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Compulsory licensing: you said “taboo”?

Matthieu Dhenne (Ipsilon) · Wednesday, November 25th, 2020

In his 1913 essay *Totem und Taboo*, Freud defined taboo as a prohibition related to what is considered sacred or impure. The famous psychoanalyst insists on the irrationality of the phenomenon. Thus, compulsory licensing, which is often seen as an impure danger, seems to be a kind of taboo for intellectual property specialists. But the numerous research studies related to COVID-19 and the need to be ready for eventual health crisis of this type in the future invite us to try to (re)examine the question rationally: what is the real nature of the compulsory license?

Ex officio license principles

The *ex officio* license in the interest of *public health* is supposed to be the exception to invoke for an extreme urgency of a health crisis like COVID-19. However, the TRIPS Agreement submits it to a large number of conditions: authorization shall be considered on its individual merits (article 31(a)); prior negotiation with the right holder (except in cases of urgency) (art. 31 (b)); duration and scope of the license limited to the purpose for which it was authorized (Article 31 (c)); the license must be non-exclusive, non-assignable (Article 31 (d) and (e)), and predominantly for the supply of the domestic market of the Member authorizing it (Article 31 (f)); authorization may be terminated if and when the circumstances which led to it cease to exist and are unlikely to recur (Article 31 (g)); adequate remuneration (Article 31 (h)) subject to judicial review or other independent review (Article 31 (i)).

By way of derogation from Article 31(f), drugs may be produced under *ex officio* license by manufacturers based in a third country and be imported into a poorer importing country which is unable to ensure access to the drugs at affordable prices and to manufacture them itself (Article 31 bis).

Ex officio license limits

This system has been used only on rare occasions and almost by developing countries alone[1]. And COVID 19 crisis led mainly to the same finding[2]. Even the exception of Article 31 bis, although it was the result of tough WTO negotiations, has only been applied once and its implementation has been strongly criticized for being too complex[3] and slow[4]. Faced with COVID-19, some have quickly noticed that the *ex officio* license was ineffective and concluded, in accordance with the dualistic logic, that expropriation was the only solution in case of need[5]. This reaction seemed

natural, since, in fact, the system seems to have been hardly ever used in Europe – except in Germany[6] – and never in the United States where all applications have been rejected[7].

Beyond an illustration of the adage *exceptio est strictissimae interpretationis*, we see in this inefficiency the result of an unclear and too strictly delimited mechanism. For instance, the public interest, which is central, is not defined. Moreover, only one exception has been provided with Article 31 bis and high-income countries opted out, even in cases of extreme urgency[8]. Yet these are the same countries that largely no longer have active ingredient manufacturing capacities within their territories, because they have been outsourced, mostly to China or India. As a consequence, for a high-income country, an *ex officio* license will also have to be granted for the same medicine in the exporting country, which must already have been supplied. In addition, such an opt out tends to compartmentalize markets, allowing total price freedom and therefore authorizes different prices depending on the areas. The risk lies eventually in pricing not related to manufacturing or development costs, but to the perceived value of a drug in the treatment of COVID-19. This type of situation has already arisen with regard to the sofosbuvir molecule for the treatment of hepatitis C[9]. Starting from 2016 increasing numbers of Americans with hepatitis C traveled to India to purchase sofosbuvir, because of its high cost in the United States[10].

Lastly, even if patents are bypassed, regulatory authorizations are still required to commercialize a drug. This means, firstly, that some regulatory rules may prevent the exploitation of the license. In the European Union, for instance, if the license is granted too early, we will fall into the so-called data protection period (8 + 2 + 1 years) during which the licensee will not be able to obtain a marketing authorization[11] and if the product covered by the patent benefits from an orphan designation its owner will benefit from a 10-year market exclusivity[12], plus 2 years in the case of the successful completion of a pediatric investigation plan[13]. Secondly, commercialization requires very long and expensive clinical trials to prove that a drug is as effective as it is safe, and all data provided to the agencies is confidential. This represents also an important constraint, at least for the most recent drugs.

Misconceptions of ex officio license

The relative ineffectiveness of *ex officio* license against COVID-19 has provoked few reactions[14]. This results from the unpopularity and the demonization of such a license, themselves inherited from the classical utilitarian model. Unfortunately, some myths persist, such as that of making the *ex officio* license an expropriation. Although it is only a limitation of the right holder's prerogatives. Indeed, a patentee remains free to use his invention (*usus*), to collect royalties (*fructus*), but is destitute of an attribute of his property, since he is forced to conclude an undesired contract (loss of the *abusus*). Another unfounded *a priori* is that *ex officio* licensing would hamper innovation by depriving of rewards for investments. Actually, the mechanism aims either at compensating for the inability to provide a market or the inability to provide it at a reasonable price[15]; cases where the patentee would not have received any royalty. Besides, we avoid the costs of numerous bilateral negotiations with potential partners, since this task will be left to the State requesting the license.

Furthermore, to the best of our knowledge, no economic study has been carried out to date to prove that compulsory licensing is detrimental to innovation. On the other hand, a recent economic study even concludes compulsory licensing increased patent applications in the chemical sector by as a minimum 20 percent after the World War I in the USA[16]. Not to mention that *ex officio* might be used as a lever for countries to encourage patented manufacturers to relocate factories in their territories or lower prices, notably to give access to healthcare in time of pandemic and to revive their economies during and after the said pandemic.

