

Research Synthesis: Patent Pools

v1.0 researched and written by Danielle Navarro, edited by Suerie Moon, last updated February 2019

Introduction

The literature around patent pool is considerable*, with most of the analyses focusing on the Medicines Patent Pool (MPP). The literature seems to be produced mostly from 2010 onwards.

Search terms

Patent Pool; Patent Pool and Biomedical, and Research and Development; Patent Pool and Research and Development

Synthesis of the literature

Features/Characteristics

Patent pools are mechanisms that aim to facilitate both research and development (R&D) and access to medicines within the context of the existing international intellectual property rights framework. Because R&D can require access to many patents held by different entities, product developers may need to negotiate rights to use IP and pay royalties to different patent owners. To address this complex patent landscape, patent pools were conceived as “one-stop shop[s],” wherein different IPR holders license their patents into the pool to be bundled together for licensing out (subject to payment of a corresponding royalty), to the other patent owners and/or to third parties (Hoffman and So 2015).

Licenses granted by patent pools have been referred to as “one-stop licenses” since it cuts the need to negotiate individual licenses with the various patent holders and instead offers all patents relevant for a particular invention in one license agreement (van Zimmeren et al. 2011). Though they were frequently used in the information technology field, Heller and Eisenberg (1998) expressed skepticism that patent pools would be attractive to drug developers considering that patent exclusivity is deemed particularly valuable and profitable in this field (Heller and Eisenberg 1998).

Advantages

The pooling of patents, which can make existing patents on compounds accessible to third parties, is expected to facilitate the development of fixed-dose combinations or paediatric formulations of existing drugs, as well as allow generic drug development to begin before the relevant patent term expires (Satyanarayana and Srivastava 2010). Patent pools, in general, are credited for lowering costs for license negotiations, decreasing the risk of patent litigation and addressing the issue of “blocking patents” (Grassler and Capria 2003).

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Examples

a. MPP

Most of the literature has focused on one particular initiative, the Medicines Patent Pool (MPP). The MPP was created by UNITAID in 2010 (Wirtz et al. 2017). Bermudez and Hoen (2010); Childs (2010) discuss the considerations in setting up the patent pool (Bermudez and Hoen 2010; Childs 2010). MPP focuses on making priority antiretroviral drugs (ARV) covered by existing patents accessible to patients in low and middle income countries (LMICs) by obtaining voluntary license agreements from various patent owners, then sublicensing the patents on non-exclusive terms to various generic drug manufacturers for the development, manufacture and distribution of generic ARV drugs (Juneja et al. 2017). Wirtz et al. (2017) lists the significant milestones achieved by the Medicines Patent Pool from 2010 to 2015, particularly those relating to the patent licenses granted and their effect on drug supply and cost savings (Wirtz et al. 2017). Another paper estimated the cost savings resulting from MPP's ARVs licenses at USD 2.3 billion from 2010 to 2028 (Juneja et al. 2017). Analysts have noted that the success of the MPP depends on whether patent-holders are willing to license their patents to the pool and be licensed to third parties (Hoen and Passarelli 2013; Hoen et al. 2011). The provisions of MPP licenses, especially those with the pharmaceutical company Gilead, have been analyzed and discussed in detail in the following papers: The Medicines Patent Pool: Promoting Access and Innovation for Life-Saving Medicines through Voluntary Licenses (Cox 2012), A Sliver of Hope: Analyzing Voluntary Licenses to Accelerate Affordable Access to Medicines (Baker 2018), Medicine Patent Pool – Pharma Philanthropy or PR? (De Luca 2015). As of 2018, the MPP reported that that its adult formulation licenses cover 87 to 91% of HIV patients in developing countries (Medicines Patent Pool n.d. a). Also, every widely-patented WHO-recommended antiretroviral medicine has been licensed to the MPP (See Medicines Patent Pool n.d. b).

b. Criticisms of MPP

I-MAK (2011) analyzed the benefits projected by the MPP in 2009 to the UNITAID Executive Board. Among others, it argued against the following claims: that the MPP would enable the development of fixed-dose combinations and solid pediatric formulations as well as “widespread voluntary licensing.” With respect to these criticisms, I-MAK (2011) provided recomputed financial savings as opposed to those asserted by the MPP (I-MAK 2011). A noted limitation of this patent pool is the voluntary nature of its licensing process, mainly relying on pharmaceutical companies granting use of their licenses to the pool and on the generic manufacturers making use of these licenses (Bermudez and Hoen 2010). Baker (2018) observes the increased yet limited geographical reach of MPP licenses, particularly that “[t]he territorial coverage of MPP licenses averages only 90% for adult licenses and 99% for pediatric licenses” in low-and middle-income countries. A number of MICs are excluded from this coverage, which mean that millions are still unable to benefit from the licensed medicines. Contrary to criticism, the MPP licenses preserve the right to use of IP flexibilities allowed under the TRIPS Agreement, e.g. patent oppositions or cancellations and compulsory licenses (Baker 2018). The application of competition law has relevance to patent pools (van Zimmeren et al. 2011; Simon et al. 2005).

