

COMPULSORY LICENSING AND NEW PROVISIONS AFFECTING IP HOLDERS DURING THE CORONAVIRUS CRISIS IN FRANCE AND GLOBALLY

Pharmaceutical companies and screening test manufacturers are facing new major challenges due to the global health crisis relating to the coronavirus (COVID-19). To strike the right balance between the interests of rights holders, third parties and the public, exceptions and limitations to patent rights have been promulgated in France and abroad.

PATENT RIGHTS AS AN INCENTIVE FOR INVESTMENT IN INNOVATIVE ACTIVITIES AND THE PRODUCTION OF KNOWLEDGE

Patent law rewards the respective inventor with an exclusive right to his or her invention for a maximum of 20 years. Patent holders generally have the exclusive right to manufacture, use, offer for sale, sell, import, export, tranship or hold an invention. Thus, any other person who wishes to operate that invention will ordinarily need to enter into a licence agreement, or else be exposed to a legal liability.

EXCEPTION TO THE EXCLUSIVE RIGHT: COMPULSORY LICENCES

From a French legal perspective, an exception occurs when patents are subject to a compulsory license where the interests of public health require it and there is no amicable agreement between the parties.

This exception is of interest to pharmaceutical companies and medical device manufacturers during the COVID-19-crisis.

Specificities of compulsory licences

Compulsory licences differ from ordinary licences in two important respects:

- First, the person seeking to use the invention need not obtain permission from the patent holder, which is not needed for compulsory licenses in some emergency situations;
- Second, the compensation to be paid to the patent holder is an adequate remuneration commensurate with the economic value of the invention and is not determined by private contractual negotiations.

Key issues

- Exceptional times, exceptional measures:
COVID-19 clearly presents an imminent threat to public health which, in some jurisdictions, is likely to justify the grant of compulsory licences and more, such as seizures of medicines or screening tests and/or the launch of generic products before the expiry of patents/SPCs.

Scope of compulsory licences

Under Article L. 613-16 of the French intellectual property code, the French government is entitled to be granted a compulsory license for patents relating to:

- (a) **a medicinal product, a medical device, an in vitro diagnostic medical device or a related therapeutic product;**
- (b) **a process for obtaining them, a product necessary for obtaining them, or a process for manufacturing such a product;**
- (c) *an ex vivo diagnostic method.*

Patents for such diagnostic products, processes or methods may be subject to the ex officio licence regime in the interest of public health only when such products, or products resulting from such processes or methods are made available to the public "in insufficient quantity or quality" or at abnormally high prices, or when the patent is exploited under conditions contrary to the interest of public health or constitute practices declared to be anti-competitive following an administrative or judicial decision that has become final.

Where the purpose of the licence is to remedy a practice that has been declared anti-competitive or in cases of urgency, the Minister responsible for industrial property shall not be required to seek an amicable agreement.

In light of the foregoing, the application of compulsory licences is allowed for medicines but also in the field of "process for manufacturing such a product (i.e. a medical device such as [a] diagnostic test)".

Recent compulsory licence case-law in the pharmaceutical industry

Recently¹, the Administrative Supreme Court (*Conseil d'Etat*) dismissed a request in summary proceedings ("*référé liberté*"), for the continued manufacturing and marketing in France of the former "Levothyrox" medicine formula operated by Merck, considering that **the requirement of urgency is not met.**

According to the reasoning of the judge, Merck had undertaken to manufacture, import and make available the "Euthyrox" medicine in France until the end of 2018, and that it has not been established that the new imports, together with existing stocks from previous imports, would not be sufficient to avoid a shortage in the short term.

In the context of COVID-19, it would be very likely that in a similar case, the Administrative Supreme Court would consider that the condition of urgency is met.

¹ Administrative Supreme Court (*Conseil d'Etat*), Summary proceedings, Collegial formation, 26 July 2018, No. 422237

SEIZURE OF MEDICINES OR SCREENING TESTS AND REQUEST TO LAUNCH GENERIC PRODUCTS BEFORE THE EXPIRY OF PATENTS/SPCS DURING THE STATE OF HEALTH EMERGENCY

Due to the COVID-19 crisis, the French government has taken a step further than the use of compulsory licenses for inventions in areas of public health interest. Law No. 2020-290 of 23 March 2020 in response to the COVID-19 epidemic, introduced a new Article L.3131-15 in the French Public Health Code (CSP), that allows the Prime Minister to:

7° order the seizure ("requisition") of all goods and services necessary for the fight against the sanitary disaster as well as any person necessary for the operation of these services or the use of these goods. The compensation of these seizures is governed by the code of defence;

8° to take temporary measures to control the prices of certain products made necessary to prevent or correct the tensions observed in the market of certain products; the National Consumer Council is informed of the measures taken in this regard;

9° if necessary, take any measures to make available to patients appropriate medicines for the eradication of the health disaster.

