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Compulsory Patent Licensing in the Time of COVID-19

Views from the United States, Canada, and Europe

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The COVID-19 pandemic that has impacted the world over the past half year has raised a myriad of legal questions in all aspects of our daily lives. The eventual development of a suitable vaccine, which will likely be the subject of patent protection in the U.S. and abroad, has run into a theoretical conflict with the possibility that the supply of the vaccine might be unable to keep up with the demand.

As a backdrop to this conflict, the granting of a patent provides a patent owner with the legal right to sue other parties from making, using, selling, or importing the patented subject matter. Compulsory patent licensing is generally understood to refer to situations where another entity—upon meeting certain criteria—can nevertheless make, use, sell, or import the patented subject matter without obtaining the patent owner's permission. Examples of conditions that may warrant an award of a compulsory license include national emergency or extreme urgency where the invention serves vital public health needs, or where a patent owner has abused its economic power in violation of antitrust laws. In the case of COVID-19 vaccines, there has been speculation about a potential role for compulsory patent licensing if a vaccine is invented and patented but supply cannot keep up with demand. While there are potentially many factors (e.g., supply chain disruption) that could cause a vaccine supply shortfall, any patent rights perceived to contribute to that shortfall would likely give rise to interest in compulsory licensing.

This article reviews the current state of compulsory patent licensing in three key patent jurisdictions: the United States, Canada, and Europe, three jurisdictions that are significantly involved in the development of COVID-19 vaccines.

United States

Unlike the patent statutes of many other nations, U.S. patent law does not include a general compulsory licensing provision. However, other domestic laws include provisions that allow for compulsory licensing of patented inventions. For example, the Atomic Energy Act,[1] Clean Air Act,[2] and Plant Variety Protection Act[3] provide for compulsory licensing. However, these provisions rarely have been used.

Additionally, the Bayh-Dole Act[4] offers the federal government a narrower set of rights, termed "march-in rights," in respect of federally funded inventions. March-in rights come with several restrictions, including that the government may only use such rights if the patented invention was developed using federal funding. To date, no administration has made use of the march-in rights afforded to it by the Bayh-Dole Act.

Compulsory licenses also exist in a nonlegislative context. Under U.S. antitrust law, compulsory licenses occasionally have been awarded as a remedy for antitrust violations. In the patent litigation context, a court may decline to award an injunction in favor of a prevailing patent owner during infringement litigation, an outcome that is somewhat akin to the grant of a compulsory license.

Internationally, the U.S., like Canada and the countries of Europe, is a signatory to the Paris Convention for the Protection of Industrial Property (Paris Convention). The Paris Convention provides that its member states have the right to take legislative measures providing for the grant of compulsory licenses to prevent the abuses which might result from the exercise of the exclusive rights conferred by the patent, for example, failure to work. In addition, the U.S. is a signatory to the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement). Article 31 of the TRIPS Agreement restricts the issuance of compulsory licenses by requiring that the applicant must have made efforts to obtain authorization from the patent owner on reasonable commercial terms and conditions; the scope and duration of the compulsory license is limited, nonexclusive, and revocable; and the patent owner is adequately compensated. Against the backdrop of these international agreements, and as mentioned above, the U.S. federal patent law does not provide for a general compulsory licensing scheme.

In a non-country-specific manner, several relevant initiatives have been launched to fight the COVID-19 pandemic. For example, the "Open COVID Pledge" states: "It is a practical and moral imperative that every tool we have at our disposal be applied to develop and deploy technologies on a massive scale without impediment. We therefore pledge to make our intellectual property available free of charge for use in ending the COVID-19 pandemic and minimizing the impact of the disease."[5] To make the pledge, individuals, companies, and other organizations that hold intellectual property rights must publicly commit to making their intellectual property assets freely available to fight the pandemic, and implement the pledge via a license falling within certain open license specifications.[6] An open license provides royalty-free use.