2. Others

The Severe Acute Respiratory Syndrome (SARS) pool was intended to be an initial experiment in the life sciences field to set up a patent pool. However, this was never operationalized and has since been discontinued. It was meant to facilitate research and development of SARS vaccines by pooling relevant patents (van Zimmeren et al. 2011). The World Intellectual Property Office Re:Search (WIPO Re:Search) project is another approach to patent pooling. The following

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organizations have granted royalty-free access to their patents related to neglected tropical disease drug development: GlaxoSmithKline (GSK), Alnylam, AstraZeneca, Eisai, MSD, Novartis, Pfizer and Sanofi (Ziegler, Gassmann, and Friesike 2014). WIPO Re:Search has its origins in the GSK Pool for Open Innovation against Neglected Tropical Diseases, which was then subsequently housed with BioVentures for Global Health (BVGH) before being moved to WIPO (Eisenberg 2014). Schoen-Angerer (2011) pointed out that WIPO Re:Search patents were only available for use in least-developed countries and therefore had very limited geographical scope; other developing countries would only be able to obtain access to the IP through negotiation (Schoen-Angerer 2011).

Suggestions for expanded models

Patent pool models have been recommended to facilitate R&D and access to the full WHO list of essential medicines (Wirtz et al. 2017) and drugs for “orphan/rare diseases” (Muthyala 2011). Patent pools have also been suggested to advance R&D in the fields of nanotechnology (Sanhai, Spiegel, and Ferrari 2007), genetics (Verbeure et al. 2006; Van Overwalle et al. 2006; Ebersole, Guthrie and Goldstein 2005) and stem cell (Winickoff, Saha and Graff 2009).

[See also the review on Voluntary Licensing](#)

Research gaps

- Analysis of interaction between patent pools and other policies intended to promote innovation or access to medicines

Cited papers with abstracts

Baker, Brook K. 2018. “A Sliver of Hope: Analyzing Voluntary Licenses to Accelerate Affordable Access to Medicines.” *Northeastern University Law Review* 10 (2): 226-315.

Abstract: As a result of global AIDS activism, governments' latent and exercised powers to bypass pharmaceutical monopolies, and halting pharmaceutical industry accommodation, a new form of voluntary licensing has emerged focused on first permitting and then facilitating generic production of certain pharmaceutical products for sale and use in many but not all low- and middle-income countries (LMICs). These so-called “access” licenses are pluralistic in detail and not free of commercial motivations for either originators or generic producers, but they do differ from arms-length, purely commercial licenses that have been broadly used in the industry for decades. Although the first of these access licenses were negotiated bilaterally by innovators at the receiving end of AIDS activism and threats of government action, including the issuance of compulsory or government-use licenses, the leading model of more public-health oriented voluntary licenses can be traced to the formation of the Medicines Patent Pool [MPP] under the financial sponsorship of Unitaid in 2010. The primary goals of this Article are: (a) to increase understanding of the history and evolution of access licenses and their key terms and conditions, including their impacts on access to medicines in territories included in and excluded from the licenses; (b) to identify and assess best-practice licensing terms for delivering meaningful access to medicines, including the impact of voluntary licensing practices on registration and uptake,

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and (c) to make policy recommendations on measures that can be taken to improve terms and conditions of access licenses, including those of the MPP. Despite the achievements of access licenses in increasing generic competition, accelerating access to newer HIV and HCV medicines in many LMICs, and reducing prices and saving money, the exclusion from coverage of significant populations in upper-middle income countries with significant disease burdens, restrained resources, and high levels of inequality, is deeply problematic. Offsetting the wholesale work that access licenses accomplish in creating aggregated markets for accelerated generic competition is concern about industry's power to bifurcate LMICs to maintain hegemony in the most commercially appealing markets and to weaken political will to oppose unworthy patents and to otherwise overcome monopoly control. As a consequence, the net plus value of voluntary licenses as an access strategy is contested. However, any fair assessment of voluntary licensing strategies must address the complementarity of this strategy with the strengths and weakness of other access strategies, including law reform, use of patent opposition procedures, and grant of compulsory and government use licenses. Although this complementarity is briefly addressed in the conclusion, more work and evidence is needed to identify optimal strategies.

Link: https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3123108

Bermudez, Jorge and Ellen 't Hoen. 2010. "The UNITAID Patent Pool Initiative: Bringing Patents Together for the Common Good." *The Open AIDS Journal* 4 (2): 37-40. <https://doi.org/10.2174/1874613601004020037>.

