The European Union's position on compulsory licensing and the TRIPS waiver in the COVID-19 pandemic

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Summary

In the context of the COVID-19 pandemic, the European Commission (EC) emphasises the option of using compulsory licensing to facilitate production of COVID-19 medical tools in its Intellectual Property Action Plan. During World Trade Organisation (WTO) negotiations over the past seven months on the proposed temporary waiver from certain intellectual property (IP) obligations under the TRIPS Agreement (TRIPS waiver), the European Union (EU) has pointed to the availability of compulsory licensing as a main reason to object to the waiver.

Compulsory licensing is an important public health safeguard, and Médecins Sans Frontières (MSF) has long advocated for the use of this tool as needed to ensure access to essential medicines.[a] Unfortunately, there are legal obstacles that can hinder the effective and rapid use of this mechanism in public health emergencies, including in the EU.

The EU should support the TRIPS waiver for COVID-19, while addressing the remaining barriers to compulsory licensing in the EU as part of its longer-term pharmaceutical strategy.

Compulsory licensing is an important legal mechanism to promote access to medicines

Compulsory licensing is when a government allows alternative producers to produce a patented product without the consent of the patent owner.[1] This legal instrument can be used to meet public health needs when access to necessary pharmaceuticals must be guaranteed.

According to the TRIPS Agreement – the international agreement on IP administered by WTO – governments are entitled to limit patent rights to protect public interests. Further, the 2001 Doha Declaration on the TRIPS Agreement and Public Health confirmed that each WTO member has not only the right to grant compulsory licences, but also the freedom to determine the grounds upon which such licences are granted. The TRIPS Agreement does not provide an exhaustive list of the reasons that might be used to justify compulsory licensing, but national emergencies, other circumstances of extreme urgency, public non-commercial use or anti-competitive practices are specifically listed as grounds that can trigger the use of the mechanism.

[a] For a more detailed discussion on the merits and limitations of compulsory licensing in the pandemic beyond the EU, please see MSF's briefing: "Compulsory licenses, the TRIPS Waiver, and access to COVID-19 medical technologies."

Compulsory licenses have been used by many countries to facilitate access to medicines before the COVID-19 pandemic.[2] In a recent example, Malaysia issued a government use compulsory license for the hepatitis C treatment, sofosbuvir, to increase access to the treatment for more than 400,000 people living with hepatitis C in the country in 2017.[3] The price of sofosbuvir dropped by 99.7%, from RM360,000 (€70,000) for an entire course of treatment with the patented medicine to RM1,248 (less than €250) for the generic version, improving the availability of hepatitis C treatment in public hospitals throughout the country.[4]

The COVID-19 pandemic has sparked interest in compulsory licensing for government use, prompting the EU to emphasise their willingness to better support the use of compulsory licenses in Europe and other countries.

Key obstacles need to be lifted for effective use of compulsory licensing in the EU

In its IP action plan published in November 2020,[5] the EC *"sees the **need to ensure that effective systems for issuing compulsory licenses are in place**, to be used as a means of last resort and a safety net, when all other efforts to make IP available have failed. (…) The Commission **calls on Member States to ensure that the tools they have are as effective as possible**, for instance, by putting in place fast-track procedures for issuing compulsory licenses in emergency situations*."

The EC acknowledges the need to improve effective use of compulsory licensing, but the protection of data and market exclusivity in EU regulations on medicinal products can actually hinder these efforts. The EC has not specified concrete actions to ensure national laws on compulsory licensing are improved to better protect public health needs.

The understanding that compulsory licensing should be used as a "last resort" is also misleading and a misinterpretation of the TRIPS Agreement. Under the TRIPS Agreement, as reaffirmed by the Doha Declaration, compulsory licensing for government use can be issued anytime a country decides it is necessary in emergencies, other situations of urgency, for public non-commercial purpose and to remedy anti-competition behaviour. There is no obligation to only use compulsory licensing as a last resort.