Finally, with an added focus on global cooperation in the race for a COVID-19 vaccine, efforts to enforce patents during the current pandemic have given rise to negative public reaction, which has significantly impacted enforcement actions. For example, Labrador Diagnostics brought suit against BioFire Diagnostics and its parent company bioMérieux S.A., alleging that two patents acquired by Labrador were infringed by bioMérieux's launch of certain COVID-19 tests.[7] Due to the public outcry against the lawsuit, eight days after filing the lawsuit, Labrador announced the grant of royalty-free licenses to third parties to use its patented technologies for COVID-19 tests. As such, and in this instance, it was the negative public outcry that effectively resulted in a compulsory patent license.

Canada

Canada has adopted a more direct federal response to the COVID-19 pandemic as it relates to compulsory patent licensing. In March 2020, the Canadian government passed the COVID-19 Emergency Response Act (Bill C-13), which introduced provisions to the Canadian Patent Act that expand the government's ability to procure patented inventions—including medicines and medical devices—in response to the COVID-19 crisis. While Canada's Patent Act already contemplated limited compulsory licensing,[8] the new provisions allow a time-limited compulsory license of patent rights even where the patentee is able to satisfy demand for its patented invention.[9] However, the authors suggest it is unlikely that the new provisions will be invoked unless a patentee fails to meet Canadian demand for its invention or the patentee's terms are unreasonable given the Canadian government's experience negotiating with patentees regarding compulsory licensing as articulated below.

The recently passed provisions enable the minister of health to apply to the commissioner of patents to allow the Canadian government, or any person specified in an application, to make, construct, use, and sell a patented invention to the extent necessary to respond to the public health emergency described in the application.[10] The application must include a confirmation from the chief public health officer that there is a public health emergency that is a matter of national concern.[11] If the commissioner authorizes the action outlined in the application, the authorization ceases when the minister of health notifies the commissioner that the authorization is no longer necessary, but not later than one year after any such authorization is granted.[12] If authorization is granted, the Canadian government and any authorized person must pay the patentee "adequate remuneration in the circumstances, taking into account the economic value of the authorization and the extent to which they make, construct, use, and sell the patented invention."[13]

As of the time this article was written, the Canadian government has not exercised the new COVID-19 provisions of the Patent Act, but it may do so if a COVID-19 vaccine receives regulatory approval but is not able to be distributed effectively by the patent owner or those authorized by the patent owner to distribute the vaccine.

Prior to Bill C-13, the Canadian Patent Act already contained a compulsory licensing section.[14] Under that section, the Canadian government, or the government of a province, may apply to the commissioner for authorization to use a patented invention.[15] The applicant must make efforts to obtain authority from the patentee to use the patented invention on reasonable commercial terms and conditions.[16] However, such negotiation is not required where there is a case of national emergency or extreme urgency.[17] It is unclear, and unlikely for that matter, whether there is any tangible difference between a "national emergency or extreme urgency" and a "public health emergency that is a matter of national concern" as required under the new COVID-19 provisions. However, the existing section differs from the COVID-19 provisions in that the patentee can appeal the commissioner's decision to the Federal Court of Canada;[18] under the COVID-19 provisions, the patentee's only recourse is an application for an order enjoining actions contrary to an authorization.[19]

There is precedent for the Canadian government seeking a compulsory license from a pharmaceutical patentee. In 2001, following anthrax terrorist attacks in the U.S., the Canadian government ordered ciprofloxacin, an antibiotic for treating anthrax, from generic manufacturer Apotex. At that time, the only manufacturer with a notice of compliance for ciprofloxacin was the patentee, Bayer. The government claimed that Bayer had an insufficient supply of the patented medicine. Bayer threatened legal action and noted that the Canadian government had not complied with the Patent Act requirement to apply to the commissioner for authorization. Eventually, Bayer agreed to supply the government with ciprofloxacin should the need arise.[20]

This episode provides several lessons for patentees. First, the Canadian government is willing to seek compulsory licenses during national emergencies. Second, patentees should ensure that the requirements of the Patent Act are in fact followed. With respect to the COVID-19 provisions, the government is still required to notify the patentee and apply to the commissioner for authorization. Third, it may be prudent for patentees to approach the Canadian government and negotiate an agreement, if possible. Just as Bayer did in the ciprofloxacin example, if the manufacturer of a viable COVID-19 vaccine can meet Canadian demand on reasonable terms and in a timely manner, then it may want to consider negotiating a supply agreement with the government.

