



# **VOLUNTARY LICENSES AND ACCESS TO MEDICINES**

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## Overview

Voluntary licensing is becoming a key issue for access to medicines and vaccines broadly as voluntary licenses have increasingly been used to manage pharmaceutical intellectual property (IP). In turn, they have had a significant impact on people's access to lifesaving medicines.

As an international medical humanitarian organisation and purchaser of medicines, Médecins Sans Frontières (MSF) has experienced first-hand positive and negative impacts of voluntary licenses on access to the medicines we provide to people in our care. MSF has also witnessed how voluntary licenses impact the ability of health authorities around the world to procure and provide essential medicines.

Voluntary licenses are private 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).<sup>a</sup> While they can allow generic 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. 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.

In the current practice of voluntary licenses, most high- and upper-middle-income countries are excluded, including many with a high burden of disease related to the treatment in question.<sup>b</sup> When countries are excluded from voluntary licenses on lifesaving medicines or vaccines, their options for securing affordable access are compromised. There is an urgent need to consider voluntary licenses from a public interest perspective and countries' responsibility to protect public health and access to medicines.

To date, countries have not played a central role in regulating voluntary licenses or preventing abusive practices that can undermine access to medicines. Nevertheless, there are policy and legal measures governments can and should take to ensure that voluntary licenses do not undermine access to medicines.

For nearly 15 years, MSF has analysed voluntary licenses for pharmaceutical patents and advocated for licensing agreements to improve and expand access to affordable medicines for

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<sup>a</sup> For a detailed explanation of different types of voluntary licenses see glossary.

<sup>b</sup> 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>

people in our care and beyond. Though voluntary licenses have been used on different health technologies, this technical briefing covers licenses related to HIV, hepatitis C, TB and COVID-19 medicines. These voluntary licenses have been signed either bilaterally between companies or via the Medicines Patent Pool (MPP) – a platform through which patent-holding pharmaceutical corporations can make licenses available to generic manufacturer sublicensees on a non-exclusive basis.<sup>c</sup>

Based on MSF’s experience and analysis of voluntary licenses on key medicines, this briefing document analyses voluntary licensing key issues, describes opportunities for government response, presents case studies and recommends steps countries can take to ensure voluntary licenses best promote access to affordable medicines.

## **Key issues with voluntary licenses for access to medicines**

Certain issues and challenges repeatedly arise in voluntary license practices, especially in bilaterally negotiated licenses. Key issues regarding voluntary licenses that can impact access to medicines include: lack of transparency, varying terms across multiple licenses for the same products, overly broad scope of patents, limitations in geographic coverage, and additional limitations that undermine the benefits of bringing in additional manufacturers and lower prices through licensing.

### **1. Lack of transparency**

One major issue with voluntary licenses is that they are often kept secret, even though these agreements can impact people who are waiting for treatments to become available. Companies often do not share the agreements, even upon request from procurers or affected civil society, preventing the public and governments from scrutinizing the terms and conditions.

Pharmaceutical companies – both patent holders and generic manufacturers – often justify this secrecy by claiming that voluntary licenses contain confidential commercial information or trade secrets (see, for example, delamanid case study). When trade secrets are broadly defined by national laws, it allows companies to claim any type of business information as confidential, including licensing terms and conditions.

Lack of transparency is an even greater concern in voluntary licenses between pharmaceutical companies and publicly funded institutions. In Brazil, for example, the government’s industrial policy fostered voluntary licenses on pharmaceuticals and biologicals for public sector

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<sup>c</sup> The Medicines Patent Pool (MPP) was established in 2010 with a mandate to license HIV treatments. Their mandate has since expanded to include treatments for hepatitis C, tuberculosis and ultimately all WHO Essential Medicines List medicines.

manufacturers (see Brazil case study). Yet access to information requests made to public institutions have not received adequate responses. Between 2012 and 2014, the Working Group on Intellectual Property (GTPI), a coalition of Brazilian civil society organizations working on access to medicines, filed 32 access to information requests with the Ministry of Health regarding voluntary licenses. Only 5% got a complete response and in 75% of the cases, the information requested (terms and conditions) was denied and termed as classified information for the sake of national security.<sup>1</sup>

Claiming licensing terms as trade secrets or classified security information is problematic. However, in many countries, current legal mechanisms to ensure transparency of licenses are weak or insufficient (see, for example, India case study). In contrast, all license agreements signed by the MPP are published in full text. Despite industry claims, publication of the terms of MPP licenses has caused no competitive or commercial harm.

## **2. Varying terms through multiple licenses**

Another issue that can impact access to medicines is when voluntary license terms vary on a given medicine, either because companies negotiate multiple agreements or because they amend existing licenses, often without publishing the amendments.

Patent holding companies often prefer to first sign secret bilateral voluntary licenses with generic manufacturers as it is easier to dictate terms and geographical scope in bilateral deals. They may subsequently enter into voluntary licensing agreements with the MPP on the same product but may offer different terms and geographic coverage compared to the confidential license signed bilaterally. The co-existence of different types of agreements on the same products, with some agreements kept secret, make it difficult to identify the actual access options for a given country (see, for example, atazanavir case study). It can also leave some manufacturers locked into less favourable agreements, even when more favourable terms exist.

## **3. Overly broad scope of patents**

Some voluntary licenses may define patents too broadly, including pending applications, appeals to rejected patent applications, and possible future patent applications related to the concerned medicines. This approach may be presented as giving more guarantees to the licensee generic producers that all of the technologies related to the concerned medicines are covered by the license agreement. Yet, including pending applications and potential future applications in a broad definition of enforceable patents in the license also creates problems.

For instance under the first bilateral voluntary license on the HIV medicine tenofovir-disoproxil-fumarate between Indian companies and Gilead in 2006, the definition referred to Gilead's

“patents” without distinguishing between granted patents and pending patent applications.<sup>2,3</sup> In 2011, Gilead’s licences on tenofovir-disoproxil-fumarate with the MPP required sublicensees to comply with the licence until all possible patent disputes have been settled. According to the agreement, a licensee will still have to pay royalties to Gilead and will still be forbidden from selling the medicine in excluded countries until all patents and patent applications have been held invalid and no further appeals are possible.<sup>4</sup>

Bilateral voluntary licenses signed by Gilead with Indian generic manufacturers in 2015 on the hepatitis C medicines sofosbuvir, ledipasvir and velpatasvir are even more stringent.<sup>5</sup> Gilead licensees can supply the medicines to excluded countries when there is no product patent and no “reasonable possibility” for Gilead to pursue a patent.<sup>d</sup> However, patents are defined as both granted patents and applications for the production of both the APIs and finished formulations of the three medicines – including secondary patents. In an atypical extension of the definition of patents, a method of use or method of manufacture patent is also considered a “product patent” under this license. Additionally, a manufacturer could only determine that there were “no patents” in eligible countries if there is no “reasonable possibility of obtaining such a product patent within a reasonable period of time,” but this includes pending applications and additional future patent applications or current or future legal actions (including appeals). Based on this definition, licensees would have difficulty establishing that there is no “reasonable possibility” that Gilead may obtain a patent in India (the manufacturing country) and an excluded country – even if existing patents were opposed, invalidated or not expected to meet patentability standards.<sup>6</sup> Such clauses create a chilling effect on generic manufacturers that may want to enter a territory outside the license where there are no granted patents.

In contrast, licenses such as the ViiV-MPP license for the HIV medicine dolutegravir contain a term allowing sales in countries outside the “territory” if there is no infringement of a blocking patent. This provides greater flexibility to manufacturers to supply medicines in countries outside the territory.<sup>e</sup> As a result, countries like Argentina, Costa Rica, Ecuador, Iran, Mongolia and Thailand, where no patents have been granted, can procure generic dolutegravir, even though they are not explicitly covered under the listed territories of the license.<sup>7</sup>

#### 4. Geographic limitations

A key issue present in many voluntary licenses is that the benefits of these agreements are not available to all populations equally due to geographic restrictions imposed on licensees. It is

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<sup>d</sup> Article 10.3(c)(ii) of Gilead’s bilateral license on sofosbuvir, ledipasvir and velpatasvir. Available from: <https://www.gilead.com/-/media/files/pdfs/other/form-ar-hcv-license-agmt-gild-11202017.pdf?la=en&hash=EA13A53F28CE66946255B7369B57EEFE>

<sup>e</sup> Based on Article 2.4 of the ViiV-MPP licence agreement read together with the MPP’s Expert Advisory Group report, available from: <https://medicinespatentpool.org/uploads/2020/04/ViiV-DTG-EAG-Report.pdf>

standard to include a clause in voluntary licenses describing the “territory” – a list of countries and territories where licensees can produce and/or market the medicine in question. Over the last 25 years patent-holding pharmaceutical corporations have slowly gained greater negotiation power over where generics can and cannot be marketed. These negotiations can exclude millions of people from access to more affordable medicines.

The determination of the list of countries/territories in a voluntary license is often justified based on country income, driven by business interests of the patent-holding company, which may leave out many countries with a high burden of disease where more affordable generic medicines are desperately needed. This may even exclude countries where the medicine is manufactured. Licensees may use additional leverage through technology transfer terms to further limit the geographic scope of a license.

