



Voluntary licenses and access to medicines

Recommendations to governments to safeguard access to medicines in pharmaceutical voluntary license agreements

Overview

Since the coming into force of the World Trade Organization's Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) between 1995 and 2005, patents and other intellectual property (IP) rights have increasingly played a role in determining where and at what price medicines are made available to people who need them. With these changes have come a number of tools and strategies for governments, companies and civil society to navigate the shifting landscape and address barriers presented by restrictive IP rights, including the use of voluntary licenses.

Voluntary licenses represent one approach to managing IP for medicines and granting permissions to alternate suppliers to enter the market with the generic products in question. While they can allow manufacturers granted a license to supply medicines at lower prices than the patent-holding pharmaceutical corporation's own products, they often come with secretive and restrictive conditions that undermine access to medicines. This brief summarises recommendations to governments to mitigate potential harm and promote more affordable access to lifesaving medicines based on Médecins Sans Frontières (MSF)'s analysis of pharmaceutical voluntary licenses.¹

As an international medical humanitarian organisation and purchaser of medicines, MSF has experienced first-hand the positive and negative impacts of voluntary licenses on access to the medicines we provide to people under our care in countries around the world. Voluntary licenses are contractual agreements through which patent-holding pharmaceutical corporations (licensors) set out the terms under which a generic version of a patented medicine can enter the market from alternate suppliers (licensees). Through license terms and conditions, pharmaceutical corporations can set limitations on where and to whom a product can be sold, control the supply of active pharmaceutical ingredients (API) and impose other restrictions on licensees.

Voluntary licenses are private commercial contracts and as such cannot be expected to achieve the optimal level of public health benefit and access to affordable medicines. When countries are excluded from voluntary licenses on lifesaving medicines, their options for getting affordable access are compromised. In the current practice of voluntary licenses, most

¹ See MSF's full analysis of voluntary licenses and access to medicines, available from: <https://msfaccess.org/voluntary-licenses-access-medicines>

high- and upper-middle-income countries are excluded, including many with a high burden of disease related to the treatment in question.²

When governments discover restrictive voluntary license conditions are undermining domestic manufacture and/or supply of needed medicines, they should take appropriate actions to mitigate the harm. The COVID-19 pandemic has also highlighted the urgent need for non-exclusive and worldwide licensing norms to encourage and allow all competent manufacturers to scale up and supply affordable medicines, vaccines and diagnostics globally without any geographical restrictions.³

Recommendations

States have a responsibility to protect and promote access to medicines. In order to deliver on this, they need to use all available resources, including regulating abusive practices in voluntary licensing that undermine access to affordable quality generic medicines for all. Governments should consider increasing transparency in voluntary licensing agreements, using compulsory licenses where appropriate, regulating voluntary licenses, and supporting mechanisms that allow challenges to frivolous patent claims to ensure that voluntary licenses best protect access to medicines. In contexts such as the COVID-19 pandemic, governments should also consider bolder measures to overcome IP challenges, including the suspension of applications and enforcement of patents and other IP and exclusivities concerning COVID-19 health technologies, such as trade secrets and clinical data exclusivities.⁴

1. Increase transparency in voluntary licensing agreements

Information on voluntary licenses and their terms should be put in the public domain, encouraging transparency and accountability. Governments can increase transparency in all voluntary licensing agreements on health technologies by establishing or strengthening existing laws regarding public access to information. This is especially relevant for licenses signed by publicly funded institutions, such as public research labs and companies.

Measures to ensure transparency could include:

- In countries where no legal requirements exist: governments should establish voluntary license registration and mandatory publication requirements under national laws. Both the patent offices and competition authorities should be given the authority to request registration of voluntary licenses and publication of the licensing terms to encourage transparency and accountability as early as possible.
- In countries where registration or submission of voluntary licenses to authorities is a legal requirement: these licenses should become part of public record and countries should develop a publicly accessible database to make information on all registered license agreements available.

