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Governmental Use of Patented Inventions during a Pandemic: A Global Survey

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Around the globe, pharmaceutical and medical device companies are helping in the fight of the COVID-19 pandemic. Many of these companies may have patents pertaining to technology that could be used for the benefit of the broader public during this time of crisis, such as patents on ventilators, diagnostic tests, pharmaceuticals or personal protective equipment. Governments around the globe have mechanisms in place that can mandate the use of patented inventions during a national emergency. In the event of such an occurrence, companies need to be aware of their rights and the variations that jurisdictions are taking to balance the use of patents for emergency relief and the public good.

Norton Rose Fulbright is at the forefront of helping pharmaceutical and medical device companies navigate the various patent regimes around the globe. Our team of experts has put together a quick-reference guide illustrating how various key jurisdictions may approach the use of patented inventions during an international or national crisis. The reference guide provides a high-level overview of the governmental authorization provisions in Canada, the United States, France, Germany, the Netherlands, the United Kingdom, Hong Kong, China, Singapore and Australia.

Of the jurisdictions included in this article, to date, Canada, France and Germany have made legislative changes, stemming from the COVID-19 pandemic, which could have an effect on the use of patented inventions. However, all of the discussed countries have existing regimes that allow for the use of patented inventions in times of an emergency such as the COVID-19 pandemic. Based on publicly available information, none of the discussed countries have yet to engage the emergency relief provisions in the face of the current pandemic. The willingness of pharmaceutical and medical device companies worldwide to work together to find solutions to COVID-19 may be why none of jurisdictions have needed to exercise their powers under these emergency relief provisions.

Any specific inquiries regarding local or global implications of emergency relief provisions impacting patent rights and their use can be directed to the key contacts.

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North America

Country		Description of Emergency Patent Regime	Compensation to the Patentee	Governmental authorizations of patents in response to COVID-19
Canada	**Existing Regime**	Sections 19–19.3 of the Canadian *Patent Act* allow the government to authorize use of a patented invention. Under these provisions, the government is first required to negotiate use with the patentee, except in cases of "national emergency or extreme urgency".	The patentee will be compensated by the authorized user with "such amount as the [Patent] Commissioner considers to be adequate remuneration in the circumstances, taking into account the economic value of the authorization."	• **Patented inventions**: To date, based on public information, the Canadian government has taken no COVID-19 official actions relating to patented inventions. • **Funds for research**: The Canadian government has pledged $275 million to coronavirus research and medical countermeasures. This funding will go to research projects underway at universities and private entities, and will also be used to ensure a domestic supply of potential vaccines. • **Supply issues**: On March 30, 2020, the Minister of Health signed the Interim Order Respecting Drugs, Medical Devices and Foods for a Special Dietary Purpose in Relation to COVID-19. This Interim Order allows Health Canada and the Canadian Food Inspection Agency to address critical supply issues for certain products in an expedited manner when shortages occur. These products include drugs and medical devices.
	COVID-19 Changes	On March 25, 2020, the Canadian government passed into law *An Act respecting certain measures in response to COVID-19*, which added a new stand-alone provision to the *Patent Act*: section 19.4. This section allows the Minister of Health to apply for government authorization to make, construct, use, and sell a patented invention for a public health emergency. It does not require the government to first negotiate use with the patentee. This new section will have limited use. The Minister of Health can only apply for government authorization under section 19.4 until September 30, 2020. Further, any authorizations will expire either a year after grant or when the Minister of Health deems it no longer necessary, whichever comes earlier.	Under section 19.4, the patentee will be compensated in an "amount that the [Patent] Commissioner considers to be 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."	

