

Submission to the UN High-Level Panel on Access to Medicines

Prepared by the Medicines Patent Pool¹

Abstract

Voluntary patent pooling in public health is a mechanism for the management of intellectual property (IP) rights that seeks to promote innovation and access, particularly in developing countries. Voluntary patent pools operate within the existing trade and IP framework and can contribute to the realization of “the right to health” and “the right to enjoy the benefits of scientific progress” as guaranteed in the Universal Declaration of Human Rights (UDHR) and in the International Covenant on Economic, Social and Cultural Rights (ICESCR). Voluntary patent pooling also provides a practical example of an approach to promote policy coherence in the field of public health.

This contribution reviews one experience in the implementation of voluntary patent pooling to improve health outcomes. It also analyses other areas in which the concept could potentially be applied to address specific access and/or innovation challenges for health technologies as well as to support the achievement of new health-related Sustainable Development Goals through 2030.

Patent Pooling in Public Health

In recent years, patent pooling has emerged as a mechanism for addressing some of the innovation and access challenges related to essential life-saving health technologies. While voluntary patent pooling has existed for decades in other fields of technology, it is a relatively new concept in the bio-medical field, where it has been adapted to pursue public health objectives. Public health-oriented patent pooling aims to improve access to medicines and facilitate innovation in the development of new products, thereby contributing to the realization of the right to health and the right to enjoy the benefits of scientific progress. By also recognizing the rights of inventors, it is a practical example of a mechanism that promotes policy coherence as sought by the UN High-Level Panel’s Call for Contributions.

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This submission begins by outlining the concept of voluntary patent pooling as it has evolved over recent years in the public health field. It then reviews the Medicines Patent Pool's approach to improving access to HIV medicines through voluntary licensing and voluntary patent pooling initiatives. The authors explore the potential applicability of voluntary patent pooling beyond HIV and the mechanism's role in addressing specific access challenges in these areas. The paper also includes an analysis of how patent pooling contributes to the advancement of human rights and the achievement of the 2030 Agenda for Sustainable Development. It concludes with some considerations for the operational implementation of voluntary patent pools in public health in general.

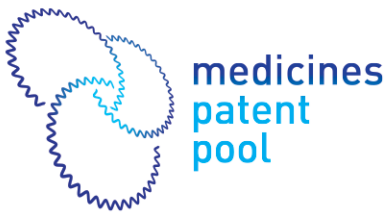
1. The concept of patent pooling in public health

Early calls for patent pooling in the bio-medical field focused on developing mechanisms to enable access to patents on upstream technology in order to facilitate further innovation.ⁱ A specific case followed the outbreak of severe acute respiratory syndrome (SARS) in 2002-2005. The filing of multiple patent applications on the genome of the virus responsible for SARS threatened to stall progress on the development of a vaccineⁱⁱ and thus the international community pushed for the provision of non-exclusive licences to facilitate innovation. While the end of the outbreak removed the sense of urgency and the SARS patent pool was never established, similar patent pools have been proposed for other upstream technologies.ⁱⁱⁱ

In 2006, the WHO Commission on Intellectual Property Rights, Innovation and Public Health (CIPIH) reviewed the arguments for the establishment of patent pools and recognized their potential for upstream technologies. In particular, the CIPIH highlighted their possible use to promote innovation relevant to developing countries.^{iv} The report suggested that the relative lack of market incentives for technologies relating to diseases that disproportionately affect developing countries could enable agreements that would otherwise be more difficult to achieve.

The 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 in facilitating innovation, but also in improving access. In recommending the development of new mechanisms to promote access to key health-related technologies, the GSPOA 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."^v

In reviewing proposals to improve research and development to meet health needs in developing countries, the WHO Consultative Expert Working Group on Research and Development (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.



