

5 Patent Pooling in Public Health

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In recent years, patent pooling has emerged as a mechanism to address some of the innovation and access challenges relating to health technologies. While patent pools have existed for several decades in other fields of technology, it is a relatively new concept in the biomedical and public health fields, where it has been adapted to pursue public health objectives. The patent pooling model represents a new type of public–private partnership (PPP) in health that relies on the licensing of patents on access-oriented terms to enable multiple third parties to develop and/or supply patented health technologies in a given geography.¹

This chapter first outlines the concept of patent pooling as it has evolved over recent years in the public health field. It then reviews its practical application in HIV through the establishment of the Medicines Patent Pool (MPP), and its subsequent expansion into hepatitis C and TB. The MPP is the first patent pool in public health designed to enhance access to affordable medicines in developing countries through the negotiation of access-oriented and transparent voluntary licences with the pharmaceutical industry. The chapter concludes with an analysis of the potential applicability of the patent pooling model in other areas by identifying the kinds of public health challenges that such a model could contribute to addressing in the context of meeting the health-related sustainable development goals (SDGs).

I The Concept of Patent Pooling in Public Health

Patent pools have long existed in various fields of technology. Early examples of patent pools include one for sewing machines in the mid-nineteenth century and the aircraft patent pool established during World War I to ensure manufacturers could have the licences needed to manufacture new airplanes.² In recent decades, patent pools have prospered primarily in the information and communication technology field, where they have often been linked to technical standards negotiated under one of the major

* The views expressed in this article are those of the author and do not necessarily represent those of the Medicines Patent Pool.

¹ For an overview of different models of public–private partnerships in health, see Kent Buse & Gill Walt, *Global Public–Private Partnerships: Part II – What are the Health Issues for Global Governance?*, 78 BULL. WORLD HEALTH ORGAN. (2000).

² Robert P. Merges, *Institutions for Intellectual Property Transactions: The Case for Patent Pools* (1999).

standard-setting organisations. In such cases, patent pools have generally been established as private consortia of patent holders, each owning intellectual property on technology considered “essential” to the implementation of that standard. By participating in the patent pool, patent holders generally commit to licensing the technology to each other and to third parties on fair, reasonable, and nondiscriminatory terms to enable the manufacturing of products that comply with the standard in question. In some cases, the administration of the patent pools themselves has been delegated to specialized entities.³

Calls for patent pooling in the biomedical field began with the rise in biotechnology patenting in the early 2000s and focused on enabling access to intellectual property on key research tools or platform technology needed by other innovators to undertake further research and development. For example, in December 2000, the United States Patent and Trademark Office (USPTO) proposed the establishment of a patent pool as a possible solution to concerns about access to biotechnology patents. Despite attempts to ensure genomic sequences remained in the public domain,⁴ the surge in patenting of genomic sequences raised some concerns that further pharmaceutical research and development could be hampered without widespread licensing of such research tools. A patent pool, it was argued, could “provide for greater innovation, parallel research and development, removal of patent bottlenecks, and faster product development.”⁵

A specific example of the need for a patent pool-type mechanism to overcome multiple overlapping patents on genomic sequences emerged following the outbreak of severe acute respiratory syndrome (SARS) in 2002–2005. The filing of patent applications on the genomic sequence of the coronavirus responsible for SARS by several institutions led to discussions on the establishment of a patent pool.⁶ The patent pool would issue licences on essential patents on a nonexclusive basis and enable developers to work on the development of vaccines for the benefit of all stakeholders.⁷ It was also hoped that a patent pool for SARS could set a helpful precedent that might lead to the establishment of analogous pools for other disease areas, such as malaria, tuberculosis, or avian influenza. The subsequent end of the outbreak removed the sense of urgency and the patent pool was never established.

In 2006, the World Health Organization (WHO) Commission on Intellectual Property Rights, Innovation and Public Health (CIPRH) reviewed the arguments for the establishment of patent pools in public health and recognized that patent pools on upstream technologies could be useful to promote innovation relevant to developing countries.⁸

³ *Id.*

⁴ Jorge Contreras, *Bermuda’s Legacy: Policy, Patents, and the Design of the Genome Commons*, 12 MINN. J. L. SCI. & TECH. 61 (2011).

⁵ U.S. PATENT AND TRADE OFFICE [USPTO], PATENT POOLS: A SOLUTION TO THE PROBLEM OF ACCESS IN BIOTECHNOLOGY PATENTS? (2000), www.uspto.gov/web/offices/pac/dapp/opla/patentpool.pdf (last visited Nov. 23, 2017).

⁶ See, e.g., James H.M. Simon et al., *Managing Severe Acute Respiratory Syndrome (SARS) Intellectual Property Rights: The Possible Role of Patent Pooling*, 83 BULL. WORLD HEALTH ORG. 707 (2005), www.who.int/bulletin/volumes/83/9/707.pdf (last visited Nov. 23, 2017).