Abstract: Developing and delivering appropriate, affordable, well-adapted medicines for HIV/AIDS remains an urgent challenge: as first-line therapies fail, increasing numbers of people require costly second-line therapy; one-third of ARVs are not available in pediatric formulations; and certain key first- and second-line triple fixed-dose combinations do not exist or sufficient suppliers are lacking. UNITAID aims to help solve these problems through an innovative initiative for the collective management of intellectual property (IP) rights – a patent pool for HIV medicines. The idea behind a patent pool is that patent holders - companies, governments, researchers or universities - voluntarily offer, under certain conditions, the IP related to their inventions to the patent pool. Any company that wants to use the IP to produce or develop medicines can seek a license from the pool against the payment of royalties, and may then produce the medicines for use in developing countries (conditional upon meeting agreed quality standards). The patent pool will be a voluntary mechanism, meaning its success will largely depend on the willingness of pharmaceutical companies to participate and commit their IP to the pool. Generic producers must also be willing to cooperate. The pool has the potential to provide benefits to all.

Link: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2842943/>

Childs, Michelle. 2010. "Towards a Patent Pool for HIV Medicines: The Background." *The Open AIDS Journal* 4 (2): 33-36. <https://doi.org/10.2174/1874613601004020033>.

Abstract: Recent WHO guidelines for antiretroviral therapy recommend switching to less toxic, but more expensive medicines for first-line and second-line ART, raising questions about the financial sustainability of many AIDS treatment programmes. At the same time, many key generic producing countries such as India now grant pharmaceutical product patents so

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competition between multiple manufacturers will not be able to play the role it has in bringing down the price of newer drugs. Overcoming these patent barriers will require a range of solutions, such as restricting patentability criteria, or compulsory licensing. One additional systematic solution is provided by the patent pool, a collective solution to the management of patent rights, initially presented by Médecins Sans Frontières to the French Foreign Ministry and subsequently the UNITAID Executive Board in 2006.

A patent pool must not be implemented at any costs, but answer medical needs, be based on economic realities and meet the access needs of the developing world, including middle-income countries.

Link: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2817875/>

Cox, Krista L. 2012. "The Medicines Patent Pool: Promoting Access and Innovation for Life-Saving Medicines Through Voluntary Licenses" *Hastings Science & Technology Law Journal* 4: 291.

Abstract: Monopolies over many life-saving drugs have led to high prices that remain out of reach for patients in the developing world, leading to a crisis of access over these essential medicines. High intellectual property barriers harm not only access to medicines, but can also impact future innovation. In order to address this problem, a proposal for a "patent pool" emerged that would rely on voluntary licenses by patent holder to enable the production of more affordable generic medicines. This article briefly describes the history of patent pools before focusing specifically on the UNITAID- supported Medicines Patent Pool. It analyzes the specific licenses of the Medicines Patent Pool, noting both the positive aspects and areas where future licenses could be improved. In addition to identifying areas for improvement, this article explores the mechanisms, including those that de-link innovation from monopoly pricing, that can be used to achieve these goals and encourage greater participation in the Medicines Patent Pool.

Link: https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2076717

De Luca, Carmela. 2015. "Medicine Patent Pool – Pharma Philanthropy or PR?," *Expert Opinion on Therapeutic Patents*, 25 (11): 1223-1227. <https://doi.org/10.1517/13543776.2015.1075004>.

Abstract: Merck recently signed an agreement with The Medicines Patent Pool (MPP) to license intellectual property relating to pediatric formulations of its integrase HIV drug, raltegravir (Ral) (the 'Agreement'). The Agreement is alleged to clear the way for cheaper formulations for use in developing and some middle income countries and allows for the development of novel pediatric formulations of Ral as well as novel combinations. Merck's license is royalty free and under the terms of the Agreement, manufacturers anywhere in the world who meet the quality assurance criteria, can manufacture and sell pediatric versions of the drug in the licensed countries under the agreed conditions without paying a royalty to Merck. The Agreement covers at least 92 countries and MPP reports that 98.1% of children with HIV in the developing world live in the included countries. The Agreement has been criticized as a public relations exercise. The article asks if the criticism is justified and explores several aspects of the Agreement in addressing the question.

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Link: <https://www.ncbi.nlm.nih.gov/pubmed/26291460>

Ebersole, Ted J., Marvin C. Guthrie, and Jorge A. Goldstein. 2005. "Patent Pools as a Solution to the Licensing Problems of Diagnostic Genetics." *Intellectual Property & Technology Law Journal* 17 (1): 6–13.

Abstract: Not available

Link: <http://www.cptech.org/cm/ebersole012005.pdf>

Eisenberg, Ashley. 2014. "Understanding Patent Pools for Global Health: Assessing Their Value in Promoting Access to Essential Medicines." Duke Global Health Institute - Duke University. <https://core.ac.uk/download/pdf/37750029.pdf>.