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United States	**Existing Regime**	The U.S. government has two statutory mechanisms through which it can unilaterally authorize the use of patents. **(1) Governmental authorization**: First, the U.S. government has broad authority under 28 U.S.C. § 1498(a) to use any U.S. patented invention. This statute applies to such use by the U.S. government or one of its contractors with the authorization or consent of the U.S. government. Authorization to use and/or manufacture any invention under 28 U.S.C. § 1498(a) is broad and without limitations. **(2) Compulsory licensing**: The Bayh-Dole Act (35 U.S.C. §§ 200-212) grants the U.S. government "march-in rights" to authorize compulsory licenses to other parties for inventions made with federal funding (either in whole or in part) under certain delineated circumstances, including where the Federal agency under which the invention was funded determines that "action is necessary to alleviate health or safety needs which are not reasonably satisfied by the contractor, assignee, or their licensees" (35 U.S.C. § 203). Petitions for march-in rights may be filed by private enterprises. The Bayh-Dole Act grants the U.S. government a "nonexclusive, nontransferable, irrevocable, paid-up license" to practice any inventions that were made with federal funding (35 U.S.C. § 202(c)(4)). Compulsory licensing under 35 U.S.C. § 203 is only available for inventions that were developed with federal funding and can be triggered in four circumstances when the contractor, an assignee or exclusive licensee, (1) has not taken, or is not expected to have taken within a reasonable time, effective steps to achieve practical application of the invention; (2) has not reasonably satisfied health or safety needs; (3) has not reasonably satisfied requirements for public use specified by Federal regulations; or (4) has granted an exclusive right to use the patented invention to another without obtaining the promise that the invention will be manufactured substantially in the United States.	**(1) Governmental authorization**: For claims under 28 U.S.C. § 1498(a), the owner can bring action against the United States in the U.S. Court of Federal Claims for monetary damages "for the recovery of his reasonable and entire compensation for such use and manufacture." **(2) Compulsory licensing**: For claims under 35 U.S.C. § 203, "any contractor, inventor, assignee, or exclusive licensee adversely affected" may appeal a march-in rights petition, within sixty days after the decision, in the U.S. Court of Federal Claims. Licenses granted under march-in rights would be "upon terms that are reasonable under the circumstances." This would likely encompass royalties to be paid to the party adversely affected.	• **Patented inventions**: To date, based on public information, the United States has taken no COVID-19 official actions relating to patented inventions. • The U.S. government has routinely utilized 28 U.S.C. § 1498 to use or take patented inventions. In the pharmaceutical context, throughout the 1960s and 1970s, federal agencies often relied upon section 1498 to purchase lower-priced generic pharmaceuticals. The use of section 1498 in the pharmaceutical context diminished in the 1970s and has not been invoked in recent years. In 2001, however, U.S. Health and Human Services Secretary Tommy Thompson leveraged the mere threat of invoking section 1498 to convince a pharmaceutical manufacturer to sell its branded U.S.-patented drug to the U.S. government at a lower price. • While several petitions for march-in rights have been filed in the United States under 35 U.S.C. § 203, no federal agency has ever granted such petitions.
	COVID-19 Changes	To date, the U.S government has not proposed changes to patent legislation in response to COVID-19.		

Europe

Country		Description of Emergency Patent Regime	Compensation to the Patentee	Governmental authorizations of patents in response to COVID-19
France	**Existing Regime**	A series of articles in the French Intellectual Property Code ("Code de la Propriété Intellectuelle", hereinafter **IPC**) provide the legal basis for compulsory licenses applicable in various types of situations. In particular, so called ex officio licenses can be granted in the public interest by the Ministry in charge of industrial property, either in the interests of public health (Art. L. 613-16 IPC); interests of national economy (Art. L. 613-18); or interests of national defense (Art. L. 613-19 IPC). Under Article L. 613-16 IPC, compulsory licenses in the interests of public health can be granted to third parties, among other things, for patents on products, processes regarding medical products or diagnostic methods. The compulsory license can be granted on the grounds that (i) the conditions under which the patent is exploited are contrary to the interest of public health; (ii) the quality or the quantity of the products based on the patent made available to the public are not sufficient or offered at abnormally high prices; or (iii) if the patent exploitation was judged to be a case of anti-competitive practice by a final court or administrative decision.	Pursuant to the existing compulsory licenses provision of the IPC, in absence of an amicable agreement between the patent owner and the compulsory licensee, the royalty is determined by the Paris First Instance Civil Court for compulsory licences in the interests of public health (Art. 613-17 IPC) .	• **Patented inventions**: To date, based on public information, France has taken no COVID-19 official actions relating to patented inventions.
	COVID-19 Changes	To date, the French government has not proposed any direct changes to patent legislation in response to COVID-19. However, on March 23, 2020, France introduced Emergency law No. 2020-290 to deal with the COVID-19 epidemic, which introduced Article L. 3131-15 to the French Public Health Code. This article authorizes the Prime Minister: 1) to order the requisition / seizure of all goods and services necessary to fight against the disaster and of any person necessary for the operation of such services or the use of such goods; 2) to temporarily control the price of products; and 3) whenever necessary, to take any measures to ensure that appropriate medicines are made available to patients for the eradication of the health disaster. The new Article L. 3131-15 to the French Public Health Code does not directly deal with patent issues, however it could allow the Prime Minister to request the requisition / seizure of medicines and/or to order the launch of generic products on French territory before any potential patent expiration.	Compensation for requisitions under Article L. 3131-15 of the French Public Health Code shall be governed by the French Code of Defense.	