⁷ World Trade Organization [WTO], World Intellectual Property Organization [WIPO], World Health Organization [WHO], *Promoting Access to Medical Technologies and Innovation* 118 (2012).

⁸ *Report of the Commission on Intellectual Property Rights, Innovation and Public Health*, WHO (2006).

The report suggested that the relative lack of market incentives for technologies that are particularly needed in developing countries could enable agreements that would otherwise be more difficult to achieve.

The subsequent WHO Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property (GSPOA) went further by recognizing the role patent pools could play not only to facilitate innovation, but also to promote access to new health products. In adopting the GSPOA, the World Health Assembly recommended the development of new mechanisms to promote access to key health-related technologies and specifically called for examining the “feasibility of establishing voluntary patent pools of upstream and downstream technologies to promote innovation of and access to health products and medical devices.”⁹

To follow up on certain elements of the GSPOA, the WHO established a Consultative Expert Working Group on Research and Development (CEWG) that was to focus on issues relating to the financing and coordination of R&D for diseases that disproportionately affect developing countries. In reviewing proposals from various stakeholders, the CEWG noted the potential for combining patent pools with possible incentive mechanisms such as prize funds to promote innovation for new formulations needed in developing countries. Moreover, the CEWG recommended patent pools (and in particular downstream pools) as cost-effective approaches to improving access in developing countries and as a way of delinking the cost of R&D from the final price of products. The discussion on “de-linkage” is one that has gathered significant attention in international discussions on the financing of R&D for diseases that disproportionately affect developing countries and is discussed in some detail in the chapter by Frederick Abbott in this volume.¹⁰

The concept of patent pooling has therefore evolved significantly from the way it has been applied in other fields of technology, where it has often been implemented through private consortia to facilitate product development and enable interoperability between products. In public health, patent pooling has been put forward as a mechanism for public health management of IP through a partnership between an entity with a public health mandate, on the one hand, and private pharmaceutical companies, on the other. Public health patent pools aim to improve access to health technologies, particularly in developing countries, and facilitate further innovation through nonexclusive voluntary licensing.¹¹

⁹ *Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property*, WHO 13 (2011), www.who.int/phi/publications/Global_Strategy_Plan_Action.pdf (last visited Nov. 23, 2017).

¹⁰ Frederick M. Abbott, Chapter 2, *infra*; see also WHO, *Research and Development to Meet Health Needs in Developing Countries: Strengthening Global Financing and Coordination. Report of the Consultative Expert Working Group on Research and Development: Financing and Coordination* (2012) [hereinafter WHO, Research and Development], <http://apps.who.int/iris/bitstream/10665/254706/1/9789241503457-eng.pdf?ua=1> (last visited Nov. 23, 2017).

¹¹ Other initiatives to establish IP pooling-type mechanisms in the biomedical field include the Pool for Open Innovation against Neglected Tropical Diseases proposed by pharmaceutical company GSK; WIPO Research, a platform established in 2011 to enable access to IP, technology, and know-how for the development of medical products for neglected tropical diseases, malaria, and tuberculosis; and Librassay, a patent pool for diagnostics and tools in support of personalized medicine and health care administered by MPEG-LA.

II Patent Pooling in HIV

The first patent pool with a clear public health mandate was established in 2010 following a decision by the Executive Board of UNITAID, a publicly funded global health initiative that is housed by the WHO.¹² With its initial mandate in HIV, the Medicines Patent Pool's mission is "to improve health by providing patients in low- and middle-income countries with increased access to quality, safe, efficacious, more appropriate and more affordable health products, through a voluntary patent pool mechanism."¹³

A *The General MPP Model*

The Medicines Patent Pool (MPP) operates as a nonprofit voluntary licensing mechanism through partnerships with the pharmaceutical industry (originator and generic) that facilitate access and promote innovation. Specifically, the MPP aims to:

- Improve access to more affordable quality-assured HIV medicines in developing countries by enhancing competition among manufacturers
- Enable the development of formulations adapted to developing country needs, such as paediatric formulations
- Facilitate the development of fixed-dosed combinations or "three-in-one pills" that combine various active pharmaceutical ingredients into a single dosage form

It operates by negotiating licences with patent holders and in turn licensing those patents to multiple manufacturers. Such manufacturers are then able to develop the licensed medicine (including new formulations and combinations) and make it available in a defined set of developing countries in exchange for royalties. Figure 5.1 provides a visual overview of how the MPP operates.