Abstract: In response to a lack of access to essential medicines in the developing world, a number of mechanisms have developed that aim to promote greater access to essential medicines, particularly antiretroviral drugs for the treatment of HIV/AIDS and drugs for the treatment of neglected diseases. These mechanisms operate in a variety of different ways, but share a common theme in that they all ultimately aim to provide greater access to affordable drugs to patients in resource poor settings. However, the existing mechanisms to facilitate increased access to essential medicines, while beneficial, all have a number of cons. Patent pools represent a novel approach to facilitating access to essential medicines and have the potential to go beyond the status quo as compared to various traditional alternatives.

This paper aims to analyze patent pools recently formed in the field of global health and whether such approaches to intellectual property management can facilitate greater access to antiretroviral medicines for the treatment of HIV/AIDS and drugs for the treatment of neglected diseases in low- and middle- income countries, both in terms of fostering the developing of new drugs and increasing the affordability and availability of drugs current in the market. Two patent pools in particular — the Medicines Patent Pool and WIPO's Re:Search Consortium — are evaluated and compared to existing mechanisms that aim to accomplish the same or similar goals.

Link: https://dukespace.lib.duke.edu/dspace/bitstream/handle/10161/8855/Eisenberg_duke_0066N_12467.pdf%3Bsequence=1

Grassler, Frank, and Mary Ann Capria. 2003. "Patent Pooling: Uncorking a Technology Transfer Bottleneck and Creating Value in the Biomedical Research Field." *Journal of Commercial Biotechnology* 9 (2): 111-118. <https://doi.org/10.1057/palgrave.jcb.3040016>.

Abstract: Patent pools have long been used to collect intellectual property rights into a basket of rights that can facilitate the licensing thereof. By pooling relevant patent rights together, the out-licensing is streamlined and made more cost efficient. Many recent patent pools involved establishing and administering patents that meet an established industry standard and then granting non-exclusive licences to the patents that are considered essential to that standard, eg consumer electronics. While there are few, if any, established industry standards in biomedical

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research, there are opportunities to pool intellectual property rights that facilitate cost-efficient technology transfers and foster better research.

Link: <https://link.springer.com/article/10.1057/palgrave.jcb.3040016>

Heller, M. A. and Eisenberg, R. S. 1998. "Can Patents Deter Innovation? The Anticommons in Biomedical Research." *Science* 280 (5364): 698–701. <https://doi.org/10.1126/science.280.5364.698>.

Abstract: The "tragedy of the commons" metaphor helps explain why people overuse shared resources. However, the recent proliferation of intellectual property rights in biomedical research suggests a different tragedy, an "anticommons" in which people underuse scarce resources because too many owners can block each other. Privatization of biomedical research must be more carefully deployed to sustain both upstream research and downstream product development. Otherwise, more intellectual property rights may lead paradoxically to fewer useful products for improving human health.

Link: <http://science.sciencemag.org/content/280/5364/698>

Hoehn, Ellen 't, Jonathan Berger, Alexandra Calmy, and Suerie Moon. 2011. "Driving a Decade of Change: HIV/AIDS, Patents and Access to Medicines for All." *Journal of the International AIDS Society* 14 (1): 15. <https://doi.org/10.1186/1758-2652-14-15>.

Abstract: Since 2000, access to antiretroviral drugs to treat HIV infection has dramatically increased to reach more than five million people in developing countries. Essential to this achievement was the dramatic reduction in antiretroviral prices, a result of global political mobilization that cleared the way for competitive production of generic versions of widely patented medicines.

Global trade rules agreed upon in 1994 required many developing countries to begin offering patents on medicines for the first time. Government and civil society reaction to expected increases in drug prices precipitated a series of events challenging these rules, culminating in the 2001 World Trade Organization's Doha Declaration on the Agreement on Trade-Related Aspects of Intellectual Property Rights and Public Health. The Declaration affirmed that patent rules should be interpreted and implemented to protect public health and to promote access to medicines for all. Since Doha, more than 60 low- and middle-income countries have procured generic versions of patented medicines on a large scale.

Despite these changes, however, a "treatment timebomb" awaits. First, increasing numbers of people need access to newer antiretrovirals, but treatment costs are rising since new ARVs are likely to be more widely patented in developing countries. Second, policy space to produce or import generic versions of patented medicines is shrinking in some developing countries. Third, funding for medicines is falling far short of needs. Expanded use of the existing flexibilities in patent law and new models to address the second wave of the access to medicines crisis are required.

One promising new mechanism is the UNITAID-supported Medicines Patent Pool, which seeks to facilitate access to patents to enable competitive generic medicines production and the development of improved products. Such innovative approaches are possible today due to the

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previous decade of AIDS activism. However, the Pool is just one of a broad set of policies needed to ensure access to medicines for all; other key measures include sufficient and reliable financing, research and development of new products targeted for use in resource-poor settings, and use of patent law flexibilities. Governments must live up to their obligations to protect access to medicines as a fundamental component of the human right to health.

Link: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3078828/>

Hoen, Ellen 't, and Carlos André Passarelli. 2013. "The Role of Intellectual Property Rights in Treatment Access: Challenges and Solutions." *Current Opinion in HIV and AIDS* 8 (1): 70–74. <https://doi.org/10.1097/COH.0b013e32835b6e5a>.