Compulsory license rules vary in national laws and EU regulation

There is no EU-wide compulsory licensing mechanism, except for the specific compulsory licensing regime provided for in regulation (EC) 816/2006[6] concerning the manufacture of pharmaceutical products for export to countries with public health problems. This regulation implements Article 31*bis* of the TRIPS Agreement, making EU Member States eligible to produce generic versions of patented pharmaceutical products specifically for export to countries with public health problems.[7] To date, this mechanism has never been used in the EU.

Apart from the special regulation to implement Article 31*bis* of TRIPS Agreement, compulsory licensing to address the needs of EU Member States is mainly governed by national laws and should predominantly be used for the supply of the domestic market. Most Member States have incorporated this mechanism into their national legal systems, although the grounds for authorisation and the procedural framework may differ. Not all Member States have a provision to use compulsory license

for the public interest, such as for use during a health emergency.[8] In practice, compulsory licensing of pharmaceuticals has only been used in the European context in some exceptional cases, such as to remedy anti-competitive behaviour[2] and in response to a failure to reach a voluntary licensing agreement between companies.[9][10]

In response to the COVID-19 pandemic, a number of countries such as Germany[11,12] and Hungary[13,14] have amended their regulations governing patents to facilitate easier and quicker processes for the grant of compulsory licensing for government use. In late 2020, the Hungarian government granted a compulsory license on remdesivir, citing their newly promulgated law.[15] The compulsory license was issued to support domestic manufacture by the Hungarian company Richter, which was approached by the government to produce the drug during the first wave of the pandemic.[16]

Yet, there is no EU level of coordination to support Member States in using the mechanism effectively to respond to IP challenges in the interest of public health. Nor are there any measures to ensure all Member States have the competencies to issue compulsory licenses.

EU legislation on data and market exclusivity hinders the effective use of compulsory licensing

The EU legislation on medicinal products[17] interferes with the effective use of compulsory licensing by Member States because it prohibits registration of generic equivalents for a defined period by the regulator (the European Medicines Agency), regardless of patent protection.[18]

According to the Regulation (EC) No 726/2004,[b] medicinal products which have been authorised for human use shall benefit from an eight-year period of data protection and a ten-year period of marketing protection. During this period, the marketing-authorisation holder benefits from the exclusive rights to the results of preclinical tests and clinical trials on the medicine.

Therefore, EU countries cannot register a generic product during the data/market exclusivity period, even when the medicine is needed for compelling public health reasons, emergencies, or when a compulsory or government use license has been issued on a medicine patent. The EU pharmaceuticals legislation has no exception to this rule.

In addition, the EU continues to export its IP rules,[19] including on data exclusivity, in bilateral trade agreements with other countries,[20] which replicates the barriers to the effective use of compulsory licensing globally.

Limitations of compulsory licensing in the pandemic

The use of compulsory licensing must meet certain requirements under the TRIPS Agreement. For example, the scope and duration of the licence must be limited to the purpose for which it was granted, and legal review should be made available for patent holders to use.[21] In practice, compulsory licenses can only be granted country-by-country and product-by-product and are only available on patents, not on other types of IP.[22] Moreover, a compulsory licensing can only be used predominantly to supply domestic markets. The special procedures of using compulsory licenses for exportation are prohibitively complex and impractical. MSF has documented the years-long ordeal on the single occasion the export mechanism for compulsory licensing was used between Canada and Rwanda.[23]

[b] Article 14 of the Regulation. Available from: https://ec.europa.eu/health/sites/health/files/files/eudralex/vol-1/reg_2004_726/reg_2004_726_en.pdf

Considering the complexity, the European generic industry stated at the European Parliament that it is unlikely that it would ever make use of this mechanism.[24]

In the context of the pandemic, cross-border collaboration may be needed for the production of more complex medical tools such as diagnostics, vaccines and certain treatments, for which compulsory licensing used by individual countries may not be effective.

While the EU IP Action Plan indicates follow-up work to be done to improve compulsory licensing mechanisms in the future, this long-term action will not help solve the current shortcomings of the use of compulsory licensing during the COVID-19 pandemic.

