Public Health Management: The Way Forward through Patent Pools

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Abstract

Patent pools covers agreements whereby two or more parties agree to pool their respective technologies and license them as a package. It facilitates public health management of IP through a partnership between an entity with a public health mandate on one hand and private pharmaceutical companies on the other hand. This model of access-oriented and nonexclusive voluntary licensing mechanisms with a clear public health mandate can contribute to achieving this goal of Universal Health coverage and can overcome a number of access and innovation challenges in the biopharmaceutical field. This can be substantiated by analyzing the successful Medicines Patent pool. The benefits of collaborative research and an efficient patent pool could also be witnessed when COVID-19 pandemic was declared as a Public Health Emergency of International Concern by the World Health Organization (WHO) on January 30, 2020, where they launched the COVID-19 Technology Access Pool (C-TAP) with a Solidarity Call to Action for sharing intellectual property on treatments and vaccines.

Keywords: *Patent pools; Public Health Management; Medicines Patent Pools; Healthcare sector; COVID-19 pandemic, Patent licensing.*

I. Introduction

Patent pool is a mutual exchange of patent rights among multiple patent holders to aggregate their patents and license them as a package. Licenses are provided to the licensee, either directly by the patentee or indirectly through a new entity that is specifically set up for the administration of the pool[2]. The rationale for patent pools is that by reducing the number of necessary transactions and by simplifying patent landscapes, they can reduce transaction costs and facilitate

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[2] J. Clark, B. Stanton, K. Tyson, Patent Pools: A Solution to The Problem of Access In Biotechnology Patents? USPTO 5 (Dec. 5, 2000) http://www.pharmacist.or.kr/sites/default/files/wp-content/uploads/2007/04/patentpool2.pdf.

technology transfer. So they significantly reduce the transaction costs of exchanging rights when compared to a series of one-shot licensing deals.

They became a common phenomenon by the nineteenth century and there were many pools in the ICE technology and biotechnology. Though of recent origin, a sector where it has evidently proved to be successful and became a model of just balancing of societal and private rights is in the healthcare sector. Its presence in the biomedical and public health fields address innovation and access challenges.

VIII. Healthcare: A Unique Sector

Healthcare sector is a unique industry due to the fact of information asymmetry. There is lack of consumer sovereignty because consumer is not the chooser like in the other industries. There is no information exchange between the buyer and the seller. Usually in other industries, with the responds of the price, the demand changes and that is what is called as demand elasticity. This is not so with pharmaceutical sector. Here it is demand inelasticity. Usually, top brand will be of high prices. So, access and affordability are always an issue in the health sector and the only possible solution is to have a good public health sector.

The patent pooling model in health represents a new type of public–private partnership (PPP) that relies on the licensing of patents on access-oriented terms to enable multiple third parties to develop or supply patented health technologies in a given geography[3].Thus it is a mechanism for public health management of IP through a partnership between an entity with a public health mandate on one hand and private pharmaceutical companies on the other hand. In other fields they have generally been established as private consortia of patent holders, each owning intellectual property on technology considered as essential to the implementation of a particular standard so that they can

[3] Esteban Burrone, *Patent Pooling in Public Health* in THE CAMBRIDGE HANDBOOK OF PUBLIC-PRIVATE PARTNERSHIPS, INTELLECTUAL PROPERTY GOVERNANCE, AND SUSTAINABLE DEVELOPMENT 93-108 (Margaret Chon, Pedro Roffe, Ahmed Abdel-Latif ed., 2018). 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(5) BULL.WORLD HEALTH ORGAN 699-709 (2000).

facilitate product development and enable interoperability between products. Due to all these reasons an exclusive study of the patent pools in the healthcare sector is of significance.

IX. Patent Pooling in Public Health

Patent pooling in the biomedical field began with the advent of 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. In December 2000, the United States Patent and Trademark Office (USPTO) proposed[4] the establishment of a patent pool as a possible solution to concerns about access to biotechnology patents. Though there were attempts to ensure that genomic sequences remained in the public domain,[5] the surge in patenting of genomic sequences raised some concerns about the hampering of further pharmaceutical research and development without widespread licensing of such research tools.[6] The necessity 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.[7]

The patent pool would issue licenses on essential patents on a nonexclusive basis and enable developers to work on the development of vaccines for the benefit of all stakeholders.[8] It was also hoped that a patent pool for SARS could set a helpful precedent that might lead to the establishment of analogous pools

[4] U.S. Patent and Trade Office (USPTO), Patent Pools: A Solution to The Problem of Access in Biotechnology Patents? (2000), (Nov. 23, 2017), www.uspto.gov/web/offices/pac/dapp/opla/patentpool.pdf.

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

[6] Esteban Burrone, *supra* note 2 at 94.

[7] *See* James H.M. Simon et al., *Managing Severe Acute Respiratory Syndrome (SARS) Intellectual Property Rights: The Possible Role of Patent Pooling,* 83(9) BULL. WORLD HEALTH ORG. 707-710 (2005).

