* at 20.

¹⁷⁶ *Id.* at 17.

¹⁷⁷ Agreement on Trade-Related Aspects of Intellectual Property Rights art. 31, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1867 U.N.T.S. 31875 [hereinafter TRIPS]. See also TREATMENT TIMEBOMB, *supra* note 1, at 17.

¹⁷⁸ See Germano, *supra* note 128, at 281–82.

¹⁷⁹ TRIPS, *supra* note 177.

¹⁸⁰ Germano, *supra* note 128, at 284–85.

¹⁸¹ TRIPS, *supra* note 177.

a national emergency, “other circumstances of extreme urgency,” or in the case of a “public non-commercial use.”¹⁸² In the case of a national emergency or “other circumstances of extreme urgency,” countries wishing to issue compulsory licenses are required to notify the patent holder of its intentions to issue a compulsory license as soon as possible.¹⁸³ Authorization to issue the compulsory license is terminated when there is no longer a national emergency or situation of extreme urgency.¹⁸⁴

Under Article 31, the scope and duration of compulsory licenses are limited to the specific authorized use,¹⁸⁵ the license must be non-exclusive,¹⁸⁶ and the license can only be used to supply the domestic market of the country issuing the license.¹⁸⁷ Finally, the patent holder must be remunerated for the use of its patent without its permission.¹⁸⁸ Such remuneration must be “adequate” and take into account the economic value of the patent that is subject to the compulsory license.¹⁸⁹

3. *The Doha Declaration: Expanding Compulsory Licensing Flexibilities under TRIPS*

In 2001, the WTO issued the Declaration on the TRIPS Agreement and Public Health, known as the Doha Declaration, which expanded the instances in which WTO member countries could utilize TRIPS flexibilities.¹⁹⁰ The Doha Declaration acknowledged that protection for intellectual property is important to facilitate the development of new medicines but emphasized that TRIPS “does not and should not prevent [WTO] members from taking measures to protect public health.”¹⁹¹ In particular, the Doha Declaration reaffirmed the right of WTO member countries to use TRIPS flexibilities “to protect public health and, in particular, to promote access to medicines for all.”¹⁹² The Declaration permits WTO member countries to determine under what circumstances compulsory licenses can be issued under Article 31 of

¹⁸² *Id.*

¹⁸³ *Id.*

¹⁸⁴ *Id.*

¹⁸⁵ *Id.*

¹⁸⁶ *Id.*

¹⁸⁷ *Id.*

¹⁸⁸ *Id.*

¹⁸⁹ *Id.*

¹⁹⁰ World Trade Organization, Ministerial Declaration of 14 November 2001, WTO Doc. WT/MIN(01)/DEC/2, 41 I.L.M. 746 (2002) [hereinafter Doha Declaration].

¹⁹¹ *Id.* ¶¶ 3–4.

¹⁹² *Id.* ¶ 4.

TRIPS.¹⁹³ Most importantly, the Declaration recognized that public health crises, including the global HIV/AIDS crisis, constitute a national emergency for which countries could grant compulsory licenses.¹⁹⁴

Part B builds on the introductory discussion of compulsory licensing and TRIPS to argue that developing countries hardest hit by the HIV/AIDS epidemic can collectively utilize TRIPS flexibilities to increase participation in the MPP and facilitate access to patented antiretrovirals.

B. Exercising Compulsory Licensing Flexibilities in Connection with the MPP

The MPP was created to respond to the changing intellectual property environment under TRIPS through the collective management of HIV medicines patents.¹⁹⁵ At the time the MPP was created, compulsory licensing was not seen as a favorable solution to overcoming patent barriers imposed by TRIPS because it requires a country-by-country approach.¹⁹⁶ However, this Comment argues that the MPP has been unable to achieve the level of patent holder participation needed to decrease drug prices and increase access on its own. This Comment suggests that collective action through compulsory licensing by governments in low- and middle-income countries is needed to boost participation in the MPP to make the MPP more effective at increasing access to medicines.¹⁹⁷

Compulsory licensing provides a legal solution to overcoming patent barriers that fits within the existing international intellectual property framework of TRIPS.¹⁹⁸ Article 31 of TRIPS permits WTO member countries to authorize the use of a patent by the government or a third party authorized by the government without the permission of the patent holder.¹⁹⁹ This means that developing countries could issue compulsory licenses authorizing the

¹⁹³ *Id.* ¶ 5(b).