#### Flaws of reliance on GNI per capita for health objectives

Companies negotiating voluntary licenses often justify their territorial decisions to exclude countries based on the fact that they are classified as middle- or high-income countries according to the World Bank ranking of countries’ gross national income (GNI) per capita,<sup>f</sup> despite the potential negative impact on access to medicines where they are needed most.

The World Bank classification scheme has not been significantly adjusted since 1989 other than for inflation. Numerous countries have moved up the income classification from low- to middle-income over time. Yet, research has demonstrated that GNI per capita was not a statistically significant predictor of health disparities, after controlling for other factors.<sup>8</sup> Countries classified as middle income are home to 75% of the world’s population, 62% of the world’s poor<sup>9</sup> and face a double burden of communicable and non-communicable disease.<sup>10</sup>

Health needs and resource gaps (such as health budgets, infrastructure, human resources, etc.) should be a much more significant factor for determining country inclusion in voluntary licenses. In early 2015, the heads of multilateral organizations engaged in global health launched the Equitable Access Initiative (EAI) to consider alternatives to GNI as a framework to assess countries’ need for external financial support for health.<sup>8</sup> The EAI similarly recommended that greater consideration should be given to countries’ health needs and domestic capacity.<sup>11,12</sup>

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<sup>f</sup> The World Bank classifies countries as low-income, lower-middle-income, upper-middle-income, and high-income. More info available from: <https://datahelpdesk.worldbank.org/knowledgebase/articles/906519-world-bank-country-and-lending-groups>.

<sup>8</sup> The Equitable Access Initiative (EAI) was launched in early 2015 by the heads of multilateral organizations engaged in global health: Gavi, the Global Fund, UNAIDS, UNDP, UNFPA, UNICEF, UNITAID, the World Bank and WHO.

Still, the World Bank, donor agencies such as the Global Fund for AIDS, Tuberculosis and Malaria, Gavi, the Vaccine Alliance, and other global health initiatives continue to rely on income classifications to define funding eligibility, resource allocation, and, in the case of pharmaceutical companies, tiered pricing and geographic exclusion in voluntary licenses. As a result, a number of countries that are categorised by the World Bank as upper-middle-income countries are left out of most voluntary licenses despite their high disease burdens and challenges addressing health needs.

For instance, Brazil and China have been excluded from all voluntary licenses covered in this briefing analysis. Most recently, despite facing a global pandemic, Gilead excluded Brazil along with most South American countries, China and Russia from a voluntary license secretly signed with a few generic companies on remdesivir, a medicine first developed for Ebola and later repurposed to treat COVID-19 (Annex 1). Under the WHO Solidarity Therapeutic Trial for COVID-19, the final results demonstrate little to no effect of the medicine in reducing mortality.<sup>13</sup> Nevertheless, Gilead's business strategy has set a negative precedent by offering a voluntary license that excludes nearly half of the world's population during a global pandemic.

Other examples of licenses that have excluded several middle-income countries include: AbbVie's 2019 MPP license agreement for glecaprevir/pibrentasvir;<sup>14</sup> Gilead's 2015 license on hepatitis C medicines;<sup>15</sup> Gilead's 2011 MPP license for several HIV treatments;<sup>16</sup> AbbVie's 2014 MPP license agreement for lopinavir/ritonavir and ritonavir (see case study); and ViiV's 2016 MPP license agreement for dolutegravir.<sup>17,18</sup>

#### *"Manufacturing only countries" and the prohibition of supplying home markets*

Some voluntary licenses even exclude countries where affordable generic medicines are manufactured, defining them as "manufacturing only countries." Licensees based in these countries can only produce and supply other countries listed under the license territories but are prohibited from supplying their home country markets.

For example, under the 2018 AbbVie-MPP voluntary license for the hepatitis C treatment glecaprevir/pibrentasvir, India is a manufacture-only country. India is home to a large hepatitis C epidemic, yet this restriction leaves people in India and Indian public health programmes without access to more affordable generic glecaprevir/pibrentasvir, even though these medicines are being manufactured in country.<sup>19</sup> The absence of a domestic market opportunity also stifles interest from Indian generic companies that might have otherwise had interest in developing this product.



Similar exclusions apply in other MPP licenses. Chinese generic manufacturers have signed sublicense agreements with the MPP on Gilead’s tenofovir alafenamide, ViiV’s dolutegravir, AbbVie’s lopinavir/ritonavir, and Bristol Myers Squibb’s atazanavir to export to other countries,<sup>h</sup> but China itself is not included in the license territory, leaving people in China without access to generic versions of these life-saving HIV medicines that are manufactured domestically.

This licensing practice raises ethical questions about harnessing the capacity of developing countries to develop, produce and supply quality medicines, while at the same time prohibiting generic companies from responding to considerable unmet medical needs domestically.<sup>20</sup>

#### Restrictive clauses concerning the use of know-how

In addition to patents, voluntary licenses may also have conditions related to sharing non-patented, practical, secret information (“know-how”) regarding the manufacture of the API and/or finished formulations. This know-how may reduce the time it takes licensed generic manufacturers to develop a generic version. However, the know-how transfer conditions may include additional restrictions of sales outside the license territory, even in countries where the medicine is off patent (see, for example, atazanavir case study). In the short term, clauses related to know-how may offer a faster route to a generic launch, but they may do so at the expense of a licensee’s ability to supply countries outside the listed territories where patents do not apply.<sup>21</sup>

### **5. Differential treatment of age groups, formulations and medical indications**

When voluntary licenses exclude or set up different terms and conditions for different versions of the same medicine, people seeking treatment may lose out. This differential treatment has been applied to different age groups, formulations and medical indications in various licenses.

Some licenses have applied different terms for formulations that can be prescribed to both adults and children. This can impact people’s access to the most appropriate treatments (see, for example, lopinavir/ritonavir case study). For example, a 50mg dose of dolutegravir may be prescribed to children living with HIV<sup>i</sup> and adults. Yet under the patent-holder ViiV’s license with the MPP, countries like Azerbaijan, Colombia, and Malaysia are included in a paediatric license, but not an adult formulations license. This means adults in these countries are left without affordable access to an important treatment. It also leaves procurers like MSF faced with complexities in procurement. Generic suppliers can request that purchase orders explicitly mention consumption by paediatric patients. However, MSF and procurement agencies often maintain advance stock to support medical projects in a timely way and requesting such data is not required from a medical standpoint and will lead to unnecessary delays.

<sup>h</sup> Refer to the licenses published by the MPP, available from: <https://medicinespatentpool.org/progress-achievements/licences/>

<sup>i</sup> Recommended for children in the ≥20kg weight band.

Other licenses have imposed restrictions based on indications. For example, TB Alliance (TBA) has created bedaquiline-pretomanid-linezolid (BPaL) as the first all-oral, 6-month treatment regimen for highly resistant forms of drug-resistant TB. The regimen has been approved by the US Food and Drug Administration for extensively drug-resistant TB treatment and was subsequently licensed by TBA to Mylan and may be licensed to other manufacturers.<sup>22</sup> However, pharmaceutical corporation Johnson & Johnson (J&J) holds the patents on the TB medicine bedaquiline, and has only licensed bedaquiline to TBA for the use of the medicine to treat drug-susceptible TB.<sup>j,23,24</sup> So treatment providers who want to prescribe BPaL will have to source bedaquiline from J&J separately and pretomanid and linezolid from Mylan or a third supplier, making procurement of the regimen complex for TB programmes. Only bedaquiline is currently covered by a patent.

## 6. Differential treatment of health care systems

Through voluntary licenses companies can apply different terms or exclusions for medicines provided within different health care systems. For instance, under the ViiV-MPP license on dolutegravir,<sup>25</sup> 12 countries are included as royalty-bearing countries, which are further categorized into different tiers with differential rates of royalties.<sup>26</sup> For these countries, the license also differentiates the “public market,” including treatment programmes provided by governments, UN agencies or non-governmental and humanitarian organisations, from the “private market,” where people are likely to pay much higher prices and out-of-pocket.<sup>27</sup>

ViiV’s license allows generic companies to supply both public and private markets in the royalty-free countries, but only the public market in the 12 royalty-bearing countries, with distinguishable packaging stating the restricted supply destination.<sup>28</sup> While this approach may have been presented as expanding the overall number of countries included in the license territory, it also presents significant problems for people who need medicines by segmenting the market.

In some countries, treatment programmes under the government that are defined as the “public market” may delay updating treatment guidelines to include new medicines, even if they have access to generic versions under a license. People who have developed drug resistance and need urgent access to newer medicines have no choice but to seek treatment with these medicines in the private health sector, where they will pay higher prices for the branded dolutegravir product in the absence of less expensive generic options.<sup>29</sup>

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<sup>j</sup> In June 2009, the TB Alliance, a not-for-profit product development partnership negotiated a royalty-free license for the worldwide development of, and access to, bedaquiline in the field of DS-TB with Janssen, a subsidiary of Johnson & Johnson. Tibotec, an affiliate of Janssen, had developed bedaquiline for the treatment of drug-resistant TB and is solely responsible for supply of bedaquiline for DR-TB.