B *Terms and Conditions in MPP Access-Oriented Licences*

Given its public health mandate, the MPP works to include terms and conditions in its licences that are important from a public health perspective. Examples of key terms and conditions in MPP access oriented licences include:

- Broad geographical scope allowing sales by generic manufacturers in countries that are home to up to 94 percent of people living with HIV in low- and middle-income countries and 99 percent of children with HIV globally; this includes 55–80 percent of middle-income countries, depending on the licence;
- Ability to sublicense in a nonexclusive and nondiscriminatory manner to multiple generic manufacturers;
- Permission to develop new formulations of existing medicines (such as new paediatric formulations) and to combine several medicines into fixed dose combinations

¹² UNITAID is a global health initiative, established to provide sustainable, predictable, and additional funding to significantly impact on market dynamics to reduce prices and increase the availability and supply of high quality drugs and diagnostics for the treatment of HIV/AIDS, malaria, and tuberculosis for people in developing countries. It is hosted by the World Health Organization. On the establishment of the MPP, see Memorandum of Understanding, Jun. 8–9, 2010, MPP-UNITAID, EB12/R7.

¹³ Memorandum of Understanding, Jun. 8–9, 2010, MPP-UNITAID, EB12/R7.

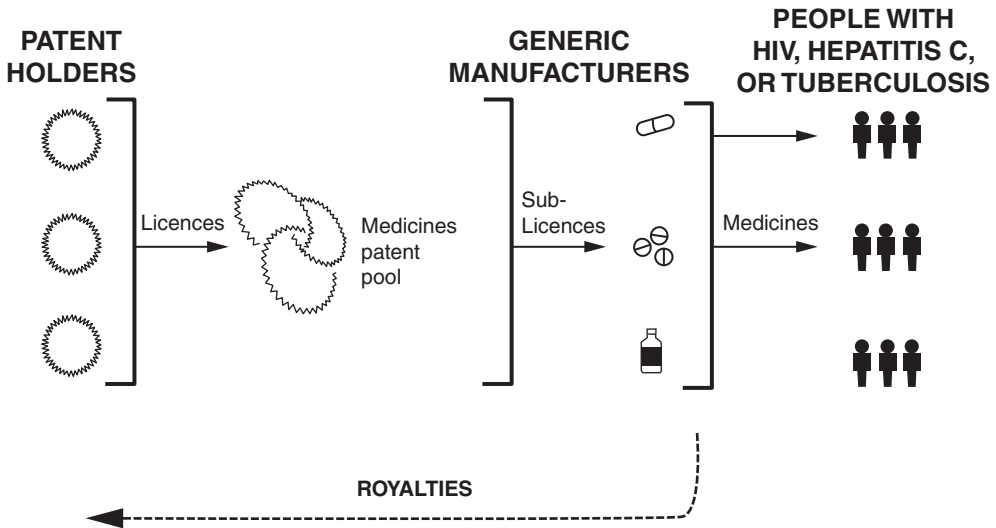


Figure 5.1. The Medicines Patent Pool model.

Flexibility for licensees to supply outside the licensed territory when no patents are being infringed or where countries outside the licensed territory issue compulsory licences;

Reasonable royalty rates, where necessary, to enable broad geographical scope, including differentiated royalties according to a country's per capita income;

Freedom by licensees to challenge any of the licensed patents;

Waivers on data exclusivity, where applicable;

Obligation to meet strict quality assurance requirements;

A key guiding principle for the MPP during its negotiations has been to enable access to new patented treatments in as many low- and middle-income countries as possible while ensuring that the licence itself does not constitute an additional barrier to access for countries not included in the licence. Hence provisions in many of MPP licences enabling supply by licensees outside the licensed territory if no patents are being infringed.

Concerns have sometimes arisen about MPP licences not including all middle-income countries. MPP licences are the result of negotiations between the MPP and patent holders and have enabled unprecedented geographical coverage for access-oriented licences. Certain countries, however, are perceived as significant commercial markets by the pharmaceutical industry and have remained outside many of the MPP licences. Exceptions have been for paediatric formulations for which geographical scope has often been greater, in view of its more limited commercial importance and key public health significance, or licences with certain public research organizations. In some cases, in order to expand the geographical scope of its licences, the MPP has agreed to focus on the public market only, while exclusivity remains in the more lucrative private market. Public national treatment programs generally provide treatment for the vast majority of people living with HIV, including many of the most vulnerable groups, in the countries included in MPP licences. The focus has therefore been in ensuring competitive supply and affordability in that segment for as many countries as possible.

C Transparency

A key characteristic of MPP licences is that they are all published in full form on the MPP website.¹⁴ This has introduced unprecedented transparency in access-oriented licensing of pharmaceuticals.¹⁵

The decision to make all agreements public was made by the MPP Board early on in the existence of the MPP, as part of its transparency policy.¹⁶ This precommitment to transparency of the licences it negotiates has enabled external third-party review of the terms and conditions of licences. Moreover, it has contributed to setting new standards in voluntary licensing by encouraging a healthy debate on terms and conditions that could or should be included in access-oriented licences.

