FUTURE-PROOFING PANDEMICS

Analysing the EU's proposal to clarify and simplify the compulsory licensing procedure

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Abstract

The 'TRIPS waiver' proposal, first submitted by India and South Africa to the WTO TRIPS Council in October 2020, has resulted in diametrically split positions amongst WTO members. But the EU has chosen a middle way. Its three-fold response seeks to provide answers to the concerns raised by the proposal that developing countries may face 'institutional and legal difficulties' when using the policy flexibilities provided by the TRIPS Agreement. Thus, the EU wishes to clarify and simplify the authorisation procedure of compulsory licensing, a policy flexibility that could provide affordable generic versions of patented pharmaceutical products. However, an onerous procedure is a long-heard complaint against compulsory licencing.

Consequently, the EU's response is more focused on improving the administrative procedure of compulsory licensing rather than on responding directly to the Covid-19 pandemic. Thus, the effect of the EU's response to the proposed waiver agreement on the wider battle against the pandemic will be limited, not least because since the beginning of the outbreak, the international community had already rallied itself to combat Covid-19. A recent case in point is that, in February 2022, six African countries received the technology needed to produce mRNA vaccines on the continent. After all, there is no proof that the TRIPS Agreement has undermined efforts in technology transfer, pharmaceutical manufacturing, etc. as the 'TRIPS waiver' proposal suggests.

Overall, this CEPS Policy Insights paper finds that the EU's proposed solutions have shifted the focus from Covid-19 vaccines supply to the compulsory licensing procedure. Thus, the merit of the 'TRIPS waiver' proposal is no longer about taking moral decisions but rather it's about technical aspects. The real impact of the EU's response will most likely benefit future users of compulsory licensing, especially when the next pandemic strikes, whenever that may be.

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Introduction

The members of the World Trade Organization (WTO) have been diametrically split in their response to the 'Waiver from certain provisions of the TRIPS Agreement for the prevention, containment and treatment of COVID-19' communication (hereunder the 'TRIPS waiver' proposal) that was originally published on 2 October 2020 and revised on 25 May 2021. A chief argument against[1] the TRIPS waiver proposal is that the policy flexibilities provided by the TRIPS Agreement, such as compulsory licensing, are sufficient to respond to the pandemic. The TRIPS waiver proposal foresees these flexibilities but argues that developing countries may face institutional and legal difficulties when applying them in practice.

Indeed, a persistent complaint against compulsory licensing is its onerous authorising procedure. It is even alleged that, because of this, compulsory licensing has not been widely used. Justifiable or not, the EU's response to clarify and simplify the compulsory licensing procedure attempts to address this long-running complaint.

This CEPS Policy Insights paper will analyse the criticism against the authorisation procedure of compulsory licensing in section one. Before the conclusion, section two will examine the EU's three-fold proposal which aims to improve the compulsory licensing procedure, including the notification procedure under Article 31*bis* for export purposes.

1. Compulsory licensing - an onerous procedure?

To prioritise public health over intellectual property rights, the TRIPS Agreement has granted its members the flexibility to adopt the measures necessary to promote the public interest, without the risks of violating the obligations to protect intellectual property rights. Transitional periods and compulsory licensing are such policy flexibilities. Compulsory licences may be granted for use by a government or third parties to enable the generic versions of a patented pharmaceutical product to be manufactured and sold for non-exclusive use, on payment of royalties. Of course, generic pharmaceutical products cost significantly less than original patented products. In the context of the Covid-19 pandemic, in the absence of voluntary licensing, compulsory licensing could provide developing countries with affordable access to Covid-19 vaccines.

But what are the grounds for authorising a compulsory licence? In short, these include 'national emergency or other circumstances of extreme urgency', 'public health' or 'insufficient or no manufacturing capacity' of particular pharmaceutical products, by virtue of Article *31bis* of the TRIPS Agreement.

[1] See also: Bacchus, J. (2020), *An Unnecessary Proposal: A WTO Waiver of Intellectual Property Rights for COVID-19 Vaccines*, Free Trade Bulletin No 78, CATO Institute, Washington, D.C.; and Mercurio, B. (2021), 'WTO Waiver from Intellectual Property Protection for COVID-19 Vaccines and Treatments: A Critical Review', *62 Virginia Journal of International Law Online*, pp. 10–31.

