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Compulsory licenses granted by public authorities: an application in the Covid-19 crisis in France? Part 2

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As many laboratories around the world are making every effort to find a treatment for Covid-19 and more clinical trials are conducted[1], it is worth considering the legal mechanisms that could facilitate the quantitatively and qualitatively sufficient, and financially acceptable, exploitation of patent rights that will prove useful in curbing the epidemic and preventing a new one.

In France, the emergency law n° 2020-290 of 23 March 2020 to deal with the covid-19 epidemic introduced a new article L.3131-15 in the public health code.

This article allows the Prime Minister, when a state of health emergency is declared, and for the sole purpose of guaranteeing public health :

- to order the **requisition of all goods and services** necessary to fight the health disaster and of any person necessary for the operation of these services or the use of these goods ;
- to take **all measures to make available to patients** appropriate **medicines for the** eradication of the health disaster;

Such measures must be *"strictly proportionate to the health risks at stake and appropriate to the circumstances of the time and place" and "shall be terminated without delay when they are no longer necessary".* Compensation for requisitions is governed by the Code of defence[2].

This text gave rise to intense discussions at the French Parliament during which the Minister of Health indicated that *"**I do not exclude the possibility of applying for compulsory licenses or price ceilings for drugs that would not** be produced in France, for example, for products with proven efficacy (...) for example, a sequestration of drugs that would otherwise leave France. **Overly complex mechanisms waste time"[3]**.*

The existing legislative framework on compulsory licenses needs to be reviewed in order to better understand why this framework is so ill-suited to the current situation

and why these emergency measures were therefore necessary.

France has had several compulsory licensing mechanisms in place since Law No. 68-1 of 2 January 1968 on patents.

We will focus on the compulsory licenses granted by public authorities, with the national territory as their object. We have dealt yesterday with compulsory license in the interest of public health (read the first part here).

Let's now have an overview on two other types of compulsory licenses under French law.

1. Compulsory license in the interest of economic development (L613-18 and R613-26 to R613-33 of the IPC)

For patents other than those referred to in Article L613-16 – i.e., in general, all those not related to public health – a compulsory licensing mechanism is also provided for in the event that such patents are not satisfactorily exploited to meet the needs of the national economy.

The conditions for the implementation of this compulsory license are as follows:

- In the first instance, the Minister responsible for industrial property shall consult the Minister for the Economy and Finance and the Minister responsible for Scientific Research and Atomic and Space Matters[4] ;
- After this consultation, it shall take a reasoned decision in which it shall urge the owner of the patent to undertake the exploitation of the patent in such a way as to satisfy the needs of the national economy, which needs must be explicitly specified[5] ;
- If, within one year of receipt of this formal notice (which could be extended for a further year in case of legitimate excuses), the exploitation is still insufficient and is "seriously prejudicial to the economic development and the public interest", the patent may be subject to the compulsory license regime by decree of the Council of State;
- This decree is issued on the basis of a joint report by at least two ministers: the minister responsible for industrial property and the minister responsible for scientific research and atomic and space matters, and possibly also the minister responsible for the subject matter of the patent[6];
- As with licensing in the interest of public health, qualified persons may then apply for a compulsory license[7] ;
- The owner of the patent and any licensees may submit their observations within two months of notification of the request[8];
- It is only at the end of these two months that the Minister in charge of industrial property may issue the order granting the license, which shall determine its duration and scope, the royalties being fixed by the Paris Court of First Instance in the absence of agreement between the parties.

Again, the license takes effect on the date of notification of the grant order to the parties.

Although somewhat less complex than the mechanism of compulsory license in the interest of public health, the mechanism of compulsory license in the interest of economic development is nonetheless extremely long, given the minimum one-year period granted to the patentee to resume satisfactory exploitation of the patent.

It therefore seems particularly ill-suited to the current crisis.

2. Compulsory license or expropriation for the needs of national defence (L613-19 and R613-34 et seq. of the IPC)

Articles L613-19 and L613-20 provide respectively for a mechanism of compulsory license and expropriation of the patent holder for national defence purposes.

These are the only mechanisms for using an invention without the authorization of the title holder that could apply not only to a granted patent but also to a patent application.

It might seem strange to pretend that a text related to national defence could apply to the current health crisis situation. However, on reading Article L. 1111-1 of the Defence Code, the contours of the notion of "national defence" seem relatively flexible:

"The defence policy aims to ensure the integrity of the territory and the protection of the population against armed aggression. ***It contributes to the fight against other threats to national security[9].*** *It ensures respect for international alliances, treaties and agreements and participates, within the framework of the European treaties in force, in the Common European Security and Defence Policy".*

It can already be noted that, with regard to compensation for requisitions, the new article L3131-15 of the Public Health code refers to the regime of compensation for requisitions for the general needs of the nation provided for in the Defence Code[10].