The commitment to transparency is not limited to the MPP licences, but also applies to the patent data collected by the MPP. Understanding the patent status of priority HIV medicines in developing countries is complex, as many patent offices do not make such information available through online databases. At the time of its establishment, the MPP set out to collect patent status data for twenty-five HIV medicines in developing countries. Supported by the World Intellectual Property Organization (WIPO) and several other stakeholders, who collaborated in collecting the information from national patent offices, the MPP was able to collect the information for a large number of low- and middle-income countries and has made that information available in an online database now called MedsPaL. The database is an online tool that provides information on the patent and licensing status of over 100 formulations for HIV, hepatitis C, and tuberculosis in more than 110 countries.¹⁷ Information on data exclusivity has recently also been added.

D Governance

In terms of governance, the MPP operates as an independent not-for-profit Swiss Foundation, linked to UNITAID via a Memorandum of Understanding (MOU) through which the operations of the MPP are funded. The first five-year MOU lasted from mid-2010 to end 2015, and was followed by a second five-year MOU from 2016 to 2020. The close link to UNITAID has been important to enable the MPP to become an integral part of the international response to HIV.

The governance board of the MPP is made up of independent experts that represent a broad base of stakeholders including members with past experience in the originator

¹⁴ The full text of MPP licences, as well as summaries of key terms and conditions, are available at: *Licenses in the MPP*, MEDS. PATENT POOL, www.medicinespatentpool.org/current-licences/ (last visited Jun. 17, 2017).

¹⁵ A recent analysis by the Access to Medicines Index concluded that “based on an analysis of the licences available for examination, those negotiated via the Medicines Patent Pool provide licensees with the highest level of flexibility and broadest geographic scope.” ATM Index 2014, at 105, <https://access-to-medicines-foundation.org/media/atmf/2014-Access-to-Medicine-Index.pdf> (last visited Nov. 23, 2017) (last visited Nov. 23, 2017).

¹⁶ See *The Medicines Patent Pool Transparency Policy*, MPP, www.medicinespatentpool.org/wp-content/uploads/MEDICINES+PATENT+POOL+TRANSPARENCY+POLICY-1.pdf (last visited May 31, 2016).

¹⁷ MEDSPAL, www.medsPal.org (last visited Oct. 14, 2016).

and generic pharmaceutical industry, civil society and patient groups, government, product development partnerships, and international organizations. In addition, an Expert Advisory Group composed of twenty-two experts is in charge of advising the MPP staff and the Board on the licences being negotiated. The group has played a central role in the MPP negotiations as part of the necessary checks and balances to ensure that licences negotiated by the MPP maintain high public health standards and are consistent with its mandate and objectives. It includes individuals with wide-ranging expertise (public health, intellectual property, economics, research and development, HIV, TB, and HCV) and with experience in organizations representing the communities of people with the three diseases (HIV, HCV, and TB).

E Prioritizing Products for In-Licensing

One of the first steps for the MPP was to establish a list of priority medicines for in-licensing based on medical and IP criteria. The idea was to ensure that the work of the MPP focuses on the licensing of products that are important from a medical perspective and that are patent-protected in developing countries with significant patent term left to expiry. The prioritization is repeated on an annual basis to ensure MPP priorities take into account the most recent clinical data, as well as changes in patent status.¹⁸

The medical prioritisation is undertaken in close collaboration with the WHO and with inputs from a group of experts with significant experience in resource-limited settings. The WHO treatment guidelines are the starting point for products that were already on the market. However, MPP's prioritization also assesses pipeline medicines that are still under development in order to accelerate generic availability of new medicines, shortly after they are approved.

The IP prioritization required collecting patent status data on twenty-five HIV medicines from a large number of developing countries. This information proved difficult to obtain and required direct interaction with many national and regional patent offices from around the world, particularly many that do not make such information regularly available through the Internet. Support from WIPO was important in establishing contacts with the national patent offices and collecting the necessary data. Having collected the patent data, several stakeholders, including procurement agencies purchasing medicines on behalf of developing country governments, requested the MPP to share that data, as it represented valuable information that was otherwise not available. The patent data was therefore published online in what has now become MedsPaL, an online tool that provides information on the patent and licensing status of over 100 formulations for HIV, hepatitis C, and tuberculosis in more than 110 countries.¹⁹

Based on the results of the prioritization, the MPP invites patent holders of priority medicines to consider licensing to the MPP on transparent and public-health oriented terms and conditions such as those outlined in part A.

¹⁸ For the most recent version, see *Target Medicines*, MEDS. PATENT POOL, www.medicinespatentpool.org/ourwork/target-medicines/ (last visited Jun. 17, 2017).

¹⁹ MedsPaL is available at www.medsPAL.org (last accessed on 14 October 2016).