Conventionally, a compulsory licence may only be authorised if efforts for voluntary licensing fail to materialise within a reasonable period of time. This prerequisite may look burdensome and time-consuming, but it may be waived if the authorisation is under 'a national emergency or other circumstances of extreme urgency…[2]'

An oft-quoted piece of evidence to support the argument that the compulsory licensing procedure is onerous is the fact that Article *31bis* of the TRIPS Agreement has been applied only once since the 2001 adoption of the Doha Declaration on the TRIPS Agreement and Public Health. In this one instance it took nearly four years, from the moment when Apotex Inc., the exporter, expressed its initial interest to manufacture triple antiviral therapy, to the first shipments that were sent to Rwanda, the importer[3]. Legislative amendment, voluntary licencing negotiations, and the 'drug-by-drug, country-by-country decision-making process' of the compulsory licensing procedure under Article *31bis*, were blamed for this long and protracted process[4].

On the other hand, although 'institutional and legal difficulties' that developing countries face are quoted as a justification for the 'TRIPS waiver', it is maybe for other reasons that some countries have been restricted from invoking compulsory licensing. The restrictions under bilateral trade agreements (e.g. the requirements for test data exclusivity for pharmaceutical product patents) and possible retaliation by trade partner countries (e.g. sanctions by the United States under Section 301) could deter some countries from invoking the policy flexibility. Additionally, some countries also did not incorporate compulsory licensing into their national legislation simply because they felt it was not necessary.

Nonetheless, within the present context of the 'TRIPS waiver' proposal, the EU's response tries to improve the efficiency of the compulsory licensing procedure, for better clarity, certainty and simplification, especially as far as exports are concerned, as will now be discussed below.

2. The EU's proposal to improve the compulsory licensing procedure

The EU's proposal is three-fold. It focuses on the administrative procedure of compulsory licensing. The impact would be possible in the long-term when a new pandemic strikes post Covid-19.

[2] These efforts include trying to obtain authorisation from the rights holder on reasonable commercial terms and conditions and within a reasonable period of time. This requirement may, however, be waived by national legislation in the case of a national emergency or other urgent circumstances or in cases of public non-commercial use, in accordance with Articles 31 (b) of the TRIPS Agreement.

[4] See here for further info.

2.1 'A national emergency or other circumstances of extreme urgency'

The first component of the EU's proposal is to determine that '… a pandemic is a national emergency or other circumstances of extreme urgency…'. Once this is done, when authorising a compulsory licence, the prerequisite of negotiating with the patent right holder would be waived in accordance with Article 31(b) of the TRIPS Agreement. The EU also proposes to extend this to Article 31*bis*[5].

Some scholars have argued that the EU's request for clarification does not imply a 'substantial flexibilisation of the system' as the possibility for this already exists. Nonetheless, such a clarification could be important when a future pandemic strikes for absolute certainty's sake. Presently, the Covid-19 outbreak has been classified, *de facto*, as a 'national emergency' after the WHO declared it an official pandemic on 11 March 2020.

De jure, the outbreak of the Covid-19 pandemic may constitute '*an emergency in international relations*'. Thus, by virtue of Article 73(b)(iii) of the TRIPS Agreement, on the strength of 'security exceptions', a government's policy measures may override the IP protection obligations[6], to protect a WTO member's essential security interests. A few governments have taken action on this ground of 'national emergency' in the wake of the outbreak. For example, in Canada, the government or 'another specified person' is empowered to supply a patented invention when responding to a public health emergency of national concern.

Nonetheless, thanks to the Doha Declaration, WTO members have the freedom not only to grant a compulsory licence but to also determine the grounds upon which compulsory licences may be granted. They equally have the right to determine what constitutes 'a national emergency or other circumstances of extreme urgency'. Moreover, it is understood that a public health crisis can represent 'a national emergency or other circumstances of extreme urgency[7].' On this account, the EU's request for clarification on the term 'national emergency' seems to have had limited impact on the Covid-19 pandemic.

