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## Compulsory licensing and Covid-19 vaccines: when fake news spoil the public debate

Matthieu Dhenne (Ipsilon) · Wednesday, April 14th, 2021

At a time when a bill aiming at granting a compulsory license in the interest of public health in case of extreme sanitary emergency has just been filed in the French Senate on April 8, 2021[1], the fake news that spoil the public debate about the compulsory licensing keep on proliferating. These fake news, which are not specific to the French media, deserve some clarifications to clean up this debate.

### “Patents are not the issue”

The French government claims that patents are not “the issue”: in other words, no patent would hinder the manufacture of vaccines.

It is true that no patents have yet been granted directly for a covid-19 vaccine as such, since such a grant requires the filing of an application with a Patent Office, which will examine it during a procedure that will last approximately two years.

However, the lack of granted patents does not mean that there are no patents that could impede the manufacture of vaccines.

Firstly, it is the patent application, not the granting of the patent, that constitutes the origin of the patent right, from which point an infringement action is possible.

Second, vaccine manufacturing involves processes, possibly pre-dating the pandemic and be the subject of patents. This is the case for messenger RNA and lipid nanoparticles, for example, for which BioNTech[2] et Moderna[3] hold numerous patents. Similarly, Oxford University holds patents on the recombinant DNA technology used in Astra Zeneca’s vaccine, to which Oxford University has granted an exclusive license[4]. Moreover, Moderna’s announcement that it will not assert its patents during the pandemic does not mean that it is waiving its rights. Moderna is not giving up anything, but rather exercising its right by subjecting access to the patented technology to certain conditions[5].

Of course, patents could prove useless without the know-how required to implement their teachings. This know-how will be particularly necessary when it comes to compiling a file in order to obtain a marketing authorization. However, there is nothing, other than the lack of political will,

to prevent the ex officio license from extending to the patent as well as to the know-how necessary for its exploitation.

### **“The insufficiency of the adapted industrial capacities is the issue”**

While the French government continues to claim that the “fill and finish” in France is equivalent to “production” (of which it is in fact only the fourth step, i.e. conditioning), it also points out the lack of “industrial capacities” to manufacture active ingredients (the first and most important step in the manufacturing process of a medicine).

There is little doubt that a company who is not free to exploit, because third-party patents reserve the use of certain techniques, will invest in acquiring such capacities.

And, even considering that it is true that patents would not hinder production, the very idea that we would not have the necessary “industrial capacities”, or that it would be too long and/or too complicated to develop such capacities, in France for instance, does not stand up to analysis: it is not necessary to be an expert in pharmaceutical production to understand that, here too, nothing is impossible when there is a political will, and that even if it takes time, it would be as much a generator of jobs as it would be useful for renewing vaccines and/or for other pandemics.

### **“Levée des brevets” (“removal of patents”) and “global public goods” (or “common goods of humanity”)**

These two “elements of language”, from now on central in the French debate, are systematically associated with the ex officio license, more particularly on the extreme left of the political spectrum, whereas they correspond neither to the reality of the patent system.

In both cases, it is a question of designating an expropriation of patents. Patents should be “removed” or made “global public goods” (or “common goods of humanity”) so that everyone can produce vaccines[6]. But such expropriations would be contrary to the TRIPS Agreement signed in the framework of the WTO, which frames the uses of patents without the authorization of the patentees (in its article 31). Thus, under this Treaty, a patent right can be limited, but in no case denied. In other words, the TRIPS Agreement prevents the expropriation that would result from a “removal of patents” that could transform them into “global public goods” (or “common goods of humanity”).

Discussions are nevertheless underway within the WTO to establish a specific exception for the Covid-19 pandemic, in order to render patents ineffective in solving the crisis[7]. However, these discussions are facing blockages. That said, such an exception, which would take the form of an IP rights waiver, seems hardly justifiable in view of the patent system’s economy. The patent right allows the temporary reservation of a technical teaching to reward research. Nevertheless, it is not an unlimited property right and the compulsory license constitutes a regulatory mechanism aimed at avoiding abuse of the right, while still guaranteeing royalties to the patentees. In other words, the mechanism of compulsory licensing would already be sufficient – if it were to work effectively – to redress the potential imbalance between the interest of public health and the stimulation of research.

At the end of the day, in any case, the importance of patents cannot be overlooked in the vaccine manufacturing process and the bill filed in the French Senate on April 8, 2021, will perhaps make it possible to no longer confuse vaccine production with fill and finish, in order to focus on the heart of the problem, the manufacture of active ingredients, so that every country can finally acquire the industrial capacities to produce vaccines.

[1] Texte n° 524, 2020-2021 déposé par M. Ronan Le Gleut le 8 avril 2021. A proposal which follows a Report from the De Boufflers Institute (May 2020) and a Collective Tribune bringing together renowned specialists in property and patent laws (academics and practitioners), who invite the French public authorities to reform the compulsory licensing procedure and to engage it to facilitate the manufacturing of Covid-19 vaccines in France (March 2021).

[2] <https://www.citizen.org/article/biontech-and-pfizers-bnt162-vaccine-patent-landscape/>

[3] <https://www.citizen.org/article/modernas-mrna-1273-vaccine-patent-landscape/>

[4] See Christopher Garrison, How the ‘Oxford’ Covid-19 vaccine became the ‘AstraZeneca’ Covid-19 vaccine

[5] See Jorge Contreras, *Deconstructing Moderna’s COVID-19 Patent Pledge*

[6] See UNESCO calls for COVID-19 vaccines to be considered a global public good

[7] Members discuss TRIPS waiver request, exchange views on IP role amid a pandemic

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