As of today, the State of Health Emergency has been extended in France for a further two-month period due to COVID-19. Assuming that new epidemics appear in the future, the same provisions may apply. Consequently, pharmaceutical companies and screening test manufacturers should keep those provisions in mind.

The current context raises important issues about the balance between patent/SPC protection and public interest with that of direct access to specific medicines and COVID-19 screening tests.

DATA EXCLUSIVITY CONSIDERATIONS

Further to the above comments regarding compulsory licensing, we would point out that a data exclusivity regime could be an obstacle for the execution of a compulsory licence or government use of a patent. Hence, it may be necessary to waive the rights conferred under data exclusivity in order to allow a compulsory licensee to obtain marketing approval of the licensed product. It is therefore appropriate to check if national regulations may provide that data exclusivity shall have no effects against a compulsory licensee granted for any of the grounds established under the applicable patent law, or against persons authorised to undertake a governmental non-commercial use of the patented product.

In all cases, as in the case of patents, exceptions may be provided for data exclusivity protection, such as for cases of emergency, and public health reasons. As mentioned earlier, COVID-19 clearly presents an imminent threat to public health which is likely to justify the voluntary waiver of or exception to data exclusivity protection. For instance, Mylan has announced additional efforts to support response to the COVID-19 pandemic by voluntarily waiving its marketing exclusivity in the U.S. for Lopinavir/Ritonavir, so as to help ensure wider availability to meet the potential needs of COVID-19 patients.

COMPARISON WITH OTHER JURISDICTIONS

The delicate balance between the rights held by patent owners and compulsory licensing has been highlighted in numerous countries due to COVID-19:

Europe

- In Germany, the Bundestag passed an amendment to the Protection against Infection Act, which gives the Federal Minister of Health far-reaching powers in the fight against the corona virus. To ensure that the population has access to medicines against the corona virus, the Federal Health Minister is now authorised to oblige research institutes and pharmaceutical companies to make patented vaccines or medicines available to the general public in return for appropriate compensation. Contrary to what might be assumed at first sight, the legal regulation is not aimed at vaccines that are currently being developed and are not yet patented, but rather at known and already patented active substances that were developed in the past for other diseases and are now being tested for their effect on corona viruses. The prerequisite for this access to the exclusive right of the patent holder, which, incidentally, is based on Section 13 of the German Patent Act (PatG), is that the Bundestag has previously identified an epidemic situation of national importance. In addition, the patent court can grant a compulsory licence according to section 24 of the Patent Act if previous licence negotiations have failed and there is a particular public interest. This is provided that – as is currently the case – the protection of public health is at issue and there is a significant public interest in access to and the affordability of medicines, then a compulsory licence might also be considered. However, a court procedure is likely to take longer than an order by the Federal Minister of Health in accordance with the IfSG. The new regulation came into force on 28 March 2020.
- In Italy, the Italian government has not implemented special provisions to or the derogation of patent law (including the current regulation of compulsory licene) so far. The intervention in healthcare has been mainly focused on staff, organisation and sanitarian protocols; the supplies of drugs and medical devices have been made mainly through contracts. However, in recent weeks an interesting case appeared in the media some: to remedy a the lack of respirators (which would have been supplied late, also due to lockdown restrictions), a joint partnership between a 3D printing start-up and the Hospital of Chiari (near Brescia, Lombardy, one of the areas in northern Italy most affected by COVID-19) produced with a 3D printer a key device (the valve) for respirators, then applied it to a snorkelling mask supplied by Decathlon, the sports goods retailer: this creative solution has been shown to be effective. The original device is already patented but, due to the emergency, the Hospital did not seek to obtain the authorization from the patent holder. There is no public information regarding the original manufacturer's formal claim, but it seems that there is no legal exception that quite fits this case. The main conclusion appears to be that, if eventually the infringement will be proved, the patent holder will be entitled to an indemnification (rather than a proper compensation of monetary damages), since the infringer would have acted in a state of necessity caused by the emergency.
- In Spain, the Spanish government has not implemented emergency regulations specifically to broaden the compulsory licensing regime in its response to COVID-19. Thus, the regime contained in the Spanish Patent