F MPP's Collaborative Partnerships

At the time of the establishment of the MPP, the Human Rights Council “welcome(d) the creation of the Medicines Patent Pool Foundation by UNITAID, with a view to improving access to appropriate, affordable antiretrovirals in developing countries.”²⁰ The resolution expressed its concern that, for millions of people throughout the world, the full realization of the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, including through access to medicines that are safe, effective, and affordable, still remained a distant goal. The MPP was therefore viewed as a mechanism that could contribute to the realization of this human right, at least in relation to HIV.

During its first year in existence the MPP received similar endorsements from a number of other international organizations and international policy processes, which helped to establish its credibility and legitimacy, including with the pharmaceutical companies the MPP aimed to partner with.²¹ For a nascent institution these endorsements were critical in signalling the expectation of the international community for key stakeholders to work with the Medicines Patent Pool.

In addition to high-level endorsements, the MPP also set out to forge partnerships with many of the leading organisations in the public health and IP fields in order to benefit from the institutional support, networks, and expertise of such organizations. This included, for example, collaboration with the WHO in many different areas (prioritisation of products for in-licensing; quality assurance; forecasting of ARV demand), which resulted in the establishment of a formal workplan of collaborative activities in 2014. MPP also sought out collaboration with the WIPO, in particular to collect patent information from developing countries, which was key for preparing for licensing negotiations. It also formed partnerships with other leading organizations working in the field of paediatric HIV through the establishment of the Paediatric HIV Treatment Initiative,²² which is working with the pharmaceutical industry to accelerate the development of needed paediatric formulations. Additionally, it collaborated with the Global Fund in the context of the latter's market dynamics strategy to ensure that uptake of MPP licences is coordinated closely with the leading funders of the HIV response.

Significant efforts were also devoted to establishing and strengthening collaboration with governments, particularly those from countries with high HIV prevalence or where MPP licences could potentially achieve the greatest public health impact. A key objective was to gather data on treatment needs, prices, and procurement challenges being faced by governments that could be used to strengthen the case for the inclusion of additional countries in the geographical scope of MPP licences. Partnerships are also being established with national patent offices, some of which have formally committed to regularly providing the patent data needed by the MPP for inclusion in MedsPaL.

²⁰ Human Rights Council Res. 15/6, U.N. Doc. A/HRC/15/L.28 at 6 (Sep. 27, 2010).

²¹ Thus, between May and July 2011, the MPP was mentioned as an important mechanism in the UN Political Declaration on HIV/AIDS of the UN General Assembly, the Deauville declaration of the G8 and the WHO Global Health Sector Strategy for HIV/AIDS 2011–16.

²² This is an initiative launched by the MPP, the Drugs for Neglected Diseases initiative (DNDi), and UNITAID, later joined by the Clinton Health Access Initiative (CHAI) and the WHO as technical partner, which aims to accelerate the development and rollout of needed HIV pediatric formulations.

Furthermore, the establishment of consultative mechanisms with leading civil society institutions and community groups was essential in consolidating the legitimacy of the MPP, to better understand the needs on the ground, discuss possible licensing terms and conditions that could be used in licences, and advance the work of the MPP to addressing overall access challenges in different countries and complement other initiatives.

Last but not least, the MPP model itself is based on partnerships with the pharmaceutical industry with which the MPP signs licences and engages regularly to ensure new patented medicines become available in developing countries at affordable prices soon after their introduction in high income countries. Originator partners have included the leading pharmaceutical companies operating in the field of HIV such as AbbVie, Bristol-Myers Squibb, Gilead Sciences, MSD, Roche and ViiV Healthcare. On the generic side, twenty-five companies have partnered with the MPP to develop and supply the new ARVs. In some cases, this includes developing new formulations that address specific gaps.

G *Lessons from HIV for Other Diseases*

Since its establishment in 2010, the MPP has entered into voluntary licences with seven patent holders on thirteen HIV medicines and one technology that can be used for the development of nano-formulations of HIV medicines. It has sub-licensed to thirteen generic manufacturers who have already supplied 17 million patient/years of WHO-recommended HIV medicines to 127 developing countries.

By the end of 2017, the work of the MPP had enabled US\$ 239 million in savings to the international community through the purchase of more affordable treatments. This is equivalent to one year of first-line treatment for over 6 million people. With the coming to market of generic versions of new ARVs, it is estimated that savings from MPP licences would reach US\$ 2.3 billion over the coming years, enabling significantly more people to access needed HIV medicines in developing countries and contributing to the achievement of Sustainable Development Goal 3.²³

A key objective of the MPP has also been to accelerate availability of quality assured generics of new HIV medicines for use in developing countries. This is achieved by negotiating voluntary licences with patent holders as early as possible in the lifecycle of the products, in some cases even before they receive regulatory approval, which enables generic manufacturers to begin development earlier. In the past, it has taken between five to ten years for new ARVs approved by the US Food and Drug Administration to become available as quality assured generics for use in developing countries.²⁴ And it took even longer to have more than two generic manufacturers competing on the market. Early licensing by the MPP, including the preparation of joint forecasts with the WHO and technical support to licensees where appropriate, is helping to facilitate and accelerate the development process.²⁵ This is contributing to significantly reducing this timeline and enable many developing countries to access new treatments at affordable prices sooner.