Rebalancing measures

MEPs[17] and French MPs[18] have proposed to adopt *ex officio* licenses respectively for the European Union and France. To this end it is nevertheless necessary to rebalance the system so that it becomes really useable. We should first of all extend the status of importing country, according to article 31 bis of the TRIPS, to high-income countries[19]. It could also be specified that the license covers patent applications, supplementary protection certificates and all elements reasonably required for the commercialization of the invention. In this sense, South Africa has recently proposed a more holistic approach to the use of TRIPS flexibilities for various forms of IP and various technologies needed to prevent and cure COVID-19[20]. Likewise, a clarification of the rules seems crucial. The notion of public interest might especially be characterized, for example, by providing, as in section 41(2) of the English Act of 1949, that drugs must be made available to the public "*at the lowest price consistent with the benefits which patentees must equitably derive from the patents*".

At last, action should also be taken concerning regulatory rules. For example, two measures ought to be considered in Europe: Introducing an exception to the protection of marketing authorization data and market exclusivity in the case of an *ex officio* license; Allowing temporary authorization if therapies, although existing, are made available in insufficient quantity or quality or at abnormally high prices.

The post Covid-19 IP World

Finally, the *ex officio* license seems to be able to serve as an economic lever for States, more particularly by helping them to encourage patented producers to relocate manufacturing to their territories and to lower prices. Thus, patent law could be a key to addressing the crisis as research for treatments and vaccines is in full swing. More generally, this crisis could lead to a strengthening of the geopolitical and economic roles of intellectual property, provided there is no misunderstanding about its purpose: it is definitely a tool to foster innovation and growth, but also a tool directed towards the society and not only towards the interest of its holder[21]. And, if they refuse to understand this, the rights holders, instead of seeing their prerogatives simply limited, risk expropriations, as has already and notably been proposed by some in France and decided upon in Germany.

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[1] *Draft reference document on the exception regarding compulsory licensing, by the*

Standing Committee on the Law of Patents, May 2019: https://www.wipo.int/edocs/mdocs/scp/en/scp_30/scp_30_3-main1.pdf.

[2] M. Dhenne, *COVID-19, patents and access to healthcare: a French perspective*, https://ssrn.com/abstract=3614409.

[3] B. Anderson, *Better access to medicines: why countries are getting "tripped" up and not ratifying article 31– bis*, Case Western Reserve Journal of Law, Technology & the Internet, 2010, p. 173.

[4] A. Nightingale, *WTO "Paragraph 6" system for affordable medicine: time for change?*, https://www.ip-watch.org/2016/11/14/wto-paragraph-6-system-affordable-medicines-time-change.

[5] F. Pochart, M. Rauline & O. de La Verteville, *Compulsory licenses granted by public authorities: an application in the Covid-19 crisis in France? Part 2*, http://patentblog.kluweriplaw.com/2020/04/24/compulsory-licenses-granted-by-public-authorities-an-application-in-the-covid-19-crisis-in-france-part-2.

[6] P. Maume, *Compulsory licensing in Germany*, in R. Hilty & K.-C. Liu (eds), *Compulsory licensing: practical experiences and ways forward*, Springer, 2015, pp. 95-120.

[7] J. R. Thomas, *March-in rights under the Bayh-Dole Act* (Congressional Research Service, August 22, 2016), https://fas.org/sgp/crs/misc/R44597.pdf.

[8] Annex to the TRIPS Agreement, Art. 1(b), footnote 3.

[9] A. Pollack, *High cost of Sovaldi hepatitis C drug prompts a call to void its patents*, The New-York Times, 19 May 2015.

[10] WebMD, *More Americans and Chinese Traveling to India for Hepatitis C Treatment*, http:/webmd.cn/en/americans-chainese-travel-india-hepatitis-c-treatment.

[11] Regulation (EC) No. 726/2004, 31 March 2004, OJEC No. L 136, p. 1, art. 14(11).

[12] Regulation (EC) No. 141/2000, 16 December 1999, OJEC No. L 018, p. 1, art. 8(1).

[13] Regulation (EC) No. 1901/2006, 27 December 2006, OJEC No. L 378/1, p. 1, art. 37.

[14] See nonetheless E. Berthet, M. Dhenne & L. Vial, *Covid-19: how to implement the ex officio license*, Les Éditions de Boufflers, 2020, https://www.institutboufflers.org/edb. See also N. Binctin, R. D. Bourdon, M. Dhenne & L. Vial, *Feedback on the Intellectual Property Action Plan Roadmap of the European Commission*, Joint Response from the Association Henri Capitant des amis de la culture juridique française and the Institut Stanislas de Boufflers, https://www.institutboufflers.org/edb/.

[15] See for instance Article 35 U.S.C. § 203 and Article L. 613-16 of the French Intellectual Property Code.

[16] P. Moser & A. Voena, *Compulsory licensing – Evidence from the Trading with the Enemy Act*, National Bureau of Economic Research Working Paper No. 15598 (2009), http://www.nber.org/papers/w15598.

[17] https://msfaccess.org/sites/default/files/2020-03/Letter_Covid_A_letter_from_European_Members_of_Parliament_to_the_Commission_25.03.2020_ENG_0.pdf.

[18] Law proposal No. 2814 of 7 April 2020 tabled in the National Assembly by the group of La France Insoumise, http://www.assemblee-nationale.fr/dyn/15/textes/l15b2814_proposition-loi.

[19] Recent statements by a member of the European Commission seem to confirm this lead. See T. Balasubramaniam, *EU Trade Commissioner Phil Hogan issues statement on European Union compulsory licensing in context of COVID-19, makes important statement about TRIPS Article 31bis*, https://www.keionline.org/33284.

[20] WTO, *Intellectual property and the public interest: beyond access to medicines and medical technologies towards a more holistic approach to TRIPS flexibilities (Communication of South Africa)*, 17 July 2020, IP/C/W/666.

[21] M. Dhenne, *Covid-19: Hope for a New World of IP?*, https://ssrn.com/abstract=3714584.

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