Patent pools (and in particular downstream pools) were also recommended as cost-effective approaches to improving access in developing countries and as a way of de-linking the cost of R&D from the final price of products.^{vi}

2. Patent Pooling for HIV medicines

UNITAID established the first patent pool with a clear public health mandate in 2010.^{vii} ^{viii} With its initial focus on 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."^{ix}

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

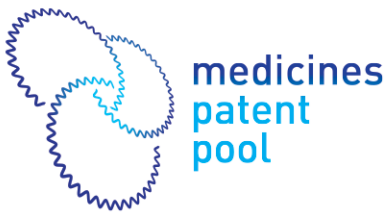
- Improve access to affordable quality-assured HIV medicines in developing countries by enhancing competition among manufacturers leading to reduced prices
- Enable the development of formulations adapted to developing country needs, such as paediatric formulations and fixed-dosed combinations

Given its public health mandate, the MPP works with IP holders to include terms and conditions in its licences that are important from a public health perspective and that promote policy coherence among trade rules, the rights of inventors and the right to health. Examples of key terms and conditions in MPP licences to date include:

- Broad geographical scope allowing sales by generic manufacturers in countries that are home to up to 93.4% of people living with HIV and 99.3% of children with HIV in low- and middle-income countries;
- Ability to sub-license in a non-exclusive and non-discriminatory manner to multiple generic manufacturers;
- Flexibility to sell outside the licensed territory under certain circumstances, including to countries that have issued compulsory licences in accordance with the TRIPS Agreement;
- Reasonable royalty rates (royalty-free for paediatric formulations);
- Freedom to develop new formulations or fixed-dose combinations;
- Waivers on data exclusivity, where applicable;
- Obligation to meet strict quality assurance requirements.

A key characteristic of MPP licences is that they are all published in full form on the MPP website. This practice has introduced significant transparency in access-oriented licensing of pharmaceuticals and contributed to setting new standards.^x ^{xi}

Since its establishment in 2010, the MPP has signed voluntary licences with seven patent holders for 12 HIV medicines, one direct-acting antiviral for hepatitis C, and for one technology that can be used for the development of



nano-formulations of HIV medicines. It has also established collaborations with two additional patent holders (for paediatric formulations as well as a medicine for an opportunistic infection).^{xii} The organisation has sub-licensed to 12 generic manufacturers who have already supplied 7.2 million patient-years of WHO-recommended HIV medicines to 117 low- and middle-income countries.

By mid 2015, the MPP's work had saved the international community USD 119.6 million through the purchase of more affordable treatments. This is equivalent to one year of first-line treatment for approximately 950,000 people.^{xiii}

With the market introduction of generic versions of new ARVs, it is estimated that savings from MPP licences could reach USD 1.4 billion over the coming years, enabling significantly more people to access needed HIV medicines in developing countries. The MPP's initial achievements thus contribute to Sustainable Development Goal 3 and specifically to SDG target 3.3 to end the AIDS epidemic, through, among other initiatives, HIV treatment scale-up.^{xiv}

The MPP seeks to accelerate the availability of quality assured generics of new HIV medicines for use in developing countries as a key objective. The organisation negotiates voluntary licences with patent holders as early as possible, in some cases even before they receive regulatory approval, to enable manufacturers to begin development earlier. The preparation of joint forecasts with the WHO, technical support to licensees where appropriate, and regular reviews of development plans also facilitate and accelerate the development process.^{xv}

The successful experience of the MPP in HIV has provided a concrete example of how voluntary patent pooling and public health-oriented voluntary licensing can contribute to addressing some of the innovation and access challenges relating to health technologies. In November 2015, following requests from certain governments and other stakeholders and extensive consultations, UNITAID extended the mandate of the MPP to hepatitis C and tuberculosis, two areas where significant access and innovation challenges remain.^{xvi}

3. Patent Pooling and its Potential Applicability to Other Public Health Challenges

Currently, the Medicines Patent Pool's mandate is limited to access programmes in these three disease areas. However, after reviewing the MPP's experience in HIV patent pooling, the High-Level Panel may like to explore other areas in which such approaches could promote research, development and innovation in the health sector and facilitate access to new products.