¹⁹⁴ *Id.* ¶ 5(c).

¹⁹⁵ See 't Hoen et al., *Driving a Decade of Change*, *supra* note 6, at 8.

¹⁹⁶ See Bermudez & 't Hoen, *supra* note 19, at 39 (noting that compulsory licensing is not a systematic solution to solving the global HIV/AIDS crisis).

¹⁹⁷ Although MSF preferred a voluntary licensing approach in its initial proposal for an HIV medicines patent pool, it did not rule out the possibility that a mandatory system should be adopted, if the voluntary approach failed. Childs, *supra* note 15, at 34. At least one scholar has suggested that countries could support the MPP by issuing compulsory licenses. Cox, *supra* note 92, at 323. This Comment explores more seriously compulsory licensing as an option to increase participation in the MPP, in arguing that compulsory licensing is an effective tool to increase participation in the MPP and respond to the treatment timebomb.

¹⁹⁸ See, e.g., 't Hoen et al., *Driving a Decade of Change*, *supra* note 6, at 3.

¹⁹⁹ TRIPS, *supra* note 177.

MPP, a third party, to use HIV medicine patents, even if the patent holder has not given the government or the MPP permission to do so. The MPP could then negotiate licensing agreements with generic manufacturers that would produce generic versions of the patented medicines for sale in developing countries or to develop new combination or pediatric treatments. The compulsory licenses could be directed to patent holders that have not licensed to the MPP or that have licensed to the MPP but excluded middle-income countries from the scope of the license.²⁰⁰ For example, compulsory licenses could be issued to Tibotec, which holds the patents needed to manufacture the drug licensed by the NIH, because Tibotec has declined to participate in the MPP.²⁰¹ In addition, middle-income countries excluded under the Gilead license could issue a compulsory license requiring Gilead to include them within the geographic scope of the license.²⁰²

Developing country governments issuing compulsory licenses would not be required to authorize the MPP to use the patents but could instead choose to use the patents themselves.²⁰³ However, including the MPP as an authorized third party is essential to ensuring that the patented medicines are available to enough generic manufacturers to stimulate competition and have a significant impact on driving drug prices down.²⁰⁴ In addition, pooling the patented medicines subject to the compulsory license in a single entity such as the MPP is essential to ensuring that generic manufacturers have access to all the patents needed to develop and produce new combination and pediatric treatments.²⁰⁵

Compulsory licenses for HIV medicines patents issued by WTO member countries would be compliant with TRIPS and the Doha Declaration provided that certain conditions are met. The Doha Declaration recognized that the HIV/AIDS epidemic constituted a public health emergency²⁰⁶ such that the requirement that governments attempt to obtain authorization from patent holders before issuing the license is waived.²⁰⁷ However, in order to comply

²⁰⁰ See Cox, *supra* note 92, at 321–22.

²⁰¹ See *id.* at 301.

²⁰² See *id.* at 319–20 (noting the role that compulsory licenses could play in increasing the geographic coverage of the MPP/Gilead license).

²⁰³ See TRIPS, *supra* note 177.

²⁰⁴ See TREATMENT TIMEBOMB, *supra* note 1, at 19 (noting that “where few generic manufacturers are allowed to produce a medicine, the impact [on reducing drug prices] will be limited because competition is limited”); see also Rosenberg, *supra* note 22.

²⁰⁵ Rosenberg, *supra* note 22.

²⁰⁶ Doha Declaration, *supra* note 190, ¶ 5(c).

²⁰⁷ TRIPS, *supra* note 177.

with TRIPS, countries wishing to issue compulsory licenses for HIV medicines must notify HIV medicine patent holders of their intention to do so.²⁰⁸ In addition, the compulsory license must terminate when there is no longer a national emergency,²⁰⁹ although this is unlikely to occur anytime in the foreseeable future with the global HIV/AIDS epidemic. Countries issuing compulsory licenses must also remunerate patent holders for the use of their patent without authorization, taking into account the economic value or importance of the patented drug.²¹⁰ Remuneration guidelines used by developing countries should be transparent and predictable to ensure fairness among patent holders.²¹¹ Further, compulsory licenses would be TRIPS-compliant provided that the use of HIV medicines patents is non-exclusive,²¹² meaning that patent holders could voluntarily license the patents to generic manufacturers or the MPP on their own. However, because TRIPS requires that patents subject to compulsory licenses can only be used to supply the domestic market of the country issuing the license,²¹³ a concerted effort by multiple developing countries is needed to increase participation in the MPP and have a measurable impact on decreasing drug prices.²¹⁴