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Germany	**Existing Regime**	The German government can authorize the use of patents pursuant to Section 13.1 of the Patent Act. The Federal government is entitled to allow the use of patented inventions in cases where the interest of public welfare or national security are affected.	Section 13.3 of the Patent Act states that the patentee is entitled to "equitable remuneration from the Federal Republic of Germany".	• **Patented inventions**: To date, based on public information, Germany has taken no COVID-19 official actions relating to patented inventions.
	COVID-19 Changes	On March 27, 2020, Germany passed the "Act for the protection of the population in case of an epidemic situation of national importance", becoming effective on March 28, 2020. This Act amends, among other things, the Infection Protection Act by providing to the Federal Ministry of Health competences within Section 13.1 of the Patent Act. The Federal Ministry of Health is enabled to authorize the use of certain patents to secure the manufacture and/or delivery of, for example, special ingredients, pharmaceuticals and/or medical devices.		
Netherlands	**Existing Regime**	Under the 1995 Dutch Patent Act (Rijksoctrooiwet 1995; **DPA**), there are five grounds on which a licence may be obtained against the wishes of a patentee, one of which being the public interest (algemeen belang). Public interest is to be interpreted broadly and must be a clear and pressing public interest which is not only served by the compulsory license, but is actually demanded. Under Article 57(1) DPA, the Minister of Economic Affairs (Minister van Economische Zaken; the Minister) may, at his own initiative or at the request of a third party, grant a compulsory licence to a third party against terms to be specifically determined by the Minister if, in his judgment, this is required in the public interest. The Minister will ascertain, unless urgency dictates otherwise, whether the patentee is willing to grant a licence voluntarily and on reasonable terms. The decision to impose a compulsory licence will be notified to the patentee and licensee. Lodging objections and filing for appeal have suspensive effect, unless the Minister's decision determines otherwise on the basis of urgency.	If a compulsory license is granted, the licensee must pay a license fee to the patentee (Art. 58(6) DPA). The DPA assumes that the patentee and the licensee may negotiate and agree on a license fee after a compulsory license has been granted. However, if no agreement can be reached, either party may request the District Court of The Hague to determine the fee. Before granting a compulsory license the court may impose the condition that the licensee puts up a security for license fees due.	• **Patented inventions**: To date, based on public information, Netherlands has taken no COVID-19 official actions relating to patented inventions.
	COVID-19 Changes	To date, the Dutch government has not proposed changes to patent legislation in response to COVID-19.		

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United Kingdom	**Existing Regime**	In the UK, there are two routes by which an implementer may practice a third party patent without the patentee's consent; via relying upon compulsory licensing and Crown use provisions. These are provided for under the Patents Act 1977 (the **Act**). **(1) Compulsory Licence Regime**: An implementer may apply for a compulsory licence under s. 48 of the Act. At any time after three years have elapsed from the date of grant of the patent, a person may apply to the UK Intellectual Property Office (**IPO**) for a licence under the patent and for the determination of the terms, provided that attempts have already been made to obtain a licence on reasonable terms over a reasonable period from the patent proprietor. The applicant must satisfy one or more "grounds" set out in s. 48A (1), for example, that a demand for the patented product in the UK is not being met on reasonable terms. The IPO will aim to secure benefit to the public, avoid any person from being unfairly prejudiced, and take account of matters such as the nature of invention, and the ability of the applicant to work the invention to the public's advantage before deciding to grant a compulsory a licence, per s. 50 of the Act. **(2) Crown Use**: Special provisions in the Act (ss. 55-59) can be relied upon to enable any government department (the **Crown**) to make unlicensed use of the patent or for the Crown to authorise such unlicensed use. This is called **Crown use**. Under Crown use, the government, and any other persons authorised by that government, may carry out acts which would otherwise be infringing without the consent of the patent proprietor. A licence is effectively ordered between the relevant government department (e.g. Department of Health) and other authorised persons (e.g. suppliers of medicines to the Department of Health) and the patentee. During a period of emergency, a government department or a person authorised by a government department can use the invention for any purpose which appears to the department necessary or expedient for, inter alia the maintenance of supplies and services essential to the life of the community or for securing a sufficiency of supplies and services essential to the well-being of the community.	**(1) Compulsory Licence Regime**: The IPO will seek to ensure that reasonable remuneration for the patent holder is provided. **(2) Crown Use**: The government department will pay to the proprietor of the patent a proper royalty.	• **Patented inventions**: To date, based on public information, the UK has taken no COVID-19 official actions relating to patented inventions.
	COVID-19 Changes	To date, the UK government has not proposed changes to patent legislation in response to COVID-19.		