² See, for example, Gilead's 2015 hepatitis C license, which excluded 50 middle-income countries (MICS), accounting for 43% of the hepatitis C burden among MICs. More details available from: <https://msfaccess.org/msf-analysis-gilead-hepatitis-c-license>. See also, Gilead's 2020 license for remdesivir, which excludes many high- and upper-middle-income countries facing high COVID-19 burdens. More details available from: <https://msfaccess.org/voluntary-licenses-access-medicines>

³ MSF. Position paper on mandatory open sharing of technologies for COVID19 to ensure equitable access for all. [Online]. 2020 [Cited 28 Sept 2020]. Available from: https://msfaccess.org/sites/default/files/2020-05/COVID19_Brief_SharingTechnologies_WHA73_ENG_2020.pdf

⁴ MSF. Overcoming intellectual property monopolies in the COVID-19 pandemic. [Online]. 2020 [Cited 28 Set 2020]. Available from: <https://msfaccess.org/overcoming-intellectual-property-monopolies-covid-19-pandemic>

- In all countries: governments should establish and strengthen public interest doctrine in legal decisions, laws and policies on freedom of information, confidential information and trade secrets. This could allow public interest override on claims of confidentiality for voluntary licensing terms concerning essential medicines, vaccines and other health technologies.

2. Consider compulsory licenses and automatic measures to address refusal to license or restrictions and exclusions in licenses

All countries have rights to freely determine the grounds to issue a compulsory license. In contrast to a voluntary license, this license for alternative production or importation of a generic version of a patented medicine is granted by the government and does not require the consent of the patent-holder. Health or competition authorities that find their country excluded from the territory coverage of voluntary licenses or identify other restrictions harmful to public health in licenses should be empowered to invoke government use of compulsory licenses, in accordance with the TRIPS Agreement and the Paris Convention for the Protection of Industrial Property.^{5,6} These agreements also state that refusal to license or other restrictions in licenses could constitute grounds for capable manufacturers to request a compulsory license from the government.

Restrictions in voluntary licenses may include, but are not limited to, limitations on accessing certain formulations or APIs of the concerned medicine, and/or restrictions stipulating that a medicine can be made in the country and exported but cannot be made available to people domestically (in “manufacturing-only” countries).⁷

Facing a global health crisis such as the COVID-19 pandemic in which pharmaceutical corporations refuse to enter into worldwide non-exclusive licenses, governments should collectively explore automatic and expedited measures to overcome IP challenges. This could include the suspension of certain obligations under the TRIPS Agreement and trade agreements concerning granting and enforcement of IP on essential health technologies, materials and products to enable open sharing of health technologies for all.⁸

3. Establish or strengthen law and policy frameworks to regulate voluntary licensing practices

Countries should establish or strengthen explicit and enforceable legal frameworks to regulate voluntary license practices. Relevant national authorities should review voluntary

⁵ Article 5 of the Paris Convention for the Protection of Industrial Property allows countries to issue a compulsory license to address abuse, including failure to work patents. The provisions under the Paris Convention are in full alignment with the TRIPS Agreement, according to Article 2 of the TRIPS Agreement.

⁶ See, for example: Malaysia Director-General of Health. Implementation of the rights of government for sofosbuvir tablet to increase access for hepatitis C treatment in Malaysia. Press statement. [Online]. 2017 Sept 20 [Cited 2020 Sept 28]. Available from: <https://kpkesihatan.com/2017/09/20/press-statement-minister-of-health-20th-september-2017-implementation-of-the-rights-of-government-for-sofosbuvir-tablet-to-increase-access-for-hepatitis-c-treatment-in-malaysia/>;

Ling C. Using compulsory licence for affordable medicines. [Online]. 2019 March 9 [Cited 2020 Sept 28]. Available from: <https://www.astroawani.com/berita-malaysia/using-compulsory-licence-for-affordable-medicines-200558>;

