

# Research Synthesis: Voluntary licensing

*v1.0 researched and written by Elise Erickson, edited by Suerie Moon, last updated June 2018*

## Introduction

The literature on voluntary licensing is thin\*, and most of the literature is quite recent (after 2012).

## Search terms

Voluntary license

## Synthesis of the literature

Voluntary licensing refers to the practice of IP-holders voluntarily granting licenses to their patents or other IP, and has increasingly been adopted to promote access to lower-cost generic medicines in low and middle-income countries. Voluntary licensing is often contrasted with compulsory licensing, in which a government authority grants a third-party a license to the IP. Voluntary licenses can take many forms, and may be bilateral (between a single licensor and licensee) or multilateral (between multiple licensors and licensees, as through a patent pool).

A few papers and reports map different existing voluntary licenses on medicines (MSF Access Campaign 2017; Amin 2007). A 2016 report from the WHO shows that voluntary licenses have allowed sofosbuvir prices to fall substantially, and discusses what conditions need to be met to allow for a competitive market under a voluntary license agreement (World Health Organization (WHO) 2016).

[See also the review on Patent Pools](#)

There is also limited literature that describes the Medicines Patent Pool (MPP), which works to increase access to HIV, hepatitis C and TB treatment in LMICs through voluntary licensing and patent pooling. The mostly descriptive literature dates primarily around 2010 when the initiative was launched (Cox 2012; Childs 2010; Bermudez and 't Hoen 2010). More recent analyses discuss the benefits and accomplishments of the MPP so far (Perry 2016), and the projected savings from voluntary licenses of ARVs through MPP by 2028 (Juneja et al. 2017). (See further discussion in our review of "Patent pools")

A few papers discuss potential access concerns relevant to voluntary licensing (Beyer 2013, MSF Access Campaign 2017, 2015). The MSF Access Campaign has highlighted access concerns in

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middle-income countries that were excluded from Gilead's voluntary license agreements on HIV and hepatitis C medicines (MSF Access Campaign 2017, 2015).

Discussion of voluntary licensing sometimes arises in papers focusing on compulsory licensing, which has attracted far more research attention. For example, some discuss how the threat of a compulsory license may invite a voluntary licensing agreement (Raju 2017), or that pharmaceutical companies will use voluntary licenses to prevent the use of compulsory licenses (or the use of other TRIPS flexibilities), thereby preventing competition in the market. Many of the papers that discuss both types of licensing, however, tend to focus on compulsory rather than voluntary licenses (Beall and Kuhn 2012). (See our review of Compulsory Licensing.)

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

### Research gaps

- Mapping of terms and conditions in voluntary licenses, including covered medicines, countries, timeframes for negotiation, period of licenses, provisions for use of TRIPS flexibilities, criteria for licensees, and suppliers in and outside of voluntary licenses.
- Comparison between bilateral (e.g. patent-holding firm to licensees) and multilateral (e.g. Medicines Patent Pool, patent-holders to 3rd party to licensees) voluntary licenses
- Further research on changes in prices and availability of medicines under voluntary license and other policies (e.g. no license, compulsory license, narrower or wider voluntary licenses, tiered pricing, donations)
- Further analysis of access concerns in voluntary licenses, such as implications for middle-income countries and for the generics industry
- Analysis of operation and costs of patent pools

### Cited papers with abstracts

Amin, Tahir. 2007. "Voluntary Licensing Practices in the Pharmaceutical Sector: An Acceptable Solution to Improving Access to Affordable Medicines?"  
<http://apps.who.int/medicinedocs/documents/s19793en/s19793en.pdf>

Abstract: Not available

Link: <http://apps.who.int/medicinedocs/documents/s19793en/s19793en.pdf>

Beall, Reed, and Randall Kuhn. 2012. "Trends in Compulsory Licensing of Pharmaceuticals Since the Doha Declaration: A Database Analysis." PLOS Medicine 9 (1): e1001154.  
<https://doi.org/10.1371/journal.pmed.1001154>.