[8] PROMOTING ACCESS TO MEDICAL TECHNOLOGIES AND INNOVATION 118 (WTO, WHO, WIPO 2012).

for other disease areas. 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 (CIPIH) 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[9].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."[10] In order 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[11]. In total the public health patent pools aim to improve access to health technologies especially in developing countries

[9] Report of the Commission on Intellectual Property Rights, Innovation and Public Health, WHO (April 25 2006), https://www.who.int/intellectualproperty/en/.

[10] GLOBAL STRATEGY AND PLAN OF ACTION ON PUBLIC HEALTH, INNOVATION AND INTELLECTUAL PROPERTY, WHO 13 (2011), https://www.who.int/phi/publications/Global_Strategy_Plan_Action.pdf.

[11] Esteban Burrone, *supra* note 2 at 95.

and facilitate further innovation through nonexclusive voluntary licensing[12]. An example of this is the Medicines Patent Pool (MPP) whose mandate includes increasing accessibility to drugs for the treatment of HIV, hepatitis C, tuberculosis, and other essential medicines.[13].

X. Medicines Patent Pool

Medicines patent pool is the first patent pool with a clear public health mandate. It 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[14]. Its mission was to improve health by providing patients in Low- and Middle Income Countries (LMICs) with increased access to quality, safe, efficacious, more appropriate and more affordable health products, through a voluntary patent pool mechanism.[15] The core work of the Medicines Patent Pool is to negotiate public-health driven licenses with patent holders and sublicensing them to generic manufacturers and product developers.

It aims to generate robust market competition which lead to reduced prices and improved access. It also leads to the development of new products. It offers a public-health driven business model that aims to lower the prices of HIV

[12] 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.

[13] Medicines Patent Pool, 2018 Annual Report: Vision and Mission 12 (2019), https://annual-report-2018.medicinespatentpool.org/downloads/MPP_2018_Annual_Report_Vision-and-Mission.pdf

[14] 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 a foundation under Swiss law that negotiates licenses for patents on medicines from the WHO "Essential Medicines List" to facilitate their production by generic manufacturers. 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.

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

medicines and facilitate the development of better-adapted HIV medicines. The MPP called sharing of patents a win-win solution because it helps original manufacturers to share their products in poor countries and still make money. There also exist some arguments that it's favorable to the Big Pharma or an indirect way of making profits in resource-poor settings without the threat of generic production. But the fact that the countries that benefit from such agreements make access to medicines faster cannot be overlooked. Interestingly, since it's in agreement with the original manufacturers, many western donors also support such programs.

XI. History of Medicines Patent Pool

In July 2008 the Executive Board of UNITAID[16] approved the principle of establishing a patent pool for medicines and was established with a base in Geneva, Switzerland and became a separate legal entity in July 2010. It was formed with an aim to provide patients in low and middle income countries with increased access to more appropriate and affordable medicines. The initial focus was in the area of pediatric anti retro virus (ARVs) and new combinations.[17] It was also possible to enhance and accelerate treatment to patients with ARVs[18] in sub Saharan Africa[19] by the introduction of generic

[16] UNITAID is an innovative global health financing mechanism whose mission is to contribute to scaling up access to treatment for HIV/aids, malaria and tuberculosis in low and middle income countries.

[17] *See The Medicines Patent Pool* , UNITAID, https://unitaid.org/project/medicines-patent-pool/#en (July 9, 2017).

[18] There also exist contradictory views regarding the same. A patent pool would act as a group compulsory license, depriving patent-holders of their rights in growing markets around the world and giving the fruits of their R&D investment to copiers for little compensation, if any. In such a system, the fear would be that any new ARVs would be automatically included in the patent pool, thus reducing the possibility for the innovator to recoup his or her R&D investment for these medicines. Furthermore, some observers have expressed concerns regarding the quality of combination products which have not been approved by major, industrialized-country regulatory authorities and, by implication, have indicated that patent pools would lead to lower-quality products being developed by copy companies without sufficient regulatory oversight.

[19]Souteyrand Y, *Global and regional progress in 2008*, WHO (July 2009),http://www.who.int/hiv/mediacen tre/statement_july2009/en/print.html .

product which was brought by the collaborations of R& D based industry and generic producers. This also helped to drive down the raw material prices.[20]

UNITAID provides funds so as to improve the access of medicines for different diseases. The MPP aims to manufacture low cost generic drugs (ARVs) for under developed and developing nations for securing licenses from originator companies and these drugs (ARVs) are made easily accessible to the low income patients. Moreover, more improved drugs can be made available. The prices of HIV medicines has crashed by 99 per cent since 2000. The average cost of treatment, which was about $ 10,000 by the turn of millennium is about US $ 70 in countries such as India.

XII. MPP Model

MPP started off to improve access to more affordable quality-assured HIV medicines in developing countries by enhancing competition among manufacturers. Now the list has been expanded even to include health technologies that could contribute to the global response to COVID-19.