## 7. Complexities of tiered royalties

Another issue with voluntary licenses is when they introduce complex systems of royalty payments that burden treatment providers and people receiving treatment by driving up prices and complicating procurement processes. For example, under ViiV's license for adult formulations of dolutegravir with the MPP, royalties ranging from 5-10% apply in countries where there is a patent granted and in force. Under this license, sublicensed generic suppliers are required to pay 5% in royalties in India, Philippines, Moldova and Vietnam; 7.5% in Egypt, Indonesia, Morocco, Armenia and Ukraine; and 10% in Turkmenistan. In MSF's experience, generic manufacturers transfer the burden of paying higher royalties on to procurers and people in need of treatment by adding the royalty rate to the prices of the end-product supplied. MSF has also received requests to provide country of destination information to generic manufacturers that supply dolutegravir and dolutegravir-based fixed-dosed combinations in order to calculate royalties and final prices, which complicates the process of procurement.

Companies should implement a simple system of royalties in voluntary licenses for ease of administration. Additionally, royalties should be applicable only in territories where there are patents in force.

## 8. Restrictions on the source and production of API

Some voluntary licenses include restrictive terms on the source and production of active pharmaceutical ingredients (APIs), which are an indispensable part of formulating the final products of medicines and constitute a significant percentage of the total cost of production. The ability to manufacture APIs under a more efficient process or procure from alternative sources plays an important role in ensuring affordable prices for finished products.<sup>30</sup> Restricting the sources of API blocks potential producers in other countries from producing and competing in international markets.

Since 2006 Gilead has signed three voluntary licenses directly with Indian generic companies and API manufacturers which include terms controlling API supply. This includes licenses for the HIV medicine tenofovir (2006); direct-acting antivirals sofosbuvir, ledipasvir and velpatasvir to treat hepatitis C (2015); and the COVID-19 medicine remdesivir (2020). Gilead signed a similar license with the MPP on the HIV medicines tenofovir and other antiretrovirals (2011). Each of these license agreements include clauses limiting licensee generic companies to only source and supply API from/to each other or Gilead, prohibiting them from sourcing or supplying API with any other companies outside of Gilead's license.<sup>k,31</sup> This caused concerns in countries that rely on API

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<sup>k</sup> Article 2.1(a) of Gilead's voluntary license on hepatitis C medicines. Full license available from: <https://www.gilead.com/-/media/files/pdfs/other/form-ar-hcv-license-agmt-gild-11202017.pdf?la=en&hash=EA13A53F28CE66946255B7369B57EEFE>

supply from the licensee generic companies, such as Brazil. Brazilian civil society challenged Gilead's patent application on tenofovir in India due to concerns that Gilead's voluntary licenses prohibited export of the medicine or API to certain middle-income countries, including Brazil, even though no patent on the medicine had been granted.<sup>32</sup>

Some licenses do not allow licensees to manufacture APIs, such as the 2017 agreement signed between company Otsuka and Mylan on the TB medicine delamanid. Currently, Mylan can only produce and supply delamanid tablets using API from Otsuka at prices set by Otsuka. The result is that Mylan's generic versions of the medicine are not priced substantially lower than Otsuka (see delamanid case study).

### **9. Anti-diversion requirements**

Many voluntary licenses include "anti-diversion" clauses, which attempt to prevent generic medicines produced under the license from being resold to individuals or countries outside of the territory, in order to preserve lucrative high- or upper-middle-income markets for the patent-holding company.

For example, ViiV's license with the MPP for dolutegravir includes an anti-diversion clause requiring "jurisdiction-specific packaging" for paediatric medicines supplied to countries which are not within the scope of their separate adult formulation license. This entails having separate packaging for paediatric versions of dolutegravir 50mg as a way for ViiV to enforce the territory of the license and prevent adults in these countries from accessing the generic version of the drug.

Gilead also included such an "anti-diversion" programme in its voluntary license with a number of Indian generic companies for the hepatitis C medicine sofosbuvir in 2014.<sup>33</sup> The extent of the burden this clause placed on generic manufacturers, treatment providers and people in need of medicine solely to protect Gilead's commercial interests was unprecedented at the time and the subject of a detailed analysis by MSF.<sup>34,35</sup> MSF's analysis highlighted how the stringent requirements under this clause burden treatment providers with dispensing restrictions that may interfere with doctor-patient confidentiality (requiring personal contact information from providers and patients, for example) and require people to be a citizen of the country where they are accessing treatment (negatively impacting refugees and migrants).<sup>36</sup>

Including an anti-diversion clause in a voluntary license could eliminate the possibility of using countries outside the defined territory using parallel importation – purchasing a medicine in one country and transporting it into another. For instance, in Gilead licenses, there are burdensome reporting requirements that attempt to deter parallel importation. In MSF's experience,

procurers end up having to share importation documentation or permits as proof to generic companies that in turn have to report to which countries they have sold the medicines. Gilead's requirements include strict monitoring of third-party distributors and resellers within licensee's distribution and supply chain, and Gilead's right to approve third-party agreements and termination rights.<sup>l</sup> Such clauses also require generic licensees to impose anti-diversion terms on their own distributors.<sup>m</sup>

## 10. Restrictions on research and clinical studies

Some voluntary licenses contain terms to prohibit licensee generic companies from conducting additional research or clinical studies with the licensed products without the consent of the patent-holding company. This could include clauses that say generic companies "shall conduct no studies or basic research or pre-clinical, clinical or other trials" with the licensed product without the written consent from the licensor.<sup>n</sup> Restrictions on the scope and extent of conducting research or clinical studies with the licensed product is concerning because it risks undermining the statutory research and experimental use exception allowed by many national laws,<sup>o</sup> and in compliance with the World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement).<sup>p</sup>

## 11. Grant-back terms

Voluntary licenses may also impede access to medicines and innovation when they include "grant-back" clauses. These clauses are used by licensors to gain control over improved manufacturing processes and formulations developed by other licensee manufacturers. They do so by requiring licensees/sublicensees to agree to "grant-back" any rights to improvements in process or formulation developed by the licensee/sublicensee that relate to the original patent.<sup>37</sup>

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<sup>l</sup> See, for example, Article 2.4 (b) and Article 3.6 of the Gilead license on hepatitis C medicines. Available from: <https://www.gilead.com/-/media/files/pdfs/other/form-ar-hcv-license-agmt-gild-11202017.pdf?la=en&hash=EA13A53F28CE66946255B7369B57EEFE>

<sup>m</sup> See, for example, Article 2.4 (b) of the Gilead license on hepatitis C medicines. Available from: <https://www.gilead.com/-/media/files/pdfs/other/form-ar-hcv-license-agmt-gild-11202017.pdf?la=en&hash=EA13A53F28CE66946255B7369B57EEFE>

<sup>n</sup> See, for example, License Agreement, By and Between Merck, Sharp & Dohme Corp and MSD Tuas Singapore PTE Ltd as the Licensor and Emcure Pharmaceuticals Ltd., as the Licensee, of May 25, 2011, Section 5.1 Copy of this license on HIV medicine raltegravir obtained on request.

<sup>o</sup> For example, Sec. 47(3) of the Indian Patent Act. According to an official response of India to WIPO questionnaire on exceptions and limitations under patent law, there is no limitations on the scope and extent to the experimental use and research of the patented product according to law. More details available from: <https://www.wipo.int/export/sites/www/scp/en/exceptions/submissions/india.pdf>

<sup>p</sup> The WTO TRIPS Agreement is an international trade agreement which came into force between 1995 and 2005. It sets minimum requirements for pharmaceutical intellectual property laws and enforcement among WTO members. Article 30 of TRIPS agreement allows countries to adapt exceptions to the exclusive rights under patent protection. Research and experimental use exception is one of the long standing common practices at national levels that is in compliance with Article 30 of TRIPS.

Under AbbVie’s 2018 license to the MPP for glecaprevir/pibrentasvir the grant-back terms in the agreement may impose restrictions on marketing of new formulations developed by sublicensees. The main license agreement contains a grant-back clause for sublicensees covering new formulations developed after taking the current license agreement,<sup>9</sup> extending to sublicense agreements signed between the MPP and sublicensee generic companies. Accordingly, if any new glecaprevir/pibrentasvir formulation is developed by sublicensees, they will need to provide AbbVie the option (and the right of first refusal) to obtain the sole right to purchase the new glecaprevir/pibrentasvir formulation for sale in the US and EU, or a sole license to any patents and know-how necessary to use the new glecaprevir/pibrentasvir formulations in the US and EU.<sup>†</sup> The grant-back clause also requires sublicensees to offer AbbVie an option to a non-exclusive and royalty-free license to commercialise the new glecaprevir/pibrentasvir formulation in all countries outside the US and EU.<sup>‡</sup> These grant-back obligations mean that AbbVie will benefit from new glecaprevir/pibrentasvir formulations developed by sublicensees to supply territory and non-territory countries. However, there is no reciprocal benefit that would allow a licensee to supply non-territory markets should they develop a new formulation.

This grant-back clause requires further analysis to understand its potential impact on competition among manufacturers that wish to develop new formulations of glecaprevir/pibrentasvir in the future. Such clauses may create disincentives for generic producers to develop long-acting formulations as their market access in high-burden countries is heavily restricted by the license.

