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French bill proposal authorizing the granting of an ex officio license in the interest of public health in the event of an extreme health emergency

Matthieu Dhenne (Ipsilon) · Wednesday, April 28th, 2021

In my last post I deciphered several fake news, which spoil the public debate about compulsory licensing, I then mentioned a French bill proposal, introduced by Mr. Ronan Le Gleut in the Senate on April 8, 2021, whose I thought important to translate, so that it can feed the international debate on compulsory licensing following the current health crisis.

It should be noted that the translated text takes up the proposals made as early as May 2020 in a Report issued by the de Boufflers Institute, and then those that were also made by a Collective Tribune of French specialists in patent law and property law published in March 2021.

"**EXPLANATORY STATEMENT**

Ladies and Gentlemen,

The place of patents in the current health crisis

In this period of serious health crisis, hope has come from the research and development of several types of vaccines against Covid-19, many of which are very effective.

Unfortunately, we still have to wait before we can vaccinate on a large scale, as the rate of production of doses is insufficient. There is little doubt that the economic actors concerned are making considerable efforts to ensure sufficient production with limited and inadequate production capacities in the face of difficulties due to the technical specificities of vaccines.

However, when some people claim that insufficient production is linked to patents held by the pharmaceutical industry, we must beware of simplistic reasoning. It should not be forgotten that patents reward research, which is often long and costly, with temporary exclusivity for the exploitation of the invention. They also contribute to the disclosure, and therefore the dissemination, of the results of the research – since the disclosure of the invention is a condition for obtaining a patent.

This being the case, it is certainly possible to make access to patented inventions more flexible from a general interest perspective by allowing companies to manufacture vaccines and treatments

developed by others through the implementation of a compulsory license. The present bill proposal thus aims to adjust the conditions for granting such a license, which could make it possible to increase the production of vaccines on French territory while respecting the property of economic actors.

The ex officio license, a tool for access to medicines that should be mobilized

A patent license can be defined as a contract by which the patent holder – the patentee – grants a third party – the licensee – the right to exploit the invention in return for a fee. If the patentee is in principle free to conclude or not such a contract, by exception, in certain cases specified by the law, the conclusion of a license agreement can be imposed on him.

Thus, there exists, too often ignored, an ex officio license in the interest of public health. This license has existed for a long time in French law as in other legal systems. Since the beginning of the Covid -19 pandemic, many countries have adopted such licenses or threatened to do so. The international order is also familiar with this mechanism, which it promotes for the benefit of countries with insufficient manufacturing capacities. It is within the framework of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), signed on 15 April 1994 and entered into force on 1 January 1995, that the ex officio license in the interest of public health can be invoked in the event of a health crisis. It should be recalled here that the TRIPS Agreement expressly authorizes the signatory States to adopt in their legislation the measures necessary to protect public health, provided that these measures are compatible with the provisions of the Agreement (art. 8, para. 1). However, these licenses are still very little used from an international and national point of view. In France, the ex officio license presupposes, among other things, that medicines are made available to the public in insufficient quantity or quality or at abnormally high prices (Art. L. 613-16 of the Intellectual Property Code; hereinafter “CPI”). In such cases, the political will is sufficient for such a license to be set up via a two-step administrative procedure: first, the Minister of Health makes the request to the Minister of Economy and Finance, who can then submit the patents in question to the ex officio license regime by way of an order; then, a call for candidates must ensure that the license is granted to any qualified third party. In the absence of an amicable agreement on the price, the amount of royalties is set by the Court.

Patent law itself sets this limit to the patentee’s right in order to avoid an exercise of the property right that would be unjustified with regard to the public’s need for access to patented products. It is therefore not an expropriation that would risk discouraging future investments in research, but a balanced mechanism that, respecting the interests of those who have invested in research and wish to carry it out, allows full access to medicines. It remains that the current mechanism deserves adjustments in order to make it as effective as possible.

The ex officio license, a tool for access to medicines that we must improve

This ex officio license, which can be implemented today since it is provided for in our Law, nevertheless suffers from a certain cumbersomeness that requires time, whereas reactivity is required in a situation like the one we are experiencing. The fact is that to date, no ex officio license has ever been implemented in France.