Issuing compulsory licenses for HIV medicines could also function as a tool to increase participation in the MPP by facilitating voluntary licensing.²¹⁵ Because compulsory licenses allow a government to override a patent holder's rights without their consent, patent holders have little control over the terms or conditions of the compulsory licenses.²¹⁶ In addition, the terms of compulsory licenses are unlikely to be uniform or predictable across countries, creating greater uncertainty for patent holders.²¹⁷ In contrast, patent holders have leverage and bargaining power when negotiating the term of voluntary licensing agreements with the MPP.²¹⁸ By voluntarily licensing to the MPP,

²⁰⁸ *Id.*

²⁰⁹ *Id.*

²¹⁰ *Id.* A detailed discussion of remuneration guidelines is beyond the scope of this Comment. For a more detailed discussion on remuneration guidelines, see James Love, *Measures to Enhance Access to Medical Technologies, and New Methods of Stimulating Medical R&D*, 40 U.C. DAVIS L. REV. 679, 688-694 (2007).

²¹¹ JAMES LOVE, WORLD HEALTH ORG., REMUNERATION GUIDELINES FOR NON-VOLUNTARY USE OF A PATENT ON MEDICAL TECHNOLOGIES 58 (2005).

²¹² TRIPS, *supra* note 177.

²¹³ *Id.*

²¹⁴ See Bermudez & 't Hoen, *supra* note 19, at 38.

²¹⁵ See TREATMENT TIMEBOMB, *supra* note 1, at 19 (noting that voluntary licensing is "an effective way to avoid expense and damaging legal battles over compulsory licensing").

²¹⁶ See GOULDING & PALRIWALA, *supra* note 14, at 15.

²¹⁷ See Bermudez & 't Hoen, *supra* note 19, at 39.

²¹⁸ See *supra* notes 141-47 and accompanying text.

patent holders could negotiate more favorable licensing terms, in particular royalty rates, than if a compulsory license is issued.²¹⁹ As a result, the threat of compulsory licensing can serve as a bargaining tool for the MPP and developing countries in negotiating licensing agreements with patent holders that are favorable from a global health standpoint; the threat of compulsory licensing may also provide a financial incentive for patent holders to voluntarily participate in the MPP.²²⁰ This threat in itself may provide a sufficient reason for patent holders to voluntarily participate in the MPP and avoid the uncertainty associated with compulsory licensing.²²¹

Several countries have already taken advantage of TRIPS compulsory licensing flexibilities with impressive results. In 2004, Malaysia became the first WTO member country to issue a compulsory license for HIV antiretrovirals.²²² After the compulsory license was issued, Malaysia began manufacturing and distributing generic antiretrovirals domestically, ultimately reducing the cost of treatment.²²³ The governments of Indonesia, Thailand, and Brazil have also issued compulsory licenses for HIV medicines with similar results.²²⁴ These instances demonstrate that issuing compulsory licenses for HIV medicines can have a measurable impact on decreasing prices and increasing access to HIV medicines.²²⁵ The potential for compulsory licensing to have similar effects when utilized in connection with the MPP will be evaluated in the next section.

C. Impact of Compulsory Licensing on Participation in the MPP and the Treatment Timebomb

Part II.B outlined four obstacles the MPP must overcome to increase participation in the pool: 1) minimal financial incentives for patent holders to participate; 2) imbalance of bargaining power in licensing negotiations; 3) slow pace of licensing negotiations and production of generic medicines; and 4) insufficient consequences for patent holders that choose not to participate in

²¹⁹ See Germano, *supra* note 128, at 291 (noting that HIV medicines patent holders subject to a compulsory license issued by the Indonesian government only received a 0.5% royalty).

²²⁰ See *id.* at 294.

²²¹ GOULDING & PALRIWALA, *supra* note 14, at 35; see also Germano, *supra* note 128, at 279–80.

²²² Germano, *supra* note 128, at 286.