## Opportunities for government action

### Regulating voluntary license practices

The issues with voluntary licenses discussed above raise the question of how practices of negotiating license agreements between private entities can be regulated. Despite the fact that a voluntary license is a commercial agreement, the effects of licensing terms may affect people’s right to health and access to medicines and as such should require government oversight and regulation. Fortunately, existing mechanisms under international and national laws offer some options to closely monitor and regulate voluntary licenses. These include provisions in the international TRIPS Agreement, national voluntary license registration and regulation laws, and national competition laws.

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<sup>9</sup> Article 3.9 of the Abbvie-MPP license for glecaprevir/pibrentasvir. Available from: <https://medicinespatentpool.org/licence-post/glecaprevir-pibrentasvir-g-p/>

<sup>†</sup> Article 3.9(a) of the Abbvie-MPP license for glecaprevir/pibrentasvir. Available from: <https://medicinespatentpool.org/licence-post/glecaprevir-pibrentasvir-g-p/>

<sup>‡</sup> Article 3.9(b) of the Abbvie-MPP license for glecaprevir/pibrentasvir. Available from: <https://medicinespatentpool.org/licence-post/glecaprevir-pibrentasvir-g-p/>

The TRIPS Agreement authorises countries to prevent abusive IP practices that “unreasonably restrain” competition, trade or technology transfer.<sup>t,38</sup> The two most often used approaches to regulate voluntary licenses through national laws are the registration of licenses and the use of competition laws to tackle abusive license terms.<sup>39</sup>

A number of countries have included a requirement for voluntary licenses to be registered or approved by the competent public authorities. For instance, under Brazilian patent law, licenses on patents need to be recorded by the Brazilian National Patent Institute (INPI) to be effective and must be registered with the Central Bank of Brazil.<sup>40</sup> In Thailand, patent licenses must be registered with the Department of Intellectual Property.<sup>41</sup> However, the requirements stop short of publishing, and countries may in practice exercise no oversight of the terms of voluntary licenses. Increasing transparency is extremely important to enable government scrutiny of licenses and prevent anti-competitive practice that may negatively impact both local and global markets (see, for example, India case study).

In addition, some voluntary license terms may constitute anti-competitive practices and be subject to anti-competition inquiry. National laws and policies prohibiting anti-competitive licensing practices may vary. For instance, Philippines’ rules and regulation on voluntary license prohibit clauses with specific requirements for sourcing raw materials.<sup>42</sup> The Indian Patent Act outlaws coercive package licensing<sup>u</sup> and license terms that require exclusive grant-back or that prevent patent challenges.<sup>43</sup> The Draft Guideline for Anti-competitive Licensing of Intellectual Property (2017) issued by the National Anti-Monopoly Bureau of China, also calls for scrutiny of terms requiring exclusive grant-back licensing and preventing patent oppositions.<sup>44</sup> For national authorities formulating such laws and policies, the United Nations Development Programme (UNDP) has published a list of typical abusive or anti-competitive provisions in voluntary licenses as a reference.<sup>45</sup>

However, national laws and regulation on voluntary licenses are not consistently applied, as evidenced by some of the challenges presented in the voluntary licenses in this analysis. Existing regulations need to be enforced to be effective. Further, given that both IP laws and competition laws set rules nationally, the effectiveness of using existing law and policy measures to regulate voluntary license practices in a transnational context still require further studies and exploration.

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<sup>t</sup> See, for example, Articles 8 and 40 of the TRIPS Agreement. More details available from: [https://www.wto.org/english/tratop\\_e/trips\\_e/intel2\\_e.htm](https://www.wto.org/english/tratop_e/trips_e/intel2_e.htm)

<sup>u</sup> Coercive package licensing is a practice whereby licensees are required to accept purchase a ‘package’ of patents and non-patented goods, even if those patents and goods are not what the licensee needs.

### **Compulsory licensing**

Countries may also find that patent-holding pharmaceutical corporations refuse to grant a license on a medicine or only agree to offer an extremely restricted scope of a license.<sup>46,47</sup> In these circumstances, countries have options available to remedy the situation, including consideration or use of compulsory licenses. 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 licenses (a form of compulsory license), in accordance with the TRIPS Agreement and the Paris Convention for the Protection of Industrial Property (see Malaysia case study).<sup>4</sup>

Particularly in contexts such as the drug-resistant tuberculosis (DR-TB) public health emergency or the 2020 COVID-19 pandemic, the decision to enable manufacture and sale of more affordable versions of urgently needed medicines must not be left to voluntary, “business as usual” commercial practices. Supporting and encouraging countries to use all of the public health safeguards available to them through the TRIPS Agreement, especially government use licenses, can overcome the limitations of relying on voluntary licenses. The power of compulsory licenses – both consideration of and use in practice – also provides an important leverage point and could possibly compel patent-holding companies to improve their practices in voluntary licensing (see Israel case study).

In response to the COVID-19 pandemic, a number of countries have amended or started changing their patent laws, rules and regulations to facilitate easier and quicker processes for the grant of compulsory licenses for government use. These countries have traditionally been excluded from past voluntary licenses on HIV and hepatitis C medicines, including Australia,<sup>48</sup> Brazil,<sup>49</sup> Canada,<sup>50</sup> Chile,<sup>51</sup> Ecuador,<sup>52</sup> Germany,<sup>53</sup> and Hungary.<sup>54</sup>

### **Enabling patent oppositions**

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 offices have rejected or revoked patents in response to patent oppositions by civil society in middle-income countries excluded from voluntary licenses. These decisions successfully prevent the establishment or extension of a patent monopoly and open up local production and supply of the medicine.<sup>55,56</sup> Rejection or revocation of a patent as a result of patent oppositions could also lead to termination of the license or “unbundling” of non-patented medicines by licensees from a broader license agreement giving them greater freedom



to operate and supply globally.<sup>v</sup> Patent oppositions can also offer licensees leverage to negotiate more flexible terms, such as the expansion of territories covered under an existing voluntary license.

## Voluntary licensing case studies

The key issues with voluntary licenses are not new, and many examples from past and current licenses demonstrate how in practice unregulated voluntary licenses can impede access to medicines. Voluntary licenses on atazanavir, delamanid and lopinavir/ritonavir show how multiple issues can occur in any given license. Similarly, responses from Brazil, India, Israel and Malaysia illustrate both the roles that countries can play to promote access to medicines and/or the opportunities for improvement in government response.

## Medicines

### Atazanavir

Atazanavir is a protease inhibitor used in combination with another treatment, ritonavir, as a second-line treatment of HIV. Generics are available, including in a fixed dose of atazanavir 300mg/ritonavir 100mg for less than 20 USD per month.<sup>57</sup> However in some countries where the medicine is patented by Bristol Myers Squibb (BMS), HIV programmes and people living with HIV face barriers in accessing these affordable formulations. While the compound patents on this medicine have expired in many countries, secondary and/or process patents remain in countries not covered by voluntary licenses (for example, Brazil, China, Mexico and Russia).

In February 2006, BMS entered into an agreement for patents on atazanavir with generic companies Aspen PharmaCare (South Africa) and Emcure Pharmaceuticals (India).<sup>58</sup> BMS subsequently entered into an agreement with Matrix, an Indian subsidiary company of the US generic company Mylan for the territories of sub-Saharan Africa and India.<sup>59</sup> In November 2011, BMS also announced an agreement with the Brazilian Ministry of Health with limited geographic scope, limited scope of the licensed IP and restrictive terms for technology transfer.<sup>60</sup> In December 2013, BMS granted the MPP a voluntary license that could be sublicensed to generic manufacturers to supply atazanavir in 110 countries, which was further extended in 2017 to include 12 additional countries: Algeria, Cook Islands, Egypt, Equatorial Guinea, Indonesia, Malaysia, Morocco, Niue, Philippines, Tunisia, Ukraine and Vietnam.<sup>61</sup>

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<sup>v</sup> 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>

These licenses demonstrate at least three abusive license practices: lack of transparency, limited geographic coverage and restrictive terms for accessing know-how.

*Lack of transparency:* Through multiple deals across more than a decade, most of which were not public, BMS created a thicket of licenses. The result was a lack of transparency that made it difficult to understand where generic formulations of atazanavir could be supplied under the terms of these licenses.

*Geographic limitations:* The BMS-Matrix license agreement on atazanavir restricted geographic coverage, even in countries where no blocking patents were granted. For example, when Mylan's Indian subsidiary won PAHO's tender for procurement of atazanavir for Venezuela in 2012 and 2014, BMS sued Mylan in the US and subsequently in Indian courts to prevent export to Venezuela. Venezuela was not included in the list of licensed territories of the Matrix/BMS license, but there were also no granted product patents on the compound, pro-drug or salt form in India or Venezuela.<sup>62</sup> Mylan was only able to export a consignment of medicine (100,000 bottles) in the last quarter of 2014, after the injunction sought by BMS was rejected by Indian courts.<sup>63</sup>

*Restrictive terms for accessing know-how:* The 2013 BMS-MPP license on atazanavir lists 110 countries in its territory. When the license was signed, there were another 34 countries where BMS had no granted patents. In principle, BMS should not have been able to prevent generic competition where it didn't have any patent rights. This was reflected in paragraph 2.7(C) of the licensing agreement, which entitled generic companies export atazanavir to these additional 34 countries.<sup>64</sup> However, if sublicensees relied on the manufacturing know-how offered by BMS, then according to the licensing agreement, supply outside of the territory constituted breach of the agreement – even in the absence of any granted patent rights.

