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Compulsory licenses granted by public authorities: an application in the Covid-19 crisis in France? Part 1

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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 a study published in 2019, WIPO[2] identified 156 countries or territories which provide for the exception regarding compulsory licensing. Such exception allows for the use of a patent without the consent of the owner[3].

The study concluded that "*the mechanism has been rarely used, considering the total number of patent grants*"***[4]***, but that in some countries such as Brazil, Canada or the United-States, "*the existence of such provisions, or announcement of intention to invoke such provisions, promotes willingness on the side of the patentees to conclude licensing agreements. Thus, the potential to issue compulsory license can be part of the policy tool*".

This possibility is strictly limited by Article 31 of the 1994 TRIPS Agreement[5], to which the majority of the world's countries are signatories as members of the World Trade Organization.

Nevertheless, according to such Article 31, this strict framework may be made more flexible "*in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use*". The 2001 Declaration on the TRIPS Agreement and Public Health clarified this concept of emergency or urgency by stating, inter alia, that "*Each member has the right to determine what constitutes a national emergency or other circumstances of extreme urgency, it being understood that public health crises, including those relating to HIV/AIDS, tuberculosis, malaria and other epidemics, can represent a national emergency or other circumstances of extreme urgency*"[6].

As the Covid-19 pandemic is undoubtedly a "case of extreme urgency", some countries have begun to adopt extraordinary measures to ease the conditions governing the use of compulsory licenses[7], and the WHO Director-General has expressed support for the establishment of open access or licensing on reasonable terms for all countries regarding drugs, vaccines and diagnostics used against Covid-19[8].

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[9].

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"[10].*

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.

The Intellectual Property Code ("IPC") refers to "licence obligatoire" for compulsory licenses granted by a judicial authority i.e. a Court, under certain conditions, and exclusively in the following cases:

- If the patent in question is not exploited, or not sufficiently to meet the needs of the French market (L613-11 to L613-14 and R613-4 et seq. IPC) ;
- If the patent in question is necessary for the exploitation of a subsequent patent or plant variety right, provided that the invention or variety protected by that subsequent right constitutes, with respect to the earlier patent, "significant technical progress and is of considerable economic interest" (L613-15 and L613-5-1 and R613-4 et seq. IPC).

Disputes relating to these licenses must be heard by the Paris Court of First Instance. However, for the time being while confinement is on-going, the Court only deals with "essential litigation" i.e. in practice, certain litigation in criminal and family matters, civil matters being limited – for the most part – to urgent summary proceedings[11]. Litigation concerning intellectual property rights is therefore excluded. The implementation of these compulsory licenses would consequently only be possible, for the time being, subject to the applicant's demonstrating urgency which, in view of the time limits laid down in the IPC, would not be easy despite the situation.

The term "license d'office" is used for compulsory licenses granted by decision of the public authorities, under certain conditions, and exclusively in the following cases:

- If required in the interest of public health (L613-16 and R613-10 et seq. IPC) ;
- If a patent is necessary for the manufacture of pharmaceutical products to be exported to countries with public health problems (L613-17-1 et seq. and R613-25-1 et seq. IPC implementing the Regulation (EC) No 816/2006 in France) ;
- If failure to use the patent in question is seriously prejudicial to economic development and the public interest (L613-18 and R613-26 et seq. IPC);
- For the needs of national defence, but in this case the license is granted directly to the State (L613-19 and R613-34 et seq. ICC).

In all these cases, the license is non-exclusive.

We will focus on these compulsory licenses granted by public authorities, with the national territory as their object.

1. Compulsory license in the interest of public health (L613-16 and R613-10 et seq. IPC)

The conditions for the application of the system of compulsory licensing in the interest of public health (1.) and the mechanism to be respected for its implementation (2.) are complex and highly regulated, which may explain why this system has never been implemented in France by the public authorities[12] and why it is relatively unsuited to the current crisis, contrary to what its title suggests.

1.1. Conditions for the application of a compulsory license in the interest of public health

(a) Conditions as to the patent at stake

In order to be subject to a compulsory license in the interest of public health, the invention in question must first be covered by a "granted patent"[13].

This regime is therefore excluded for patent applications, which constitutes a first limit to the use of this mechanism in the current crisis. For example, if research led to the discovery of a new molecule to treat the virus, a patent application would be filed and the patent granted probably within several years. The compulsory license under Article L613-16 would therefore be inapplicable immediately. One may also question the application of these provisions to supplementary protection certificates, a separate title from patents, which are not specifically mentioned. This absence adds a bias.

In order to be subject to a compulsory license in the interest of public health, the invention must also relate to :

- A medicinal product, a medical device, an *in vitro* diagnostic medical device, an ancillary therapeutic product;
- Process for obtaining them, a product necessary for obtaining them or a process for manufacturing such a product ;
- An *ex vivo* diagnostic method.