The aim is to make them available faster and cheaper to the greatest possible number of people, in order to have the greatest impact in terms of public health. This means negotiating with the pharmaceutical companies on the one hand to give MPP these licenses and on the other hand to select and monitor the generic producers of these treatments[21]. It enable the development of formulations adapted to developing country needs such as pediatric formulations, also facilitate the development of fixed-dosed combinations or "three-in-one pills" that combine various active pharmaceutical ingredients into a single dosage form.

The model has made it more efficient for the generic companies to negotiate with the MPP for access rights to a license than to do it themselves directly.

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[20]Dionisio D, Gass R, McDermott P, et al., *What strategies to boost production of affordable fixed-dose antiretroviral drug combinations for children in the developing world*? PUBMED (July 2009), http://www.ingentaconnect.com/ content/ ben/chr/2007/00000005/00000002/art00002.

[21] Par Fabrice Delaye, *Medicines Patent Pool can be conduit for access to affordable Covid-19 treatments,* GENEVA SOLUTIONS, https://www.heidi.news/geneva-solutions/medicines-patent-pool-proposed-as-main-conduit-for-inexpensive-covid-19-treatments (last updated on jun. 2, 2020).

MPP is concerned with the most favorable in terms of public health, that is getting the best prices, the widest geographical coverage and the best quality downstream. In certain cases there may be no payment, in some cases the generic companies may have to pay reduced royalties. The pool sees to it that the parties who take license meet with the agreed standard. A highlight of the mechanism is that it offers benefit to all those are involved.[22]

The incentive for pharmaceutical companies to give up its intellectual property for a treatment in some countries is their realization that they are not losing anything for the simple reason that there is no market in low-income countries. On the other hand, there is a gain in terms of image and social responsibility. This is more effective than trying to earn a few extra cents[23]. The Pool works to stimulate competition by saving generics companies the uncertainty of having to negotiate with several patent holders for the right to produce a particular medicine, making it easier for them to enter the market. They help in providing a fair royalty to the right holders, make it easier for innovators to access the patents needed to develop new products and it also helps people living with HIV/AIDS by providing the necessary medicines that too at an affordable cost.

XIII. Working of MPP

It operates by negotiating licenses with patent holders[24] 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.

Once the best possible license on a patent is obtained, MPP calls for expressions of interest among companies. A committee evaluates the applicants and selects those that have both the means to produce at scale, and the best quality control. Subsequently, agreements are signed and sub-licenses are

[22] *The Medicines patent pool, Stimulating Innovation, improving access* (January 2011) http://www.wipo.int/edocs/mdocs/mdocs/en/wipo_gc_lic_ge_12/wipo_gc_lic_ge_12_ref_factsheet.pdf.

[23] *Id.*

[24] The MPP first prioritizes the HIV medicines that need fast-tracked access. It then invites manufacturers for negotiating for licensing. Its first round of negotiations that began in 2010. MPP says that most of the manufactures have responded positively to their proposal.

issued to local manufacturers. The companies obtain the licenses, and are then closely monitored through reports of sales and quarterly meetings. MPP publish everyone's progress in order to maintain competition and bring prices down. The right of audit at any time is reserved with the MPP. Thus MPP is the most successful example of patent pooling in biotechnology and life sciences in general.

The pool is governed by two main bodies: the Governance Board and the Expert Advisory Group. Every member of the Governance Board is selected among the most dedicated and competent experts for a standard term of two years - there is no cap limitation on the number of terms. Transparency and accountability are ensured by the appointed body of External Auditors, which conducts an annual audit of the pool's accounts and reports to the Board for its approval, as well as ensures the compliance with the foundation's by-laws. The Expert Advisory Group provides consultations to the Board and the Executive Director, upon request, with regards to ongoing negotiations and decisions on licensing agreements. Unlike the Board members, experts of the group do not receive a regular salary[25].

Any violations of the foundation's policies are investigated by the MPP Compliance Officer. The fulfilment of legal requirements is ensured by pro bono legal consultations by several companies.

In order to prioritize medicines for in-licensing, it's important to know which medicines were patented where. Through on-line searches and the support of WIPO and many patent offices, the MPP managed to obtain information and is made public. Thus a patent status database was launched in April 2011. In October 2016, MPP launched MedsPaL[26] as the most comprehensive open access/free database providing information on the patent and licensing status of patented medicines on the World Health Organization (WHO) Model List of Essential Medicines (EML) and select products under investigation for the

[25] Medicines Patent Pool Foundation By-Laws, http://www.medicinespatentpool.org/wp-content/uploads /By-Laws-August-20165.pdf (last updated May 15, 2017).

[26] MedsPaL, https://medicinespatentpool.org/what-we-do/medspal/ (last updated Oct. 14, 2016).

treatment of HIV, tuberculosis and COVID-19 in low- and middle-income countries (LMICs).

Contents of MedsPal include granted patents and pending patent applications relating to specific medicinal formulations, with bibliographical details, legal status,[27] expected expiry dates, links to actual patent documents on Espacenet.[28] It also contains information on patent licenses that enable generic access in LMICs licenses negotiated by the MPP (with links to the full licenses), bilateral licenses between originators and generics, public commitments not to enforce patents , compulsory licenses, if publicly available[29].