### Delamanid

Delamanid – a medicine recommended by WHO to treat drug-resistant tuberculosis – was launched at a price of US\$ 1,700 for a six-month regimen, making it one of the most expensive oral TB medicines. Many people need the medicine for up to 20 months, further escalating costs.<sup>65</sup> Delamanid's high price contributes significantly to MSF's expenses for treating people with extensively-drug-resistant TB (XDR-TB). Japanese company Otsuka holds the primary patents of delamanid in a number of countries, including in many high-burden countries.<sup>w</sup>

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<sup>w</sup> The primary patent on delamanid (WO2004033463) has been granted in China, India, Russia, and South Africa and is pending Brazil, all of which are TB high-burden countries. More details available from: [https://www.medsopal.org/?product\\_standardized\\_name%5B%5D=Delamanid+50+mg&page=1](https://www.medsopal.org/?product_standardized_name%5B%5D=Delamanid+50+mg&page=1)

Instead of licensing the patents on the medicine non-exclusively and transparently, Otsuka signed secretive deals in 2017. Otsuka signed an initial license agreement with generic pharmaceutical company R-Pharm to supply delamanid in Eastern Europe and Central Asian countries.<sup>66</sup> They signed a second license with the US pharmaceutical company Mylan for distribution in India, South Africa and where Otsuka has no commercial presence.<sup>67</sup> Despite the existence of these licenses, prices of delamanid have not fallen significantly as they should with the availability of a generic source.<sup>68</sup>

The delamanid licenses demonstrate at least three abusive licensing practices: lack of transparency, restrictions on the source and production of API, and geographic limitations.

*Lack of transparency:* Terms and conditions of these licenses are unknown, making it difficult to determine whether the agreements are aligned with public health needs or are merely a strategy to keep Otsuka's control of the market. The TB community has requested that Otsuka and the licensees make the license public, but the companies have not responded.

*Restrictions on the source and production of API:* According to Mylan, it can produce delamanid but must use API sourced from Otsuka. Mylan can only begin using its own API to produce delamanid in late 2021 – a year before the patent expires and the expected entry of other producers. As API represents a significant portion of the final price of a medicine,<sup>69</sup> by not allowing Mylan to independently manufacture or source APIs independently, the agreement inhibits the generic manufacturer from offering finished delamanid formulations at lower prices.

*Geographic limitations:* Otsuka's voluntary license with Mylan does not cover all "high-burden countries" (HBC) affected by TB, TB and HIV coinfection, and multidrug-resistant TB. As a result, these HBCs cannot benefit from the lower prices that may be achieved when Mylan begins producing finished formulations with its own API in 2022.

### Lopinavir/ritonavir

The HIV medicine lopinavir/ritonavir, recommended as a first-line treatment for all HIV-positive infants and children as well as part of second-line treatment for adults, is one of the most widely patented medicines globally with exclusivity potentially running until 2024.<sup>x</sup> For years the patent

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<sup>x</sup> A patent application on a heat-stable formulation of LPV/r has been granted in a few low- and middle-income countries. More details of the patent status of LPV/r in low- and middle-income countries can be found at MedsPal database. Available from: [https://www.medsPal.org/?product\\_standardized\\_name%5B%5D=Lopinavir%2FRitonavir+100%2F25+mg&page=1](https://www.medsPal.org/?product_standardized_name%5B%5D=Lopinavir%2FRitonavir+100%2F25+mg&page=1)

holder AbbVie (formerly Abbott) has enforced its monopoly and charged very high prices in several middle-income countries, such as Brazil and Malaysia.<sup>70</sup>

AbbVie signed a voluntary license agreement with the MPP in 2014 for some paediatric low-strength formulations of the treatment of HIV in young children in 102 countries. In 2015, with major stockouts of adult lopinavir/ritonavir in South Africa, AbbVie issued a voluntary license for the adult formulation of lopinavir/ritonavir and ritonavir with the MPP but limited this license to 54 African countries. All countries outside of Africa remained excluded from access to generic adult formulations of lopinavir/ritonavir and ritonavir where patents were in force.<sup>71</sup>

These licenses demonstrate at least two abusive licensing practices: geographic restrictions and differential treatment of age groups.

*Geographic restrictions:* The 2014 paediatric agreement was limited to 102 countries, excluding a number of middle-income countries, such as Argentina, Brazil, China and Ukraine.<sup>72</sup> When AbbVie finally agreed to sign a voluntary license with the MPP for adult formulations in 2015, it prohibited supply for people in all countries outside of Africa where its patents were in force, including Israel (see Israel case study).<sup>73</sup>

*Differential treatment of age groups:* The agreement initially excluded adult formulations and was limited to only some paediatric formulations. AbbVie only licensed the liquid formulation of lopinavir/ritonavir and the specific 40mg/10mg oral formulation of lopinavir/ritonavir that is used for children under three years old to the MPP.<sup>74</sup> The license left out the 100mg/25mg paediatric tablet formulation used for children older than three years because they were concerned that adults could be treated with a double dose of the paediatric tablet. To maintain its monopoly over the adult formulation market, AbbVie's voluntary license with the MPP left a significant gap for children over 3 years old as well as adults in need of suitable generic formulations of lopinavir/ritonavir in the countries not covered by the territory.<sup>75</sup> The discrepancy between the coverage for adults and children in this license shows a clear conflict between what is needed to increase access to optimised treatment regimens and the commercial interests of pharmaceutical corporations.

## *Country responses*

### *Brazil's voluntary licenses under the framework of national industrial policies*

Some countries may adopt industrial policies aimed at strengthening national production capacity for health technologies including for medicines and vaccines, attracting investments and building know-how. For example, Brazil has adopted an industrial policy based on product

development partnerships<sup>y</sup> (PDPs) in the field of pharmaceutical and biological products to encourage domestic production of generic medicines needed to support Brazil's public health system. These PDPs may be between foreign patent-holding corporations and national companies (including public laboratories) and are negotiated as part of a broader technology transfer agreement involving some level of IP licensing. Between 2004 and 2018, the Brazilian government approved 141 PDPs for pharmaceuticals and biologicals, of which 66 included 29 foreign companies. The contracts offer public purchases of the product as an incentive in exchange for technology transfer, licensing of patents, and price reductions for the first few years until a generic is ready. The contracts involve exclusive supply of the product in exchange for complete technology transfer (including for the API) and voluntary licensing.

However, these voluntary licenses often result in restrictive terms and conditions for access and insufficient technology transfer outcomes. For example, the Working Group on Intellectual Property from the Brazilian Network for the Integration of Peoples, coordinated by the Brazilian Interdisciplinary AIDS Association (ABIA), identified a number of problems in a detailed review of the PDP contract between the US-based company Bristol Myers Squibb (BMS) and the public laboratory Farmanguinhos (hosted by Fiocruz) for the antiretroviral medicine atazanavir.<sup>76</sup> This analysis demonstrates that there should be stronger regulation of licenses, especially when they involve essential medicines and public entities.

Some of the problems observed in the BMS-Farmanguinhos contract were:

1. The locally produced generic could not be exported to any country and even exportations based on humanitarian grounds needed authorization from the licensor.
2. The agreement included an obligation to buy the original product from the licensor during an initial five-year technology transfer term (100% of the national demand in the first 3 years and 50% in the last 2 years). As per the original timeline, the purchase obligation with the licensor would last until 2017. However, due to delays, this obligation was extended until 2019. Because the licensed patent expired in 2017, this agreement effectively created an additional exclusivity term.
3. The agreement licensed only the base-compound patent<sup>z</sup> and did not include all the relevant atazanavir secondary patents in the agreement.<sup>aa</sup>
4. The agreement expressly prohibits Fiocruz from developing combinations, such as atazanavir/ritonavir. This combination is a key component of second-line HIV treatments, as recommended by WHO.

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<sup>y</sup> Known as "partnerships for productive development" in Brazil's policy.

<sup>z</sup> Brazilian patent number: BR9701877-5

<sup>aa</sup> In 2019, the Brazilian patent office granted a secondary patent on atazanavir (BR 0509595-6) and it remains to be seen how this may affect the supply of the generic version resulting from the PDP. Civil society organization filed for a revocation in 2020.

5. A year-by-year price reduction commitment included in the agreement was not achieved in the first three years, as the price remained the same from 2012 to 2015.
6. As of 2020, the technology transfer has still not been concluded,<sup>77</sup> nine years after the signature of the agreement, and BMS continues to be the major supplier of this medicine in Brazil.<sup>bb</sup>

### *India's lack of transparency of licenses*

As many of the bilaterally negotiated licenses signed by multinational pharmaceutical corporations are with Indian generic companies, the issue of transparency is particularly important in India. Yet, India's current legal mechanism for transparency of licenses is insufficient.