The new COVID-19 provisions build on the extant sections of the Patent Act that allow the Canadian government to obtain a compulsory license to a patented invention. Historical precedent has shown that the government is willing to exercise these provisions. Patentees can ensure that the Canadian government follows the procedures under the Patent Act and may consider preemptively negotiating an agreement for any invention that is likely to be in high demand due to the COVID-19 crisis. Furthermore, if the patentee might not be able to meet Canadian demand, firms with the capacity to manufacture the patented invention should be on standby in the event that the government requires assistance.

Europe

Compulsory patent licensing in Europe is governed by international agreements, European Union law, and national law. In general, the previously mentioned Paris Convention recognizes each country's own competence to set the conditions for compulsory patent licenses. However, there are certain mutual regulations for European countries that lead to many similarities in how individual countries deal with compulsory licensing issues.

The first international ruling on compulsory licenses with direct impact on European countries is the TRIPS Agreement.[21] The TRIPS Agreement allows compulsory licensing as part of the agreement's overall intention to balance necessary access to existing products and technology against promoting investment into research and development of new products and technologies. To receive a license under Article 31 of the TRIPS Agreement,[22] normally, the individual or company seeking a license must have first shown significant attempts to obtain a voluntary contractual license from the patent owner on reasonable commercial terms and conditions. If a compulsory license is ultimately issued, the licensee needs to pay adequate remuneration to the patent holder. In the case of a national emergency or other circumstances of extreme urgency or in cases of public noncommercial use or anticompetitive practices, there is no need to try to attempt to obtain a voluntary license in advance. Importantly, Article 31 is required to work together with a country's national law, and an important precondition of Article 31 is that the law of the member state allows compulsory licenses in general. Therefore, the additional conditions need to be taken from a country's national law.

In addition to the TRIPS Agreement, a 1998 European Union Biotech Directive (98/44/EC)[23] regarding plant variety

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with the applicant's standards. Thus, the TTAB concluded that the applicant owned the SOCK IT UP trademark when it was filed.

On the issue of likelihood of confusion, the TTAB determined that the similarity of the goods and channels of trade, buyer's care and sophistication, and commercial success of the opposer's mark weighed in favor of the opposer and a finding of a likelihood of confusion. However, the TTAB further concluded that the applicant's SOCK IT UP mark was inherently distinctive when taken as a whole. Moreover, when considering the meaning of the marks, the applicant argued that SOCK IT UP was a play on the term "suck it up," while the opposer argued that SOCK IT TO ME was an expression meaning to "give it to me." The TTAB found that a multitude of meanings could be ascribed to the two marks, and that the relevant public would not perceive their connotation and commercial impression as similar. Based on this finding, the dissimilarity of the marks outweighed the other factors, and the TTAB dismissed the opposition.

Unlawful Use

In re Stanley Brothers Social Enterprises, LLC, Serial No. 86568478, 2020 U.S.P.Q.2d 10658 (T.T.A.B. June 16, 2020). Stanley Brothers filed a trademark application for registration of the mark CW in connection with "hemp oil extracts sold as an integral component of dietary and nutritional supplements." These goods contained cannabidiol (CBD), an extract of the cannabis plant. The examining attorney refused registration under sections 1 and 45 of the Trademark Act based on Stanley Brothers' unlawful use of CBD under (1) the Food, Drug, and Cosmetic Act (FDCA) and (2) the Controlled Substances Act (CSA).