The recent introduction of an article L. 3131-15 in the Public Health Code (hereinafter "PHC") is, however, a step in the right direction and is likely to facilitate the improvements that we wish to defend here, since it allows the Prime Minister "*by regulatory decree issued on the report of the minister responsible for health, for the sole purpose of guaranteeing public health :* […] *9° Where necessary, [to] take any measure allowing the provision to patients of appropriate medicines for the eradication of the health disaster*".

In order to optimize the existing mechanism, it would be appropriate to make a few changes:

– to make the conditions for submitting a patent to the ex officio license more flexible or even in the case of an extreme health emergency to accelerate the granting of the ex officio license. Indeed, the rapidity of the authorities' response in the management of a crisis of the magnitude of the one we are experiencing is indeed essential;

– to guarantee the effective exploitation of the invention subject of the ex officio license.

By now, the difficulties in applying the mechanism of ex officio licensing in the interest of public health concern the two phases of granting this license, i.e. the procedure for submitting the industrial property title to the ex officio licensing regime on the one hand, and the procedure for applying for the ex officio license on the other. To this end, several provisions could be amended in the legislative parts of the Intellectual Property Code and the Public Health Code.

I. Relaxing the conditions for submitting a patent to an ex officio license

Purpose of the ex officio license

If we strictly follow the article L. 613-16 of the Intellectual Property Code ("IPC"), the ex officio license in the interest of public health is only intended for granted patents, thus omitting patent applications.

However, as the Covid-19 pandemic has triggered several research projects, both in terms of preventive treatments (vaccines) and curative treatments (drugs) as well as diagnostic methods, it is to be expected that several patent applications will be filed in the near future, although these can only be expected to be granted in several years.

Consequently, the omission of the reference to patent applications by article L. 613-16 of the IPC may strongly prejudice the interest of the implementation of the ex officio license mechanism in the context of the current health crisis. To remedy this, the current text should be amended so that it also mentions patent applications.

Conditions for ex officio license

For a patent to be subject to ex officio licensing, its subject matter must, among other things, be "*made available to the public in insufficient quantity or quality or at abnormally high prices, or where the patent is exploited under conditions contrary to the interests of public health* […]".

In relation to the Covid-19 pandemic, the criteria of insufficient quantity and/or abnormally high

price seem to be the most relevant. In particular, insufficient quantity is characterized when a Covid-19 health product incorporating a patented invention is not accessible to all French citizens who need it.

However, the mechanism of the compulsory license loses its interest if it can only be implemented after having effectively noted a situation of stock shortage or extreme tension in supply. However, as it stands, this reading can be supported by the letter of article L. 613-16 of the IPC, written in the present tense: the objects incorporating the patent "*are made available to the public in insufficient quantity or quality or at abnormally high prices* […]".

The solution seems to be self-evident, especially when urgency guides the reading, as should be the case with the current health crisis: the submission of the patent to the ex officio license regime seems possible, not only when the insufficient quantities are proven, but also when it is reasonably possible to affirm, notably with regard to various projections based on objective criteria (mathematical projections, situations abroad, etc.) that these quantities will indeed be insufficient on the day the license is issued and therefore that the license will indeed be legitimate from the first day of its application.

Consequently, a third alternative condition of "extreme health emergency" should be added to article L. 613-16 of the IPC so that an ex officio license can be granted before the irreparable happens, i.e., that some patients are denied treatment due to lack of available products. This is justified by the need to help public health when it is most needed, not several months later when the shortage is obvious.

II. Guarantee the effective exploitation of the licensed invention by an ex officio license

Once the decision submitting the patent to the ex officio license regime has been published, any qualified person may apply to the Minister of Economy and Finance to be granted a license to exploit the invention (art. L. 613-17, para. 1, IPC). In the event that the ex officio license concerns not only the manufacture but also the marketing of a drug for the treatment of Covid-19 (or even a vaccine), the candidate licensee will have to obtain a marketing authorization in order to benefit from the required legal qualification; he will be able to do so either by developing his own product (a), or by soliciting the patent holder (b).

a) Obtaining an authorization from the development carried out by the candidate for the ex officio license

Marketing authorizations (MA)

The applicant for a license may develop a generic of the medicine covered by the patent(s) under license and apply for a marketing authorization (hereinafter "MA") for it. However, this application for marketing authorization will be refused as long as the protection of the marketing authorization data and the market exclusivity of the originator drug are in force (art. R. 5121-28 and art. L. 5121-10-1 of the Public Health Code for national MAs; art. 14, par. 11, of Regulation (EC) n° 726/2004 for centralized MAs).