MedsPaL seeks to address the challenges faced when seeking patent information on medicines. There always exist complexity of patent documents and patent procedures, issues with the technical and legal knowledge required to search and assess patent documents, the need to go to each national patent office to check the patent status, unavailability of electronic national patent registers and unavailability of those in the national language.

XIV. Features of MPP licenses.

By evaluating the licensing agreements[30] the key features of MPP can be summarized as follows

Wide geographical scope: Despite certain geographical limitations, terms and conditions present in MPP licenses were recognized as providing wide access, containing great flexibilities and having the broadest geographical scope. Up to 131 countries are covered in MPP's licenses and hence the geographical scope for sale is high.

Quality assured products: Licensees must obtain approval from WHO Pre-qualification, or a Stringent Regulatory Authority. Where such approval is not

[27] e.g. filed, granted, opposed, expired.
[28] The European Patent Office public database.
[29] It is updated by automated data feeds, online searches, patent holder disclosures (MPP licenses, Pat-Informed, disclosures to patent offices), collaborations with patent experts and collaborations with national/regional patent offices (collaboration agreements).
[30] ANNEXURE 1: LICENSING AGREEMENT OF MPP.

yet available, temporary approval from a WHO Expert Review Panel may be obtained.

Sublicenses: Sublicense can also be issued to qualified entities worldwide in a nonexclusive and non-discriminatory manner to multiple generic manufacturers. 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 license itself does not constitute an additional barrier to access for countries not included in the license. Hence provisions in many of MPP licenses enabling supply by licensees outside the licensed territory if no patents are being infringed.

Permission to develop new formulations of existing medicines and to combine several medicines into fixed dose combinations.

Flexibility to encourage generic competition: Allows for the manufacturing of active pharmaceutical ingredient and finished formulations anywhere in the world. Sales to countries outside the agreed countries are also permitted where there is no granted patent or where sales of a generic version do not infringe on an existing patent, such as in cases in which a compulsory license has been issued.

There also exist *Additional flexibilities for licensees.* Licensees can challenge any of the licensed patents. In certain cases, a technology transfer package is provided to all the sub-licensees, but there is no obligation to use the technology.

Royalties : In certain cases the license is royalty-free[31]. In others[32] three percent royalty for adult formulations in countries where granted patents on ARV are in force. Royalties to be collected by MPP and channeled back to a community-based HIV organization in the country paying the royalty. Royalties not payable for paediatric formulations or for sales of adult formulations in Sub-Saharan Africa and India

Disclosure of company patent information: The licensee discloses the list of all pending and granted patents at the time of signing the license.

[31] ABACAVIR – PAEDIATRICS (ABC).
[32] ATAZANAVIR (ATV).

Waivers for data exclusivity: Data exclusivity is waived in countries with such form of protection, thus facilitating regulatory approval of generics.

Compatible with the use of trade-related aspects of intellectual property rights agreement flexibilities.

Transparency: Key feature with the MPP licenses is its transparency. They are all published in full form on the MPP website[33]. This has introduced unprecedented transparency in access-oriented licensing of pharmaceuticals as a part of its transparency policy[34].It also applies to the patent data collected by the MPP.

Thus it can be seen that by having very flexible features it promotes patent holders from joining the MPP. The terms and conditions in MPP licenses thus seeks to improve treatment options for the broadest number of people living in developing countries.

XV. MPP Experiences

In 2010 after its establishment, the MPP has entered into voluntary licenses with seven patent holders on thirteen HIV medicines and one technology that can be used for the development of nano-formulations of HIV medicines and the main aim was to accelerate availability of quality assured generics of new HIV medicines for use in developing countries.

In November 2015, following extensive consultations, the mandate of the MPP was expanded to hepatitis C and tuberculosis.[35] While there are significant

[33] The full text of MPP licences, as well as summaries of key terms and conditions see Licenses in the MPP, MEDS. PATENT POOL, https://medicinespatentpool.org/progress-achievements/licences/ (last updated Jun. 17, 2017).

[34] An analysis by the Access to Medicines Index concluded that based on an analysis of the licences available for examination, those negotiated through the Medicines Patent Pool provide licensees with the highest level of flexibility and broadest geographic scope. ATM Index 2014, 105(Nov. 17, 2004), https://accessto medicinefoundation.org/media/atmf/2014-Access-to-Medicine-Index.pdf . *See* also The Medicines Patent Pool Transparency Policy, MPP, https://medicinespatentpool.org/uploads/2020/05/MEDICINES-PATENT-POOL-TRANSPARENCY-POLICY-301014.pdf (last visited May 31, 2016).

[35] *The Medicines Patent Pool Expands Mandate to Hepatitis C and Tuberculosis Treatment*, MPP (Nov. 6, 2015), https://medicinespatentpool.org/news-publications-

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.