Abstract: Background: It is now a decade since the World Trade Organization (WTO) adopted the "Declaration on the TRIPS Agreement and Public Health" at its 4th Ministerial Conference in Doha. Many anticipated that these actions would lead nations to claim compulsory licenses (CLs) for pharmaceutical products with greater regularity. A CL is the use of a patented innovation

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that has been licensed by a state without the permission of the patent title holder. Skeptics doubted that many CLs would occur, given political pressure against CL activity and continued health system weakness in poor countries. The subsequent decade has seen little systematic assessment of the Doha Declaration's impact.

**Methods and Findings:** We assembled a database of all episodes in which a CL was publically entertained or announced by a WTO member state since 1995. Broad searches of CL activity were conducted using media, academic, and legal databases, yielding 34 potential CL episodes in 26 countries. Country- and product-specific searches were used to verify government participation, resulting in a final database of 24 verified CLs in 17 nations. We coded CL episodes in terms of outcome, national income, and disease group over three distinct periods of CL activity. Most CL episodes occurred between 2003 and 2005, involved drugs for HIV/AIDS, and occurred in upper- middle-income countries (UMICs). Aside from HIV/AIDS, few CL episodes involved communicable disease, and none occurred in least-developed or low-income countries. **Conclusions:** Given skepticism about the Doha Declaration's likely impact, we note the relatively high occurrence of CLs, yet CL activity has diminished markedly since 2006. While UMICs have high CL activity and strong incentives to use CLs compared to other countries, we note considerable countervailing pressures against CL use even in UMICs. We conclude that there is a low probability of continued CL activity. We highlight the need for further systematic evaluation of global health governance actions.

Link: <http://journals.plos.org/plosmedicine/article?id=10.1371/journal.pmed.1001154>

Bermudez, Jorge, and Ellen 't Hoen. 2010. "The UNITAID Patent Pool Initiative: Bringing Patents Together for the Common Good." *The Open AIDS Journal* 4 (January): 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/>

Beyer, Peter. 2013. "Developing Socially Responsible Intellectual Property Licensing Policies: Non- Exclusive Licensing Initiatives in the Pharmaceutical Sector." In *Research Handbook on*

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Intellectual Property Licensing, edited by Jacques de Werra. Cheltenham, UK: Edward Elgar Publishing Limited. <http://apps.who.int/medicinedocs/documents/s22380en/s22380en.pdf>.

Abstract: Not available

Link: <http://apps.who.int/medicinedocs/documents/s22380en/s22380en.pdf>

Childs, Michelle. 2010. "Towards a Patent Pool for HIV Medicines: The Background." *The Open AIDS Journal* 4 (January): 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 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: 291–324.

Abstract: Not available

Link: [http://heinonline.org/HOL/Page?handle=hein.journals/hascietlj4&div=12&g\\_sent=1&casa\\_token=&collection=journals](http://heinonline.org/HOL/Page?handle=hein.journals/hascietlj4&div=12&g_sent=1&casa_token=&collection=journals)

Friedman, Michael A., Henk den Besten, and Amir Attaran. 2003. "Out-Licensing: A Practical Approach for Improvement of Access to Medicines in Poor Countries." *The Lancet* 361 (9354): 341–44. [https://doi.org/10.1016/S0140-6736\(03\)12331-8](https://doi.org/10.1016/S0140-6736(03)12331-8).

Abstract: Not available

Link: [http://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(03\)12331-8/abstract](http://www.thelancet.com/journals/lancet/article/PIIS0140-6736(03)12331-8/abstract)

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)." *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

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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://www.ncbi.nlm.nih.gov/pmc/articles/PMC5444652/>

MSF Access Campaign. 2015. "Access to Sofosbuvir, Ledipasvir and Velpatasvir: Analysis & Key Recommendations on Gilead's Voluntary License."