Law applies, which, apart from the compulsory licensing when reasons of public interest exist, provide for another mechanism that the State can use to alleviate the effects of the health crisis caused by COVID-19: the expropriation of patents. This mechanism, more aggressive and extraordinary than compulsory licences, allows the State to take ownership of patents by means of "fair compensation" and if there is a "cause of public utility or social interest". However, Royal Decree 463/2020 of 14 March declaring in Spain the state of emergency of the health crisis situation caused by COVID-19, empowered the Spanish Minister of Health to "intervene and temporarily occupy industries, factories, workshops, holdings or premises of any kind, including privately owned health centres, services and establishments, as well as those operating in the pharmaceutical industry", and "carry out temporary requisitions of all types of goods and impose mandatory personal services" that contribute to the adequate protection of public health (Article 13). This Royal Decree has been developed, amongst others, by Order SND/276/2020 of 23 March which imposes information, supply and manufacturing obligations on manufacturers and marketing authorisation holders of medicinal products classified as essential for the management of the health crisis (these are included in its Annex I). These manufacturers and marketing authorisation holders must establish the necessary measures to guarantee the supply of such medicinal products to health services and centres, which may be required to be supplied daily.

- In the UK, the existing legislation already provides the right for the Government to use patented inventions *for* the Crown, without requiring the patentee's consent ("Crown use"). The legislation specifically identifies the Government's right to manufacture and supply drugs and medicines. In most circumstances compensation will be payable by the Government to the patentee (or its exclusive licensee) for such use. Such compensation is to be agreed by reference to the loss suffered; based on what *actual* manufacturing could have been undertaken and having regard to the lost profit. In the absence of agreement, the Court will determine the award on those same principles. The legislation also includes special enhanced provisions during a "*period of emergency*" where declared by an Order in Council of the Government. Crown use has been invoked previously by the UK's Minister of Health for a limited period, to import a drug from Italy for the UK's National Health Service because there were no supplies in the UK (*Pfizer v. Ministry of Health*).² However, its use has been rare. By contrast, in 2019, the deadlock in access and pricing negotiations between NICE and Vertex Pharmaceuticals over its *Orkambi* drug (a drug to relieve certain symptoms in children with cystic fibrosis) led to campaigners calling for the Government to invoke Crown use to resolve the issue. No such use was invoked, and at the time the (then relevant) Government Minister (Steve Brine) said that Crown use was only "*really intended to deal with emergency use*". Although the current pandemic state of COVID-19 may justify "emergency use", it is unlikely the Government will invoke Crown use unless patent rights are blocking access to essential medicines or pricing is abusive. Instead, recognising the adverse publicity fallout of such behaviours, we anticipate seeing a more conciliatory approach, at least during the pandemic, with voluntary licences offered on free or commercially

² More recently, Crown use was successfully established in *IPCom v. Vodafone* relating to the Government's emergency access to the mobile telecommunications network.

favourable terms where supply is otherwise restricted, or there is inactivity in research or exploitation.

Americas

- In the US:
 - the government has “march-in” rights under the Bayh-Dole Act to force the funded company to license its rights to a third party to bring the patented invention to market “*upon terms that are reasonable under the circumstances*”.³ This “march-in” procedure has until now never been used in the pharmaceutical industry. The government’s position in the past has been that this right may only be used where a company does not bring the product to market, not to lower prices;
 - the federal government could exercise its eminent domain rights under the US constitution, which gives it the right to force a compulsory licence in the face of a public health threat. This is the case even if the R&D was funded privately. The government’s rights, and the patent owner’s remedy against this governmental “taking,” is reflected in the US federal code 28 USC Sec. 1498.
- In Canada, Bill C-13, the COVID-19 Emergency Response Act passed into law on 25 March 2020. It specifies that if the Federal Minister of Health considers there to be a public health emergency, the Commissioner of Patents may allow the Canadian state to produce, sell and use a patented invention. Unlike existing compulsory licensing provisions, the new law allows the government to issue a licence without first negotiating with the rights holder or establishing its own ability to supply a product. Patentees must be compensated, but the law states only that they should receive “*any amount the Commissioner considers to be adequate remuneration in the circumstances*”, considering the economic value of the permit. Licences issued under the new legislation are non-transferable and will be cancelled if the state of national emergency comes to an end. The provision expires at the end of September 2020, after which no patent permit can be granted.
- In Australia, no concrete steps have been taken, but recent reports state that the opposition Labour Party has asked the government to make use of Crown use provisions as part of its response to the pandemic. Shadow industry minister Brendan O’Connor asked the government: “*To detail how Crown use of patents may be invoked, particularly for use for repurposed manufacturing businesses, to address shortages of essential goods impacted by disrupted supply chains.*”
- In Chile, Chile’s Chamber of Deputies passed a resolution calling on the country’s government to declare its support for issuing compulsory licences on patented products that can be used to help treat coronavirus sufferers. On 17 March 2020, the lower legislative assembly voted a resolution which requests the Minister of Health to instruct government departments to report on the vaccines, medicines, tests and equipment that should be considered essential for purposes of issuing patent licences. Furthermore, the document calls on the Chilean government to ask the World Health Organization to collect information on the R&D costs associated with relevant treatments.