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 license 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 license, 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 license in TB, on the other hand, was for a medicine that has been stalled in clinical development for a number of years. The MPP license is expected to contribute to accelerating its development by facilitating access to the IP by other potential developers.[36]

XVI. Licensing issues in MPP

A. New Use of Known Products

There were certain issues with the licensing agreement of the MPP. If a new use of one of the known products licensed is discovered then the licensee will be required to pay royalty for this new treatment as well. This can be clearly seen in the issue between Gilead and MPP which included 4 products for HIV treatment, tenofovir disoproxil fumarate (TDF), emtricitabine (FTC), elvitegravir (EVG), cobisitat (COBI) and a combination pill comprising all four drugs known as the 'Quad'. The license allows the patented products to be used

post/the-medicines-patent-pool-expands-mandate-to-hepatitis-c-and-tuberculosis-treatment/.

[36] The Medicines Patent Pool Announces First License for Tuberculosis Treatment, MPP (Jan. 25, 2017), https://medicinespatentpool.org/news-publications-post/medicines-patent-pool-announces-first-licensing-agreement-with-a-pharmaceutical-company/.

in a field of use as defined in the license. For products using TDF as the sole ingredient, the field of use is HIV and Hepatitis B. However, the problematic part arises with EVG and COBI, where the field of use covers these products for *any use* that is consistent with use approved by the FDA or other applicable foreign regulatory authority. Thus if a new use of one of these known products is, then the licensee will be required to pay royalty for this new treatment as well. It also means that in order to sell this, the licensee will be locked into the restrictions provided by this current license.

However, countries like India do not allow new use patents. This means that if the extended field of use provision was absent generics would have been able to produce this treatment without needing to pay a royalty to the patent holder. However, the presence of this 'any use' clause, has the same effect as a new use patent being granted, even in countries which do not allow it. This does not encourage new use patents per se, but for all purposes of the generic company, it effectively grants one.

While a generic can choose to terminate a license on a product, it cannot choose to opt out of only the 'new use' of the product. Thus, it doesn't present a realistic choice for a generic company which is producing the product for its original use already, since it is unlikely that it would make business sense to stop a product that is already selling to start producing another one.

B. **Forming a global patent system**

As per the terms of the license under a MPP a royalty would be charged even in countries in which the product is not patented. Adding this 'new use' product to the equation, royalty will have to be paid in countries which do not allow 'new use' patents too. I-Mak has pointed out that the TDF patent has only been granted in Indonesia, and yet royalties need to be paid for it in all territories with a change in the royalty rate from 3% -> 5% if the patent is granted. Also, the license cannot be severed based on territory. Thus even if a product is not patented in India in the first place, it's 'new use' will now be protected under this license and royalties will have to be paid on it, effectively granting 'new use patent'-like privileges over the product in all territories covered by the license, as well as the other restrictions brought on by the license.

C. Unjust Enrichment

The terms of the license holds good even in the case of a controversial patent as long as the status of the patent is under dispute. In a country like India, by pushing the case through various levels of adjudication, this could take up enough years of royalty generation so as to not actually make much of a difference whether the patent is eventually granted or not.

d. Restriction to certain countries

The production of the Active Pharmaceutical Ingredient (API) for the licensed drug is restricted to Indian generic companies located in India. This removes countries like Brazil, China and Thailand from the equation, as well as Indian companies with manufacturing sites outside India.

Though MPP is a well-intentioned project, it is important that they should take into account these licensing issues so as to ensure that the current negotiations with other pharmaceutical companies can at least take these into consideration

XVII. COVID -19 pandemic and patent pools

COVID-19 pandemic was declared as a Public Health Emergency of International Concern by the World Health Organisation (WHO) on January 30, 2020. It has shown us the benefits of collaborative research. The World Health Assembly on May 2020 discussed on patent pooling to manage the pandemic with the open sharing of data and information [37]. Costa Rica suggested pooling of rights to deal with the pandemic through free or minimal, affordable licensing to ensure the outcomes of efforts can be used by countries with limited economic resources to deal with the problem. India assumed the chairmanship of the Executive Council [38].

On Friday 29 May 2020, the World Health Organization and 37 countries launched a launched the COVID-19 Technology Access Pool (C-TAP) with a

[37]Balakrishna Pisupati, *Patent Pooling, A Covid Success Story,* https://www.thehindubusinessline.com /opinion/patent-pooling-a-covid-success story/article31891866.ece (last updated Jun. 22, 2020).

[38] Heena Lamba Singh, *India: Contribution Of IPR Regimes In Fight Against COVID-19 Pandemic*, (June 09, 2020), https://www.mondaq.com/india/patent/949744/contribution-of-ipr-regimes-in-fight-against-covid-19-pandemic.

