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Quick Reference Guide: Compulsory Patent Licensing During COVID-19 Crisis

The COVID-19 pandemic and the economic impact of lock down or shelter in place orders create new risks every day. One risk to pharmaceutical, life sciences, and other health care technology companies as research on COVID-19 treatments and vaccines progress is the risk that the patents related to those treatments and vaccines may be suspended or involuntarily licensed to governments and even competitors. Assessing these risks, the impact that compulsory licensing may have on investments in research and new product development, and the potential for compulsory licenses in key jurisdictions being granted to resulting intellectual property rights is essential to any business strategy for companies developing technology related to COVID-19.

To assist you in considering these issues, we have prepared a brief summary of the laws and regulations directed to patent suspension and compulsory licensing in key jurisdictions around the globe. The information below is intended to provide an overview of the issues that may arise as governments continue to search for ways to address COVID-19.

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UNITED STATES

"March-in" Rights (Bayh-Dole Act)

The Bayh-Dole Act creates two instances in which patent holders may lose rights to the U.S. government.

First, the act authorizes the government to practice, for governmental uses, patents developed using federal funds. This right may be exercised at any time by the government, meaning that if there are governmental labs that could produce whatever drug or device the patent covers, production could begin immediately. In addition, this is a fully paid-up right and, as a result, does not require the government to compensate the patent holder for exercising such rights.

Second, and potentially more important to consider with respect to the risks related to COVID-19, the U.S. government has the right to "march-in" and either license or demand licensing of the patents to third parties under certain conditions. The authority to "march-in" rests with the government agency that provided the funding, e.g., NIH or NSF. If the agency decides it may "march-in," it notifies the patentee in writing that it may exercise its authority, which begins a quasi-litigation process that lasts at least 180 days (likely more) and results in a written agency decision. That decision may, in turn, be appealed to federal court, potentially resulting in years of litigation. Given the length of these procedures, the fact that they are limited to federally funded patented inventions, and the fact that no government agency has ever exercised "march-in" rights, it seems unlikely that the Bayh-Dole Act will be invoked in response to the COVID-19 pandemic.

Government Use and Section 1498 Protections (28 U.S.C. § 1498)

Originally enacted in 1918 to shield wartime contractors from severe patent infringement liability, § 1498 applies to use or manufacture "by or for the United States," including "by a contractor, a subcontractor, or any person, firm, or corporation for the Government and with the authorization or consent of the Government." When invoked, § 1498 vests the Court of Federal Claims with exclusive jurisdiction, and the United States appears as the accused infringer, with all the normal defenses available. Section 1498 also limits available remedies by forbidding injunctions and limiting damages to "reasonable and entire compensation." Historically, government agencies have used § 1498 to reduce prices; for example, during an anthrax scare of 2001, HHS used the threat of § 1498 to reduce the price of generic Cipro to below $1 a tablet (compare $4.67 a tablet wholesale). While not strictly a compulsory licensing scheme, § 1498 could significantly limit potential infringement exposure for use of patented COVID-19 treatment technology during the pandemic, at least for government or government-authorized manufacture and/or use.

Pending Emergency Legislation

While some countries have enacted emergency legislative measures that provide compulsory patent licensing in response to the COVID-19 pandemic, the United States has not. The legislative response, if there will be one, is in its early stages. Most recently, Sen. Sasse (R-Neb.) proposed measures to enable free access to patented COVID-19 treatment technology for the duration of the national emergency, in exchange for a 10-year extension of patent term, as part of the Facilitating Innovation to Fight Coronavirus Act.

CANADA

The COVID-19 Emergency Response Act

Section 19 of Canada's Patent Act allows the Canadian government and provincial governments to apply to the Commissioner of Patents for the Commissioner's discretionary authorization for government use of patented inventions, but it has only rarely been invoked. On March 25, 2020, in response to the COVID-19 pandemic, the Canadian government enacted the COVID-19 Emergency Response Act. The Act amended Section 19 to require the Commissioner of Patents to authorize use of patented technology upon a determination that a public health emergency of national concern exists, as confirmed by the Chief Public Health Officer. The Act expands authorization beyond the government and its agents to any third party specified in the application. Moreover, applicants need not attempt to license the patented technology from the patentee prior to requesting authorization. The Commissioner's authorization authority expires on September 30, 2020. Patentees may be entitled to adequate "remuneration in the circumstances," as determined by the Commissioner.

