Bird & Bird & COVID-19

Q&A on the use of patented products and processes without authorisation of patent holder National compulsory licence laws

Contents

Introduction

Background

The COVID-19 pandemic has sparked speculation in the media about the extent to which patents might be used to block the manufacture, sale or use of medical devices, diagnostic kits, therapeutic drugs and vaccines. In practice, it seems extremely unlikely that patent holders will try to block the use of a patented product or process needed for the fight against COVID-19, motivated by a desire to contribute to the world's response to COVID-19 and avoid any negative PR.

In the short term, companies that have or develop products (be they devices, kits, drugs or vaccines) protected by patents will likely choose to make those products available at an affordable price (cost plus) if not for free. Insofar as they are unable or unwilling to meet demand themselves, they will likely either charge an affordable royalty or not enforce their rights/license them royalty free.

Two widely reported examples are Gilead's decision to withdraw its orphan drug designation in the US for Remdesivir and AbbVie's announcement that it would not seek to enforce its patent rights covering Kaletra. Many companies have also taken the "Open COVID pledge"[1] by virtue of which they agree to offer royalty-free licences to their IP (patents or otherwise) to anyone interested in tackling the pandemic. At an international level, the WHO is also considering resolutions designed to set up mechanisms for patent pools.[2]

Any potential disputes over patent rights or patent protected products are therefore more than likely to be resolved in the short term through decisions to sell or licence for free (or at most cost plus). Nevertheless, it is useful to know the scope to which patent law enables national governments to grant compulsory licences, should they chose to do so. Indeed, the mere existence of these provisions will at least in some cases encourage right-owners to agree to sell and/or licence on reasonable terms.

Compulsory licensing is a term which broadly covers two types of use. On the one hand, it covers use by the government or, more likely, by private companies for or on behalf of the government or state, in particular in cases of national health emergencies such as an epidemic (what would be known in the UK and certain Commonwealth countries such as Australia as Crown Use and in civil law countries such as Germany as State Use Orders). On the other hand, it covers use by private companies for themselves either to meet an unmet public health demand or for purely commercial reasons (e.g., a dependent patent). In general, the latter type of compulsory licence is procedurally cumbersome to obtain and therefore unlikely to be relevant to meet short term needs in cases of national health emergencies.

As a matter of international law, compulsory licensing laws, at least for WTO member states, is governed by Article 31 and 31bis of TRIPS (Other Use without Authorization of the Right Holder).[3] Under Article 31, national laws authorising the grant of compulsory licences are permitted subject to certain conditions, including that efforts have been made to obtain a licence from the right holder, that such use is predominantly for the supply of the domestic market and that the right holder is compensated. An exception to the first of those conditions is a case of national emergency, although even then the right holder should be notified.

In response to the difficulties of certain lower income countries obtaining access to anti-virals to treat HIV back in the 1990s, the "predominantly for the supply of the domestic market" condition of Article 31 was finally amended a few years ago by the addition of Article 31bis so as to permit compulsory licensing of drugs for export to countries lacking domestic manufacturing capabilities. So far, so good. However, the position of the various WTO member states under Article 31bis is not straightforward. The problem for many high income countries is that first, because

[1] https://openCOVIDpledge.org/
[2] https://medicinespatentpool.org/mpp-media-post/the-medicines-patent-pool-and-unitaid-respond-to-access-efforts-for-COVID-19-treatments-and-technologies/
[3] https://www.wto.org/english/docs_e/legal_e/31bis_trips_04c_e.htm

the manufacture of most drugs these days has been outsourced to China and India, they now lack domestic manufacturing capability and second, they chose to opt out of the inbound aspects of the Article 31bis regime[4]. For many higher income countries, it remains to be seen whether their national compulsory licence laws will be of any use in practice. That said, it is notable that some higher income countries are seeking to increase their domestic manufacturing capacity especially of potential COVID-19 vaccines.

For most countries, therefore, whilst their national patent law includes compulsory licensing provisions, the precise ambit of those provisions varies considerably from country to country. Furthermore, in the light of the COVID-19 pandemic, some countries have sought to strengthen their national compulsory licensing provisions.

In the longer term, the position with regard to patent rights will likely become less straightforward. Some of the rights that are acquired during the pandemic may have value beyond COVID-19. It should also be borne in mind that commercial licences, as well as any compulsory licences granted in the public interest during the pandemic itself, are likely to be limited e.g., to demand, to the duration of the pandemic, or to another set period of time. Therefore, as the pandemic hopefully starts to abate, companies should start considering whether any renegotiation of COVID-19-related licences will be required.

This overview is intended to summarise the established and recently introduced national compulsory licensing laws in order to assist our clients in understanding the position. This document does not constitute legal advice and if you require more information, please feel free to reach out to the country contacts in this document.