Abstract: **PURPOSE OF REVIEW:** The purpose of this study is to review relevant literature published from January 2011 to July 2012 that specifically addresses the impact of intellectual property protection on access to antiretroviral drugs.

RECENT FINDINGS: The articles reviewed discussed the relation of intellectual property protection and access to medicines. For most authors, the World Trade Organization (WTO) Trade-Related Intellectual Property Rights Agreement (TRIPS) and the 10-year anniversary of the 2001 WTO Doha Declaration on TRIPS and Public Health formed an important background for the review of the current state of play.

SUMMARY: Intellectual property plays an important role in implementing policies to ensure HIV treatment and care programmes. From the review, three main themes emerged: the implementation of the Doha Declaration, the role of generic competition in antiretroviral treatment scale-up and innovative licensing mechanisms. The attention for the effects of intellectual property on access to HIV medicines opened the path for new initiatives for the management of patents using public health objectives as the key driver such as the UNITAID-backed Medicines Patent Pool. Some of the literature addressed the question whether more fundamental changes in the intellectual property architecture were necessary.

Link: <https://www.ncbi.nlm.nih.gov/pubmed/23201855>

Hoffman, Steven J., and Karen So. 2014. "Assessing 15 Proposals for Promoting Innovation and Access to Medicines Globally." *Annals of Global Health* 80 (6): 432. <https://doi.org/10.1016/j.aogh.2015.02.004>.

Abstract: **BACKGROUND:** There is widespread recognition that the existing global systems for innovation and access to medicines need reform. Billions of people do not have access to the medicines they need, and market failures prevent new drugs from being developed for diseases that primarily affect the global poor. The World Health Organization's Consultative Expert Working Group on Research and Development: Financing and Coordination (CEWG) analyzed numerous proposals for reform. The aim of this article is to build on these previous inquiries.

METHODS: We conducted a structured analysis that grouped proposals into five broad opportunities for global policy reform to help researchers and decision makers to meaningfully evaluate each proposal in comparison with similar proposals. Proposals were also analyzed along

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three important dimensions-potential health impact, financial implications, and political feasibility-further facilitating the comparison and application of this information.

FINDINGS: Upon analysis, no one solution was deemed a panacea, as many (often competing) considerations need to be taken into account. However, some proposals, particularly product development partnership and prizes, appeared more promising and feasible at this time and deserve further attention.

CONCLUSION: More research is needed into the effectiveness of these mechanisms and their transferability across jurisdictions.

Link: <https://www.ncbi.nlm.nih.gov/pubmed/25960092>

I-MAK. 2011. "Financial Impact of Medicines Patent Pool: I-MAK/ITPC Counter Analysis." <http://apps.who.int/medicinedocs/documents/s19792en/s19792en.pdf>.

Abstract: Not available

Link: <http://apps.who.int/medicinedocs/documents/s19792en/s19792en.pdf>

Juneja, Sandeep, Aastha Gupta, Suerie Moon, and Stephen Resch. 2017. "Projected Savings through Public Health Voluntary Licences of HIV Drugs Negotiated by the Medicines Patent Pool (MPP)." Edited by Eduard J. Beck. PLOS ONE 12 (5): e0177770. <https://doi.org/10.1371/journal.pone.0177770>.

Abstract: The Medicines Patent Pool (MPP) was established in 2010 to ensure timely access to low-cost generic versions of patented antiretroviral (ARV) medicines in low- and middle-income countries (LMICs) through the negotiation of voluntary licences with patent holders. While robust data on the savings generated by MPP and other major global public health initiatives is important, it is also difficult to quantify. In this study, we estimate the savings generated by licences negotiated by the MPP for ARV medicines to treat HIV/AIDS in LMICs for the period 2010–2028 and generate a cost-benefit ratio-based on people living with HIV (PLHIVs) in any new countries which gain access to an ARV due to MPP licences and the price differential between originator's tiered price and generics price, within the period where that ARV is patented. We found that the direct savings generated by the MPP are estimated to be USD 2.3 billion (net present value) by 2028, representing an estimated cost-benefit ratio of 1:43, which means for every USD 1 spent on MPP, the global public health community saves USD 43. The saving of USD 2.3 billion is equivalent to more than 24 million PLHIV receiving first-line ART in LMICs for 1 year at average prices today.

Link: <https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0177770>

Medicines Patent Pool. n.d. a. "Who We Are - MPP in Numbers." Medicines Patent Pool. Accessed February 12, 2019b. <https://medicinespatentpool.org/>.

Abstract: Not available

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Link: <https://medicinespatentpool.org/>

Medicines Patent Pool. n.d. b. "What We Do - Licence Overview." Medicines Patent Pool. Accessed February 12, 2019a. <https://medicinespatentpool.org/what-we-do/global-licence-overview/>.

