PINK SHEET
CITELINE REGULATORY

14 Mar 2024 | **News**

European Parliament Clears EU-Wide Compulsory Licensing Proposal

by Ian Schofield

The draft regulation, which includes a ban on exports of drugs manufactured under an EU compulsory license, will be discussed with the EU member states after the June parliamentary elections.

Members of the European Parliament (MEPs) have given the green light to new rules that they say will "ensure the EU's access to key patented products in times of crisis" by allowing the European Commission to issue EU-wide compulsory licenses on originator drugs and other products such as microchips.

In a plenary session on 13 March, MEPs *adopted* an amended version of the commission's proposed regulation on compulsory licensing that was approved by its legal affairs committee (JURI) in February. (Also see "*EU Committee OKs More Pharma-Friendly Compulsory Licensing Plan*" - Pink Sheet, 15 Feb, 2024.)

The vote by parliament constitutes its first-reading position on the draft regulation, which will be taken up by the new assembly when it begins discussions with the Council of the EU after the European elections on 6-9 June.

Specified Scope & Duration

Under the regulation, the EU would be able to issue a "special permission with specified scope, territorial coverage and duration for the use of [a] patent without authorization of the rights holder in cross-border emergencies," the parliament said.

Compulsory licenses could be issued by the commission in "clearly defined emergencies such as cross-border health crises, gas supply crises or single market emergencies" if there was no

voluntary agreement between the rights holder and the potential licensee within one month.

Before launching a compulsory licensing procedure, the commission would have to "identify all related intellectual property rights and their holders," the parliament noted.

Any decisions on a license would require a recommendation by a "topic-relevant advisory body" composed of representatives of national institutions responsible for granting national compulsory licenses, and should be taken "only after receiving comments from rights holders and licensees."

Before a compulsory license was terminated, the commission would have to consult both parties to the license and "put in place an adequate transitional period."

Appropriate Remuneration Needed

The draft regulation states that the rights holder would be entitled to "appropriate remuneration" for the use of its patent and to "adequate compensation if a compulsory license required disclosure of a trade secret.

Only "strictly necessary information" would be disclosed, the parliament says, and the commission should "determine the remuneration depending on the total gross revenue generated by the licensee through activities related to the compulsory license."

The draft legislation also contains a set of obligations for both rights holders and licensees, such as the need to disclose information necessary for the compulsory license for the rights-holder or an "obligation to label products manufactured under compulsory license for [the] licensee."

If these obligations were breached, the commission could impose a fine not exceeding 6% of the company's total turnover in the previous year.

Export Ban Retained

In a move that will please the R&D-based industry but anger medicines access advocates, the parliament retained the commission's original proposal to ban the export of products manufactured under an EU compulsory license to countries outside the EU.

The parliament's trade committee had earlier said that rather than a ban, there should be an export "restriction" that took account of the possibility for exports under a compulsory license as per the World Trade Organization's TRIPS (Trade-Related Aspects of Intellectual Property Rights) Agreement. However, the JURI rejected this amendment in its February report on the draft regulation.

Ahead of the vote, a group of civil society organizations and individuals published an open letter

to the parliament stating that an export prohibition was contrary to both the TRIPS flexibilities and to "the EU's position on export restrictions at the WTO."

They said the ban was "problematic, especially considering the use of a Union Compulsory License would likely be triggered by situations that would affect not only EU countries but also countries outside of the EU, either in the region or globally."

The civil society groups noted that the commission has acknowledged in its proposal that drugs produced under an EU compulsory license could theoretically be exported outside the EU under Regulation 816/2006, which governs compulsory licenses issued at national level.

However, they said that "this procedure, intended exclusively for export, is widely deemed cumbersome and has never been used. More importantly, it currently cannot be used to simultaneously supply both EU countries and countries outside the EU."

Despite these entreaties, the parliament retained the proposed export ban.

After the vote, Left group MEP Helmut Scholz, who was responsible for the trade committee's opinion on the draft regulation, said the new compulsory licensing system was "an important step to prepare the EU for future health crises."

"However, I deeply regret that MEPs fail to recognize the realities of our interconnected world," he declared. "Unfortunately, a conservative majority has not been ready to go beyond soapbox speeches for global solidarity by allowing for easier exports in health emergencies."

The European pharma industry federation EFPIA said when the proposal was launched last year that it could be "used to broadly abrogate the IP [intellectual property] rights of innovators" and "appears to disregard lessons learned from the COVID pandemic response." (Also see "*EU-Wide Compulsory Licensing Plan Draws R&D Industry Ire*" - Pink Sheet, 27 Apr, 2023.)