Compulsory licensing and the TRIPS waiver proposal at WTO

To address the unprecedented challenges of the COVID-19 pandemic while ensuring global and diverse production and supply requires a more expedited option to suspend all IP monopolies, as proposed by the temporary TRIPS waiver, tabled by India and South Africa, and sponsored by 62 countries as of May 2021. The proposal provides a more pragmatic and appropriate approach than national and uncoordinated actions based on compulsory licenses alone. It would be a faster policy option for governments to facilitate increased manufacturing and access to health technologies. In addition, the proposed waiver of IP would remove countries' fears of retaliation for invoking a compulsory license and would solve other heavy bureaucratic obstacles.

The fact that the EU stressed that use of compulsory licenses was sufficient while opposing the proposal for a temporary waiver from certain IP obligations during COVID-19 pandemic is incoherent. This position ignores that both options share the same end objective to allow production of COVID-19 medical tools without the IP holders' consent, and ignores the fact that governments, including EU Member States, face practical and legal difficulties to make effective use of compulsory license in this pandemic.

The EU should reverse its rhetoric at WTO and acknowledge that an additional legal option is needed to mitigate the shortcomings of the existing rules on compulsory licensing, building upon its own experiences. While future improvements of compulsory licensing mechanism are welcome, the current emergency requires an additional option that all WTO members can use immediately without waiting for the overall rules to be adapted and reformed.

Compulsory and voluntary licenses

Voluntary licenses are agreements between an IP holder and another manufacturer to allow the production of an IP-protected product. MSF's past experience shows that voluntary licensing contains inherent limitations for its dependence on companies' willingness to set up the terms and conditions, and often come up with limiting factors.[25] More than one year into the COVID-19 pandemic, it is evident that relying on the willingness of multinational pharmaceutical companies does not guarantee supply diversity and global equity in access.[26] Major multinational pharmaceutical corporations rejected initiatives promoting global open sharing of technologies, such as the COVID-19 Technology Access Pool coordinated by World Health Organization and continue with secretive and limited bilateral licensing. Companies mostly engage in contract manufacturing agreements, which do not provide legal rights for the contractor producers to further develop the concerned technology and supply independently.[26]

In resisting the TRIPS waiver proposal for COVID-19, the EU has insisted that voluntary licensing and transfer of technologies are preferred with compulsory licenses as a last resort. However, the EU has taken no concrete actions to promote global open licensing nor provided a clear policy road map to ensure effective and full transfer of technologies to capable producers, including in developing countries, to facilitate diversity in production and supply.

Conclusion and key recommendations

Compulsory licensing is a critical public health safeguard that can effectively remove patent barriers on medicines and improve access.

In the context of discussions on a temporary IP waiver, the EU position of using compulsory licensing only as a "last resort" misinterprets the rights and obligations concerning compulsory licensing for government use. The EU position does not reflect the conflicting EU regulations on data and market exclusivity that can effectively undermine the use of compulsory licenses by EU Member States. The EU also lacks concrete measures to overcome the lack of willingness and action of major pharmaceutical corporations to engage initiatives promoting global open sharing of COVID-19 technologies and full transfer of technology to developing countries. The EU's position at the WTO appears contradictory to EU's own experience.

Key recommendations:

- The EU should support the temporary IP waiver for COVID-19 at WTO and constructively engage in text-based negotiations.
- As part of the EU Pharmaceutical Strategy for Europe, the EU pharmaceuticals legislation[c] needs to be amended to introduce automatic waivers to data and market exclusivity in cases of public health need and when a compulsory license is issued by a Member State. This is a precondition for an effective use of compulsory licensing in the EU by all Member States.
- National legislation on compulsory licenses needs to be improved so all Member States are equipped to most effectively make use of the option in response to a public health concern.
- The EU should not use trade policies and instruments – such as the IP enforcement report and trade agreements – to pressure other countries against lifting IP rights in order to protect their own population in response to a public health concern.
- In the long-term, the structural constraints of compulsory licensing in the TRIPS Agreement, particularly on import and export, need to be addressed at the WTO.

[c] Provisions on data exclusivities contained in EU Directive (EC) 2001/83 and Regulation (EC) 726/2004.

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