The TTAB noted that registration will not generally be refused based on unlawful use unless a violation of federal law is indicated by the record or other evidence, or when the applicant's activities relevant to the application involve a per se violation of federal law. The TTAB found that the applied-for goods were a "food" where Stanley Brothers identified the goods as an integral component of its dietary and nutritional supplements. Moreover, the TTAB indicated that the CBD in the goods qualified as a "drug or biological product for which substantial clinical investigations have been instituted and for which the existence of such investigations has been made public." Additionally, there was no evidence that CBD was marketed in food before the clinical investigations of CBD were instituted. Accordingly, the goods were unlawful under the FDCA, and the TTAB affirmed the refusal. The TTAB did not reach the refusal based on unlawful use under the CSA.

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rights provides a certain degree of clarity with which inventions are patentable or not in the field of biotechnology on ethical grounds. Specifically, Article 12 provides that, where a plant breeder cannot acquire or exploit a plant variety right without infringing a prior patent, it may apply for a compulsory license for nonexclusive use of the invention protected by the patent. Consistent with Article 31 of the TRIPS Agreement, these licenses require a preceding unsuccessful attempt to obtain a contractual license, and the plant variety or invention needs to constitute significant technical progress of considerable economic interest compared with the invention claimed in the patent or the protected plant variety.[24]

Many European Union countries have implemented guidelines concerning compulsory licenses from the Biotech Directive into their intellectual property statutes,[25] although possible requirements for the grant of such licenses may differ between the countries. Even though European Union directives are generally not directly applicable in a member state, the European Court of Justice has ruled that individual provisions of a directive can, in some cases, have direct effects in a member state without the need for implementation by that member state, under the following conditions: (1) the directive has not been transposed into that member state's national law or has not been properly implemented; (2) the provisions of the directive are mandatory and sufficiently clear and precise; and (3) the provisions of the directive confer rights on individuals. Accordingly, in situations where certain member states of the European Union have not implemented a particular directive, there are good chances it is, at least in part, still valid in such state.

Additionally, there is the Compulsory License Regulation (816/2006)[26] that establishes a procedure for the grant of compulsory licenses in relation to patents and supplementary protection certificates concerning the manufacture and sale of pharmaceutical products, when such products are intended for export to eligible importing countries in need of such products in order to address public health problems. The license under this regulation is subject to a reasonable compensation, which in situations of national emergency or in other circumstances of extreme urgency is limited to a maximum of 4 percent of the total price to be paid by or for the importing country. This regulation is directly applicable in the European Union member states, so there is no need to implement it into national law like the aforementioned directive.

Finally, there is the national law in all member states of the European Union and in the non-European Union states throughout Europe. In general, compulsory licensing under Europe's myriad of national laws constitutes a rare exception, and is subject to strict procedures that have to be followed, with appropriate remuneration for the owner of the licensed patent rights. Data from the European Patent Office is consistent with the view that compulsory licensing is a rare event in European jurisdictions.[27]

In view of COVID-19, several countries have taken additional measures. Detailing all countries is outside the scope of this article, but Germany and the U.K. will serve as examples.

Germany—where section 13 of the German Patent Act[28] generally allows limitation of patents—has introduced the Act on the Protection of the Population in Case of an Epidemic Situation of National Significance of March 27, 2020.[29] This act amends the German Infection Protection Act by directly empowering the German Federal Ministry of Health, in the context of the epidemic situation of national importance, "without prejudice to the powers of the Federal States, . . . to order, in accordance with § 13(1) of the Patent Act, that an invention in respect of one of the products referred to in point 4 before the list be used in the interest of public welfare or in the interests of federal security."[30] Thus, the Ministry of Health can directly decide that a patent may be used by third parties. Again, the patent owner will receive an appropriate compensation.