[4] See: https://medicineslawandpolicy.org/2020/04/never-say-never-why-the-high-income-countries-that-opted-out-from-the-art-31bis-wto-trips-system-must-urgently-reconsider-their-decision-in-the-face-of-the-COVID-19-pandemic/

Australia

Does your national patent law provide in the context of a health emergency such as a pandemic like COVID-19 for the state to do or authorise others to do acts which facilitate treatment of patients and which a patentee would otherwise have the right to prevent?
Yes – Crown Use provisions set out in chapter 17 part 2 of the Patents Act 1990 (Cth). a) Describe in general terms the scope of the law and how it could be used by the state or third parties to facilitate the treatment of patients infected by COVID-19. Section 163 allows the Commonwealth, State or Territory government to exploit an invention for Crown purposes if the relevant Minister is satisfied that the government has tried without success to obtain a licence on reasonable terms. Crown purposes in this context means the provision of government services either by the government or an authorised agent. The Crown Use must be approved by the Minister in writing and provided to the patentee with 14 days' notice. Section 163A specifically provides for Crown Use during emergencies if a relevant Minister considers exploitation of the invention is necessary because of an emergency. The Minister may authorise exploitation for Crown purposes in writing. No prior notice or negotiation with the patentee is required, however, notice must be given to the patentee as soon as practical after the exploitation starts. Crown Use is subject to remuneration as agreed between the government and patentee or determined by a court to be just and equitable. b) Has this law been used in previous health emergencies and/or in the present COVID?-19 We are not aware of any examples of Crown Use or compulsory licensing in response to previous health emergencies or COVID-19. There have been calls by the Opposition for the Federal Government to consider using the Crown Use provisions, however, there is no indication that the Government plans to adopt this approach.
In view of the COVID-19 pandemic, has your country enacted any new patent law intended to facilitate the treatment of patients infected by COVID-19?
No
Does your national patent law currently provide for the compulsory licensing of a patent by a third party, which is likely to be of relevance in a pandemic such as COVID-19 in particular by meeting a short term need to treat patients infected by COVID-19?
Yes - Compulsory licensing provisions set out in chapter 2, parts 2 and 3 of the Patents Act 1990 (Cth) a) Describe in general terms the scope of the law and how it could be used by third parties to facilitate the treatment of patients infected by COVID-19. Section 133 of the Patents Act 1990 (Cth) provides that the Federal Court may make an order granting a compulsory licence to exploit a patented invention under certain circumstances. This requires that the demand for the invention is not being met on reasonable terms, exploitation of the invention is essential to meet demand, the applicant has tried for a reasonable period without success to obtain a licence from the patentee and the patentee has given no explanation for failing to exploit the patent to meet the demand. The Court must also be satisfied that granting the compulsory licence is in the public interest. In addition, sections 136D and 136E allow the Federal Court to issue a compulsory licence to manufacture and

export a pharmaceutical invention to address a public health emergency in another country. This type of compulsory licence is only available in relation to export from Australia. It must be shown that all the product will be exported and that the importing country has measures in place to prevent the product from being further exported.

Applications for both types of compulsory licence may be made by any third party. In the case of general compulsory licences, there is no requirement to show a need arising from an emergency, however, this type of licence will only be granted if the patentee is uncooperative.

A section 133 licence could be requested in response to the COVID-19 crisis, however, it would only be granted if the patentee refused to either meet the relevant demand themselves (or through their licensees) or offer a licence on reasonable terms. It would also be a relatively slow process, as it is necessary to show that the applicant has attempted to negotiate a licence for a reasonable period of time.

A section 136E licence is more likely to be relevant to the COVID-19 crisis, however, as it only applies to exporting pharmaceuticals from Australia, its use would be limited.

b) Has the compulsory licensing law been used in previous health emergencies and/or in the present COVID-19 pandemic?

We are not aware of any use in those circumstances.

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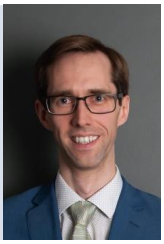

Belgium

Does your national patent law provide in the context of a health emergency such as a pandemic like COVID-19 for the state to do or authorise others to do acts which facilitate treatment of patients and which a patentee would otherwise have the right to prevent?
No
In view of the COVID-19 pandemic, has your country enacted any new patent law intended to facilitate the treatment of patients infected by COVID-19?
No
Does your national patent law currently provide for the compulsory licensing of a patent by a third party, which is likely to be of relevance in a pandemic such as COVID-19 in particular by meeting a short term need to treat patients infected by COVID-19?

Yes - compulsory licensing in the interest of public health set out in Section XI.38 of the Belgian Code of Economic Law ("CEL"). The grant of such a compulsory license can be accelerated in case of an emergency health situation such as COVID-19.

Beyond this provision, Sections XI.39 and XI.37, 40-44 CEL provide that compulsory licenses may also be granted for (i) the manufacture of pharmaceutical products for export to countries with public health problems and (ii) lack of exploitation or dependency. In the context of COVID-19 these rules could also be invoked, although this may be difficult as the requirements are stringent and the procedure is quite cumbersome.

a Describe in general terms the scope of the law and how it could be used by third parties to facilitate the treatment of patients infected by COVID-19.

Art XI.38 CEL

In the interest of public health, a non-exclusive compulsory license can be granted by royal decree (decision of the Council of Ministers). The procedure is as follows.

Request

The applicant first submits a request to the Minister of Economy, with a copy to the Advisory Committee on Bioethics ("AdvComm").

In his request, the applicant must demonstrate:

- a serious health risk
- that he has the means or the bona fide intention to obtain the means necessary for the essential and continuous manufacture and use in Belgium of the patented invention.

AdvComm's opinion

The Minister shall transmit the request to the AdvComm within ten days. The AdvComm will invite the patent holder to make known his position on the possible granting of a compulsory license within one month. The AdvComm will issue a reasoned and non-binding opinion to the Minister of Economy on the merits of the request.

Royal Decree

Within a period of three months as of the receipt of the AdvComm's opinion, the Minister of Economy shall submit a draft reasoned royal decree (including a proposal for compensation for the patent holder) to the Council of Ministers for discussion, which will take a final decision.