This list covers almost all inventions in the medical and pharmaceutical field, although it should be noted that it does not cover *in vivo* diagnostic methods, but these are not in the current debate.

On the other hand, this list does not cover inventions outside the medical or pharmaceutical field. Thus, for example, if France were faced with a drinking water supply problem, the compulsory license could not be imposed on water collection systems or water treatment filters, but only on products for treating patients suffering from the problem. Nor would it likely apply to products that inactivate or remove viruses and bacteria from water.

(b) Conditions relating to unsatisfactory market supply

A compulsory license in the interest of public health may be implemented only if the market is unsatisfactorily supplied for, inter alia, at least one of the following reasons :

- The products, products resulting from processes, or methods, covered by the patent are made available to the public in **insufficient quantity,** or
- They are made available to the public in **insufficient quality,** or
- They are made available to the public at **abnormally high prices[14]**, […]

A product of satisfactory quality, available in sufficient quantity but at an abnormally high price could thus enter the mechanism. This is what some parliamentarians have recalled, between 2014 and 2017, during the discussions on the social security financing bills. For four years, senators have proposed adding to Article L138-19-1 of the Social Security Code, relating to the price of hepatitis C drugs, a paragraph indicating that in the absence of an amicable agreement between the CEPS[15] and the companies holding the exploitation rights on the price of these drugs, the mechanism of compulsory licenses in the interest of public health could be implemented[16]. These proposed amendments, which were systematically rejected because they merely recalled the existence of a mechanism already provided in the law, were intended solely to spark debate on the non-use of this mechanism to control the price of medicines.

A good quality product, at a reasonable price but with volumes that cannot satisfy demand, could also enter into this mechanism. This is the hypothesis addressed by the bill to combat shortages of medicines and vaccines, tabled on 16 April 2019 in the Senate[17]. This text proposes to add an article L5124-9-2 to the Public Health Code, according to which, in the event of a marketing stoppage or recurrent supply disruptions of medicines of major therapeutic interest[18], certain activities (such as manufacturing, importing, exporting and wholesale distribution) could be carried out, exceptionally and for a limited period, by public institutions, under a compulsory license in the interest of public health, the conditions of implementation of which would be specified by a specific decree.

The use of compulsory licensing *"whenever necessary to obtain supplies of generic medicines or to limit the price of innovative medicines in the interest of public health"* is also one of the recommendations of the CNCDH[19] in its opinion of 22 May 2018 on abuse in the health system[20].

1.2. The implementation of the mechanism of compulsory license in the interest of public health

The implementation of such compulsory license mechanism consists of two phases.

(a) An amicable phase

The text provides, in the first instance, for an amicable phase between the patent holder and the Minister of Industrial Property.

However, this amicable phase is not required *"in case of urgency"* (L613-16 last paragraph of the ICC)[21]. Most probably, this derogation was not seen in itself sufficient to make this text suitable for the current pandemic situation, since the health minister is now considering the grant of compulsory licenses not on the basis of this text but on the basis of the extraordinary powers granted to him by the emergency law of 23 March 2020 (see above).

(b) A phase of consultation between the various ministries and decision-making

This phase is organized as follows:

- The Minister responsible for industrial property shall, at the request of the Minister responsible for public health, refer the matter to a special committee comprising representatives of the health sector and the industrial property sector. The composition of this commission is very dense and requires various appointments, making its creation difficult[22].
- This committee shall collect the observations of the patentee and any licensees and could hear them, as well as the applicant for the license[23]. It shall deliver a reasoned opinion not later than two months after the matter has been referred to it[24].
- At the request of the Minister responsible for public health and on the basis of the opinion of the Commission, the Minister responsible for industrial property shall issue an initial order making the patent in question subject to the compulsory license system[25].
- This order is automatically entered in the National Patent Register ("NPR")[26]. It is an appeal by the State to the attention of "any qualified person", i.e. a person having the capacity to produce the invention which is the subject of the patent. This may be a private or public person (such as the National Public Health Agency, as provided for in Article L.1413-4 of the Public Health Code). This person then asks the Minister in charge of industrial property to issue a second order in which it is granted a compulsory license[27]. In the current state of operation of the INPI related to the crisis, the registration in the NPR could take several weeks.
- The Commission has a further two months from that request to deliver a second reasoned opinion, after hearing the comments of the license applicant, the patentee and any licensees[28].
- It is on the basis of this second opinion that the Minister responsible for industrial property shall issue the decree granting the license, which shall lay down certain conditions of the license, in particular its duration and scope of application, excluding royalties[29].
- Negotiation of the price of the license is left to the parties[30] but subject to the approval of the two aforementioned Ministries. In the absence of an approved agreement, the Paris Court of First Instance which will decide in an accelerated manner[31]. The Paris Court of First Instance currently (while confinement is on-going) only deals, in civil matters, with urgent summary proceedings[32]. The implementation of these provisions would therefore only be possible at present if the applicant could demonstrate urgency.