Abstract: Not available

Link: <https://medicinespatentpool.org/what-we-do/global-licence-overview/>

Muthyala, Ramaiah. 2011. "Orphan/Rare Drug Discovery through Drug Repositioning." Drug Discovery Today: Therapeutic Strategies 8 (3-4): 71-76. <https://doi.org/10.1016/j.ddstr.2011.10.003>.

Abstract: Not available

Link: <https://www.sciencedirect.com/science/article/pii/S174067731100043X>

Sanhai, Wendy R., Jack Spiegel, and Mauro Ferrari. 2007. "A Critical Path Approach to Advance Nanoengineered Medical Products." Drug Discovery Today: Technologies 4 (2): 35-41. <https://doi.org/10.1016/j.ddtec.2007.10.003>.

Abstract: Still needed in nanotechnology is a product development toolkit containing both scientific and business strategies to stimulate innovation. Among the scientific tools envisioned are evaluative and predictive test methods, such as animal- and computer-based predictive models, characterization assays, toxicity tests and quantitative imaging methods to track biodistribution of nanoparticles in complex biological systems. These tools will help bridge scientific gaps and elucidate potential benefits and risks related to use of nanoengineered medical products. In addition, relevant business strategies, if carefully designed, will help overcome many of the hurdles in this field. This article describes some needed scientific/regulatory and business tools of this field and introduces one collaborative effort underway - a Critical Path Initiative [FDA's Critical Path Initiative:<http://www.fda.gov/oc/initiatives/criticalpath/>] - structured to bridge some existing gaps.

Link: <https://www.ncbi.nlm.nih.gov/pubmed/24980838>

Satyanarayana, Kanikaram, and Sadhana Srivastava. 2010. "Patent Pooling for Promoting Access to Antiretroviral Drugs (ARVs) - A Strategic Option for India." The Open AIDS Journal 4 (2): 41-53. <https://doi.org/10.2174/1874613601004020041>.

Abstract: The current HIV/AIDS scenario in India is quite grim with an estimated 2.4 million people living with HIV/AIDS (PLHA) in 2008, just behind South Africa and Nigeria. The anti-retroviral drugs (ARVs) remain the main stay of global HIV/AIDS treatment. Over 30 ARVs (single and FDCs) available under six categories viz., NRTIs (nucleoside reverse transcriptase inhibitors), NNRTIs (non- nucleoside reverse transcriptase inhibitors), Protease inhibitors, the new Fusion inhibitors, Entry inhibitors-CCR5 co-receptor antagonists and HIV integrase strand transfer inhibitors. The major originator companies for these ARVs are: Abbott, Boehringer Ingelheim

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(BI), Bristol-Myers Squibb (BMS), Gilead, GlaxoSmithKline (GSK), Merck, Pfizer, Roche, and Tibotec. Beginning with zidovudine in 1987, all the drugs are available in the developed countries. In India, about 30 ARVs are available as generics manufactured by Aurobindo, Hyderabad, Andhra Pradesh; Cipla Limited, Goa; Emcure Pharmaceuticals, Pune, Maharashtra; Hetero Drugs, Hyderabad, Andhra Pradesh; Macleods Pharmaceuticals, Daman; Matrix Laboratories, Nashik, Maharashtra; Ranbaxy, Sirmour, Himachal Pradesh; and Strides Arcolab, Bangalore, Karnataka. The National AIDS Control Organization (NACO) set up in 1992 by the Govt. of India provides free ARVs to HIV positive patients in India since 2004. The drugs available in India include both single drugs and FDCs covering both first line and second line ARVs. Even while there are claims of stabilization of the disease load, there is still huge gap of those who require ARVs as only about 150,000 PLHA receive the ARVs from the Govt. and other sources. Access to ARVs therefore is still a cause of serious concern ever since India became fully Trade Related Aspects of Intellectual Property Rights (TRIPS)-complaint in 2005. Therefore, the Indian pharmaceutical companies cannot make generics for those for drugs introduced post-2005 due to product patent regime. Other concerns include heat stable, other better formulations and second line ARVs for adults and more drugs and formulations for paediatric groups, that are still to be widely available in India and other developing countries. To examine whether strong intellectual property (IP) protection systems are to be considered important barriers for the limited or lack of access to ARVs, we studied the patent profile of the ARVs of the originator companies within and outside India. We could record 93 patents in the United States Patent & Trademark Office (USPTO). The originator companies have been also aggressively filing and enforcing patents in India. There have been a few efforts by companies like Gilead and GSK to grant licenses to generic manufacturers in developing countries, ostensibly to promote access to ARVs through lower (two-tier) pricing. These steps are considered as too little and too late. There is an urgent need to look for alternative strategies to promote access to ARVs both linked to and independent of IPRs. Patent pooling as a viable strategy mooted by the UNITAID should be seriously explored to promote access to ARVs. India is ideally suited for trying out the patent pool strategy as most of the global requirement of affordable ARV drugs for HIV/AIDS treatment is sourced from Indian generic companies.