Accelerated procedure

In the event of a public health crisis (such as the COVID-19 pandemic) and upon the proposal of the Minister in

charge of public health, the Government may, by order deliberated in the Council of Ministers, take measures to accelerate the procedure. It may, where appropriate, provide that the opinion of the AdvComm is not required.

The license

Such license can be limited in time and/or in scope. A reasonable compensation must be paid to the patent owner. The license is registered in the Register.

At the request of any interested party, the Council of Ministers may, by means of a new royal decree, revoke the compulsory license granted if, after the expiry of the period fixed for exploitation, the licensee has not exploited the patented invention in Belgium through a substantial and continuous manufacture.

Art. XI.39 CEL:

A non-exclusive compulsory license for the manufacture of pharmaceutical products for export to countries with public health problems may be granted by royal decree (decision of the Council of Ministers) on the basis of Regulation No 816/2006.

An adequate remuneration must be paid to the right holder.

The amount of product(s) manufactured under the licence shall not exceed what is necessary to meet the needs of the importing country or countries cited in the application.

If the product(s) covered by the compulsory licence are patented in the importing countries cited in the application, the product(s) shall only be exported if those countries have issued a compulsory licence for the import, sale and/or distribution of the products.

XI.37 and 40-44 CEL:

A non-exclusive compulsory license for lack of (sufficient) exploitation may be granted by ministerial decree if:

- three years since the grant of a patent or four years since the filing of the patent application, whichever comes last, have passed;
- the patent owner has not sufficiently exploited the invention and does not justify this inaction by legitimate excuses;
- the license is granted mainly for the supply of the Belgian market;
- the applicant proves that that he has the means or the bona fide intention to obtain the means necessary for the essential and continuous manufacture and use in Belgium of the patented invention.

A non-exclusive compulsory license for "dependent invention" may also be granted by ministerial decree:

- if the invention protected by the patent cannot be used without infringing the rights related to an earlier patent;
- to the extent necessary to exploit the invention, provided that with respect to the subject of the earlier patent, the "dependent invention" represents an important technical progress of considerable economic importance.

In both cases, the applicant must:

- prove that he has contacted the patent owner first and has been unable to obtain from him a license on fair conditions;
- pay a fair compensation to the patent owner;
- address his request to the Belgian Minister of Economy, who will submit the file to the Commission for Compulsory Licensing for advice.

Within four months after the positive notification of the Minister's decision, an agreement must be concluded between the patent owner and the licensee setting out their mutual rights and obligations.

If no agreement is reached within four months, one of the parties can summon the other party. The court, sitting in summary proceedings, will then ultimately determine the parties' mutual rights and obligations.

b Has the compulsory licensing law been used in previous health emergencies and/or in the present COVID-19

pandemic?

We are not aware of any case of compulsory license in the present pandemic or in other health emergency situations in the past.

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China & Hong Kong

China

Does your national patent law provide in the context of a health emergency such as a pandemic like COVID-19 for the state to do or authorise others to do acts which facilitate treatment of patients and which a patentee would otherwise have the right to prevent?
Yes. The PRC Patent Law ("Patent Law") contains provisions under Article 49 which allows the compulsory licensing of patents for domestic supply under special circumstances. a Describe in general terms the scope of the law and how it could be used by the state or third parties to facilitate the treatment of patients infected by COVID-19. **Article 49:** Under Article 49, compulsory licensing for the exploitation of an invention or utility model (including those for drugs, medical devices and others) is possible under a national emergency or extraordinary state of affairs, or for public interest needs. Under Article 53, it is stated that such licensing should be mainly to supply the domestic market. Under Article 6 of the Measures on Compulsory Licensing of Patent Exploitation (the "Measures") it is required that the licensing be initiated by the relevant authorities (e.g. National Health Commission) under the State Council recommending to the CNIPA to grant the compulsory license. **Other provisions:** Exclusivity: Under Article 56 of the Patent Law, the compulsory license is not exclusive. Termination: Under Article 31 of the Measures, termination of the compulsory license automatically occurs if the granted period has expired, or if the patent is expired or invalid. Under Article 32 of the Measures, it also provides that prior to the expiry of the compulsory license, if the reasons for granting it no longer exist, the patentee may request CNIPA to terminate the compulsory license. Rights of Patentee: The patentee is able to provide their opinions within 15 days of receiving notice of the compulsory license. Under Article 58 of the Patent Law, the patentee may also appeal the decision or the amount of licensing fees to the court within three months. Alternatively, the parties may also file the administrative review against the CNIPA decision/ruling in 60 days in accordance with Article 41 of the Measures and Administrative Review Law. b Has this law been used in previous health emergencies and/or in the present COVID-19 pandemic? To date, we are not aware of any cases where these provisions have been used in health emergencies or for COVID-19.
In view of the COVID-19 pandemic, has your country enacted any new patent law intended to facilitate the treatment of patients infected by COVID-19?
Yes.

a Describe in general terms the scope of the new law and how it could be used by third parties to facilitate the treatment of patients infected by COVID-19.

On 15 February 2020, The State Administration for Market Regulation (“SAMR”), National Medical Products Administration ("NMPA") and Chinese National Intellectual Property Administration (“CNIPA”) co-issued the document: "Ten Items to Support Resumption of Work and Production", which states that priority examination should be given at request for patent applications for the prevention and treatment of COVID-19.

b Has this new law been used in the present COVID-19 pandemic?