With regard to the remuneration of the patent holder, Article 31 of the TRIPS Agreement provides that *"the right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization"*. On the basis of such provision, a Senate report on drug policy[33] has stated that *"The risk in the event of recourse to a compulsory license is therefore that the national judge will order the State to pay the price charged by the laboratory, which price will, from the point of view of public finances, be added to the cost of purchasing or at least producing the drugs produced on the basis of the compulsory license"*. This needs to be qualified. The State would only be liable for this "adequate remuneration" if it took the license directly, and not if the license was taken by private companies such as generic producers. Furthermore, it is conceivable that a national judge would not impose exactly the amount of

royalties requested by the patent holder but would determine one according to the circumstances of the case such as the average rate of royalties paid in the relevant field, the nature of the invention, the expenses incurred by the patent holder for the development of the invention, the cost of obtaining and maintaining the patent and other relevant elements[34].

The deterrent effect of the mechanism of compulsory licensing in the interest of public health is primarily due to the complexity and length of the consultation and decision-making process described above. Moreover, this license takes effect only from the notification of the granting order to the parties[35] i.e. at least four months after the referral to the special commission.

This complexity and the length of the process make this mechanism unsuitable for the current crisis.

Also read the second part on dealing with two other types of compulsory licenses provided under French law can.

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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] World Intellectual Property Organization

[3] 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

[4] For EPO Member States : see also the *Report* by the *European Patent Academy* on *Compulsory Licensing in Europe, 2018*: https://www.epo.org/learning-events/materials/compulsory-licensing-in-europe.html

[5] https://www.wto.org/english/docs_e/legal_e/27-trips.pdf

[6] https://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm

[7] This is the case specifically for France, the State of Israel, Canada and Germany.

[8] https://www.who.int/dg/speeches/detail/who-director-general-s-opening-remarks-at-the-media-briefing-on-covid-19—6-april-2020 ; http://patentblog.kluweriplaw.com/2020/04/12/coronavirus-international-patent-pool-in-the-making/?doing_wp_cron=1586886685.0229070186614990234375

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

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

[11] Circular of 14 March 2020 relating to the adaptation of the criminal and civil activity of the

courts to the measures of prevention and fight against the pandemic COVID-19

[12] even after a decision of the Council of State enjoining the Minister of Health to take measures or refer the matter to the competent authorities in order to ensure the availability of certain compulsory vaccines, and even though this decision expressly referred to the possibility of a compulsory license in the interest of public health, the Ministry of Public Health did not in the end make use of this mechanism (see the debates in the Senate on this issue: https://www.senat.fr/questions/base/2017/qSEQ17070010S.html); the attempt to implement this mechanism by patient associations for the drug Levothyrox failed (Conseil d'État, Juge des référés, formation collégiale, 26 July 2018, 422237).

[13] It does not matter that this patent has already been licensed, even if it is an exclusive license

[14] The law does not give any guidelines on how to interpret this concept, which will therefore be of variable geometry depending on whether one seeks to correlate the price to the actual therapeutic contribution of the medicine, to the investments made by the rights holder, or to other criteria….

[15] Economic Committee for Health Products ("Comité économique des produits de santé" in French)

[16] Discussions on Social Security Financing Bills for 2018 (amendment 489), for 2017 (amendment 367), for 2016 (amendment 423), for 2015 (amendment 223)

[17] Article 7 of the bill to combat shortages of medicines and vaccines tabled in the Senate on 16 April 2019: http://www.senat.fr/leg/ppl18-463.html

[18] Mentioned in Article L5111-4 of the Public Health Code

[19] National Consultative Commission on Human Rights

[20] "Acting against abuse in the health system: a necessity to respect fundamental rights", recommendation n°7: https://www.cncdh.fr/fr/publications/agir-contre-les-maltraitances-dans-le-systeme-de-sante-une-necessite-pour-respecter-les

[21] Reflecting the waiver provided in Article 31(b) of the TRIPS Agreement

[22] See R613-10 et seq. of the IPC, which provide for the composition and functioning of this commission

[23] R613-22 of the IPC

[24] R613-13 to R613-16 of the IPC

[25] L613-16 and R613-17 of the IPC

[26] R613-17 of the IPC

[27] R613-18 of the IPC

[28] R613-19 of the IPC

[29] R613-20 and 21 of the IPC

[30] L613-17 of the IPC but the law is not clear as to when these royalty negotiations should take place and in particular whether they can begin before the compulsory licensing order is made.

[31] R613-24 of the IPC

[32] Circular of 14 March 2020 relating to the adaptation of the criminal and civil activity of the courts to the measures of prevention and fight against the pandemic COVID-19

[33] Information Report No. 739, filed June 29, 2016: https://www.senat.fr/rap/r15-739/r15-7391.pdf

[34] On the notion of "adequate remuneration", see the draft reference document of the Standing Committee on Patent Law, §86 et seq.

[35] L613-17, para. 2 of the IPC

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