Link: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2819698/>

Schoen-Angerer, Tido von. "Statement by MSF in Response to WIPO Announcement of Re:Search, Consortium for Neglected Tropical Diseases, TB and Malaria." Médecins Sans Frontières Access Campaign, October 25, 2011.

Abstract: Not available

Link: <https://msfaccess.org/statement-msf-response-wipo-announcement-research-consortium-neglected-tropical-diseases-tb-and>

Simon, James H.M., Eric Claassen, Carmen E. Correa and Albert D.M.E. Osterhaus. 2005. "Managing Severe Acute Respiratory Syndrome (SARS) Intellectual Property Rights: The Possible Role of Patent Pooling." Bulletin of the World Health Organization, 83(9). 707-710.

Abstract: Patent applications that incorporate the genomic sequence of the severe acute respiratory syndrome (SARS) coronavirus, have been filed by a number of organizations. This is likely to result in a fragmentation of intellectual property (IP) rights which in turn may adversely

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affect the development of products, such as vaccines, to combat SARS. Placing these patent rights into a patent pool to be licensed on a non-exclusive basis may circumvent these difficulties and set a key precedent for the use of this form of mechanism in other areas of health care, leading to benefits to public health.

Link:http://apps.who.int/iris/bitstream/handle/10665/73239/bulletin_2005_83%289%29_707-710.pdf?sequence=1&isAllowed=y

Van Overwalle, Geertrui, Esther van Zimmeren, Birgit Verbeure, and Gert Matthijs. 2006. "Models for Facilitating Access to Patents on Genetic Inventions." *Nature Reviews Genetics* 7 (2): 143–54. <https://doi.org/10.1038/nrg1765>.

Abstract: The genetics community is increasingly concerned that patents might lead to restricted access to research and health care. We explore various measures that are designed to render patented genetic inventions accessible to further use in research, and to diagnosis and/or treatment. They include the often-recited research or experimental-use exemption, conventional one-to-one licensing and compulsory licensing, as well as patent pools and clearing-house mechanisms. The last two alternatives deserve special attention in the area of human genetics.

Link: <https://www.nature.com/articles/nrg1765>

Verbeure, Birgit, Esther van Zimmeren, Gert Matthijs, and Geertrui Van Overwalle. 2006. "Patent Pools and Diagnostic Testing." *Trends in Biotechnology* 24 (3): 115–20. <https://doi.org/10.1016/j.tibtech.2006.01.002>.

Abstract: Not available

Link:[https://www.cell.com/trends/biotechnology/fulltext/S0167-7799\(06\)00019-9?_returnURL=https%3A%2F%2Flinkinghub.elsevier.com%2Fretrieve%2Fpii%2FS016777990600199%3Fshowall%3Dtrue](https://www.cell.com/trends/biotechnology/fulltext/S0167-7799(06)00019-9?_returnURL=https%3A%2F%2Flinkinghub.elsevier.com%2Fretrieve%2Fpii%2FS016777990600199%3Fshowall%3Dtrue)

Winickoff, David E., Saha Krishanu and Gregory D. Graff. 2009. "Opening Stem Cell Research and Development: A Policy Proposal for the Management of Data, Intellectual Property, and Ethics." *Yale Journal of Health Policy, Law and Ethics* 9 (1): 52.

Abstract: Intellectual property scholars and the biomedical community have noted a decline in the tradition of openness and sharing in the biomedical sciences over the past thirty years. This decline appears to be a function of multiple factors. First, and best known, are changes in intellectual property (IP) law, specifically the Federal Circuit's re-interpretation of patent law to expand the scope of patentable claims; the passage of the Bayh-Dole Act of 1980, allowing universities to patent inventions made in the course of federally-funded research; and the creation of new legal rights and mechanisms for the privatization and commercialization of scientific data. Second, and perhaps as a direct consequence, universities and their life science researchers have significantly increased interaction with the private sector, whether through accepting sponsored research, licensing IP, or spinning off companies. These activities have dramatically increased the exchange of discoveries, capital, and labor across the industrial-

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academic interface, and they have added more private money to the mix of research support for university life sciences. But the increase in university participation in economic life has also introduced tensions between the emerging commodification of knowledge and longstanding scientific norms regarding open access and dissemination of research results, data, research tools, and other scientific advances.

In traditional sociological accounts, the advance of science is predicated upon mechanisms of open information, peer review, and materials exchange, which are socially reinforced by norms that undergird open access. Knowledge that is withheld from community scrutiny cannot be validated or agreed upon by the community. On this basis, it is presumed that greater degrees of openness promote not only efficiency in the advance of science, but also trust in the scientific endeavor by society. Moreover, in standard economic accounts, the mechanisms of open exchange also have important efficiency, equity, and ethical implications in terms of the direct contributions that science makes to social welfare, particularly in the development of new technologies, products, and services. In theory, actors across industrial and state sectors can put scientific knowledge to efficient and equitable use when it is freely accessible as a public good, assuming full information and virtually costless transactions. When the results of scientific investigation are withheld in secrecy or maintained as private property, practical applications may be delayed, directed only towards lucrative markets, or priced in ways that are socially inefficient or unjust.