Yes. It is reported in China Intellectual Property News that as of 9 April 2020, CNIPA had conducted the priority examination for 358 patents for the prevention and treatment of COVID-19.

Does your national patent law currently provide for the compulsory licensing of a patent by a third party, which is likely to be of relevance in a pandemic such as COVID-19 in particular by meeting a short term need to treat patients infected by COVID-19?

Yes. In addition to Article 49, Articles 48, 50 and 51 of the Patent Law also allow for the granting of a compulsory license of an invention or utility model patent.

a Describe in general terms the scope of the law and how it could be used by third parties to facilitate the treatment of patients infected by COVID-19.

Article 48 Patent Law:

Under Article 48 of the Patent Law the granting of a compulsory license is allowed:

1 where, within three years as of the date on which the patent right is granted and within four years as of the date of filing the application for a patent, a patentee , without any legitimate reason, fails to have the patent exploited or fully exploited; or

2 where a patentee's exercise of the patent right is considered in accordance with the law to be monopolistic and its negative impact on competition needs to be eliminated or reduced.

Under Article 73 of the Implementing Rules of PRC Patent Law (the “Implementing Rules”), the term "insufficient utilization of the patent" is defined as a situation in which the way, or the scale to which, the patentee (and its licensee) utilize the patent fail to meet domestic demand for the patented product or method.

Under Article 5 of the Measures, it states that "if a patentee fails to fully or sufficiently exploit a patent within 3 years of the date the patent right was granted, or within 4 years of the date the patent was applied for, then an entity or individual meeting the conditions for exploitation of the patent may request the compulsory license pursuant to Article 48.1 of the Patent Law.

If the exercise of a patent right by a patentee is deemed monopolistic according to law, then an entity or individual meeting the conditions for exploitation may, pursuant to Article 48.2 of the Patent Law, request the compulsory license, in order to eliminate or reduce adverse effects on competition."

Article 50 Patent Law:

Under Article 50 of the Patent Law for compulsory licensing of drug patents for the manufacture and export to certain countries or regions for public health reasons.

Under Article 73 of the Implementing Rules, it states that the drug mentioned in Article 50 of the Patent Law covers the drug of a product patent, and the drug derived directly by a method patent, including the active ingredients and any diagnostic supplies necessary for the use of the drug.

Under Article 7 of the Measures, compulsory licensing is initiated by the request of the entities, however, the importing countries or regions should be:

1 a country or region deemed severely underdeveloped, or

2 a developed or developing member of the World Trade Organization (WTO) (and it must send notice to WTO the

wish to import).

If such compulsory licensing is granted, CNIPA can specify requirements in the decision and the relevant authority under the State Council will provide the relevant information to WTO in accordance with Article 23 and 24 of the Measures respectively (which outline import measures and labelling etc.).

Article 51 Patent Law:

Under Article 51 of the Patent Law, it provides that if a later patent represents a major technological advancement of remarkable economic significance, compared with an earlier invention or utility model for which a patent right has already been granted, but that is directly dependent on the earlier patent, the patentee of the later patent may apply to the CNIPA for the grant of a compulsory licence to exploit the earlier patent

Similarly, where the patentee of the later patent has been granted a compulsory licence (as described above), the patentee of the earlier patent may apply to the CNIPA for the grant of a compulsory licence to exploit the later patent.

Other provisions:

Exclusivity:

Under Article 56 of the Patent Law, the compulsory license is not exclusive.

Termination:

Under Article 31 of the Measures, termination of the compulsory license automatically occurs if the granted period has expired, or if the patent is expired or invalid.

Under Article 32 of the Measures, it also provides that prior to the expiry of the compulsory license, if the reasons for granting it no longer exist, the patentee may request CNIPA to terminate the compulsory license.

Rights of Patentee:

The patentee is able to provide their opinions within 15 days of receiving notice of the compulsory license.

Under Article 58 of the Patent Law, the patentee may also appeal the decision or the amount of licensing fees to the court within three months. Alternatively, the parties may also file the administrative review against the CNIPA decision/ruling in 60 days in accordance with Article 41 of the Measures and Administrative Review Law.

b Has the compulsory licensing law been used in previous health emergencies and/or in the present COVID-19 pandemic?

To date, we are not aware of any cases where these provisions have been used in health emergencies or for COVID-19.

Hong Kong

Does your national patent law provide in the context of a health emergency such as a pandemic like COVID-19 for the state to do or authorise others to do acts which facilitate treatment of patients and which a patentee would otherwise have the right to prevent?

Yes.

a Describe in general terms the scope of the law and how it could be used by the state or third parties to facilitate the treatment of patients infected by COVID-19.

The relevant provisions are in sections 68-69 of the Patents Ordinance (Cap. 514 of the Laws of Hong Kong) (the "PO").

Under section 68 of the PO, the Chief Executive in Council may, by regulation, declare a period of extreme urgency

whenever they consider it to be necessary or expedient in the public interest for the maintenance of supplies and services essential to the life of the community or for securing sufficient supplies and services essential to the life of the community.

Pursuant to section 69 of the PO, during a period of declared extreme urgency, a public officer authorized in writing by the Chief Executive or any person authorized in writing by such public officer may in relation to:-

- a patented invention, without the consent of the proprietor of the patent; or
- an invention in respect of which an application for a patent has been filed, without the consent of the applicant,
- do any act in Hong Kong in relation to the invention as appears to the public officer or person authorized to be necessary or expedient in connection with the urgency giving rise to the declaration under section 68. Such acts are referred to as "Government use".