Under Section 69 of the Patents Act of India, companies are required to register licenses with the Patent Office. However, under the same provision, if the patentee or licensee requests, the Patent Controller shall "take steps to ensure that the terms of the license are not disclosed to any person except under the order of a court."<sup>78</sup> This provision can create barriers for treatment advocates to increase transparency as they would be required to obtain a court order in these cases – a lengthy and expensive process.

India also provides some rules related to transparency through the 2005 Right to Information Act. The Act allows public access to data held by the government. It excludes commercial and IP-related information but allows such disclosure in the public interest.<sup>79</sup> However, the public interest exception is not particularly helpful when such IP-related agreements are shielded by the Patents Act of India's court order requirement discussed above. The Competition Commission of India similarly has a mandate to look into such bilateral licenses, has stayed away from examining the impact of the licenses on the pharmaceutical market and generic competition.

The pharmaceutical industry and other stakeholders have been lobbying in India to keep licensing terms out of the public domain on the grounds of preserving commercial interest.<sup>80</sup> However, the public interest need for transparency should always take precedence over consideration of commercial interests.

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<sup>bb</sup> In contrast to this voluntary license deal's 9-year process, when Brazil issued a compulsory license for efavirenz, the local development of a generic version took 21 months, making the generic available to the public health system in under 2 years. This was accomplished without any technology transfer.

### *Israel's compulsory license addresses worldwide barriers to HIV medicine*

A recent example from the government of Israel illustrates the important interplay between government-led responses like compulsory licenses and the improvement of voluntary measures by companies.<sup>cc</sup> In March 2020, the Ministry of Health of Israel issued a compulsory license on the HIV treatment lopinavir/ritonavir to enable the generic supply as a potential repurposed treatment for COVID-19.<sup>dd</sup> That same day, in response to Israel's issuance of a compulsory license, AbbVie notified the MPP that it will not enforce its patents over lopinavir/ritonavir for any purpose anywhere in the world (a "non-assert declaration").<sup>81</sup> After years of restricted access to lopinavir/ritonavir across the world as one of the most widely patented medicines, the fact that one single government took action to implement a TRIPS public health safeguard in the context of the COVID-19 pandemic has transformed and improved access for people living with HIV.

### *Malaysia successfully addresses voluntary license exclusion*

In 2014, when pharmaceutical company Gilead issued a voluntary license on a revolutionary new hepatitis C treatment, sofosbuvir, Malaysia – an upper-middle-income country – was excluded from the territory of the license. In 2017, the government of Malaysia issued a government use license for sofosbuvir to increase access to the treatment for more than 400,000 people living with hepatitis C in Malaysia.<sup>82</sup> The decision was made after the Ministry of Health's efforts to be included in the voluntary license and price negotiations with the patent holder were unsuccessful.<sup>83</sup> The compulsory license eliminated patent barriers and the price of sofosbuvir dropped from RM360,000 for a full course of treatment with the patented medicine to RM1,248 for the generic version, improving the availability of hepatitis C treatment in public hospitals throughout the country.<sup>84</sup> Malaysia's decision to issue the compulsory license also spurred Gilead to expand its voluntary license for sofosbuvir and other hepatitis C treatments, adding Belarus, Malaysia, Thailand, and Ukraine.<sup>85</sup>

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<sup>cc</sup> A patent application on a heat-stable formulation of lopinavir/ritonavir has been granted in a few low- and middle-income countries. More details of the patent status of lopinavir/ritonavir in low-and-middle income countries can be found at MedsPal database. Available from:

[https://www.medsPal.org/?product\\_standardized\\_name%5B%5D=Lopinavir%2FRitonavir+100%2F25+mg&page=1](https://www.medsPal.org/?product_standardized_name%5B%5D=Lopinavir%2FRitonavir+100%2F25+mg&page=1)

<sup>dd</sup> Lopinavir/ritonavir was later found lacking efficacy in COVID-19 treatment and discontinued from the WHO Solidarity Trial. <https://www.who.int/news-room/detail/04-07-2020-who-discontinues-hydroxychloroquine-and-lopinavir-ritonavir-treatment-arms-for-covid-19>

## Recommendations

### 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. Countries 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.

At a minimum, companies should be required to publish the main terms of their bilateral licenses and any additional or updated agreements related to the same medicine. This should include the scope of the territory, formulations of the medicine covered, terms on API sourcing, the patent landscape, and royalty rates. This information will not cause commercial harm when disclosed, as evidenced by the experience of the MPP.

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.
- In all countries: governments should establish and strengthen public interest doctrine in legal decisions, laws and policies on right to/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 to allow their publication or inspection.

### 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 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 issue a compulsory license, in accordance with the TRIPS Agreement and the Paris Convention for the Protection of Industrial Property.<sup>ee</sup> Refusal to license or other restrictions in licenses could also trigger the process for generic 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).<sup>86</sup>

Facing a global health crisis such as the COVID-19 pandemic in which pharmaceutical corporations refuse to enter into worldwide non-exclusive licenses, countries 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.<sup>87</sup>

### 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 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 scope.** Prohibit overly broad patent definitions. Patents should be defined to mean only granted patents. Licensees should be able to supply countries even if these countries are not covered by the license territory when patent claims are pending or no patents have been granted for the concerned medicine, or there are granted patents, but not infringed.
- b. **Geographic restrictions.** Prohibit licensing terms that prevent licensees from supplying API and/or finished products to countries outside of the licensed territories unless there is a granted blocking patent in effect. Regardless of licenses, manufacturers should be able to supply countries when patent applications are pending or under challenge, there are no

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<sup>ee</sup> 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.

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).<sup>ff</sup>

- 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.
- d. **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 simply because they accepted technology transfer from a licensor.
- e. **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.<sup>88</sup>
- f. **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.<sup>89</sup>
- g. **API source restrictions.** Prohibit licensing terms that prevent or restrict sourcing and supplying of raw materials including API. Licensees should be able to purchase from a quality-assured supplier or produce API of their own choice.
- 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.<sup>90</sup>
- i. **Unfair grant-back terms.** Prohibit exclusive “grant-back” terms for any improvements in the licensed medical technology by the licensee. If generic manufacturers are able to innovate a

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<sup>ff</sup> According to a general waiver granted under WTO, least-developed countries (LDCs) which 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](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](https://www.wto.org/english/tratop_e/trips_e/ldc_e.htm)

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 research and clinical studies on the concerned products and technologies. Licensees should not be required to seek permission from the licensor when conducting further research on the licensed technologies and products. Manufacturers conducting research are already 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.<sup>88</sup>
- 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. India particularly, as home to the Indian generic industry which has entered into a number of voluntary licenses, should scrutinise licenses from the aspect of how they impact access and competition domestically as well as for export to other countries.

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

Patent oppositions can play a role in overcoming patent monopolies, potentially freeing generic manufacturers from restrictive voluntary licenses, and offering licensees greater negotiating power. Therefore, all countries should prioritise implementation of an opposition system that allows civil society and generic manufacturers to challenge the validity of weak patent claims, along with other TRIPS Agreement public health safeguards to improve the quality of patent examination.

### Conclusion

The key issues around voluntary licensing practices are of even greater importance at this crucial time for public health, with important COVID-19 technologies that all people urgently need under development, and are already the subject of voluntary license agreements. This analysis and MSF's experiences have found that while voluntary licenses may promote more affordable access to medicines for some people in some countries, they often come with abusive licensing terms and practices that needlessly undermine access to medicines for others. Patent-holding

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<sup>88</sup> 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](https://www.wipo.int/edocs/mdocs/scp/en/scp_29/scp_29_3.pdf)

pharmaceutical corporations can and should act voluntarily to promote access to medicines by publishing their licenses and refraining from including harmful provisions, but people and public health programs cannot only rely on the voluntary actions of pharmaceutical industry. This is particularly true as the negotiating power of generic companies and the MPP to advocate for pro-public health provisions is limited. Ultimately, responsibilities lie with governments to protect and promote access to medicines.

In order to deliver on their public health responsibilities, countries need to use all available resources, including addressing abusive practices in voluntary licensing that undermine access to affordable quality generic medicines for all. Countries should consider increasing transparency of 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, countries should also consider bolder measures to overcome IP challenges.<sup>91</sup> For example, India and South Africa have recently proposed a waiver of applications and enforcement of patents and other IP and exclusivities concerning COVID-19 health technologies, such as trade secrets and clinical data protection.<sup>92</sup>

### Acknowledgments

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## Glossary

**Anti-diversion clause:** A provision that prevents a voluntary license licensee or its subsidiaries from re-selling or exporting the licensed products to a country outside of the geographic scope of the license agreement. Anti-diversion clauses may include specific obligations for the licensee or its subsidiaries to use special packaging or identification for the products produced and supplied under the license, and to adapt special enforcement measures to prevent “diversion” of the product.

**Biologicals:** As defined by WHO, “biologicals are a diverse group of medicines which includes vaccines, growth factors, immune modulators, monoclonal antibodies, as well as products derived from human blood and plasma.” More details available from: <https://www.who.int/health-topics/biologicals>

**Coercive package licensing:** A practice whereby licensees are required to accept purchase a “package” of patents and non-patented goods, regardless of whether the licensee needs access to these goods.