3.1. Patent pooling to enhance access to affordable health products in developing countries

As demonstrated in the case of HIV, non-exclusive voluntary licensing through a patent pool can be a cost-effective mechanism to enhance access to needed health technologies in developing countries. World leaders acknowledged “voluntary patent pooling and other business models which can enhance access to technology and foster innovation,” in the 2015 Addis Ababa Action Agenda, the financing framework for the SDGs.^{xvii} Moreover, according to a recent WHO/WIPO/WTO study, new models of socially responsible licensing, such as patent pools, protect IP rights while ensuring that new medical technologies are available and affordable for underserved communities.^{xviii}

In principle, the model could be applied to other patented health products for which competition among multiple manufacturers could contribute to improving access in developing countries. This could include, for example, patented health technologies needed to achieve the SDGs such as certain medicines for other communicable diseases (SDG target 3.3) non-communicable diseases (SDG target 3.4), essential medicines (SDG target 3.8) or vaccines (SDG target 3.8). The case of medicines included in the WHO Model List of Essential Medicines may merit attention. In each case, the public health need, feasibility of implementation, likely impact, as well as the potential interest of patent holders in participating, would need to be assessed.

3.2. Patent pooling to facilitate R&D and access in combination with innovative incentives

(a) The case of antimicrobial resistance

The recent WHO Global Action Plan on Anti-Microbial Resistance^{xix} reviews the urgent need for new antibiotics and for increased investments. Discussions are ongoing on possible new incentive mechanisms that would contribute to strengthening the current antibiotic pipeline.^{xx} There is general agreement that incentives should be designed in a manner that de-links the financing of R&D from the prices of new antibiotics, in order that companies might be offered improved incentives to develop new antibiotics and to remove their incentives to maximize sales to finance R&D in ways that may accelerate the development of resistance. There is also broad recognition that there may be a need for novel IP-based approaches in this area, recently promoted in a pharmaceutical industry statement on combatting AMR at the World Economic Forum in Davos.^{xxi}

A number of recent proposals have identified patent pooling as a way in which IP on new antibiotics could be managed in a public health-oriented manner.^{xxii} Further analysis is needed to explore their feasibility and to

understand how the current pooling model could be best adapted to the different requirements of fighting antibiotic resistance.

(b) The case of upstream tuberculosis

Combining patent pooling with incentive mechanisms has also been proposed in the context of addressing the challenges in TB drug development. The “3P: Push Pull and Pool 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.^{xxiii} The “push” and “pull” incentives would be linked to the pooling of intellectual property in order to promote open collaborative research to spur 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 are available at affordable prices. The initiative is already supported by several leading TB organisations and is of interest to key countries with high TB prevalence.

3.3. Patent pooling to facilitate follow-on innovation

Licensing through a patent pool can provide a simple mechanism for entities engaged in follow-on innovation to obtain access to the necessary IP to undertake further R&D. This could include, for example, entities seeking to develop new formulations of patented medicines that have limited market potential but that address specific public health needs in developing countries.

In HIV, this model is being applied to the development of new formulations of existing HIV medicines, in particular for children. With the MPP’s entry into tuberculosis, the model could also be used to re-purpose existing drugs for TB patients. There may be many other opportunities in which follow-on innovation could be facilitated through non-exclusive voluntary licensing. In these instances, patent pooling could contribute to making patented medicines available to multiple developers on public health-oriented terms and extend the benefits of scientific progress to more populations.

3.4. Patent pooling to overcome “patent thickets” to access upstream technology

In certain instances, patent thickets^{xxiv} on upstream technology can become a barrier to the development of health products. The SARS case mentioned above is one example of the potential of a large number of overlapping patent applications to block the development of needed vaccines and diagnostics. Similar concerns have been raised in relation to other upstream technology (e.g. research tools, genomic sequences, vaccines),^{xxv} leading to calls for collaborative licensing models such as patent pools.^{xxvi} The objective in these cases is to facilitate access to technology enabling further scientific development.

4. Patent Pooling, the Right to Health and the Right to the Benefits of Scientific Progress

Access to medicines is an integral part of the right to the highest attainable standard of health under international human rights law. General Comment 14 of the UN Committee on Economic, Social and Cultural Rights provides some helpful guidance on the interpretation of the right to health,^{xxvii} outlining a number of principles that are essential including: availability, accessibility, appropriateness and quality. By increasing the availability of affordable and appropriate quality medicines, patent pooling initiatives in public health can contribute to the realization of the right to health.