²²³ *Id.* at 288. The compulsory license was successful in reducing the cost of three antiretroviral drugs by eighty-one percent. In addition, the compulsory license led pharmaceutical companies to make additional price reductions on other first and second-line treatments. *Id.*

²²⁴ *Id.* at 289–93; see also GOULDING & PALRIWALA, *supra* note 14, at 13.

²²⁵ GOULDING & PALRIWALA, *supra* note 14, at 16.

the pool.²²⁶ Part C demonstrates how collective action by governments in low- and middle-income countries through compulsory licensing could be used to overcome these and other roadblocks to increase participation in the MPP and facilitate access to patented antiretrovirals.

Compulsory licensing can provide an additional financial incentive for patent holders to voluntarily license to the MPP.²²⁷ To be compliant with TRIPS, low- and middle-income countries issuing compulsory licenses must remunerate patent holders for the unauthorized use of their patents.²²⁸ Remuneration under compulsory licenses issued for public health reasons in low-income countries typically ranges between zero and six percent of the price of the generic product.²²⁹ In contrast, patent holders have been able to negotiate royalties between three and five percent in voluntary licenses with the MPP.²³⁰ Since patent holders have little control over the terms of compulsory licenses,²³¹ patent holders are likely to voluntarily license to the MPP if remuneration from the compulsory license would be less than the royalties the patent holder would receive from the MPP.²³² In this way, the mere threat of compulsory licensing and uncertainty over the terms of compulsory licenses places pressure on patent holders to voluntarily license to the MPP.²³³ This threat of compulsory licensing can serve as an additional bargaining tool in licensing negotiations, lessening the imbalance of bargaining power in licensing negotiations between patent holders, pool administrators, and generic manufacturers.²³⁴

Compulsory licensing could also be used to expand the geographic scope of existing MPP licensing and sublicensing agreements. In addition, compulsory licenses could make patents available where the holders had previously been unwilling to negotiate with the MPP or the MPP had been unable to conclude a licensing agreement despite years of negotiations.²³⁵ Most importantly for responding to the treatment timebomb, the exercise of TRIP flexibilities would

²²⁶ See *supra* Part II.B.

²²⁷ See *supra* notes 216–19 and accompanying text.

²²⁸ TRIPS, *supra* note 177.

²²⁹ Marla L. Mellino, *The TRIPS Agreement: Helping or Hurting Least Developed Countries' Access to Essential Pharmaceuticals?*, 20 FORDHAM INTEL. PROP. MEDIA & ENT. L. J. 1349, 1364 (2010).

²³⁰ See Cox, *supra* note 92, at 310.

²³¹ See GOULDING & PALRIWALA, *supra* note 14, at 12.

²³² See *supra* note 219 and accompanying text.

²³³ Cox, *supra* note 92, at 320; see also GOULDING & PALRIWALA, *supra* note 14, at 13.

²³⁴ Cox, *supra* note 92, at 320; see also GOULDING & PALRIWALA, *supra* note 14, at 13.

²³⁵ See Cox, *supra* note 92, at 320.

allow developing countries to bypass the twenty years of patent protection guaranteed to medicines under TRIPS.²³⁶ As a result, generic manufacturers could begin developing and distributing new and more affordable medicines right away, without first having to obtain the patent holders permission or conclude a voluntary licensing agreement.²³⁷ Finally, by incorporating compulsory licensing into the MPP, criticism and reputational damage would no longer be the only significant consequences facing patent holders that decline or refuse to license to the MPP. Rather, patent holders that do not license to the MPP would face the very real possibility that their HIV medicines patents could be used without their consent and on potentially unfavorable terms by multiple developing countries collectively exercising their TRIPS flexibilities.

By issuing compulsory licenses, developing countries have the potential to increase participation in the MPP and make the MPP better equipped to facilitate access to new and more affordable HIV medicines. Developing countries should include the MPP in compulsory licenses to ensure that the patented medicines are available to multiple generic manufacturers to simulate competition and that generic manufacturers have access to all the patents needed to develop combination or pediatric treatments.²³⁸ However, developing countries must overcome at least two obstacles before compulsory licensing can be used to make the MPP more effective at responding to the treatment timebomb. To successfully increase participation in the MPP and increase access to medicines, countries wishing to issue compulsory licenses under TRIPS must have the capacity and legal know-how to exercise TRIPS flexibilities.²³⁹ In addition, developing countries must be prepared to face and overcome backlash from patent holders and developed countries.²⁴⁰

TRIPS flexibilities are only available to a country if that country's domestic law permits some form of compulsory licensing.²⁴¹ Thus, countries must enact legislation and have administrative procedures in place before they can take advantage of TRIPS flexibilities and issue compulsory licenses.²⁴²

²³⁶ See Germano, *supra* note 128, at 279.