In the U.K., so-called "Crown use" (section 55(1) of the Patents Act)[31] provides that any government department and any person authorized in writing by a government department may, for services of the Crown, conduct acts, without the consent of the patent owner or also exclusive licensee, which would otherwise be considered as patent infringement. In a period of emergency, like the COVID-19 pandemic, the powers granted under section 55 are extended by section 59 to include the power to use the invention for any purpose that appears to be necessary or expedient for a variety of reasons aimed at the protection of life.

Conclusion

While the COVID-19 pandemic has raised significant issues and discussion points related to compulsory patent licensing, the foregoing review of the state of the law in the United States, Canada, and Europe leads to a reasonable conclusion that compulsory patent licensing is a rare event, even in today's uncharted times in the midst of a global pandemic. While all three jurisdictions provide for some form of compulsory patent licensing, it is a legal remedy that is seldom employed. The court of popular opinion, and avoiding a negative public outcry, may be the best remedy for ensuring compulsory licensing in the event that a vaccine is developed but at supply levels insufficient to meet the demand. ■

Endnotes

1. 42 U.S.C. § 2183.
2. *Id.* § 7608.
3. 7 U.S.C. § 2404.
4. 35 U.S.C. § 203(a).
5. OPEN COVID PLEDGE, https://opencovidpledge.org (last visited Oct. 28, 2020).
6. *Id.*
7. Labrador Diagnostics LLC v. BioFire Diagnostics, LLC, No. 20-348 (CFC) (D. Del. filed Mar. 9, 2020).
8. Patent Act, R.S.C. 1985, c. P-4, ss. 19–19.1 (Can.).
9. *Id.* s. 19.4.
10. *Id.* s. 19.4(2).
11. *Id.*
12. *Id.* s. 19.4(3).
13. *Id.* s. 19.4(5).
14. *Id.* ss. 19–19.1.
15. *Id.* s. 19(1).
16. *Id.* s. 19.1(1).
17. *Id.* s. 19.1(2).
18. *Id.* s. 19.2.
19. *Id.* s. 19.4(8).
20. David Spurgeon, *Canadian Government Almost Swamped by Ciprofloxacin*, 323 BRITISH MED. J. 1026 (2001).
21. Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299, 33 I.L.M. 1197 [hereinafter TRIPS Agreement].
22. *Id.* art. 31.
23. Council Directive 98/44/EC, 1998 O.J. (L 213) 13.
24. *Id.* art. 12(3).
25. *See* World Intellectual Prop. Org. [WIPO], *Draft Reference Document on the Exception Regarding Compulsory Licensing*, WIPO Doc. SCP/30/3 (May 21, 2019), https://www.wipo.int/edocs/mdocs/scp/en/scp_30/scp_30_3-main1.pdf.
26. Commission Regulation 816/2006, 2006 O.J. (L 157) 1.
27. EUROPEAN PATENT ACAD., COMPULSORY LICENSING IN EUROPE (2018), http://documents.epo.org/projects/babylon/eponot.nsf/0/8509F913B768D063C1258382004FC677/$File/compulsory_licensing_in_europe_en.pdf.
28. Patentgesetz [PatG] [Patent Act], Dec. 16, 1980, BGBL I at 1, last amended by Gesetz [G], Oct. 8, 2017, BGBL. I at 3546, art. 4 (Ger.), https://www.gesetze-im-internet.de/englisch_patg/englisch_patg.html.
29. Gesetz zum Schutz der Bevölkerung bei einer epidemischen Lage von nationaler Tragweite [Act on the Protection of the Population in Case of an Epidemic Situation of National Significance], Mar. 27, 2020, BGBL I at 587 (Ger.), http://www.bgbl.de/xaver/bgbl/start.xav?startbk=Bundesanzeiger_BGBl&jumpTo=bgbl120s0587.pdf.
30. *Id.* art. 1.
31. INTELLECTUAL PROP. OFFICE, MANUAL OF PATENT PRACTICE (2020) (UK), https://www.gov.uk/guidance/manual-of-patent-practice-mopp/section-55-use-of-patented-inventions-for-services-of-the-crown.