Government use includes any act which would otherwise infringe the patent concerned (e.g. any act of making, putting on the market, using, importing, or stocking a patented product, or any act of using a patented process, or offering the process for use with actual or constructive knowledge that the use of the process is prohibited etc.) or give rise to a right under section 88 of the PO to bring proceedings in respect of the application for a standard patent.

Any Government use of an invention after the publication of a standard patent application or the grant of a short-term patent for the invention must be made on terms as agreed between the Government and the patentee. Such an agreement may be made either before or after the Government use.

These provisions may be invoked by the Chief Executive in Council in health emergencies or at times of pandemic if they consider it to be necessary or expedient in the public interest for the maintenance of or securing pharmaceutical or other supplies and services in relation to the treatment of patients infected by the pandemic. However, it is envisaged that declarations under section 68 are only to be made when the livelihood of Hong Kong is at stake, such as in times of war or great disaster where the supplies and services essential to the life of the community as a whole are being threatened. Therefore, it is unlikely that these provisions will be invoked in the present COVID-19 pandemic unless the situation becomes so severe or out of control that the livelihood of Hong Kong is at stake.

b Has this law been used in previous health emergencies and/or in the present COVID-19 pandemic?

We are not aware of any cases where the Chief Executive in Council has declared a period of extreme urgency under section 68 of the PO and exercised its rights under section 69 of the PO in previous health emergencies and/or in the present COVID-19 pandemic.

In view of the COVID-19 pandemic, has your country enacted any new patent law intended to facilitate the treatment of patients infected by COVID-19?

No.

Does your national patent law currently provide for the compulsory licensing of a patent by a third party, which is likely to be of relevance in a pandemic such as COVID-19 in particular by meeting a short term need to treat patients infected by COVID-19?

Yes.

Standard Patents

Under sections 64-67 of the PO, Compulsory Licences for standard patents may be granted.

Import Compulsory License

Under sections 72A-72J of the PO, an import compulsory license for patented pharmaceutical products may be granted

Export Compulsory License:

Under sections 72K-72R of the PO, an export compulsory licence for patented pharmaceutical products may be

granted.

a Describe in general terms the scope of the law and how it could be used by third parties to facilitate the treatment of patients infected by COVID-19.

Standard Patent:

Under sections 64-67 of the PO, a compulsory license may be requested after 3 years from the grant of a standard patent:

- If the patented invention is not being worked to the fullest extent that is reasonably practicable;
- Where the demand for the product in Hong Kong is not being met on reasonable terms;
- Where the ability to work the invention is prevented by the import of a product (or if a process a product made from the process);
- Where the proprietor to refuses to grant a license on reasonable terms; or
- If conditions imposed by the proprietor are unfairly prejudicial.

The court must be satisfied prior to granting a compulsory license that the applicant has made reasonable efforts to obtain authorization from the proprietor on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time.

Under sections 64-66 of the PO if a proprietor wishes to oppose an application, they may, in accordance with rules of court, give to the court notice of opposition; and the court shall consider the opposition in deciding whether to grant the application.

Import/Export Compulsory Licenses

Import Compulsory License:

Under sections 72A-72J of the PO, an import compulsory license for patented pharmaceutical products may be granted in situations of 'extreme urgency'.

Under section 72B of the PO, for the purposes of section 72 the Chief Executive can declare a situation of 'extreme urgency' when it is necessary or expedient in the public interest to maintain/procure supplies and services essential to the life of the community.

Under section 72B, an import compulsory license issued under these sections is not exclusive.

Under section 72C, the import compulsory license may be granted to a public officer or any other person to do in HK in relation to the product all or any of the following which appears necessary or expedient in connection with the extreme urgency giving rise to the declaration:

- importing, putting on the market, stocking or using the product;
- any other act which would, apart from this section, amount to an infringement of the patent concerned.

Under section 72H, termination of the period of extreme urgency terminates the compulsory license.

Export Compulsory License:

Under sections 72K-72R of the PO an export compulsory licence for patented pharmaceutical products may be granted which allows manufacturers in HK to use the TRIPS Agreement Protocol to make and export pharmaceutical products to other WTO members who are under a national emergency or extreme urgency (this must be declared by the importing country).

Under section 72L, at any time after the grant of a standard patent or a short-term patent in respect of a patented pharmaceutical product, any person may apply to the Director for the grant of an export compulsory licence.

Under section 72M, an export compulsory licence under the patent concerned, is subject to such terms and

conditions as may be imposed, and is granted to an applicant to make a patented pharmaceutical product and to sell the product for export to an eligible importing member.

Under section 72N, the compulsory license is non-assignable but is also not exclusive.

Under section 72P, remuneration is payable to the patent owner, as determined by the government.

b Has the compulsory licensing law been used in previous health emergencies and/or in the present COVID-19 pandemic?

To date, we are not aware of any cases where these provisions have been used in health emergencies or for COVID-19.

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Czech Republic

Does your national patent law provide in the context of a health emergency such as a pandemic like COVID-19 for the state to do or authorise others to do acts which facilitate treatment of patients and which a patentee would otherwise have the right to prevent?

Yes – section 20 (2) of the Czech Patents Act allows for the granting of a compulsory licence in cases where an important public interest is endangered.

a Describe in general terms the scope of the law and how it could be used by the state or third parties to facilitate the treatment of patients infected by COVID-19.

