Compulsory Licensing in the EU

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Medicines Law & Policy (ML&P) welcomes the opportunity to respond to the call for evidence for an impact assessment of compulsory licensing in the EU. Compulsory licensing can be an effective way to secure access or increase access to health products by allowing others than the patent holder to make use of patents and supplementary protection certificates (SPCs) without the consent of the patent holder, often against the payment of a royalty. World Trade Organization (WTO) law provides for compulsory licence and other flexibilities in the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). Compulsory licensing is one of the key flexibilities of the TRIPS Agreement to deploy for reasons of public health, reaffirmed by the WTO Members in the 2001 Doha Declaration on the TRIPS Agreement and Public Health. An overview of the use of compulsory licences for health products by governments since 2001 can be found in the TRIPS Flexibilities Database. See also here.

Compulsory licensing is only relevant in cases where there is a patent and the patent holder has refused to enter into a voluntary arrangement. Compulsory licensing does not assure access to know-how that cannot be obtained through the patent. Therefore, additional measures will be needed to ensure know-how and other forms of intellectual property (IP) are available for sharing when needed to produce and supply health products.

The issuing of compulsory licences is the competence of EU Member States. Effective and efficient use of compulsory licences within the EU for health products will require legislative changes to the EU pharmaceutical legislation to introduce data- and market exclusivity waivers and a reversal of the EU's opt-out of TRIPS Article 31 (bis). Further, ML&P recommends that EU and EU Member State funding for health innovations is accompanied by the requirement that IP, including know-how developed with that funding, is shared with others that are able to make use of the innovation. For that purpose, internationally recognised licensing initiatives can be used.

Specifically, ML&P recommends the EU should:

1. Introduce data- and market exclusivity waivers

EU pharmaceutical legislation provides for data- and market exclusivity of up to 11 years during which period a generic or biosimilar product cannot be marketed in the EU. An entity that has been allowed to produce or import under a compulsory licence a product that still enjoys data- or market exclusivity cannot obtain marketing authorisation or commence marketing in the EU under such legislation, even in a situation of a health emergency. The lack of such waivers was identified as a barrier to effective use of compulsory licence in the Chair's report of the Dutch Commissie Dwanglicenties.

ML&P makes the following recommendations to correct this:

- **Introduce a data compensation** regime by replacing the EU data exclusivity regime with a data protection regime that acknowledges the investments required to generate the clinical test data but does not allow the investor to exclude others from using the data.
- **Introduce waivers to data and market exclusivity** to facilitate effective use by governments of patents in the public interest, through compulsory licensing. Such waivers are compatible with WTO law and a number of WTO Members have introduced such waivers in national law.

For more details on these proposals see here and here.

2. Opt-in to WTO TRIPS Article 31 (bis)

In 2003, the EU opted-out of the '2003 August 30 decision' (since 2017, TRIPS Article 31(bis)). This opt-out means that EU countries cannot use the TRIPS provision to allow the importation of products produced under a compulsory licence elsewhere when production capacity within the EU is insufficient. By ruling out the use of Article 31(bis) for importation in all circumstances, even in 'situations of national emergency or other circumstances of extreme urgency', EU countries have left themselves dangerously exposed to the Art. 31(f) problem, eg. that a compulsory licence issued predominantly for the supply of the domestic market restricts exports to countries lacking sufficient domestic manufacturing capacity. ML&P, therefore, recommends that the EU opts back in the WTO TRIPS Article 31(bis) mechanism. Being able to import needed products under this mechanism may be of particular importance during a pandemic. For further details see here.

3. Condition public funding of health innovation to ensure know-how access

A compulsory licence does not necessarily provide access to know-how and other forms of IP needed to produce products without the collaboration of the patent-holder. Such access can be of particular importance for more complex products such as vaccines. Such IP and know-how is often developed with significant public financing. For example, this was the case of Covid-19 vaccines. ML&P recommends that the EU and its Member States adopt a policy to ensure that public funding for health innovations is accompanied by the requirement that intellectual property, including know-how, regulatory test data, (biologic) materials developed with that funding, are shared, possibly against compensation, with others that have the capacity to make use of the innovation. This can be done through collaboration with internationally recognised licensing organisations such as the WHO Covid-19 Technology Access Pool or the Medicines Patent Pool.

For further details see here and here.

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