In the field of HIV, patent pool licences seek to ensure faster availability of new HIV medicines in developing countries. Accessibility at affordable prices is central to the work of the MPP and is achieved through competition among multiple manufacturers, which leads to lower prices. The development of more appropriate formulations that meet the specific needs of people with HIV in developing countries (including children) is also central to the MPP model. Finally, all MPP licences have strict quality assurance provisions.

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”.^{xxviii} The MPP was considered a mechanism that could contribute to the realization of the right to health, at least in relation to one major disease: HIV. More recently, the 2015 Social Forum of the Human Rights Council devoted to access to medicines identified the MPP as a “good practice in promoting access to medicines.”^{xxix}

The right of everyone to share in scientific advancement and its benefits is also part of the Universal Declaration of Human Rights. In this context as well, ensuring that the benefits of science are available and economically affordable is a central feature and very much in line with the objectives of public health patent pools as described above. In addition, access to scientific advances to undertake further research is also critical to the “right to science.” The UN Special Rapporteur’s report on the right to science emphasized approaches that encourage collaboration and the possible use of incentives for entities that are “ready to share knowledge, materials and technologies for product development.” In that context, the report highlighted the role of the HIV patent pool in promoting collaboration and “facilitat[ing] new drug combinations for simpler treatment.”^{xxx} A further report noted that “this “collective management” of patent rights is an approach that might be extended to promote access to other medicines.”^{xxxi}

5. Considerations with respect to implementation

From an operational perspective, public health voluntary licences and patent pools operate within the existing trade and IP framework and do not require changes to international legal instruments. They recognize the rights of inventors, while also recognizing the importance of ensuring that public health considerations guide the management of IP, in particular in addressing access and innovation needs in developing countries.

From an institutional perspective, the governance and institutional structures of patent pools can vary significantly. In the case of the MPP, the organisation was established as an independent, non-profit foundation. It was established and is fully funded by WHO-hosted UNITAID. This arrangement has enabled the MPP to be integrated in the international response to the HIV epidemic, to have the needed political credibility and to work in close partnership with all stakeholders, including governments, civil society, patient groups and industry.

Other patent pool initiatives, such as proposals to establish a patent pool for antibiotics,^{xxxii} would rely on public funding and a governance structure that directly or indirectly includes governments. While this may require significant political buy-in, it also contributes to providing legitimacy to the instrument, which is critical for its success and to attracting patent holder participation. It also ensures that the mandate of the patent pool remains firmly grounded on public health principles.

6. Conclusion

Patent pooling mechanisms contribute to improve policy coherence in rules between rights of inventors, international human rights laws, trade rules, and public health objectives. In accordance with Article 7 of the TRIPS Agreement, patent pools "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."

Voluntary licensing through public health patent pools offers a mechanism to manage IP rights for the public interest, respecting the rights of innovators while promoting access to medicines. Access-oriented and non-exclusive voluntary licensing through patent pooling mechanisms with a clear public health mandate contribute to achieving this goal and overcome a number of access and innovations challenges. In doing so, they also support the realization of the right to health and the right of all to benefit from scientific progress as well as international efforts to reach new Sustainable Development Goals in the future.

ⁱ See for example, USPTO, *Patent Pools: A Solution To The Problem Of Access In Biotechnology Patents?*, December 2000.

ⁱⁱ See for example Simon J. *et al*, “Managing Severe Acute Respirator Syndrome (SARS) Intellectual Property Rights: the Possible Role of Patent Pooling” in *Bulletin of the World Health Organization*, September 2005, 83(9). Also, WHO/WIPO/WTO *Promoting Access to Medical technologies and Innovation*, 2013.

ⁱⁱⁱ See WHO, Friede M *et al*, “Innovation for vaccines against poverty diseases: The need for new support mechanisms” available at:

http://www.who.int/immunization/research/forums_and_initiatives/02_Friede_Business_Model.pdf?ua=1 (accessed on February 15, 2016)

^{iv} WHO, *Report of the Commission on Intellectual Property Rights, Innovation and Public Health 2006*

^v WHO, *Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property*.