Abstract: Not available

Link: [https://www.msfaccess.org/sites/default/files/MSF\\_assets/HepC/Docs/HepC\\_statement\\_AnalysisOfGileadLicense\\_ENG\\_2015.pdf](https://www.msfaccess.org/sites/default/files/MSF_assets/HepC/Docs/HepC_statement_AnalysisOfGileadLicense_ENG_2015.pdf)

MSF Access Campaign. 2017. "HIV & Opportunistic Infection Treatment: Spotlight on Access Gaps."

[https://msfaccess.org/sites/default/files/HIV\\_Brief\\_SpotlightOnAccessGaps\\_ENG\\_2017.pdf](https://msfaccess.org/sites/default/files/HIV_Brief_SpotlightOnAccessGaps_ENG_2017.pdf).

Abstract: Not available

Link: [https://msfaccess.org/sites/default/files/HIV\\_Brief\\_SpotlightOnAccessGaps\\_ENG\\_2017.pdf](https://msfaccess.org/sites/default/files/HIV_Brief_SpotlightOnAccessGaps_ENG_2017.pdf)

Perry, Greg. 2016. "UN High Level Panel on Access to Medicines: Contribution 115." High-Level Panel on Access to Medicines. 2016. <http://www.unsgaccessmeds.org/inbox/2016/2/28/greg-perry>.

Abstract: Voluntary patent pooling in public health is a mechanism for the management of intellectual property (IP) rights that seeks to promote innovation and access particularly in developing countries. Voluntary patent pools operate within the existing trade and IP framework and can contribute to the realisation of "the right to health" and "the right to enjoy the benefits of scientific progress" as guaranteed in the Universal Declaration of Human Rights (UDHR) and in the International Covenant on Economic, Social and Cultural Rights (ICESCR). Voluntary patent pooling also provides a practical example of an approach to promote policy coherence in the field of public health. This contribution reviews one experience in the implementation of voluntary patent pooling to improve health outcomes. It also analyses other areas in which the concept could potentially be applied to address specific access and/or innovation challenges for health technologies as well as to support the achievement of new health-related Sustainable Development Goals through 2030.

Link: <http://www.unsgaccessmeds.org/inbox/2016/2/28/greg-perry>

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Raju, K D. 2017. "Compulsory v Voluntary Licensing: A Legitimate Way to Enhance Access to Essential Medicines in Developing Countries." *Journal of Intellectual Property Rights* 22: 23–31.

Abstract: Compulsory licensing (CL) (the TRIPS language is that other use without the authorisation of the right holder, A.3) is provided under the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) regime under the World Trade Organization (WTO). Across the world, the CL on IPRs is granted on similar grounds like unreasonably exorbitant prices of a medicine; patent being not worked in the country; where substantial public interest is affected by the way in which IPR holder is exercising his rights etc. The Doha Declaration on Public Health provides special privileges for countries without manufacturing facilities. Presently, more and more multinational pharma companies are turned into strategic alliances with domestic companies for manufacturing patented drugs in order to avoid CL. For example, the Swiss drug maker Hoffman La Roche has entered into an agreement with Emacure Pharmaceuticals for locally manufacturing three patented cancer drugs in India. Strides Arcolab has entered into collaboration with US Pharma Gilead Sciences for manufacturing HIV/Drugs. The first CL case in India has compelled multinational pharmaceutical companies to change their strategy of strategic collaborations and technology transfers with domestic companies. It is argued that a threat of CL encourages parties for entering into voluntary licensing and it is economical and an alternative option (not exclusive) for developing countries in providing essential medicines to poor people.

Link: <http://docs.manupatra.in/newsline/articles/Upload/31AC60C2-ABCC-4799-A388-0F56ED7C9ECF.pdf>

World Health Organization (WHO). 2016. "Global Report on Access to Hepatitis C Treatment: Focus on Overcoming Barriers." <http://apps.who.int/iris/bitstream/10665/250625/1/WHO-HIV-2016.20-eng.pdf?ua=1>.

Abstract: Not available

Link: <http://apps.who.int/iris/bitstream/10665/250625/1/WHO-HIV-2016.20-eng.pdf?ua=1>

*\* 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.*

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*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 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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