But, if we want to heed to the complaints voiced by Apotex Inc., where the generic pharmaceutical manufacturer was compelled to negotiate with three patent holders who held a 'proliferation of fragmented and overlapping rights[8]', the EU's request for clarification could help to improve the efficiency of compulsory licensing, also for export purposes, under Article 31*bis* of the TRIPS Agreement.

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[5] This is because, under normal circumstances, Article 31*bis* may only override Articles 31(f) (predominantly for the supply of the domestic market) and (h) (adequate remuneration).

[6] Abbott, F. (2020), *The TRIPS Agreement Article 73 Security Exceptions and the COVID-19 Pandemic*, South Centre Research Paper 116, South Centre, Geneva, August. Also, Zaman, K. (2022), 'The Waiver of Certain Intellectual Property Rights Provisions of the TRIPS for the Prevention, Containment and Treatment of COVID-19: A Review of the Proposal under WTO Jurisprudence', *European Journal of Risk Regulation*, pp. 1-19.

[7] Article 5(b)(c), Doha Declaration on the TRIPS Agreement and Public Health.

[8] Heller, M. and Eisenberg, R. (1998), 'Can Patents Deter Innovation? The Anticommons in Biomedical Research', *Science*, Vol. 280, pp. 698-701.

2.2 'The remuneration should reflect the price charged under the compulsory licence'

The second component of the EU's proposal aims to determine that, under circumstances caused by a pandemic, remuneration should reflect the price charged by the manufacturer of the pharmaceutical products that were produced under the compulsory licence.

As a principle, when authorising a compulsory licence, in accordance with Article 31(h) and paragraph 2 of Article *31bis* of the TRIPS Agreement, 'adequate remuneration' should be paid to the patent right holder by taking into account the 'economic value' of the licence to the importing member.

In general, WTO members have the freedom to determine the level of 'adequate remuneration' in the context of compulsory licensing. In the meantime, the United Nations Development Programme (UNDP) and the WHO have recommended a range of royalty rates from; 1.) 4 %, 2-4 % based on the generic product price; 2.) 0.02-4 % based on the generic product price and dependent on the UNDP Human Development Index rank of the concerned country; 3) 4 % based on US or European country product prices, and all with a variation of ± 2 % considering other relevant factors[9].

Taking the above into the consideration, the EU's proposed solution provides another criterion on 'adequate remuneration', with uniformity and clarity as far as generic pharmaceutical supplies are concerned.

2.3 One single notification for 'exporting members'

The third component of the EU's response to the 'TRIPS waiver' proposes that exporting members may provide just one single notification with a list of all countries to which the generic versions of pharmaceutical products are to be supplied directly, or indirectly, through international joint initiatives. 'Notification' is a request obliged by Article 31*bis* of the TRIPS Agreement; Paragraph 2(b)(c) of the Annex to the TRIPS Agreement provides the details as far as exports are concerned.

However, the impact of the EU's 'one notification' proposal and its ability to actually help countries, especially developing countries, to use the Article 31*bis* system is hard to assess at the moment.

Firstly, the likelihood of generic pharmaceutical manufacturers in developing countries, such as India and South Africa, to become exporters is slim. This is because to be a potential exporter of a generic pharmaceutical product, for example a Covid-19 vaccine, the exporter/ manufacturer must be located in a country where the particular patent is in force and requires a compulsory licence for export. To date, among the developing countries with manufacturing capacity, only five Covid-19 related patent applications have been submitted in South Africa,

[9] UNDP and WHO, *Remuneration Guidelines for Non-Voluntary Use of a Patent on Medical Technologies*, pp. 51-7.

and one in India. With such an insignificant number of patent applications, it is highly unlikely that Indian and South African pharmaceutical manufacturers would be able to become exporters.

And then what about the world's top recipient countries of Covid-19 patent applications and with high manufacturing capacity? Presently, the top three recipients are the United States, that has received 18 425 applications, the World Intellectual Property Office (WIPO) that has received 10 460 applications under the Patent Cooperation Treaty (PCT) system, and the European Patent Office (EPO) that has received 4 175 applications[10].