^{vi} 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.

^{vii} UNITAID/EB/12/2010/R7

^{viii} 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.

^{ix} Memorandum of Understanding between the MPP and UNITAID

^x 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* available at:

<http://www.accesstomedicineindex.org/>

^{xi} The full text of MPP licences, as well as summaries of key terms and conditions, are available at:

<http://www.medicinespatentpool.org/current-licences/>

^{xii} This includes licences with AbbVie, Bristol-Myers Squibb, Gilead Sciences, MSD, National Institutes of Health, the University of Liverpool and Viiv Healthcare. In addition, collaborations have also been established with Janssen (on paediatrics) and with Roche on a medicine for an opportunistic infection.

^{xiii} Based on a treatment cost of USD 125.68 per patient per year as per GPRM 2014.

^{xiv} MPP, *Progress and Achievements of the Medicines Patent Pool 2010-2015* (2015); E. Burrone and G. Perry, “Ensuring new medicines reach those in most need”, *Lancet HIV*, 09/2015; 2(9):e362-e363

^{xv} Further details available at: MPP, *Progress and Achievements of the Medicines Patent Pool 2010-2015* (2015)

^{xvi} See the independent feasibility studies published on the MPP website in July 2015

^{xvii} Addis Ababa Action Agenda of the Third International Conference on Financing for Development

^{xviii} WHO/WIPO/WTO *Promoting Access to Medical technologies and Innovation*, 2013.

^{xix} WHA resolution 68.7

^{xx} See, for example, AMR Review, *Securing New Drugs For Future Generations: The Pipeline Of Antibiotics*, 2015; Kieny, M.P., “Creating and Intergovernmental Consortium for New Antibiotics: a New Development Model” in *AMR Control*, 2015; Chatham House, *Towards a New Global Business Model for Antibiotics*, 2015

^{xxi} Declaration by the Pharmaceutical, Biotechnology and Diagnostics Industries on Combating Antimicrobial Resistance, January 2016.

^{xxii} Kieny, M.P., “Creating and Intergovernmental Consortium for New Antibiotics: a New Development Model” in *AMR Control*, (2015); Chatham House, *Towards a New Global Business Model for Antibiotics* (2015)

^{xxiii} See proposal selected by WHO European Region as a possible health R&D demonstration project:

http://www.who.int/phi/implementation/EURO_procedure_for_selection_of_demo_projects.pdf; a summary of the original proposal “Accelerating Innovation and Access to Medicines for Tuberculosis through Open Collaboration: A Push, Pull, Pool Approach” at http://www.who.int/phi/implementation/10_summary_EN.pdf and a more recent summary entitled *3P: Push. Pull. Pool. Better TB treatment. Faster. Proposal to accelerate innovation and access to new*

treatment regimens for TB available at: http://www.msfaaccess.org/sites/default/files/TB_3P2pager_Dec-2015_ENG.pdf

^{xxiv} 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” in Shapiro C., *Navigating the Patent Thicket: Cross Licenses, Patent Pools, and Standard-Setting* (March, 2011).

^{xxv} See WHO, Friede M et al, “Innovation for vaccines against poverty diseases: The need for new support mechanisms” and USPTO, *Patent Pools: A Solution To The Problem Of Access In Biotechnology Patents?*, December 2000

^{xxvi} For example, Geertrui van Overwalle ed. *Gene Patents and Collaborative Licensing Models: Patent Pools, Clearinghouses, Open Source Models and Liability Regimes* (2009)

^{xxvii} Committee on Economic, Social and Cultural Rights, General Comment 14, The right to the highest attainable standard of health (Twenty-second session, 2000), U.N. Doc. E/C.12/2000/4 (2000)

^{xxviii} UN Document A/HRC/15/L.28:

^{xxix} UN Document A/HRC/29/44

^{xxx} Document A/70/279

^{xxxi} UN Document A/HRC/20/26

^{xxxii} Kieny, M.P., “Creating and Intergovernmental Consortium for New Antibiotics: a New Development Model” in *AMR Control*, (2015)