Under Section 20 (2) of the Czech Patents Act, the Industrial Property Office may grant a compulsory licence if an important public interest is endangered.

In a decision granting the compulsory licence, the Office will set out the conditions, scope and duration of the licence, taking into account circumstances of the case. It can be mainly granted to ensure supplies for the domestic market.

The compulsory licence cannot be assigned otherwise than as part of the transfer of an enterprise (or part thereof) that is allowed to use the licence.

The Office will, at the patentee's request, revoke the compulsory licence or change its conditions, where (i) the patentee proves that the circumstances for granting the licence have changed and are unlikely to recur, or (ii) if the licensee does not use the licence for a period of 1 year, or (iii) if the licensee is in breach of conditions of the licence.

The licensee can waive its right to use to licence by notifying the Office.

The patentee is entitled to a licence fee. If there is no agreement between the parties, the court may determine the amount of the licence fee, taking into account importance of the invention and usual licence fees in the given field of technology.

b Has this law been used in previous health emergencies and/or in the present COVID-19 pandemic?

We are not aware of any such use.

In view of the COVID-19 pandemic, has your country enacted any new patent law intended to facilitate the treatment of patients infected by COVID-19?

No.

Does your national patent law currently provide for the compulsory licensing of a patent by a third party, which is likely to be of relevance in a pandemic such as COVID-19 in particular by meeting a short term need to treat patients infected by COVID-19?

Yes – section 20 (2) of the Czech Patents Act allows for the granting of a compulsory licence in cases where an important public interest is endangered. Dealing with the COVID-19 pandemic and especially the associated population health risks can, in our view, be considered as such an important public interest.

a Describe in general terms the scope of the law and how it could be used by third parties to facilitate the treatment of patients infected by COVID-19.

Please see Q1 for detailed information.

b Has the compulsory licensing law been used in previous health emergencies and/or in the present COVID-19 pandemic?

We are not aware of any such use.

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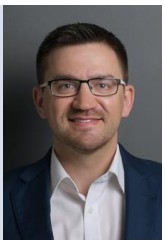

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Denmark

Does your national patent law provide in the context of a health emergency such as a pandemic like COVID-19 for the state to do or authorise others to do acts which facilitate treatment of patients and which a patentee would otherwise have the right to prevent?

Yes – Section 47 of the Danish Patent Act provides for a compulsory license in a health emergency.

a Describe in general terms the scope of the law and how it could be used by the state or third parties to facilitate the treatment of patients infected by COVID-19.

Section 47 of the Danish Patent Act states that anyone who wants to exploit an invention commercially for which another party has a patent can obtain a compulsory license when an essential public interest makes it necessary.

"Essential public interest" includes, inter alia, public interest such as national security, the supply of medicines and food, the power supply, the communication system etc.

The compulsory license may only be granted to those who have not been able to obtain a license on reasonable terms and who can be presumed to be able to use the invention in a reasonable and justifiable manner and in accordance with the license.

The compulsory license does not prevent the patentee from using the invention himself or granting a license to others.

It's the Danish Maritime and Commercial High Court at the first judicial instance that decides whether a compulsory license should be granted and determines the terms and remuneration payable for the license.

The remuneration is determined on the basis of general principles of tort law, and ordinary licensing considerations and calculations.

b Has this law been used in previous health emergencies and/or in the present COVID-19 pandemic?

We are not aware of any cases on the use of the above-mentioned compulsory license in the context of COVID-19 or previous health emergencies.

In view of the COVID-19 pandemic, has your country enacted any new patent law intended to facilitate the treatment of patients infected by COVID-19?

No, but the Danish government has published a new ministerial order in the context of COVID-19 (issued under the Act on Measures Against Infectious Deceases as amended on 17 March 2020), in effect establishing an emergency medicine plan.

The Order states, inter alia, that the Danish Medicines Agency may order that prices of medicines must not rise or may only increase with a percentage set out by the Agency. If, in the opinion of the Danish Medicines Agency, the price of a drug has risen disproportionately, the Agency may also order the company to change the price to a level determined by the Agency - after which the drug must not be sold at a price deviating from the price that is set.

a Describe in general terms the scope of the new law and how it could be used by third parties to facilitate the treatment of patients infected by COVID-19.

No, but the Danish government has published a new ministerial order in the context of COVID-19 (issued under the Act on Measures Against Infectious Deceases as amended on 17 March 2020), in effect establishing an emergency medicine plan.

b Has this new law been used in the present COVID-19 pandemic?

No.

Does your national patent law currently provide for the compulsory licensing of a patent by a third party, which is likely to be of relevance in a pandemic such as COVID-19 in particular by meeting a short term need to treat patients infected by COVID-19?

Sections 45-50 of the Danish Patent Act contains provisions related to the grant of compulsory licenses.

These provisions could become relevant in the course of a pandemic such as COVID-19, not least as leverage for promoting voluntary licensing agreements.

a Describe in general terms the scope of the law and how it could be used by third parties to facilitate the treatment of patients infected by COVID-19.

A compulsory license may be granted to the public or to a private party by the Danish Maritime and Commercial High Court as the court of first instance if:

- as mentioned above, an essential public interest makes it necessary;
- a patented invention, 3 years from the grant of the patent and 4 years from the filing of the patent application, is not practiced to a reasonable extent in the country. In such circumstances the person who will practice the invention in this country can obtain a compulsory license thereto, unless there are good reasons for the failure to exploit the invention.