³ 35 U.S.C. § 203(a)

- In Ecuador, a commission of the Ecuadorian National Assembly passed a resolution on 20 March 2020 asking the country's health minister to issue compulsory licences on products whose availability is important to the public health response to COVID-19. The Education, Culture, Science and Technology Commission also asks the minister to make use of article 501 of the Código Ingenios, which authorises third parties to access and use a patentee's data, including clinical test data.

Asia

- In mainland China, the Chinese government has not implemented any emergency regulations to broaden the compulsory licensing regime in response to COVID-19. There are existing compulsory licensing provisions under Chapter VI of the Patent Law, but these have not been invoked. However, BrightGene has copied Gilead's "*remdesivir*", the most promising candidate against the deadly pathogen. BrightGene, however, made clear that the generic version is still in an R&D phase, and that its final marketing requires permission from the patent holder, Gilead. In parallel, Gilead is providing the medicine for free for studies to test *remdesivir* in adult patients with mild-to-moderate or severe respiratory disease caused by the novel coronavirus.
- In Hong Kong, there are no new emergency regulations to broaden the government's power to use patented inventions in response to COVID-19. The Hong Kong Patent Order (Cap 514) already contains provisions for (i) compulsory licensing (Part 8) and (ii) government usage of patents in a period of extreme urgency (Part 9), but neither of these has been invoked.
- In Israel, the Minister of Health issued a precedential permit for the use of three Israeli patents covering the anti-retrovirus medicine "*Kaletra*" (Abbvie) in order to import quantities of a generic version of the medicine for use in the treatment of patients suffering from the COVID-19 virus. Kaletra, which is generally used for the treatment of HIV, has been found useful in the treatment of some patients suffering from the virus.

PRACTICAL CONSIDERATIONS

According to the new Article L.3131-15 in the French Public Health Code (CSP) cited above, during the State of Health Emergency it would be allowed in France (i) to seize medicines ("*requisition of all goods*") and/or (ii) to ask for the launch of generic products on French territory before the expiry of patents/SPCs ("*take any measures to make available to patients appropriate medicines*").

Importantly, it should be noted that the seizures provided in this new article could be compensated by the code of defence, but which would not be at the upper end of the scale. However, it seems that a patentee is not entitled to claim damages or to obtain compensation if an early launch of the generic medicine is requested by the French government.

Likewise, although Article L.3131-15 CSP has been introduced by Law No. 2020-290 relating only to COVID-19, the provisions are included in a broader section entitled: "State of Health Emergency" ("*Etat d'urgence sanitaire*"), that could be ordered only in the event of "*a health disaster endangering, by its nature and severity, the health of the population*" (Article L.3131-12 CSP).

Regarding the grant of compulsory licences, as it stands under French law, an important limitation should be also considered by public authorities. That is, the above French provisions to grant compulsory licences (Article L. 613-16 of the French intellectual property code) cannot impose obligations to disclose trade secrets. However, the question of sharing know-how or trade secrets for the manufacture of medicines already arises before a patented medicine is offered for sale.

For those countries that have used them, compulsory licences have made it possible to obtain significant price reductions or to obtain supplies of generic medicines; this generates savings necessary to substantially improve access to vital therapies for HIV (Brazil, Thailand, Indonesia, etc.) or more recently for certain cancers (India). Paradoxically, the US government itself used the threat of compulsory licensing in 2001 to obtain a significant reduction in the price of ciprofloxacin (in order to stockpile this anthrax antidote for a possible attack).

The COVID-19 crisis affects not only patent law. However, COVID-19 clearly presents an imminent threat to public health which, in most jurisdictions, is likely to justify the grant of compulsory licences and more.

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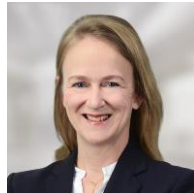
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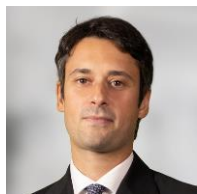
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