Kintada L. Compulsory licensing for hepatitis C medication in Malaysia. Public Citizen. [Online]. 2019 April 10 [Cited 2020 Sept 28]. Available from: <https://www.citizen.org/news/compulsory-licensing-for-hepatitis-c-medication-in-malaysia/>

⁷ MSF. MPP licence agreement with AbbVie for glecaprevir/pibrentasvir. [Online]. 2019 Aug [Cited 2020 Sept 28]. Available from: https://msfaccess.org/sites/default/files/2019-08/HCV_Brief_MPP-AbbVie-Voluntary-License_2019_Updated.pdf

⁸ MSF. Overcoming intellectual property monopolies in the COVID-19 pandemic. [Online]. 2020 [Cited 28 Set 2020]. Available from: <https://msfaccess.org/overcoming-intellectual-property-monopolies-covid-19-pandemic>

licenses concerning medicines and prohibit licensing terms that impede competition and undermine people's and national health programmes' options to purchase more affordable medicines. This includes, but is not limited to, recommended regulations on the following:

- a. **Broad patent definitions.** Prohibit overly broad patent definitions. Patents should be defined to mean only granted patents. Licensees should be able to supply countries when patent claims are pending or no patents have been granted for the concerned medicine, even if these countries are not covered by the license territory.
- b. **Geographic restrictions.** Prohibit licensing terms that prevent licensees from supplying API and/or finished products to countries outside of the licensed territories. Regardless of licenses, manufacturers should be able to supply countries when patent applications are pending or under challenge, there are no granted patents on the concerned technologies or products, a compulsory license issued on the concerned product, or the country has no obligation to implement a pharmaceutical product patent regime (e.g. least-developed countries).⁹
- c. **Domestic supply restrictions.** Prohibit licensing terms that prevent licensees from supplying the medicine domestically. Manufacturers should be allowed to supply their local populations. It is not reasonable or ethical that a medicine is made in a country, but not available to people in that country.¹⁰
- d. **Product usage restrictions.** Prohibit licensing terms that limit access to selected formulations or indications of a medicine. A license should ensure the rights of the licensee to commercially produce and supply all possible formulations of the medicine that are suitable for the treatment of adults and children and to supply the medicine for all indications as approved by regulatory bodies.¹¹
- e. **Excluding health systems.** Prohibit licensing terms that only allow licensees to supply the public health system and non-profit treatment programmes, preventing access to more affordable medicines in the private healthcare system. The segmentation of public and private health care systems in license terms can leave some people who are not covered by public health care schemes with greater difficulties accessing treatments.¹²
- f. **API source restrictions.** Prohibit licensing terms that prevent or restrict sourcing and supplying of raw materials including API. Licensees should be able to purchase or produce API of their own choice.
- g. **Restrictive technology transfer.** Prohibit terms that impose additional restrictions on licensees taking technology transfer offered under a voluntary license. For example, manufacturers should not be prevented from supplying countries outside the listed territories when there are no granted patents in those countries or if a compulsory license is issued by the concerned government simply because they required technology transfer from a licensor.

⁹ According to a general waiver granted under WTO, least-developed countries (LDCs) who are WTO members are exempted from implementing pharmaceutical patents mechanism until 2033 and from implementing other obligations under the TRIPS Agreement until July 2021. See: https://www.wto.org/english/news_e/news15_e/trip_06nov15_e.htm, and https://www.wto.org/english/tratop_e/trips_e/ldc_e.htm

¹⁰ See, for example, MSF. MPP licence agreement with AbbVie for glecaprevir/pibrentasvir. [Online]. 2019 Aug [Cited 2020 Sept 28]. Available from: https://msfaccess.org/sites/default/files/2019-08/HCV_Brief_MPP-AbbVie-Voluntary-License_2019_Updated.pdf