A dependency license may be granted where the patented invention cannot be exploited commercially without infringing another patent if the invention represents an important technical advance of significant economic importance.

The compulsory license may only be granted to those who have not been able to obtain a license on reasonable terms and who can be presumed to be able to use the invention in a reasonable and justifiable manner and in accordance with the license.

The compulsory license does not prevent the patentee from using the invention himself or granting a license to others

It's the Danish Maritime and Commercial Court that decides as the court of first instance whether a compulsory license should be granted and determines the terms and remuneration for the license.

The remuneration is determined on the basis of general principles of tort law, and ordinary license considerations and calculations.

b Has the compulsory licensing law been used in previous health emergencies and/or in the present COVID-19 pandemic?

We are not aware of any such use.

However, as mentioned above, one should bear in mind that while there is very little case law on compulsory licensing, it is generally recognized that the existence of the rules play a significant role as leverage for promoting voluntary licensing agreements.

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Finland

Does your national patent law provide in the context of a health emergency such as a pandemic like COVID-19 for the state to do or authorise others to do acts which facilitate treatment of patients and which a patentee would otherwise have the right to prevent?
Yes. The Finnish Patents Act (550/1967) includes provisions on compulsory licensing (please also see answer to Q3) in the event of considerable public interest. Please note that the Patents Act only allows expropriation of a patent by the State or another party in cases of war (or threat of war) or in relation to defense of the country. a Describe in general terms the scope of the law and how it could be used by the state or third parties to facilitate the treatment of patients infected by COVID-19. A person who wishes to commercially exploit an invention for which another person holds a patent may obtain a compulsory licence to do so under Section 47 of the Patents Act as a result of an event of a considerable public interest. This Section is of a general nature. A prerequisite for the granting of a compulsory license is that it may only be granted to a person deemed to be in a position to exploit the invention in an acceptable manner. Before filing a claim for a compulsory licence, the licensee must have made a verifiable effort to obtain, on reasonable commercial terms, a licence to the patented invention in accordance with Section 49. A compulsory licence does not prevent the proprietor of the patent from exploiting the invention himself or from granting licences under the patent. According to Section 50, Subsection 1 of the Patents Act, compulsory licences are granted by a court of law, which shall also decide the extent to which the invention may be exploited and shall determine the remuneration to be paid, and any other conditions, under the licence. In the event of a substantial change in the circumstances the court may, on request, revoke the licence or lay down new conditions. The requirement for a "considerable public interest" may relate to, for instance, public health and/or ensuring the availability of medication to the public. The general understanding seems to be that a pandemic such as COVID-19 may affect public health and/or the availability of medication to the public in such a way that a considerable public interest could exist for compulsory licensing. However, as the assessment of the existence of considerable public interest is done on a case-by-case basis there is no relevant legal guidance on the matter, it is uncertain whether considerable public interest exists due to the COVID-19 pandemic. b Has this law been used in previous health emergencies and/or in the present COVID-19 pandemic? We are not aware of any cases in which compulsory licensing under the Patents Act would have been used in the context of previous health emergencies and/or the COVID-19 pandemic.
In view of the COVID-19 pandemic, has your country enacted any new patent law intended to facilitate the treatment of patients infected by COVID-19?
No.
Does your national patent law currently provide for the compulsory licensing of a patent by a third party, which is likely to be of relevance in a pandemic such as COVID-19 in particular by meeting a short term need to treat patients infected by COVID-19?
Yes. As stated above, Section 47 of the Patents Act stipulates that compulsory licensing is possible in the event of considerable public interest. The provision on compulsory licensing does not differentiate between short and long

term usage of the license.

a Describe in general terms the scope of the law and how it could be used by third parties to facilitate the treatment of patients infected by COVID-19.

In the event of considerable public interest, a person who wishes to commercially exploit an invention for which another person holds a patent may obtain a compulsory licence to do so under Section 47 of the Patents Act. The Section is of general nature.

The requirement for a "considerable public interest" may relate to, for instance, public health and/or ensuring the availability of medication to the public. The general understanding seems to be that a pandemic such as COVID-19 may affect public health and/or the availability of medication to the public in such a way that a considerable public interest could exist for compulsory licensing. However, as the assessment of the existence of considerable public interest is done on a case-by-case basis and as noted below, there is no relevant legal guidance on the matter, it is uncertain whether considerable public interest exists due to the COVID-19 pandemic.

Please see answer to Q1(a) for more detailed information on the requirements and granting of compulsory licenses.

b Has the compulsory licensing law been used in previous health emergencies and/or in the present COVID-19 pandemic?

We are not aware of any such use.

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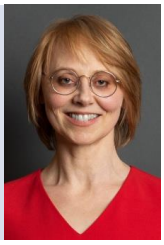

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France

Does your national patent law provide in the context of a health emergency such as a pandemic like COVID-19 for the state to do or authorise others to do acts which facilitate treatment of patients and which a patentee would otherwise have the right to prevent?

Yes - Articles L. 613-16 and L. 613-17 of the French Intellectual Property Code (hereafter "IPC") provide for a compulsory non-exclusive health license.

a Describe in general terms the scope of the law and how it could be used by the state or third parties to facilitate the treatment of patients infected by COVID-19.

