

THE EU NEEDS TO BE ABLE TO ISSUE COMPULSORY LICENSES FOR SOME MEDICINES DURING A CRISIS

During a health crisis, having timely access to effective medicines can be a matter of life or death. When a company does not have enough production capacity, or because it charges unaffordable prices for a patented vaccine or treatment, issuing an EU-wide compulsory license for that medicine can allow other companies to manufacture it. The biggest advantage this would procure is to give EU citizens greater access to essential medicines or medical devices. To ensure swift and effective responses during a health crisis, the process for granting a compulsory license cannot be overcomplicated or contain bottlenecks.



2

PROVIDE FLEXIBILITY ON THE IDENTIFICATION OF RIGHTS-HOLDERS

The European Commission should be able to grant a compulsory license even when not all the intellectual property rights and their owners could have been identified. Allowing for flexibility in a crisis is important, as for some medicines having to do a full mapping could take too much time and cost lives.² The example of the HIV medication ritonavir (see [link](#)) shows how many patents and rights-holders can end up being linked to one product.³ In this type of situations, the mapping exercise should continue after the license has been granted.

3

MAKE IT POSSIBLE TO WAIVE VOLUNTARY LICENSE REQUIREMENTS

It should be possible for the Commission to grant a license without prior efforts from companies to reach a voluntary licensing agreement, as these negotiations could end up delaying access to essential goods.⁴ This would be in line with the TRIPS Agreement, according to which efforts are not necessary *"in the case of a national emergency or other circumstance of extreme urgency, or in cases of public non-commercial use"*.⁵

1

FACILITATING THE SHARING OF TRADE SECRETS

The European Commission should be able to oblige patent owners to share protected know-how (trade secrets), where necessary, to ensure swift production by other companies. This might be the case for more complex health technologies in which drug production can be unnecessary lengthy.¹

¹ As a way of comparison, it took 8 months for researchers in South Africa to find the 'recipe' to produce an mRNA COVID-19 vaccine. Lazare S. ['What Moderna Reveals About the Cruel Absurdity of "Innovation" Under Pharmaceutical Monopolies'](#), In these Times, February 2022

² t'Hoen E. ['Something is going terribly wrong with the EU Compulsory Licensing Regulation'](#), Medicines Law & Policy, March 2024

³ idem

⁴ Another issue is that they might come with abusive licensing terms and practices. For example, lack of transparency, restrictive terms for accessing know-how, or restrictions on the source of API which hinder the generic manufacturer's capacity to offer the medicine at lower prices. See Médecins Sans Frontières ['Voluntary licenses and access to medicines'](#), October 2020.

⁵ Agreement on Trade-Related Aspects of Intellectual Property Rights, Article 31(b). See also WTO, ['Compulsory licensing of pharmaceuticals and TRIPS'](#), accessed on 29 January 2025.

BEST INSTITUTIONAL POSITION FOR CONSUMERS ON...



Sharing of trade secrets



The Parliament text empowers the Commission through a clearly defined framework with the capacity to oblige the rights-holder, where necessary, to share with the licensee the know-how that is needed for producing the "crisis-relevant product".



Identification of intellectual property rights and rights-holders

The Commission text provides enough flexibility for the Commission to issue a compulsory licence even if not all the patents and rights-holders are identified in a reasonable period of time.



Requirements on voluntary licensing

Although the Commission's proposal works best, the final text must also include the language added by Council in Recital 3, acknowledging that under the TRIPS Agreement the requirement on prior efforts on voluntary licensing may be waived" in the case of a national emergency or other circumstances of extreme urgency, or in cases of public-non commercial use".