Solidarity Call to Action for sharing intellectual property on treatments and vaccines. MPP would serve as the operational conduit for patent sharing. MPP has been instrumental in pushing for the establishment of a pool with respect to COVID-19. The MPP has also updated their Medicines Patents and Licenses database (MedsPal) to include the status of patented candidate products for COVID-19. Currently the only candidate product on the MedsPal database that is described in the database as being for the treatment of coronaviridae viral infections is Remdesivir (remdesivir is an experimental drug, not currently approved for treating COVID-19). Though MPP was in existence for a longer time, formation of such global pool was quite a new initiative. The earlier existed mega pools were only at industry-wide levels.

This initiative complements the European Commission-led Covid-19 Tool Access Accelerator (ACT), which has already raised over 7 billion Euros for R&D and expanded distribution of future drugs. ACT has been supported by industry, non-profits such as the Bill and Melinda Gates Foundation and the Global Alliance for Vaccines (GAVI), and the UN-hosted drug purchasing facility, UNITAID.

Through C-TAP, WHO is now asking public and private funders of R&D to commit to IP knowledge-sharing, in particular through open licensing. It aims to collect patent rights, regulatory test data and any other information and IP that will help in the development of vaccines and drugs and improve diagnostic abilities. This can ultimately lead to global public good[39].

According to GISAID, the global initiative to sharing of all influenza data, as of June 22, 49,781 genome sequences of the Covid virus have been shared, voluntarily, by researchers from around the world. The importance of this sharing, supported by the number of pre-peer review publications of results from research on various aspects of dealing with the pandemic made available

[39] Namratha Murugeshan, Are *Patent Pools an Effective Solution to COVID-19's IP Barriers?* (May 26, 2020), https://spicyip.com/2020/05/are-patent-pools-an-effective-solution-to-covid-19s-ip-barriers.html.

for free, online, has enormously speeded up the effort to find medicines and vaccines to stop/contain the spread of this novel virus [40].

The Trade Related Intellectual Property Regime (TRIPS) allows countries to grant compulsory licenses to companies to produce a patented product at times of emergencies. In April 2020, the European Commission, the European Medicines Agency and the European medicines regulatory network alluded to options for areas where regulatory flexibility is possible to address some of the constraints that may be faced within the context of COVID developments. This voluntary pool is an alternative to the compulsory licensing and voluntary licensing options mooted by various governments and advocates.

Several COVID-19 health technologies such as diagnostic testing devices and drug treatments are developed and are undergoing clinical trials. Similar to the HIV and proposed SARS patent pools, a COVID-19 patent pool could serve to improve accessibility to essential medicines or future vaccine and improve standardization of diagnostic testing. As the COVID-19 patent pool is developed, the WHO will need to determine which patents are essential and recruit them for the pool in order to initiate meaningful license negotiations that can increase access to IP. Due to the emergence of COVID-19 being a relatively recent event, patents specific to the current strain have not yet been issued and the applications have generally not even been published yet (early patent publication and expedited examination is often available upon request). However, patents directed to coronaviridae viral infections, such as Gilead's patent for Remdesivir, have previously been issued and these patents could form the foundation for a patent pool in its early stages, if these therapeutics are proven effective against COVID-19. If implemented properly, a COVID-19 patent pool could encourage innovation and improve accessibility to life-saving medications, encourage further innovation, as well as streamline and accelerate the adoption of diagnostic standards. More than scientific advancement, the focus of such a pool is to make sure that the outcomes of such advancement is

[40] Marie-Paule Kieny and Charles Gore, *The World Needs a Master Plan for Covid-19 Patents. We are Creating One*. (April 10, 2020), https://www.barrons.com/articles/the-world-needs-a-master-plan-for-covid-19-patents-were-building-one-51586524940.

made available across the globe, particularly to countries that would not be able to afford the same otherwise[41].

Thus the major benefits of patent pool in dealing with the COVID 19 pandemic are:

- Patent pooling can ensure fast (R&D) Research and development of a medicinal drug which may play a role during a pandemic like COVID-19 while being transparent about patent rights and legal issues.
- Patent pooling may enable and allow the drug manufacturing companies to combine distinct medications into single/fixed doses to create better medicines
- Patent pooling also can aid in teaming of big pharma companies with generics companies globally for coming up with the required medicine(s)
- Patent pooling may enable immediate licensing across several manufacturers globally leading to the quick availability of medicines [42].

While there are obvious benefits to the creation of this voluntary pool, concerns have been expressed as to how a voluntary pool can possibly incentivize firms and pharma companies to share their IP. Further, while patent pools were proposed even during the public health crises of the SARS outbreak in 2002 and the H1N1 pandemic in 2009, they were not formed, therefore leaving this open to doubts over its success during public health emergencies. Also, given that patent pools are not common in the pharma sector, it further adds to doubts over its success. Given the high costs of production involved in the pharma sector, a long incubation period in the form of clinical trials and regulatory barriers alongside the search for market exclusivity for products, the possibility of collaboration has been very minimal. Apart from this, the creation of a voluntary patent pool cuts into the power of countries to exercise compulsory licensing as a mechanism to ensure the availability of life-saving drugs. The

[41] Namratha Murugeshan, Are *Patent Pools an Effective Solution to COVID-19's IP Barriers?*, (May 26, 2020), https://spicyip.com/2020/05/are-patent-pools-an-effective-solution-to-covid-19s-ip-barriers.html.