²³ Sandeep Juneja, et al., *Projected savings through public health voluntary licences of HIV drugs negotiated by the Medicines Patent Pool (MPP)*, PLoS ONE 12(5): e0177770 (2017), available at: <https://doi.org/10.1371/journal.pone.0177770>; *Five Years of Patent Pooling in Public Health*, MPP (2015); Esteban Burrone and Greg Perry, *Ensuring New Medicines Reach Those in Most Need*, 2 LANCET HIV e362 (2015).

²⁴ *Id.*

²⁵ See also *Progress and Achievements of the Medicines Patent Pool 2010–2015*, MPP (2015).

The experience of the MPP in HIV has provided a concrete example of how patent pooling can contribute to addressing some of the innovation and access challenges relating to health technologies more generally. While the design of the HIV patent pool was guided by the specific circumstances in HIV, some of these circumstances may also apply to other areas in public health.

From an access perspective, the model was predicated on new patented medicines already on the market and a need for access in developing countries that could best be met through competition among multiple manufacturers to reduce the price to affordable levels. From an innovation perspective, the model sought to address the need for follow-on innovation in relation to products needed mostly in developing countries (e.g., paediatric formulations for HIV treatment) and for products that require combining technology patented by more than one entity (fixed dose combinations).

In November 2015, following extensive consultations, the mandate of the MPP was expanded to hepatitis C and tuberculosis.²⁶ While there are significant differences between the two disease areas, in both cases there are new medicines that have recently obtained regulatory approval or are in late-stage development that have patents pending or filed in several developing countries. There are significant access needs in low- and middle-income countries, and sustainable supply through competition among manufacturers could contribute to addressing some of the access gaps. The specific circumstances, however, are very different between the two disease areas and these differences need to be reflected in the way the model is implemented and the kinds of provisions that may be included in the licences.

In terms of innovation, while there has been significant private investment in R&D for hepatitis C in recent years, leading to multiple new HCV treatments reaching the market, investments in tuberculosis R&D have been very limited, with only two new products have reached the market in the past forty years. Thus, while patent pooling in HCV will likely be primarily aimed at facilitating affordable access for products that are already on the market, patent pooling in the field of tuberculosis could be very important in relation to upstream technology to enable collaborative research and the development of new TB regimens. Hence, the first MPP licence in HCV was for a medicine already widely used in high income markets that had recently been included in the WHO Model Essential Medicines List (EML). The objective of the licence, therefore, was to enable manufacturing of generic versions of the medicines for the competitive supply in 112 low- and middle-income countries. The first MPP licence in TB, on the other hand, was for a medicine that has been stalled in clinical development for a number of years. The MPP licence is expected to contribute to accelerating its development by facilitating access to the IP by other potential developers.²⁷

²⁶ See Press Release, *The Meds. Patent Pool Expands Mandate to Hepatitis C and Tuberculosis Treatment*, MPP (Nov. 6, 2015), www.medicinespatentpool.org/the-medicines-patent-pool-expands-mandate-to-hepatitis-c-and-tuberculosis-treatment/ (last visited Nov. 23, 2017).

²⁷ See *The Medicines Patent Pool Announces First License for Tuberculosis Treatment*, MPP (Jan. 25, 2017), www.medicinespatentpool.org/the-medicines-patent-pool-announces-first-licence-for-tuberculosis-treatment/ (last visited Nov. 23, 2017).

III Patent Pooling and its Potential Applicability to Other Public Health Challenges

While the previous section provides an overview of one specific experience in the implementation of patent pooling to address access and innovation challenges in public health, this part will look at its broader applicability. The following provides an overview of the kinds of challenges in public health that this new kind of PPP can contribute to address. These include:

- (1) Patent pooling to enhance access to affordable health products in poor countries, sectors, and regions
- (2) Patent pooling to facilitate follow-on innovation
- (3) Patent pooling to facilitate R&D and access in combination with innovative incentives
- (4) Patent pooling to overcome “patent thickets”

A Patent Pooling to Enhance Access to Affordable Health Products in Poor Countries, Sectors, and Regions

Underlying this model is the idea that competition between multiple manufacturers can be an effective way to bring prices down to affordable levels for many health products, therefore facilitating access, particularly for people, countries, sectors, or regions that would otherwise be unable to afford them. Access-oriented licensing to multiple manufacturers through a patent pool enables competition to take place where it may have otherwise not been possible and facilitates access to needed medicines to poor countries or poor sectors of society. The brokering role of a public health organization like a patent pool enables a reduction in transaction costs for all parties and ensures that licences include provisions that are key to ensure consistency with public health principles. This includes, for example, terms that enable broad access to as many people as possible, in particular, the most vulnerable, and that ensure that the licence removes as many barriers to access as possible without introducing new barriers or restrictions that may negatively affect the attainment of its public health goals.