UNITED KINGDOM

"Crown Use" Provisions

The UK Patents Act 1977 allows the UK government to be able to carry out acts that, absent the consent of the holder, would otherwise infringe certain rights of their patent. Sections 55 to 59 provide that such measures may be taken at any time to the extent that they are required for "services of the Crown," and may be authorized retrospectively. If invoked, an effective license is prescribed between the patent holder and the government, and rights to make use of the patent (by way of example, to design and assemble a ventilator) can be offered to third parties. Such measures are very rarely used by the government, although recently, in a case in the E&W High Court (*IPCom v Vodafone* 2020 EWHC 132), Vodafone was able to successfully rely on the written authorization of the government to access emergency telecommunications standards belonging to IPCom as constituting Crown use, and so avoided liability for patent infringement.

These powers could be relevant in the current pandemic, particularly as section 56 of the Patents Act provides that one of the relevant circumstances for Crown use is "the production or supply of specified drugs and medicines." Further, broader emergency powers found in section 59 of the Act allow Crown use to be exercised for any purpose where the government deems it necessary or expedient, including for "the maintenance of supplies and services essential to the life of the community" and "securing a sufficiency of supplies and services essential to the well-being of the community." In any such case, provision is made for the rights holder to be appropriately compensated (often by negotiation).

Compulsory Licensing Framework Under TRIPS

Like many other European countries, the United Kingdom is also party to the Agreement on Trade-Related Aspects of Intellectual Property Rights ("TRIPS"), allowing the government to grant compulsory licenses and, unlike Crown use provisions, waive the need for a party to obtain authorization from a rights holder on reasonable commercial terms and conditions. However, such measures are required only if patent holders are noncooperative. At this stage, the UK government has not made any policy announcements regarding possible compulsory licensing of patents in response to the current pandemic. If invoked, the terms of a compulsory license will be decided on a case-by-case basis and will depend on the particular facts of the case, but it is likely that a license will be limited in time and scope. Patentees will always be entitled to reasonable compensation.

AUSTRALIA

"Crown Use"

Sections 160A to 170 of the Australian *Patents Act 1990* provide a regime for use of patented technology for the services of the "Crown," namely Commonwealth, State, or Territory government, in the absence of authorization from the patentee. The regime was amended in February 2020 to make clear that Crown Use rights can be invoked for the provision of any service for which a Commonwealth, State, or Territory government has primary responsibility for providing or funding. Such services may extend to those provided by a private (nongovernment) entity. Further, although the February amendments introduced obligations on the Crown to seek to negotiate with a patentee for authorization to exploit the invention on reasonable terms (including as to remuneration) and to give notice prior to commencing any Crown Use, these obligations do not apply where exploitation is required because of an "emergency." Although the term "emergency" is not expressly defined in the legislation, the Explanatory Memorandum to the amending Act provides a number of examples, including a pandemic. The regime provides a right of "appeal" for a patentee by way of an application to the court for a declaration that Crown Use is not necessary for the proper provision of the relevant service (and, accordingly, for an order that the unauthorized use cease).

Australia has not yet invoked the Crown Use regime in response to the COVID-19 pandemic. However, in a speech to Parliament on March 23, 2020, Brendan O'Connor, Shadow Commonwealth Minister for Employment, Industry, Science and Small Business, called for the Commonwealth government to indicate whether it is considering using its Crown Use rights "particularly for urgent manufacturing of supplies, such as facial masks or goods in short supply due to disrupted supply chains." The Commonwealth government has not yet publicly responded.

Compulsory Licensing

The compulsory licensing regime contained in sections 133 to 136A of the *Patents Act 1990* (also recently amended) provides a further avenue by which patented inventions may be used without the patentee's consent. The court may order a compulsory license be granted where: (i) demand for the technology is not being met on reasonable terms; (ii) authorization to exploit the invention is essential to meet that demand; (iii) the applicant has attempted for a reasonable period to obtain a license on reasonable terms from the patentee without success; (iv) the patentee has given no satisfactory reason for failing to exploit the patent to the extent necessary to meet demand; and (v) the grant of a license is in the public interest. In addition, sections 136D to 136M of the *Patents Act 1990* specifically provide that a court may grant a compulsory license to exploit a patented pharmaceutical invention to the extent necessary to manufacture and export the pharmaceutical product, if the proposed use of the product is to address a public health issue in an eligible importing country, including in circumstances of national emergency. In each case, the patentee is compensated as agreed or determined by the court.