Asia

Country		Description of Emergency Patent Regime	Compensation to the Patentee	Governmental authorizations of patents in response to COVID-19
Hong Kong	**Existing Regime**	In Hong Kong, the government may declare a period of "extreme urgency" for the maintenance of supplies and services essential to the life of the community. During such period, the government may use a patented invention without obtaining consent from the patentee under sections 68-69 of the Patents Ordinance. In particular, for extreme urgency arising from a public health problem, the government may grant an import compulsory licence to any person for importing, putting on the market and using a patented pharmaceutical product under sections 72B-72C of the Patents Ordinance.	Section 71 of the Patents Ordinance requires the Hong Kong government to pay the patentee or the exclusive licensee compensation for any loss resulting from his not being awarded a contract to supply the patented product. In accordance with section 72E of the Patents Ordinance, in the case of an import compulsory license granted under sections 72B-72C, payment from the government is required only if remuneration has not been paid to the patentee of the pharmaceutical product in an exporting WTO country. If required, the amount of the payment is to be agreed between the government and the patentee or determined by the court, but in any case shall not exceed 4% of the total purchase price for the product payable by the import compulsory licensee.	• **Patented inventions**: To date, based on public information, the Hong Kong government has taken no COVID-19 official actions relating to patented inventions.
	COVID-19 Changes	To date, the Hong Kong government has not proposed changes to patent legislation in response to COVID-19.		
People's Republic of China	**Existing Regime**	In China, the government may grant a compulsory license under article 49 of the Patent Law for exploitation of an invention patent or utility model patent in case of national emergency, extraordinary state of affairs or if public interests so require. Under article 50 of the Patent Law, for the benefit of public health, the government may grant a compulsory license for manufacture of a patented drug and for its export.	According to article 57 of the Patent Law, the compulsory licensee shall pay reasonable royalties to the patentee, the amount of which should be agreed between the licensee and patentee or adjudicated by the patent administration department of the government.	• **Patented inventions**: To date, based on public information, the Chinese government has taken no COVID-19 official actions relating to patented inventions.
	COVID-19 Changes	To date, the Chinese government has not proposed changes to patent legislation in response to COVID-19.		

Country		Description of Emergency Patent Regime	Compensation to the Patentee	Governmental authorizations of patents in response to COVID-19
Singapore	Existing Regime	In Singapore, the government has two powers under the Patents Act which may apply to the COVID-19 pandemic: (1) Governmental use; and (2) Importation of any relevant health product. (1) Government Use: The government can authorize the use of a patent under Section 56(1)(b) of the Patents Act "for or during a national emergency or other circumstances of extreme urgency". This may be done without the consent of the patentee, although the government is obliged to inform the patentee "as soon as reasonably practicable". (2) Importation of a Health Product: Under Section 56(1A) of the Patents Act, the government can also import any relevant health product, and do anything in relation to any relevant health product so imported, for or during a national emergency or other circumstances of extreme urgency, provided that the government first notifies the Council for TRIPS of its intention.	(1) Government Use: Section 62(1) of the Patents Act states that the government shall remunerate the patentee an agreed amount, or an amount determined by an agreed method between the government and the patentee having regard to the economic value of the patent. If there is no agreement, the court can determine the remuneration under Section 58 of the Patents Act. (2) Importation of a Health Product: in relation to the import or subsequent use of a relevant health product, a patentee will not receive any remuneration if it has received, or will receive, any other remuneration in respect of that relevant health product (Section 62(2) of the Patents Act).	• Patented inventions: To date, based on public information, the Singapore government has taken no COVID-19 official actions relating to patented inventions.
	COVID-19 Changes	To date, the Singapore government has not proposed changes to patent legislation in response to COVID-19.		