However, it is not clear that efficiency and equity in the applications of science are always better served by greater openness. In terms of efficiency, openness can introduce a "free rider" problem, undermining incentives to invest in developing scientific discoveries that can contribute to social welfare. Indeed, this is arguably why our IP laws grant private exclusive rights for inventors to develop inventions into useful applications. Furthermore, in terms of equity, as Chander and Sunder argue in *The Romance of the Public Domain*, freely accessible materials and information are not necessarily accessed equally by all: Those with greater ability to exploit an open access information resource, such as those with greater knowledge, social stature, or control over complementary assets, will tend to benefit disproportionately. They suggest, however, that "[t]here are strategies available... to help ... restructure the distribution of benefits ... especially the possibility of creating 'limited commons property' regimes for. . . information." The solution for greater efficiency as well as equity in the exploitation of science, it seems, lies in finding a proper balance or hybridization between openness and enclosure, public good and private asset. Striking the most efficient and equitable balance between public and proprietary science is quite difficult in practice, in no small measure because the very categories of basic and applied science are breaking down in practice. Nevertheless, many legal commentators warn that with Bayh-Dole, the pendulum may have swung too far towards a private competitive model of university science.

Link: <https://digitalcommons.law.yale.edu/yjhple/vol9/iss1/2/>

Wirtz, Veronika J, Hans V Hogerzeil, Andrew L Gray, Maryam Bigdeli, Cornelis P de Joncheere, Margaret A Ewen, Martha Gyansa-Lutterodt, et al. 2017. "Essential Medicines for Universal Health Coverage." *The Lancet* 389 (10067): 403–76. [https://doi.org/10.1016/S0140-6736\(16\)31599-9](https://doi.org/10.1016/S0140-6736(16)31599-9).

Abstract: Not available

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Link: [https://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(16\)31599-9/fulltext](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(16)31599-9/fulltext)

Ziegler, Nicole, Oliver Gassmann, and Sascha Friesike. 2014. "Why Do Firms Give Away Their Patents for Free?" *World Patent Information* 37 (June): 19–25. <https://doi.org/10.1016/j.wpi.2013.12.002>.

Abstract: Within the trend of increasing patent commercialisation and open innovation, a recent phenomenon where firms give away their patents free of charge can be observed. This seems contradictory to the original intention of the patent system (enabling firms to create temporary monopolies to appropriate returns from their R&D investments). Consequently, this paper explores why firms make their patents available for free and which benefits they may gain from this behaviour. Adopting the open source software phenomenon as a background and using firm data from 26 patent release cases, we identify a typology consisting of four motives of 'free patent release approaches': profit making, cost cutting, innovation catalysing, technology providing. Further, we discuss the motives of these firms to offer their patents as 'open source'. We find that firms may obtain valuable technological input for subsequent innovations as well as social benefits in return for their free patent release.

Link: <https://www.sciencedirect.com/science/article/pii/S0172219013001592>

Zimmeren, Esther van, Sven Vanneste, Gert Matthijs, Wim Vanhaverbeke, and Geertrui Van Overwalle. 2011. "Patent Pools and Clearinghouses in the Life Sciences." *Trends in Biotechnology* 29 (11): 569–76. <https://doi.org/10.1016/j.tibtech.2011.06.002>.

Abstract: Not available

Link: <https://www.ncbi.nlm.nih.gov/pubmed/21733589>

** For the purposes of this review, we have established three categories to describe the state of the literature: thin, considerable, and rich.*

- *Thin: There are relatively few papers and/or there are not many recent papers and/or there are clear gaps*
- *Considerable: There are several papers and/or there are a handful of recent papers and/or there are some clear gaps*
- *Rich: There is a wealth of papers on the topic and/or papers continue to be published that address this issue area and/or there are less obvious gaps*

Scope: While many of these issues can touch a variety of sectors, this review focuses on medicines. The term medicines is used to cover the category of health technologies, including drugs, biologics (including vaccines), and diagnostic devices.

Disclaimer: The research syntheses aim to provide a concise, comprehensive overview of the current state of research on a specific topic. They seek to cover the main studies in the academic and grey literature, but are not systematic reviews capturing all published studies on a topic. As with any research synthesis, they also reflect the judgments of the researchers. The length and

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detail vary by topic. Each synthesis will undergo open peer review, and be updated periodically based on feedback received on important missing studies and/or new research. Selected topics focus on national and international-level policies, while recognizing that other determinants of access operate at sub-national level. Work is ongoing on additional topics. We welcome suggestions on the current syntheses and/or on new topics to cover.

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