While to date this has only been applied to HIV, and more recently to HCV, its application could potentially also be extended to other health technologies that are patented in developing countries and for which widespread nonexclusive licensing through a patent-pool-like mechanism could contribute to enable affordable access in developing countries. This could include, for example, patented health technologies needed to achieve the Sustainable Development Goals, such as certain medicines for other communicable diseases (SDG target 3.3), noncommunicable diseases (SDG target 3.4), essential medicines (SDG target 3.8), or vaccines (SDG target 3.8).

One specific area that may merit particular attention is patented medicines that are included in the WHO EML. In its submission to the UN High Level Panel on Access to Medicines, WHO recommended “the expansion of the MPP to all disease areas, and for all patented essential medicines on the WHO EML to be licensed into the Pool.” Another example is a recent statement by pharmaceutical company GSK, of its intent to “commit its future portfolio of cancer treatments to patent pooling” and its interest in exploring this possibility with the MPP.

B Patent Pooling to Facilitate Follow-on Innovation

Licensing through a patent pool can provide a simple mechanism for entities engaging in follow-on innovation to obtain access to the necessary IP to undertake further research and development. This could be, for example, entities seeking to develop new formulations of patented medicines that address specific public health needs in developing countries for which there are limited market incentives.

In HIV, this model is being applied to the development of new adapted formulations of existing HIV medicines, such as paediatric formulations. With the MPP's entry into tuberculosis, the model could also be used to facilitate the re-purposing of certain antibiotics for use in TB. There may be many other opportunities in which follow-on innovation could be facilitated through nonexclusive voluntary licensing. In these instances, patent pooling can contribute to making patented medicines available to multiple developers on public health-oriented terms and contribute to further innovation and the development of new health products.

C Patent Pooling to Facilitate R&D and Access in Combination with Innovative Incentives

There are instances in which additional incentives are being considered as a manner to promote research and development in areas in which existing commercial incentives may be insufficient. Linking such incentives to licensing models that are clearly anchored in public health principles has been proposed as one approach in such circumstances. Two specific examples that have recently attracted significant attention in which such an approach could potentially be applied are (a) new antibiotics to combat antimicrobial resistance (AMR), and (b) new regimens for the treatment of tuberculosis.

1 The Case of Antimicrobial Resistance

The recent WHO Global Action Plan on Antimicrobial Resistance²⁸ describes the urgent need for new antibiotics and for increased investments in research and development. Discussions are ongoing on possible new incentive mechanisms that would contribute to strengthen the current antibiotic pipeline.²⁹ There is general agreement that incentives should be designed in a manner that de-links the financing of research and development from the sales of new antibiotics and for a need to consider innovation, access, and conservation holistically. There is also broad recognition that there may be a need for novel approaches to IP management in this area, including by the pharmaceutical industry in the 2016 Davos statement on combating antimicrobial resistance.³⁰

²⁸ *Global Action Plan on Anti-Microbial Resistance*, WHO (2015), http://apps.who.int/iris/bitstream/10665/193736/1/9789241509763_eng.pdf?ua=1 (last visited Nov. 23, 2017).

²⁹ See, e.g., *Securing New Drugs for Future Generations: The Pipeline Of Antibiotics*, REVIEW ON ANTIMICROBIAL RESISTANCE [AMR] (2015); Maurie-Paule Kieny, *Creating and Intergovernmental Consortium for New Antibiotics: a New Development Model*, AMR Control 26 (2015); *Towards a New Global Business Model for Antibiotics: Delinking Revenue From Sales*, Chatham House (2015).

³⁰ *Declaration by the Pharmaceutical, Biotechnology and Diagnostics Industries on Combating Antimicrobial Resistance (AMR)*, INT'L FED'N OF PHARM. MFRS. & ASS'N (Jan. 2016), www.ifpma.org/partners-2/declaration-by-the-pharmaceutical-biotechnology-and-diagnostics-industries-on-combating-antimicrobial-resistance-amr/ (last visited Nov. 23, 2017).

Public-health oriented patent pooling can contribute to de-link R&D funding from sales³¹ and a number of proposals have identified patent pooling as a way in which IP on new antibiotics could be managed in a public health-oriented manner.³² This can contribute to ensuring affordable access for those in need, within a global development and stewardship framework, such as the one discussed at the WHO.³³ Further analysis would be needed to explore its feasibility and understand how the model could be best adapted to fulfil this role.