**Compulsory license:** A compulsory license is a 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. The Doha Declaration on TRIPS Agreement and Public Health confirms that countries are free to determine the grounds of compulsory licenses. Examples of different grounds for compulsory license include, for instance to remedy anti-competitive practices, failure to work or insufficient working of the patent, when the patented medicine is unaffordable or unavailable making it inaccessible to patients and when public health is at stake including but not limited to emergency/extreme urgency, epidemics and public non-commercial use.

**Evergreening:** Evergreening is a term used to describe the practice of extending the monopoly period of a medicine through multiple secondary patents. In addition to enforcing 20-year patent terms on new active ingredients, pharmaceutical corporations repeatedly abuse the patent system to delay the entry of lower-priced generic competition. They often file patents on new use or forms of a known medicine, formulations (including e.g. tablets and syrups), combinations, common biological processes, known manufacturing techniques, and other routine improvements related to the medicine.

**Grant-back:** A provision in a license agreement that requires the licensee to transfer or license back or allow use of all improvements made to the licensed product to the licensor during the period of the license.

**Parallel importation:** Parallel importation is a practice of purchasing a medicine in one country and then importing it to another, which does not require the consent of the patent holder.

**Know-how:** A set of non-patented practical secret information, gained from experience and testing, and is significant and useful for the licensee for the manufacture of the licensed product.

**Non-assert declaration:** A declaration where a right holder commits not to enforce their patents in certain stated countries allowing generic manufacturer to produce or supply the medicine in those countries without the fear of an infringement suit. Immunity from suit is an alternative agreement to non-assert declaration, whereby the patent holder waives the right to sue, subject to certain terms and conditions.

**Non-exclusive license:** In a non-exclusive license there can be one or more licensees. The licensor grants the licensee the right to use the intellectual property but is also free to exploit it further by allowing multiple other licensees.

**Secondary pharmaceutical patents:** Secondary patents are filed by pharmaceutical corporations on routine improvements and other aspects of a known active ingredient like new forms, new use, formulations, combinations, etc. (as opposed to primary patent which covers an active ingredient for medicinal use). The use of secondary patents to create new monopolies and delay the entry of legitimate generic competition has generated concerns among patient groups and policymakers worldwide. Civil society and patient groups may file patent oppositions on secondary patent claims on the ground that they are inherently obvious/non-inventive.

**Trade secret:** Any information that is generally not known to the public, or to those in a particular industry and the holder of that information is able to derive commercial value from being kept secret.

**Voluntary license:** Voluntary licenses are contractual agreements signed between patent holders (licensors) and other entities (licensees) that specify the terms and conditions under which a patented medicine can be used, produced or marketed by licensed generic manufacturers. There are three types of voluntary licenses in the context of pharmaceutical industry—out-licensing, in-licensing and marketing or distribution arrangements. Out-licensing refers to a type of license where the licensor on a product allows licensees (usually a generic manufacturer) to market, supply and distribute the product with terms or conditions as negotiated by both parties. In-licensing refers to a type of license where a pharmaceutical corporation licenses a compound at the clinical or pre-clinical stage from a university, research laboratory, or another company and

develops the compound further to bring it to the market as an approved medicine. Rights holders may also enter into marketing or distribution arrangements with generic manufacturers, where the latter may simply sell the patented version of the product.

## Annex 1: Geographic scope of Gilead's voluntary license for remdesivir<sup>hh</sup>

In May 2020 Gilead signed a voluntary license with generic manufacturers in Egypt, India and Pakistan for the COVID-19 medicine remdesivir. The license includes 127 countries and territories with following distributions:

- Almost all high-income countries are excluded, except for some island countries and Panama, including those hardest hit by COVID-19.
- Many upper-middle-income countries are excluded, including those hardest hit by COVID-19.
- All lower-middle-income countries are included in the license, except Bolivia and West Bank and Gaza.
- All low-income countries are included, except for Yemen and Syrian Arab Republic.

Income Categories of Countries and Territories Included and Excluded from Gilead's Voluntary License				
Income category	Low-Income <sup>ii</sup>	Lower-Middle-Income	Upper-Middle-Income	High-Income
<b>Included</b>	Afghanistan, Burkina Faso, Burundi, Central African Republic, Chad, Democratic Republic of Congo, Eritrea, Ethiopia, Gambia, Guinea, Guinea-Bissau, Haiti, Democratic People's Republic of Korea, Liberia, Madagascar, Malawi, Mali, Mozambique, Niger, Rwanda, Sierra Leone, Somalia, Sudan, South Sudan, Tajikistan, Togo, Uganda	Algeria, Angola, Bangladesh, Benin, Bhutan, Cambodia, Cameroon, Cape Verde, Comoros, the Congo, Cote d'Ivoire, Djibouti, Egypt, El Salvador, Eswatini, Ghana, Honduras, India, Kenya, Kiribati, Kyrgyzstan, Lao People's Democratic Republic, Lesotho, Mauritania, Federated States of Micronesia, Moldova, Mongolia, Morocco, Myanmar, Nepal, Nicaragua, Nigeria, Pakistan, Papua New Guinea, Philippines, Sao Tome and Principe, Senegal, Solomon Islands, Sri Lanka, Tanzania, Timor-Leste, Tunisia, Ukraine, Uzbekistan, Vanuatu, Viet Nam, Zambia, Zimbabwe	Armenia, Azerbaijan, Belarus, Belize, Botswana, Costa Rica, Cuba, Dominica, Dominican Republic, Equatorial Guinea, Fiji, Gabon, Georgia, Guatemala, Guyana, Grenada, Indonesia, Jamaica, Kazakhstan, Libya, Maldives, Marshall Islands, Namibia, Samoa, South Africa, St. Lucia, St. Vincent and the Grenadines, Suriname, Thailand, Tonga, Turkmenistan, Tuvalu	Antigua & Barbuda, Aruba, Bahamas, Barbados, Bermuda, British Virgin Islands, Cayman Island, Curacao, Mauritius, Nauru, Palau, Panama, Seychelles, Sint Maarten, St. Kitts and Nevis, Trinidad and Tobago, Turks and Caicos

<sup>hh</sup> To review the full license, see: <https://www.gilead.com/purpose/advancing-global-health/covid-19/voluntary-licensing-agreements-for-remdesivir>

<sup>ii</sup> List of low, lower-middle, upper-middle and high-income countries as per World Bank classification available from: <https://datahelpdesk.worldbank.org/knowledgebase/articles/906519-world-bank-country-and-lending-groups>



Income category	Low-Income	Lower-Middle-Income	Upper-Middle-Income	High-Income
<b>Excluded</b>	Syrian Arab Republic, Republic of Yemen	Bolivia, West Bank and Gaza	Albania, American Samoa, Argentina, Bosnia and Herzegovina, Brazil, Bulgaria, China, Colombia, Ecuador, Iran, Iraq, Jordan, Kosovo, Lebanon, Malaysia, Mexico, Montenegro, North Macedonia, Paraguay, Peru, Russia, Serbia, Turkey, Venezuela	Andorra, Australia, Austria, Bahrain, Belgium, Brunei Darussalam, Canada, Channel Islands, Chile, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, French Polynesia, Germany, Gibraltar, Greece, Greenland, Guam, Hong Kong, Hungary, Iceland, Ireland, Isle of Man, Israel, Italy, Japan, Republic of Korea, Kuwait, Latvia, Liechtenstein, Lithuania, Luxembourg, Macao, Malta, Monaco, Netherlands, New Caledonia, New Zealand, Northern Mariana Islands, Norway, Oman, Poland, Portugal, Puerto Rico, Qatar, Romania, San Marino, Saudi Arabia, Singapore, Slovak Republic, Slovenia, Spain, St. Martin (French part), Sweden, Switzerland, Taiwan, United Arab Emirates, United Kingdom, United States, Uruguay, Virgin Islands (U.S.)

## Annex 2: Resources on voluntary licenses

Much has been written in the last 15 years on voluntary licenses. This Annex provides a non-exhaustive list of resources related to voluntary licenses and access to medicines.