²³⁷ *Id.* at 292 (noting that Thailand began importing generic medicines only five weeks after it issued a compulsory license).

²³⁸ Rosenberg, *supra* note 22.

²³⁹ See Germano, *supra* note 128, at 284–85.

²⁴⁰ TREATMENT TIMEBOMB, *supra* note 1, at 17; see also *HIV/AIDS, TRIPS, and Second-Line Therapy*, *supra* note 167.

²⁴¹ TRIPS, *supra* note 177.

²⁴² See Germano, *supra* note 128, at 284–85.

However, the procedures for issuing compulsory licenses are complex and cumbersome,²⁴³ and countries often lack the legal capacity and know-how needed to exercise TRIPS flexibilities.²⁴⁴ To overcome this hurdle, organizations such as the World Intellectual Property Organization or the WTO could create technical guidelines to assist countries in establishing TRIPS legislation and administrative procedures.²⁴⁵

In addition, countries that issue compulsory licenses under TRIPS are likely to face backlash from patent holders and developed countries.²⁴⁶ For instance, in 1997, forty-one pharmaceutical companies and the South African Pharmaceutical Manufacturers Association filed a lawsuit against the South African government after it passed legislation to issue compulsory licenses for patented HIV medicines.²⁴⁷ Similar incidents have occurred in Brazil²⁴⁸ and Thailand.²⁴⁹ In addition, both South Africa and Thailand were placed on the United States' "watch list" after they issued compulsory licenses, subjecting them to potential trade sanctions for failing to provide adequate protection for intellectual property.²⁵⁰ The backlash is not confined to countries issuing compulsory licenses; patent holders that oppose compulsory licensing are also likely to face criticism from the international global health community, which can have a significant impact on patent holder behavior.²⁵¹ Developing countries can act in concert with one another and with the international

²⁴³ *Id.* (quoting a WHO representative who cited a "widespread lack of clarity about the options available" and a "lack of local legal and technical expertise to incorporate and implement TRIPS flexibilities in national law and policy" as major obstacles to issuing compulsory licenses). *See also* TREATMENT TIMEBOMB, *supra* note 1, at 17 (noting that there is "impenetrable paperwork" required to exercise and implement TRIPS flexibilities).

²⁴⁴ TREATMENT TIMEBOMB, *supra* note 1, at 17.

²⁴⁵ *See id.* at 18.

²⁴⁶ *Id.* at 17 (citing "heavy political pressure from companies and foreign governments . . . not to use the flexibilities" as reasons why countries may be hesitant to issue compulsory licenses). *See also* HIV/AIDS, TRIPS, and Second-Line Therapy, *supra* note 167 (noting that compulsory licensing has not been used much by low- and middle-income countries because of the repercussions these countries may face from large pharmaceutical companies if they issue compulsory licenses).

²⁴⁷ Mellino, *supra* note 229, at 1368; *see also* Germano, *supra* note 128, at 280–81.

²⁴⁸ A similar incident occurred in 2001 after the Brazilian government threatened to issue compulsory licenses for patented antiretrovirals if pharmaceutical companies did not authorize generic production of the patented medicines in Brazil. Germano, *supra* note 128, at 281.

²⁴⁹ In 2007, Thailand issued several compulsory licenses for antiretroviral drugs owned by Merck and Abbott. HIV/AIDS, TRIPS, and Second-Line Therapy, *supra* note 167. Shortly thereafter, Abbott announced that it would not sell seven of its newest pharmaceutical products in Thailand. *Id.*

²⁵⁰ *See* Mellino, *supra* note 229, at 1376–77; HIV/AIDS, TRIPS, and Second-Line Therapy, *supra* note 167.