GERMANY

German Patent Act

The German Patent Act has always included two pathways to access patented technology without the consent of the patentee. First, the federal government may suspend the effect of a patent for the public good. This has been invoked only once, in immediate WWII postwar history. Second, any person may seek a compulsory license, if this is in the public interest. Following failed out-of-court negotiations, such license has to be applied for with the German Federal Patent Court and is subject to judicial review through the German Federal Supreme Court. Only four cases in the pharma space have been handled—two defeated, one granted (in an originator–originator dispute over an HIV treatment), and one settled. Under each scenario, the patentee is entitled to a compensation, in the first case from the federal government, in the second case from the beneficiary of the compulsory license.

Prevention and Control of Infectious Diseases in Humans Act

In addition to the preexisting provisions of the German Patent Act, the German Parliament recently enacted an act in the context of the pandemic, which delegates far-reaching executive powers to the federal and other governments. Now, the Federal Ministry of Health (and not just the German Federal Patent Court) may grant third parties the right to use a patent. Again, the patentee is entitled to compensation from the government.

FRANCE

Compulsory Licensing under the French IP Code

Similar to the German legislation, the French IP Code provides for the possibility to seek a compulsory license, if a product is not available in sufficient quantities or at excessive prices. The compulsory license may be granted by the French ministry.

CHINA

Compulsory Licensing Provisions

Articles 48–50 of China's patent laws allow for compulsory licensing and accord with the WTO's TRIPS Agreement. Articles 49–50 are most relevant to the COVID-19 pandemic. Article 49 allows the patent administration department to grant compulsory licenses "[w]here a national emergency or any extraordinary state of affairs occurs, or public interests so require." And Article 50 allows for compulsory licensing for drug manufacturing "[f]or the benefit of public health." No compulsory licenses have ever been enacted under Articles 48–50; however, the measures to implement compulsory patent licensing are set forth by Order No. 64 of the State Intellectual Property Office.

Patent Collisions

The Wuhan Institute of Virology seemingly filed its own patent applications to secure access to important methods of treatment of COVID-19, or at least strengthen negotiation leverage with the owner of a dominant patent portfolio. On January 21, 2020, several doctors from the Institute filed a patent application for the use of an antiviral drug, remdesivir, to treat COVID-19. Gilead Sciences holds the patent on remdesivir, however. Thus, while Gilead may hold the patent on the drug, the Institute could potentially block Gilead's ability to market the drug for treating COVID-19. These competing patents could set up cross-licensing opportunities. Whether and how these competing patents affect the availability of remdesivir for treating COVID-19 remains to be seen.

JAPAN

Compulsory Licensing and Government Use Provisions

Article 93 of the Japanese Patent Act provides that a party wishing to use a patentee's invention that "is particularly necessary for the public interest" may ask the Minister of Economy, Trade, and Industry for a compulsory license in the event that an agreement regarding the license is not reached between the patentee and the requesting party after consultation or that such consultation is not possible.

Japanese "Bayh-Dole" Act

In 1999, the Japanese government enacted its own version of the Bayh-Dole Act, which allowed universities and other private entities to obtain patent rights for inventions developed using government research funds. Among other things, inventors who receive government funding must agree to grant the government a royalty-free license to the right to use their patented technology when such use is in the public interest. They must also agree to grant licenses to third parties at the government's request in situations when the patented technology has not been used within a reasonable time.

KOREA

Compulsory Licensing and Government Use Provisions

Article 107 of the Korean Patent Act relates to compulsory licenses. Under Article 107, if a patented invention falls under any of the following subparagraphs of paragraph (1), a party seeking to practice patented technology may ask the Commissioner of the Korean Intellectual Property Office to adjudicate for the establishment of a nonexclusive license, provided that the party previously requested such a license from the patentee and was refused:

- If the patented invention has not been practiced in the Republic of Korea for at least three consecutive years, except in cases of a natural disaster, *force majeure* event, or other justifiable event;
- If the patented invention has not been practiced for business purposes in the Republic of Korea on a substantial scale for at least three consecutive years without any just grounds, or fails to meet the demand in the Republic of Korea to an appropriate extent under reasonable terms and conditions;
- If it is particularly necessary to practice the patented invention for the public interests;
- If it is necessary to practice the patented invention to rectify unfair trade practices found through judicial or administrative proceedings; or
- If it is necessary to practice the patented invention to export medicines to a country that intends to import the medicines (including active ingredients necessary for manufacturing the medicines and diagnostic kits necessary for using such medicines) to treat diseases that threaten the health of the majority of its citizens.

However, Article 107 does not require a prior request to the patentee for a license when using the patented invention non-commercially is in the public interest.

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