Could we have gone even further, taking literally the words of the French President Macron equating the current crisis to a "war" and considering that this epidemic does indeed constitute a "threat to national security" justifying the application of the system of compulsory licensing or expropriation for the needs of national defence?

That is what the State of Israel seems to have done as Israel would indeed be the first country where a compulsory licence related to Covid-19 would have been granted and this licence would have been issued under section 104 of the Patent Law allowing the State to circumvent the patent law for national defence purposes. This license authorizes the State of Israel to import from India a generic version of AbbLife Kaletra, solely for the treatment of patients with coronavirus. This would be the first compulsory license issued in the country under Article 104 since the introduction of this provision in 1967.

The advantage of using this mechanism lies in the fact that it could apply not only to granted patents, but also to patent applications and probably also to supplementary protection certificates.

Its implementation is relatively less complex than that of compulsory licensing in the interest of public health:

- The Minister in charge of national defence shall send a request for compulsory license to the Minister in charge of Industrial Property explaining "all useful details" on the conditions necessary to meet the needs of national defence, in particular the scope of the license (total or partial), its duration and the fate of any improvements[11].
- The Minister responsible for intellectual property shall issue a grant order laying down the conditions of the license in the light of that request.
- The owner of the patent then communicates its price request for the license, through registered letter[12]. The texts do not specify the deadline by which this letter must be sent.
- In the absence of an amicable agreement on this remuneration, the matter may be referred to the Paris Court of First Instance. This referral can only take place after a minimum of four months following receipt of the registered from the patent owner[13]. If the invention which is the subject of the patent application or patent, or its applications, is of a secret nature, the Paris Court of First Instance shall rule under special conditions preserving such secrecy[14] which shall also apply to the court hearing any appeal[15].

This implementation is also faster. Indeed, unlike licensing in the interest of public health :

- The granting order is much quicker since it does not require an amicable agreement to be reached, nor does it require a special commission to be set up (the amicable phase only begins *a posteriori* and on the sole subject of the amount of the license, not on its principle or on the other conditions);
- The license for national defence purposes shall take effect on the date of the request of the Minister responsible for national defence[16].

Therefore, it appears to be a much shorter mechanism than the compulsory license in the interest of public health and therefore one could have imagined that it would be implemented for the purposes of the current crisis.

Nevertheless, if the government had thought of using it at all, it would probably have given rise to a great deal of discussion and criticism since it would have been based on a broad interpretation of the concept of "national defence".

In conclusion, no existing compulsory licensing mechanism was really adapted to the current situation.

It is therefore understandable that the Government preferred to resort to the emergency measures of Law 2020-290 and in particular to the new article L3131-15 of the Public Health Code, which provides, in a much more flexible and less regulated manner, for the possibility of taking requisition measures and any measures to make available to patients appropriate medicines for the eradication of the health disaster, while recalling, in its last paragraph, that such measures must be *"strictly proportionate to the health risks at stake and appropriate to the circumstances of the*

time and place" and that *"they shall be terminated without delay when they are no longer necessary"*. It should also be noted that these emergency measures would also apply to other industrial property rights such as registered designs which are likely to protect certain medical devices, such as masks; another limitation of the current texts was the restriction on patents.

Aware of the inapplicability of the current system, the government was correct to envisage a new legal mechanism.

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[1] As of the date of this article, over 100 clinical trials have been listed on the EU Clinical Trials Register: https://www.clinicaltrialsregister.eu/ctr-search/search?query=covid-19

[2] L2234-1 et seq. of the Code of Defence

[3] Public sitting of March 19, 2020 in the Senate: http://www.senat.fr/cra/s20200319/s20200319.pdf

[4] R613-26 of the IPC

[5] R613-26 of the IPC

[6] R613-28 of the IPC

[7] R613-29 of the IPC

[8] R613-30 of the IPC

[9] With regard to the concept of "national security", the preceding paragraph of the same article provides that "The purpose of the national security strategy is to identify all threats and risks likely to affect the life of the Nation, in particular with regard to the protection of the population, the integrity of the territory and the permanence of the institutions of the Republic, and to determine the responses that the public authorities must provide".

[10] Article L3131-1, 7° of the Public Health Code; L2234-1 et seq. of the Defence Code

[11] R613-34 of the IPC

[12] R613-36 of the IPC

[13] R613-36 of the IPC

[14] set out in Articles R613-37 to R613-41 of the IPC

[15] R613-42 of the IPC

[16] L613-19 al. 3 of the IPC

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