Oceania

Country		Description of Emergency Patent Regime	Compensation to the Patentee	Governmental authorizations of patents in response to COVID-19
Australia	Existing Regime	In Australia, there are three statutory regimes which may apply to the COVID-19 pandemic: (1) Crown Use; (2) Compulsory Licences; and (3) Patented Pharmaceutical Invention (PPI) Compulsory Licences. **(1) Crown Use**: The Crown use provisions in Chapter 17 of the Australian Patents Act provide that, in certain circumstances in relation to Crown purposes, the exploitation of a patented invention by Australia's Commonwealth (National), State or Territory governments without the licence or approval of the patent owner will not constitute patent infringement. Crown use applies broadly to services both primarily provided and funded by Australian governments. Most relevant to the current COVID-19 pandemic, however, is section 163A that provides for the invocation of Crown use in emergencies and that this occur in a streamlined fashion compared to Crown use in ordinary times (i.e. simply upon the order of a relevant government Minister). **(2) Compulsory Licence**: Whereas the exercise of Crown use in emergencies is the sole prerogative of Australian governments, the compulsory license provisions in Chapter 12 of the Australian Patents Act provide that any person (including private citizens, bureaucrats, corporations and government ministers) may apply to the Federal Court of Australia for an order requiring the patent owner to grant the applicant a licence to exploit the patented invention in Australia if certain conditions are met. The conditions are complex and extensive and involve the additional time, cost and uncertainty of an application to the Court. Accordingly, Australian governments would likely only consider using the general compulsory licence provisions only if a proposed patent exploitation could not be achieved within the Crown use framework described above. **(3) PPI Compulsory Licence**: Australia has also implemented Article 31 of WTO Agreement on Trade-Related Aspects of Intellectual Property (**TRIPS**) which provides an international mechanism to allow Member States to authorise the manufacture of patented pharmaceuticals for export to "eligible importing countries". The Australian mechanism in Chapter 12 Part 3 of the Australian Patents Act is intended to help provide affordable medicine in developing countries with a particular focus on pandemic disease including HIV/AIDS, malaria and diabetes. Note that the statutory provisions are not limited to developing nations and may apply to middle or high income nations who make a request in times of national emergency.	**(1) Crown Use**: Section 165 of the Australian Patents Act provides that the remuneration payable to the patent owner for the exploitation of the invention may be agreed upon between an Australian government and the patent owner (before, during or after the exploitation). In the absence of such an agreement, the patent owner or relevant government authority may apply to the Federal Court, which must then determine an amount of remuneration that is just and reasonable, having regard to the economic value of the exploitation of the invention and any other matter the court considers relevant. The court may also take into account any compensation already paid, directly or indirectly, in relation to the exploitation of a patented invention. **(2) Compulsory Licence**: Section 133(5) of the Australian Patents Act provides that the remuneration paid by the licensee under a general compulsory licence may be agreed between the licensee and patent owner. In the absence of such an agreement, the Federal Court will determine a remuneration amount that is just and reasonable, having regard to the economic value of the licence, the right of the patentee to obtain a return on investment commensurate with the regulatory and commercial risks involved in developing the invention, and the public interest in ensuring that demand in Australia for the original invention is met on reasonable terms.	• **Patented inventions**: To date, based on public information, the Australian governments have taken no COVID-19 official actions relating to patented inventions, nor have they flagged an intention to do so. • In the past, however, the Commonwealth government has not been shy to aggressively pursue public measures at the expense of the intellectual property rights (e.g. plain packaging of tobacco products).[1] In that context, it seems likely that the government (as well as its State and Territory counterparts) would, if necessary, avail themselves of the provisions already at their disposable if the current cooperation between nation states, and private and public organisations in pursuit of suitable vaccines and treatments were to break down or that the global supply of a vaccine or treatment were constrained in a manner detrimental to the health and welfare of Australians.

1 Another example is Australia's reliance on Article 27 of the TRIPS Agreement to amend the Australian Patents Act to exclude from patentability human beings and the biological processes for their generation.

Country		Description of Emergency Patent Regime	Compensation to the Patentee	Governmental authorizations of patents in response to COVID-19
Australia	Existing Regime	The PPI compulsory licence provisions are long, complex and are supplemented by extensive regulations. With rapidly worsening conditions apparent in the Asia-Pacific region and beyond, however, the PPI compulsory licence may rapidly become of interest to the Commonwealth government and Non-Government Organisations if and when effective vaccines or treatments are found for COVID-19.	(3) PPI Compulsory Licences: Section 136J of the Australian Patents Act provides that the remuneration paid by the licensee under a PPI compulsory licence may be agreed between the licensee and patent owner or, in the absence of such an agreement, the amount must be determined by the Federal Court taking into account the economic value to the eligible importing country of the use of the PPI.	
	COVID-19 Changes	To date, the Australian government has not proposed changes to patent legislation in response to COVID-19. The existing emergency regime described above was only recently (and substantially) amended in February this year.		

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