### HIV/AIDS:

1. In 2006, Gilead Sciences entered into voluntary license agreements with generic companies vis-à-vis the HIV medicines tenofovir and emtricitabine. Knowledge Ecology International (KEI) made a request to Federal Trade Commission for an investigation into anticompetitive aspects of these licenses. See request letter dated 12 Feb 2007:  
<http://www.keionline.org/misc-docs/ftcgilead12feb07.pdf>
2. IMAK conducted a detailed analysis of the clauses of Gilead Sciences' 2006 voluntary license agreements with generic companies for HIV medicines. See: *Analysis of key clauses from Gilead Sciences, Inc's example licence agreement*, 17 Sep 2006:  
<http://static1.1.sqspcdn.com/static/f/129694/787553/1177448309380/IMAK+Analysis+of+Gileads+example+licence+LPPD+Advisor.pdf?token=cWCsxNkxeWbelU0nrfjeaN8rUUk%3D>
3. The debate on effectively addressing access barriers with competition has been dominated largely with pharma justifying voluntary licenses as better alternative to compulsory licenses. Oxfam's research analysing the effectiveness of voluntary licenses in access barriers highlighted some of the critical concerns around it. See: *Voluntary licensing practices in the pharmaceutical sector: An acceptable solution to improving access to affordable medicines*, 2007:  
<https://www.i-mak.org/wp-content/uploads/2017/10/Oxfam-VoluntaryLicensingResearchIMAKWebsite.pdf>
4. In 2011, Medicines Patent Pool announced its first voluntary licenses agreement with Gilead Sciences for the HIV medicines tenofovir, emtricitabine, cobisistat and elvitegravir. MSF while reviewing the agreement, highlighted some serious limitations of the voluntary licenses. See: *MSF review of the July 2011 Gilead licences to the Medicines Patent Pool*, December 2011:  
<https://msfaccess.org/msf-review-july-2011-gilead-licences-medicines-patent-pool>
5. While Gilead Science celebrated its 2011 voluntary licenses agreement with MPP for HIV medicines tenofovir, emtricitabine, cobicistat and elvitegravir as a successful contribution towards addressing access barriers to life saving medicines, the low- and middle-income countries excluded from the benefits of the Patent Pool raised serious question on the failure

of original intent of establishing the Pool as a mechanism to overcome patent barriers. Thai civil society shared their concerns in an open letter dated 22 July 2011. See: *Open Letter from Thai Civil Society: One Step forward, Two Steps back: the Agreement between the Medicine Patent Pool and Gilead Sciences, Inc, 22 July 2011:*

<https://donttradeourlivesaway.wordpress.com/2011/07/22/open-letter-from-thai-civil-society-one-step-forward-two-steps-back-the-agreement-between-the-medicine-patent-pool-and-gilead-sciences-inc/>

6. IMAK and ITPC proposed a way forward to ensure that voluntary licenses are pursued in strategic, access-maximizing manner rather than ending up as a tool for the pharmaceutical industry to manage competition, segment developing markets and collect royalties even in absence of patent rights. See: *Voluntary Licensing: Optimizing Global Efforts and Measuring Impact*, 10 September 2010:  
<http://www.i-mak.org/wp-content/uploads/2017/10/OptimizingVoluntaryLicensingIMAK-ITPC10Sep2012.pdf>
7. In light of MPP's 2011 inaugural agreement with Gilead Science's for HIV medicines excluding lower-middle income and middle-income countries, a group of civil society members from the Global South met MPP and UNITAID representative on 2 Oct 2011 and raised their concerns on MPP's failure to uphold its mandate of effectively addressing access barriers. The meeting was followed up with a letter dated 10 Oct 2011, reiterating these issues and listing demands to correct those issues. See:  
<https://www.i-mak.org/2011/10/11/implications-of-the-patent-pool-licenses-with-gilead-part-ii/>
8. Professor Brook K. Baker from Northeastern U. School of Law analyzed the 2011 MPP licensing agreement with Bristol-Myers Squibb (BMS) for second-line antiretroviral, atazanavir (ATV). See: *Analysis of Territorial Access Issues in the MPP/ BMS Atazanavir License*, 16 Dec 2013:  
<http://infojustice.org/wp-content/uploads/2013/12/baker12162013.pdf>
9. In Jan 2011, Tibotec announced voluntary license agreements with generic companies for a new HIV medicine rilpivirine hydrochloride. KEI analysed the agreement terms made available information via a press release and shared concerns regarding a limited geographical scope, market segmentation, etc. See: *KEI comments on Tibotec voluntary licenses of a new HIV-AIDS product- Rilpivirine Hydrochloride, 28 Jan 2011:*  
<https://www.keionline.org/21489>

10. In 2014, ViiV Healthcare Co. entered into a license with MPP for HIV medicine dolutegravir. Prof. Brook Baker analysed the license. See: *Analysis of ViiV/MPP Dolutegravir Licenses – Pluses and Minuses*, 23 April 2014:  
<http://infojustice.org/wp-content/uploads/2014/04/Analysis-of-ViiV-MPP-License.pdf>
11. Due to persistent problem of stockouts for HIV medicine lopinavir/ritonavir (LPV/r) from its sole supplier, AbbVie, in South Africa, MSF urged the South African government to put the public's health first and override AbbVie's patent with a compulsory license in order to allow generic versions of LPV/r to be used in the country. See: *MSF Press Release*, 27 October 2015:  
<https://www.msf.org/south-africa-should-override-patent-key-hiv-medicine-after-widespread-stock-out-problem>
12. MSF's Access Campaign has been monitoring patent barriers, prices, licensing and availability of antiretroviral medicines through a report published annually. The 18<sup>th</sup> edition included detailed analyses of a number of voluntary licenses. See: *Untangling the Web of ARV Price Reductions, 18th Edition*, July 2016:  
<https://www.msfacecess.org/untangling-web-antiretroviral-price-reductions-18th-edition>
13. Complete text of Gilead Science's first voluntary license signed with Indian generic companies to manufacture and sell tenofovir-disoproxil-fumarate and emtricitabine, June 2006. See:  
<https://www.gilead.com/-/media/files/pdfs/other/originaldflicenseagreement.pdf?la=en&hash=8A28DA24E3B6A75D190561DD52C3E865>

### Hepatitis C:

1. In 2014, Gilead Sciences signed voluntary licenses with generic companies for hepatitis C medicine sofosbuvir. MSF raised several concerns regarding Gilead's anti-diversion program that was a part of these agreements, based on critical issues like patient's privacy, autonomy, confidentiality of patient data, coercion and policing of medical providers, etc. See: *Barriers to access and scale up of hepatitis C treatment: Gilead's anti-diversion program*, 2015:  
<https://msfacecess.org/barriers-access-and-scale-hepatitis-c-treatment-gileads-anti-diversion-program>
2. On September 14, 2014, Gilead announced a voluntary license agreement with seven Indian manufacturers and API manufacturers for hepatitis C direct-acting antivirals (DAAs) sofosbuvir, ledipasvir and velpatasvir. MSF's analysis of this agreement highlighted key

concerns and recommended modifications to the license. See *MSF analysis of Gilead Hepatitis C license*, March 2015:

<https://msfaccess.org/msf-analysis-gilead-hepatitis-c-license>

3. Medecins Sans Frontieres analyzed AbbVie's license agreement with MPP in November 2018, for hepatitis C medicines glecaprevir/pibrentasvir (G/P) and provided recommendations. See: *MSF Access Campaign analysis of the MPP Licence Agreement with AbbVie for glecaprevir/pibrentasvir (G/P)*, March 2019:

[https://msfaccess.org/sites/default/files/2019-03/HCV\\_Brief\\_MPP-AbbVie-Voluntary-License\\_2019.pdf](https://msfaccess.org/sites/default/files/2019-03/HCV_Brief_MPP-AbbVie-Voluntary-License_2019.pdf)

4. For detailed terms of Gilead Science's 2014 licensing agreement, as well as subsequent agreements, See:

<https://www.i-mak.org/2011/10/11/implications-of-the-patent-pool-licenses-with-gilead-part-ii/>

#### COVID-19:

1. Costa Rica's proposal for a voluntary pooling mechanism as a tool to address possible access barriers for medical products and technologies for COVID-19 was followed up with WHO's solidarity call to countries to participate in the MPP. While patent pool can be effective, the voluntary nature of the MPP has proven to result in numerous limitations. Looking into this, South Centre published an article titled, *Making Covid-19 Medical Products Affordable: Voluntary Patent Pool and TRIPS Flexibilities*, 16 June 2020. See:

<https://www.southcentre.int/wp-content/uploads/2020/06/SouthViews-Chaudhuri.pdf>

2. Gilead Sciences' May 2020 voluntary licensing agreement with generic manufacturers for remdesivir excluded more than 70 countries from benefitting from generic competition. Public Citizen in its statement highlighted that despite of significant public investment of (over \$70.5 million) into the medicine's development, nearly half of world population was excluded from accessing the medicine. See: *Remdesivir Should Be in the Public Domain; Gilead's Licensing Deal Picks Winners and Losers*, May 2020:

<https://www.citizen.org/news/remdesivir-should-be-in-the-public-domain-gileads-licensing-deal-picks-winners-and-losers/>

3. Professor Brook K. Baker's analysis of Gilead's voluntary license agreement with generic manufacturers on Remdesivir highlighted how the promises of "global access" by the pharma giant was nothing but a farce as it covered only 52% of the global population leaving the other

48% to the whim of Gilead's monopoly-based predations. See *Gilead Remdesivir Licenses: Half Measures are Not Nearly Good Enough*, May 2020:

<https://healthgap.org/gilead-remdesivir-licenses-half-measures-are-not-nearly-good-enough/>

4. Fundación GEP while analysing Gilead's licencing agreement on remdesivir, criticised it for excluding Latin American countries that need COVID-19's medicines urgently. See *COVID19-South America: Gilead block access to coronavirus treatment for 440 million people*, May 2020:

<https://www.fgep.org/covid19-south-america-gilead-block-access-to-coronavirus-treatment-for-440-million-people/>

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