Looking at the patent application numbers, the United States seem to be the most likely candidate exporter, especially because of its high capacity in generic pharmaceutical manufacturing. However, the country may not be inclined to invoke Article 31*bis* as it opted out of the mechanism, although noting that it would be open to an 'opt-in' at a later date if circumstances warranted such a move.

At the same time, for those applications submitted to the WIPO, we do not know which countries they will eventually be enforced in, since the patent examination process is still ongoing. It is possible that, after passing the patent examination at the 'international stage', a considerable number of patent holders would enforce their rights in some developing countries (at the 'national stage'[11]), such as in India and South Africa. Having said that, one essential consideration when electing jurisdiction for patent enforcement is that patent holders will want to protect their rights in countries with strong legal enforcement mechanisms.

The same 'unknown' can be extended to those Covid-19 patents submitted to the EPO. These patents may well be enforced eventually by the EPO contracting members, such as Germany, Belgium and Spain, and they all have high pharmaceutical manufacturing capacity[12]. In theory, they could all become an exporter country within the definition of Article 31*bis*.

Nonetheless, just like the United States, the EU and its Member States opted out of Article 31*bis*. Whether they would one day opt-in would of course depend on the specific circumstances at hand.

It must be highlighted that the Article 31*bis* mechanism may only be invoked under exceptional circumstances (which may be the reason why it has been used only once thus far). In the first place, the objective of compulsory licencing is 'never to issue lots of compulsory licences but to provide cheaper medicines for the poor.' Under most procurement scenarios, before

[10] Other big recipients of COVID-19 patent applications are: Russia (129), Australia (124), Canada (124), and Japan (61). For details, see Lens Patent Search: Coronavirus (as of 14 January 2022).

[11] As an international patent system, by filing one patent application under the Patent Cooperation Treaty (PCT), in theory applicants can simultaneously seek protection for an invention in 154 PCT contract states.

[12] For countries' pharmaceutical manufacturing capacity, see IFPMA (2021), *Towards Vaccinating the World, Landscape of Current COVID-19 Supply Chain and Manufacturing Capacity, Potential Challenges, Initial Responses, and Possible "Solution Space"*, IFPMA Discussion Document.

resorting to Article 31*bis* for export/import purposes, affordable supplies would usually already become available from countries where the relevant patents are not in force. Sometimes, once compulsory licensing is discussed, prices for the originator pharmaceutical product can be reduced through negotiation to an affordable level without recourse to a compulsory licence. Donations may also be yielded[13]. Alternatively, the originator company may have agreed to grant a voluntary licence to a generic producer.

In the context of the Covid-19 pandemic, Gilead Sciences has concluded non-exclusive voluntary licensing agreements with generic pharmaceutical manufacturers based in Egypt, India and Pakistan to further expand the supply of remdesivir, an antiviral medication developed by Gilead for emergency use to treat Covid-19, to 127 countries. These agreements not only enable technology transfer of the Gilead manufacturing process for remdesivir, but they also authorise the local licensees to set their own prices for the generic pharmaceutical product they manufacture. Additionally, in February 2022, it was announced that six African countries – Egypt, Kenya, Nigeria, Senegal, South Africa and Tunisia – would be the first on the continent to receive the technology needed to produce an mRNA vaccine.

3. Conclusion

To bring about an effective response and eventual end to the Covid-19 pandemic, pharmaceutical manufacturers have been actively conducting voluntary licensing and technology transfer/coordination activities. New manufacturing plants have also been constructed in developing countries, such as South Africa, to scale up pharmaceutical manufacturing capacity. These undertakings have not been hampered by compulsory licensing, however onerous its authorisation procedure might be.

Nonetheless, the EU's response has addressed the concerns raised by the TRIPS waiver proposal on 'institutional and legal difficulties' that countries may face when using policy flexibilities provided by the TRIPS Agreement. But the solutions advocated by the EU's proposal move beyond the pandemic. If adopted, it will most likely benefit future users during a new emergency situation (such as the next pandemic) with a simplified compulsory licensing procedure and universal legal clarity on what actually constitutes 'economic remuneration'.

[13] Such success was achieved when Thailand and Brazil used compulsory licensing as a negotiating tool to seek supplies of affordable antiretroviral treatments for their citizens living with HIV/AIDS.