[42] Neha Manoria, *India: Medicine Patent Pool (MPP) And Its Role In Battling COVID 19,* (Aug. 18, 2020), https://www.mondaq.com/india/patent/976980/medicine-patent-pool-mpp-and-its-role-in-battling-covid-19. .

proposal being for a voluntary pool, a patentee can simply choose not to participate in the same. Considering that COVID-19 presents a goldmine to pharma companies, it remains to be seen how many will voluntarily share their patented products in the pool[43].

However, there seems to be enough pressure from the public and media on private entities, particularly pharma companies, that seeks to push them into sharing their products and patents in more open manners and to add to the efforts of tackling the virus, alongside emergency measures taken up by governments to overcome patent barriers. So, there need to be some mechanism working in favour of more collaborative research rather than privatized research methods; and having a voluntary pool for sharing IP can possibly push collective efforts in the right direction[44].

XVIII. INDIA AND MEDICINES PATENT POOL

MPP has entered into sub-licensing agreement with many Indian companies with respect to many medicines.

One of the first major generic companies to tap into the patent pool was the generic-drugs maker Aurobindo Pharma Ltd for the manufacture of several antiretroviral medicines.[45] The agreement enabled Aurobindo to manufacture products licensed to the Pool by Gilead Sciences in July 2011.[46] The development speeded-up access to critical HIV medicines in developing

[43] Namratha Murugeshan, *Are Patent Pools an Effective Solution to COVID-19's IP Barriers?*, (May 26, 2020), https://spicyip.com/2020/05/are-patent-pools-an-effective-solution-to-covid-19s-ip-barriers.html.

[44] *Id.*

[45] The products include emtricitabine (FTC), cobicistat (COBI), elvitegravir (EVG), and the fixed-dose combination of these medicines known as the Quad (a combination of FTC, COBI, EVG, and tenofovir). News, Events and Press releases of Medicines Patent Pool, https://medicinespatentpool.org/news-publications/mpp-in-the-media/.

[46] The Pool signed its first licence agreement with a pharmaceutical company, Gilead Sciences, in July 2011, securing several public-health related improvements on the status quo for voluntary licences.

countries. By this agreement, the advantage to Aurobindo was that it could sell tenofovir to a larger number of countries and without paying royalties.[47]

Later MPP, Shilpa Medicare and Gilead Sciences have entered into an agreement whereby they can produce five key HIV medicines for sale in over 100 countries depending on the medicine. In this agreement there is a 3-5 per cent royalty payable by Shilpa to the patent-holder, Gilead, depending on the medicine. The technology transfer, as a result of the agreement, will allow Shilpa to make its chemically similar version of these drugs at a lower price. The four-medicines-in-one Quad, is an important drug that simplifies treatment delivery.[48]

AIDS drug atazanavir was made available by a licensing agreement signed by multinational drug-major Bristol-Myers Squibb and MPP. This medicine is used in the second-line treatment of HIV/AIDS whereas the earlier agreements were covered with first line treatments. BMS has existing agreements on this drug with the Pune-based Emcure and the Gurgaon-based Ranbaxy, besides multinationals Mylan and Aspen. But these agreements cover about 50 countries. The MPP agreement more than doubles the countries covered, and allows for more players to make the drug. As more companies participate, the resulting competition will further drive down medicine prices. Royalties are not applicable in the vast majority of the countries and are waived for all pediatric products, any royalties collected under this license agreement will be reinvested in local HIV/AIDS groups in those countries[49].

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[47] P.T. Jyothi Datta, *Aurobindo, first major generic drugs-maker to tap into Patent Pool*, THE HINDHU BUSSINESS LINE, Oct. 11, 2011, https://www.thehindubusinessline.com/companies/aurobindo-first-major-generic-drugs-maker-to-tap-into-patent-pool/article20347086.ece1, (last updated Mar. 12, 2018).

[48] P. T. Jyothi Datta, *Shilpa Medicare in pact with medicines patent pool for entering HIV space,* THE HINDHU BUSSINESS LINE, Jun. 26, 2013, https://www.thehindubusinessline.com/companies/shilpa-medicare-in-pact-with-medicines-patent-poolfor-entering-hiv-space/article20627390.ece, (last updated Mar. 12, 2018).