²⁵¹ Mellino, *supra* note 229, at 1369. The lawsuit against South Africa was eventually dropped after the pharmaceutical companies faced backlash from the international community, including MSF. *Id.*

community to place pressure on patent holders or developed countries seeking to limit the exercise of TRIPS flexibilities to deter such action in the future.²⁵²

While compulsory licensing is not without controversy, encouraging developing countries to issue compulsory licenses can serve as a favorable, legal solution to overcome patent barriers imposed by TRIPS and respond to the treatment timebomb. In some cases, the mere willingness of developing countries to engage in compulsory licensing can serve as a sufficient incentive for patent holders to voluntarily participate in the MPP.²⁵³ However, because compulsory licenses must be issued on a country-by-country basis, collective action by developing countries is needed to increase access to medicines on the urgent timeframe required by the treatment timebomb.²⁵⁴ Only a concerted effort by low- and middle-income countries to issue compulsory licenses for patented HIV medicines can represent a viable solution to increasing participation in the MPP and facilitating access to new and more affordable antiretrovirals.

CONCLUSION

Significant progress has been made in recent decades to reduce drug prices and increase access to antiretrovirals to respond to the global HIV/AIDS crisis.²⁵⁵ However, the global health community is facing an impending treatment timebomb, due in part to the increased patenting of HIV medicines in developing countries in compliance with TRIPS.²⁵⁶ A new collective action mechanism is needed to facilitate access to patented HIV medicines to overcome patent barriers underlying the treatment timebomb that have resulted from the implementation of TRIPS.²⁵⁷

The MPP is a new approach to managing intellectual property designed to increase access to new and more affordable antiretroviral treatments that was created to respond to the treatment timebomb and overcome patent barriers

²⁵² See Germano, *supra* note 128, at 294 (noting that by acting together, countries will have greater strength when going up against pharmaceutical companies and developed countries); Mellino, *supra* note 229, at 1369.

²⁵³ GOULDING & PALRIWALA, *supra* note 14, at 13; see also Germano, *supra* note 128, at 283.

²⁵⁴ See Bermudez & 't Hoen, *supra* note 19, at 39 (noting that compulsory licensing is less likely to reach economies of scale rapidly because they must be issued on a country-by-country basis).

²⁵⁵ See *supra* note 21 and accompanying text.

²⁵⁶ See 't Hoen et al., *Driving a Decade of Change*, *supra* note 6, at 1, 7–8.

²⁵⁷ *Id.* at 1, 7.

imposed by TRIPS.²⁵⁸ By pooling HIV medicine patents in a single entity, the MPP makes it easier for generic manufacturers to gain access to all the patents needed to develop and produce new combination and pediatric treatments.²⁵⁹ The MPP faces problems in attracting key patent holders to the pool and concluding broad licensing agreements, limiting its ability to effectively respond to the treatment timebomb.

This Comment has argued that the MPP is a valuable tool to increase access to new and more affordable HIV medicines if the incentives to participate can be increased. Compulsory licensing provides a legal solution under TRIPS to increase participation in the MPP and overcome patent barriers imposed by TRIPS. However, compulsory licenses must be issued on a country-by-country basis.²⁶⁰ As a result, a concerted effort by developing countries hardest hit by the HIV/AIDS epidemic and least able to provide affordable treatment is needed to make the MPP more effective at increasing access to new and more affordable HIV medicines.

While compulsory licensing represents a viable solution to increasing participation in the MPP to facilitate access to HIV medicines in developing countries, a patent pool is only one of a broader set of policy changes needed to increase access to treatment in response to the global HIV/AIDS crisis.²⁶¹ More funding for drug donation programs and research for new treatments, as well as support for global health initiatives from developed countries and pharmaceutical companies, is needed to ensure that access to medicines is protected “as a fundamental component of the human right to health.”²⁶² In the meantime, however, developing countries can collectively exercise their compulsory licensing flexibilities to push for more participation in the MPP and ensure that patent barriers imposed by TRIPS are not jeopardizing the ability to respond to the impending HIV/AIDS treatment timebomb.

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²⁵⁸ *Id.* at 8.

²⁵⁹ *See* Rosenberg, *supra* note 22.

²⁶⁰ Bermudez & ‘t Hoen, *supra* note 19, at 39.

²⁶¹ *See* ‘t Hoen et al., *Driving a Decade of Change*, *supra* note 6, at 1.

²⁶² *Id.*

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