More specifically, the research currently being carried out on Covid-19 is likely to result in marketing authorizations for fixed combinations of active ingredients that can benefit from

autonomous protection of their data and their own market exclusivity, even though the active ingredients that are the subject of these combinations, taken individually, have already been authorized for several years.

However, there is no exception to these protections/exclusivities based on the granting of an ex officio license.

Temporary Use Authorizations (TUAs)

– In order to overcome this blockage, the candidate for a license could request a temporary authorization for use (ATU). This tool, regularly used by the *Agence nationale de sécurité du médicament et des produits de santé* (*ANSM*), authorizes the use of "*certain drugs* [to] *treat serious or rare diseases where there is no appropriate treatment*" (art. L. 5121-12 of the Public Health Code). This seems to respond to the Covid-19 issue since the ATU allows "*early access to new treatments when there is a real public health need*".

As such, it is possible that certain originator treatments of Covid-19 do not benefit, at least initially, from a true MA but only from a UTA. However, these UTAs might not be considered as true "*appropriate treatments*", which would then allow the granting of a UTA to the candidate licensee for the product incorporating the invention covered by the ex officio license.

However, this would require the candidate licensee to obtain a UTA before the treatments currently being tested could be marketed for the benefit of the laboratories holding the patent rights. The candidate licensee, by definition lagging behind, would not be a winner.

Thus, in order to ensure that UTAs can also be applied in cases where marketing authorizations have been obtained – in particular by patentees – but where the drugs in question are made available to the public in insufficient quantities or at abnormally high prices, article L. 5121-12 of the CSP should be amended to allow broader access to UTAs.

b) Obtaining a marketing authorization by soliciting the patent holder

In order to benefit from the required legal qualification, the candidate for a license could no longer develop his own product but directly solicit the patentee. In practice, a patent license on a drug often entails, in parallel, the transfer of a copy of the MA, called MA bis, or the provision to the licensee by the patentee of all the documents and data necessary for the licensee to file an application and obtain MA.

Furthermore, patent licenses almost always include a license of the corresponding know-how so that the license can be implemented in practice, which is part of the "technical" qualification of the licensee.

However, the provisions of article L. 613-17 of the IPC do not consider these elements. Consequently, the article should be amended to ensure that the ex officio license also entails the provision to the licensee by the patentee of all elements reasonably necessary for the commercialization of the patented invention.

Bill Proposal authorizing the granting of an ex officio patent license in the interest of public health in the event of an extreme health emergency

Sole Article

I. The Intellectual Property Code is hereby amended as follows:

1. Article L. 613-16 is amended as follows:

(a) After the reference to "L. 613-17", the end of the first paragraph shall be worded as follows: "*any patent application or any patent granted for the purpose of*" ;

(b) The penultimate paragraph is amended as follows:

- at the beginning, the words "*Patent applications or*" are added;
- after the word "*high*", the following words are inserted: "*or in the event of extreme health emergency*" are inserted;

2. The following words shall be added to the first sentence of the first paragraph of Article L. 613-17: "*which shall also entail communication of the corresponding know-how and provision by the owner of the patent of all the elements at his disposal necessary for the marketing of the invention*"

II. 1° of I of Article L. 5121-12 of the Public Health Code, as amended by resulting from Act no. 2020-1576 of December 14, 2020 on the financing of social security of December 14, 2020, is supplemented by the words: "*or existing treatments are the subject of patents or patent applications subject to the system of ex officio in the interest of public health pursuant to articles L. 613-16 to L. 613-16 of the L. 613-16 to L. 613-18 of the Intellectual Property Code and are made available to the public in insufficient quantity or quality or at abnormally high prices. abnormally high prices*".

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