[49] P. T. Jyothi Datta, *BMS-Medicines Patent Pool pact opens up manufacture of generic versions of AIDS drug,* THE HINDHU BUSSINESS LINE, Dec. 12, 2013, https://www.thehindubusinessline.com/companies/bms-medicines-patent-pool-pact-

During the 20th International AIDS conference in Melbourne, MPP announced an agreement with seven drug makers for the manufacture of two anti-AIDS medicines. Among these there were India-based companies Cipla, Emcure, Aurobindo, Micro Labs and multinational Mylan's India subsidiary.[50]

A licensing agreement was reached between MPP and Gilead Sciences on tenofovir alafenamide (TAF). The license allowed manufacturers in India and China to develop generic versions of TAF for 112 countries that are home to more than 92 per cent of people living with HIV in the developing world[51]. And it signed six sub-licenses with Aurobindo, Cipla, Desano, Emcure, Hetero Labs and Laurus Labs, allowing them to make generic anti-AIDS medicine Tenofovir Alafenamide (TAF).[52]

Emcure, Hetero and Natco's sub-licenses from MPP was the first one to increase access to new hepatitis C medicines for developing world patients. The agreement was regarding the making of generic versions of Bristol-Myers Squibb's hepatitis C drug daclatasvir.[53] The companies signed non-exclusive, royalty free agreements with Bristol-Myers Squibb (BMS) and the United Nations-backed MPP to produce and sell the anti-viral daclatasvir in 112 low and middle-income countries.[54]

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opens-up-manufacture-of-generic-versions-of-aidsdrug/article20698464.ece1 (last updated Mar. 12, 2018).

[50] P.T.Jyothi Datta, Cipla, Aurobindo in Medicines Patent Pool agreement on anti-AIDs drugs, THE HINDHU BUSSINESS LINE, July 17, 2014, https://www.thehindubusinessline.com/companies/Cipla-Aurobindo-in-Medicines-Patent-Pool-agreement-on-anti-AIDs-drugs/article20821033.ece, (last updated July 17, 2014).

[51] MPP–Gilead agreement: Opportunity for Indian drugmakers, THE HINDHU BUSSINESS LINE, Jul. 24, 2014, https://www.thehindubusinessline.com/companies/mppgilead-agreement-opportunity-for-indian-drugmakers/article20826827.ece, (last updated Mar. 12, 2018).

[52] *Indian drug makers in UN patents pool,* THE HINDHU BUSSINESS LINE, Sep. 26, 2014, https://www.thehindubusinessline.com/economy/Indian-drug-makers-in-UN-patents-pool/article20874831.ece, (last updated Sep.26, 2014).

[53] *Indian drug firms dip into patent pool for Hep C drug,* THE HINDHU BUSSINESS LINE, Jan. 20, 2016, https://www.thehindubusinessline.com/companies/indian-drug-firms-dip-into-patent-pool-for-hep-c-drug/article8130728.ece, (last updated Jan. 19, 2018).

[54] G Naga Sridhar , *Natco Pharma inks pact to sell hepatitis c treatment drug*, THE HINDHU BUSSINESS LINE, Jan. 21, 2016,

All these agreements help in providing access to affordable medicines to patients using established mechanisms where the priority is the patients [55]. The agreement increased the availability of the drugs. It also increased competition and will be a big boost to national treatment programs. Governments would be able to include them in their list of available medicines.

XIX. CONCLUSION

Patent pools in the health sector, especially public health patent pools is one of the best innovative model of a PPP that can manage privately held IP right to protect public interest. Negotiating public-health driven licenses with patent holders and sublicensing to generic manufacturers and product developers is the core work of the Medicines Patent Pool. This shows complete justice to the purpose of IP rights and has the crux of Article 7 of TRIPS. 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. The potential of this model needs to be exploited with focus on universal health coverage. This would be one of the best models how a pro-competitive patent pool should work. But at the same time certain criticisms leveled against these should be kept in mind. One of the arguments pointed out is the incoherence of the pool's aim to provide equal access to all of the pooled patents with the absence of a standardized licensing agreement. Various proposals for the license were claimed to be available for any interested party to get acquainted with and express its opinion[56].The second point of criticism was the ambiguous status of the object of the sub-license provided by the MPP and its first contributor. There is issues of Gilead

https://www.thehindubusinessline.com/companies/natco-pharma-inks-pact-to-sell-hepatitis-c-treatment-drug/article8133625.ece, (last updated Jan. 19, 2018).

[55] *Medicines Patent Pool signs deal with 5 Indian companies for HIV drug,* BUSSINESS STANDARD, http://www.business-standard.com/content/b2b-pharma/medicines-patent-pool-signs-deal-with-5-indian-companies-for-hiv-drug-114092600945_1.html, (last updated Sep. 26, 2014).

[56] Love, J. *KEI comments on the ITPC Letter to the Medicines Patent Pool Foundation and UNITAI,* (2011), http:// www.keionline.org/node/1294 (last updated May1 5, 2017).

Sciences and its sub licenses[57]. This initiative will be a good role model if the issues raised in its licensing term are also given due consideration. Patent pools work to develop a robust framework for identifying priority medicines and thus it can have the greatest public health mandate and enable wider access to essential medicines in low and middle income countries.

[57] Tripathy, S. *Bio-patent Pooling and Policy on Health and health Technologies that Treat HIV/ AIDS: A Need for Meeting of Open Minds* in GLOBAL GOVERNANCE OF INTELLECTUAL PROPERTY IN THE 21ST CENTURY 29-50 (Perry, M. ed.,2016).