¹¹ MSF. Untangling the web of ARV price reductions, 18th Ed. [Online]. 2016 [Cited 2020 Jul 29]. Available from: https://msfaccess.org/sites/default/files/MSF_assets/HIV_AIDS/Docs/UTW_Drug_Profiles_LPV_r.pdf

¹² MPP. Dolutegravir-adult license overview. [Online]. 2014 [Cited 2020 Aug 1]. Available from: <https://medicinespatentpool.org/licence-post/dolutegravir-adult-dtg/>

- h. **Anti-diversion.** Prohibit anti-diversion terms that introduce stringent policing measures on licensees and treatment providers that could compromise patient confidentiality and introduce dispensation requirements that could lead to treatment interruptions. Licensees and those purchasing medicines should not be required to undermine patient confidentiality and act as IP enforcers on behalf of pharmaceutical corporations.¹³
- i. **Unfair grant-back terms.** Prohibit mandatory, unilateral and exclusive “grant-back” terms for any improvements in the licensed medical technology by the licensee. If generic manufacturers are able to innovate a more efficient process and/or better formulation of the original product, they should not be required to offer this technology first and only to the licensor, limiting people’s access to the improved product.
- j. **Research restrictions.** Prohibit terms that put restrictions on licensees conducting follow-on research and clinical studies on the concerned products and technologies. Licensees should not be required to seek permission from the licensor when conducting research on the patented technologies and products. Manufacturers conducting research should be protected against patent infringement claims by research and experimental use exceptions – important public interest safeguards enshrined in many national laws, in compliance with the TRIPS Agreement.¹⁴
- k. **Compliance and enforcement.** Establish mechanisms to enable relevant national authorities to review voluntary licenses and scrutinize potentially prohibited terms. Relevant procedures for monitoring and filing complaints should be enabled to ensure enforceability of the concerned regulations.

4. Encourage and support patent challenges to overcome restrictions in standard voluntary licenses

Patent oppositions, including those filed by civil society and patient groups, play an important role in countries that have been excluded from the territory of a license and in key manufacturing countries. In some cases, patent oppositions have successfully prevented the establishment or extension of a patent monopoly when a decision from the patent office results in a rejected or revoked patent. Where voluntary licenses are already in place, rejection or revocation of a patent could lead to termination of the license or “unbundling” of non-patented medicines from a broader license agreement.¹⁵ They can also offer licensees leverage to negotiate more flexible terms, such as the expansion of territories covered under an existing voluntary license.

¹³ MSF. Indian generic companies should reject Gilead’s controversial hepatitis C ‘Anti-Diversion’ programme. Press release. [Online]. 2015 Mar 9 [Cited 2020 Sept 29]. Available from: <https://www.msf.org/indian-generic-companies-should-reject-gilead%E2%80%99s-controversial-hepatitis-c-%E2%80%99anti-diversion%E2%80%99>

¹⁴ Article 30 of the TRIPS Agreement allows members to provide exceptions to the exclusive rights of patents. Research and experimental use exceptions are important public policy safeguards embedded in many national laws. See WIPO’s compilation of references on research exception, available from: https://www.wipo.int/edocs/mdocs/scp/en/scp_29/scp_29_3.pdf

¹⁵ See, for example, Guha S. Patent Office rejected tenofovir: celebrating opportunity for generic manufacturers? Spicy IP. [Online]. 2009 Sept 5. [Cited 2020 Sept 28]. Available from: <https://spicyip.com/2009/09/patent-office-rejected-tenofovir.html>; and I-MAK. Evaluating the potential impact of Aurobindo’s unbundling of the Medicines Patent Pool (MPP)–Gilead Sciences (Gilead) license on tenofovir: a need for increased transparency. [Online]. 2011 Dec [Cited 2020 Sept 28]. Available from: <http://www.i-mak.org/wp-content/uploads/2017/10/2012FINALAUROBINDOIMPACTANALYSIS.pdf>