Proposal: Compulsory Licensing for Export under the TRIPS Agreement: Balancing the Drawback?

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According to article 31(f) of the TRIPS Agreement, the production of pharmaceutical products under compulsory licenses must be predominantly supplied for the domestic market. This provision was highly criticized, for it hinders the import of such pharmaceuticals to countries that are unable to produce them. Accordingly, TRIPS was amended to include proposals resulting from the Doha Declaration. This led to the incorporation of article 31bis, that allows the exportation of generic drugs, which are more affordable and more accessible for developing countries. Thus, countries with no or insufficient manufacturing capacity can get access to patented drugs produced under compulsory licenses by a foreign provider. The Amendment entered into force in 2017. However, the question remains: can the compulsory licensing for export consecrated under article 31bis of the TRIPS Agreement be considered as a sustainable solution in balancing the right of the IP owner and public health considerations?

The paper examines the reception of the TRIPS Amendment. It underlines that, undoubtedly, compulsory licensing for export constitutes an important step forward to solve the problem of access to medicines in developing countries and realize the right to health of the population. At the same time, it is pointed out that the numerous conditions imposed for the use of the system make it difficult for developing countries to effectively ensure broader access to pharmaceutical products at low cost and in a timely manner. From a theoretical point of view, while considering neighboring flexibilities and IP-related contracts, we propose to qualify compulsory licensing for export as “parallel license”. Appreciated accordingly with the aims of intellectual property law and the necessity to promote access to medicines, the analysis comes to the observation that, to some extent, “parallel license” might not that much be beneficial neither for the patent owner nor for the access to medicines.