2 The Case of Upstream Tuberculosis

Combining patent pooling with incentive mechanisms has also been proposed in the context of addressing some of the challenges in TB drug development. The “3P: Pull, Pool, Push” project aims to improve financial incentives for TB drug development both at the pre-clinical and clinical stage and ensure access and affordability of new regimens once developed.³⁴ The “push” and “pull” incentives would be linked to the pooling of intellectual property in order to ensure open collaborative research can take place leading towards the development of new TB regimens. In terms of access, the project envisages licensing for the competitive production of the final products to ensure that new TB regimens become available at affordable prices. The initiative is already supported by several leading organizations in the field of tuberculosis, such as the Stop TB Partnership, the TB Alliance, the Union Against Tuberculosis and Heart Disease, and Médecins sans Frontières, and has met with significant interest from some high-burden TB countries.

IV Patent Pooling to Overcome “Patent Thickets”

In certain instances, patent thickets³⁵ on upstream technology can become a barrier to the development of health products. The SARS case mentioned above is one example where concerns were raised that many overlapping patent applications could become a barrier to the development of needed vaccines and diagnostics. Similar concerns have

³¹ WHO, *Research and Development*, *supra* note 10.

³² Kieny, *supra* note 29; Chatham House, *supra* note 29.

³³ World Health Assembly [WHA], *Global Action Plan on Antimicrobial Resistance*, WHA68.7 (May 26, 2015).

³⁴ For proposal selected by WHO European Region as a possible health R&D demonstration project, see *Summary Report on the nomination of Experts and the shortlisting of Health R&D Demonstration Projects*, WHO (2013), www.who.int/phi/implementation/EURO_procedure_for_selection_of_demo_projects.pdf (last visited Nov. 23, 2017); for a summary of the original proposal, see *Accelerating Innovation and Access to Medicines for Tuberculosis through Open Collaboration: A Push, Pull, Pool Approach (“the 3P Project”)*, WHO (2010), www.who.int/phi/implementation/10_summary_EN.pdf (last visited Nov. 23, 2017); and for a more recent summary entitled, see *3P: PULL, POOL, PUSH, Better TB treatment. Faster. Proposal to accelerate innovation and access to new treatment regimens for TB*, THE ACCESS CAMPAIGN, www.msfaaccess.org/sites/default/files/TB_3P2pager_Dec-2015_ENG.pdf (last visited Jun. 18, 2017).

³⁵ While there are many definitions of a “patent thicket,” one that is widely cited definitions is “an overlapping set of patent rights requiring that those seeking to commercialize new technology obtain licenses from multiple patentees.” Carl Shapiro, *Navigating the Patent Thicket: Cross Licenses, Patent Pools, and Standard-Setting*, 1 THE INNOVATION POLY AND THE ECON. 119 (2011).

been raised in relation to other upstream technology (e.g., research tools, genomic sequences, vaccines),³⁶ leading to calls for collaborative licensing models such as patent pools to contribute to addressing them.³⁷ The objective in these cases is to facilitate access to research tools and early stage technology enabling further scientific development.

Conclusion

Public health patent pools represent an innovative type of PPP that can be used to manage privately held IP rights in the public interest. Article 7 of the TRIPS Agreement states that “the protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.” Access-oriented and nonexclusive voluntary licensing through patent pooling mechanisms with a clear public health mandate can contribute to achieving this goal and overcoming a number of access and innovation challenges in the biopharmaceutical field.

As shown in the case of HIV, a patent pool can contribute to spurring further innovation (e.g., in relation to paediatric and fixed dose combinations) and to improve access in developing countries. While the design of the patent pool can vary depending on the specific public health challenge a patent pool is trying to address, a firm grounding in public health principles and close collaboration and partnership with key stakeholders seems central to ensuring that it responds to needs and attracts the interest of patent holders and other partners that need to contribute to its success.

While the patent pooling model has so far only been applied to specific diseases (HIV, HCV, TB), the new SDG framework, with its focus on universal health coverage, calls for consideration to be given to the potential applicability of the model beyond these specific diseases. In particular, it would be timely to explore its applicability in relation to other health technologies facing access and innovation challenges that could potentially be addressed (at least in part) through a PPP model based on licensing and patent pooling. This chapter provides several examples of the potential of public health-oriented patent pools to contribute to the implementation of the SDGs, such as in the field of antimicrobial resistance or in relation to patented essential medicines included in the WHO EML. While all such proposals would need to be studied in detail to explore their feasibility and potential public health impact, the experience in HIV, HCV, and TB provides an interesting model that may be applied or adapted to other circumstances.

³⁶ See Martin Friede et al., *Innovation for Vaccines Against Poverty Diseases: The Need for New Support Mechanisms*, WHO (2014); USPTO, *supra* note 5.

³⁷ See, e.g., CAMBRIDGE UNIVERSITY PRESS, *GENE PATENTS AND COLLABORATIVE LICENSING MODELS: PATENT POOLS, CLEARINGHOUSES, OPEN SOURCE MODELS AND LIABILITY REGIMES* (Geertrui van Overwalle ed., 2009).

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