Article L. 613-16 of the IPC sets 3 conditions that must be met for such a license:

1 No amicable agreement could be reached with the patent holder (please note: this condition is not required in cases of emergency or if the patent is exploited under conditions that have been judged to be anti-competitive).

The health emergency caused by the COVID-19 pandemic would allow the government to proceed without having to fulfil this condition.

2 The invention protected by the patent must be:

- a medical product, a medical device, a medical device for in vitro diagnosis, an additional therapeutic product; or
- a process for obtaining / a product necessary for obtaining / or a process for manufacturing one of the product or device mentioned above in i); or
- an ex vivo diagnostic method.

This list doesn't include patents for inventions which would prevent the spread of COVID-19 that are unrelated to a medical, therapeutic or diagnostic product/method. This license could therefore be used to facilitate the treatment of patients, but not for every aspects of the protection of the public against COVID-19, notably regarding non-medical way to prevent the spread of the virus. Furthermore, it refers to patents and it's not clear if it could also apply to patent applications or supplementary certificates of protection.

3 In cases where:

- the products resulting from these processes or these methods are made available to the public in insufficient quantity or quality or at abnormally high prices; or
- the patent is exploited under conditions contrary to the interest of public health; or
- the patent is exploited under conditions that have been judged anti-competitive by a final administrative or Court decision.

Therefore if the patent holder would not be able to manufacture/market the product/method in sufficient quantity/quality to treat patients infected by COVID-19 the government would be able to request a compulsory license to facilitate the treatment of patients by following the process set by the IPC (article R. 613-10 to R. 613-25 of the IPC).

Process to request the license:

1 Request made by the Minister in charge of the Public Health to the Minister in charge of the Industrial Property (in the current government it would be the Minister of Economy and Finance).

2 The Minister in charge of the Industrial Property will then refer the matter to a committee constituted of

professionals from the health sector and notifies the patent holder within 48 hours.

3 The patent holder and/or its licensees have fifteen days to submit comments from receipt of notification.

4 The committee must give its opinion within two months.

5 Immediately after the delivery of the committee's opinion, the Minister in charge of Industrial Property shall issue a general administrative order granting the compulsory license.

6 The order shall be notified to the patent holder, its licensees and the director of the French Industrial Property Office (INPI).

Pursuant to article L.613-17 of the IPC:

1 Failed negotiations for an amicable license (except in case of emergency or if the patent is exploited under conditions that have been judged anti-competitive)

2 Request made by the Minister in charge of the Public Health to the Minister in charge of the Industrial Property (in the current government it would be the Minister of Economy and Finance).

3 The Minister in charge of the Industrial Property will then refer the matter to a committee constituted of professionals from the health sector and notifies the patent holder within 48 hours.

4 The patent holder and/or its licensees have fifteen days to submit comments from receipt of notification.

5 The committee must give its opinion within two months.

6 Immediately after the delivery of the committee's opinion, the Minister in charge of Industrial Property shall issue a general administrative order granting the compulsory license.

7 The order shall be notified to the patent holder, its licensees and the director of the French Industrial Property Office (INPI).

Pursuant to article L.613-17 of the IPC:

1 Once the order has been published, any qualified person may apply to the Minister in charge of the Industrial Property for the grant of a license.

2 A second ministerial order grants the license to the person judged qualify to exploit it. This second ministerial order establishes the scope of exploitation, notably the territory and the duration of the rights granted. This licence is always non-exclusive and the rights of the licensee are personal (the license can't be assigned or transferred to a third party)

3 It is also important to note that this license is not free; royalties must be paid by the licensee resulting from negotiations, or, failing that, set by the Court of First Instance of Paris.

However, the main issue with this system would be the important delay between the issue of the patent and the granting of the compulsory license, even if the state of emergency caused by the COVID-19 would allow the government to proceed without having to try to find an amicable agreement with the patent holder. Indeed, once initiated, this process would at least take several months.

The IPC also provides for compulsory license:

- for the protection of economic development and the public interest (Article L. 613-18);
- in case of anti-competitive practices in the field of semi-conductors technology (Article L. 613-19-1);
- for purposes of national defence (Article L. 613-19 and Article L. 613-20 which also provides the possibility to expropriate the patent holder);

However, the first two kind of compulsory license don't appear to be of use in the case of the COVID-19 pandemic and regarding the compulsory license/expropriation for purposes of national defence, it's meant to apply in case of

warfare and not during a health crisis since this situation is already regulated by Articles L. 613-16 and L. 613-17 of the IPC.

b Has this law been used in previous health emergencies and/or in the present COVID-19 pandemic?

The process for requesting a compulsory health licence has not been used since its creation in 1953.

In view of the COVID-19 pandemic, has your country enacted any new patent law intended to facilitate the treatment of patients infected by COVID-19?

Some legal and regulatory provisions adopted to fight the COVID-19 pandemic may be applied to patents.

a Describe in general terms the scope of the new law and how it could be used by third parties to facilitate the treatment of patients infected by COVID-19.

Law No. 2020-290 of March 23, 2020 on emergency measures to manage the COVID-19 pandemic declared a state of health emergency (Article 4 of the Law) and established new articles in the French Public Health Code (hereafter, the "PHC"), in particular article L. 3131-15 of the PHC which allows the Prime Minister to:

- "Order the 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. Compensation for such requisitions is governed by the Code of Defence" (Article L. 3131-15, 7° of the PHC);

- "Where necessary, take all measures to provide patients with appropriate medicines for the eradication of the health disaster" (Article L. 3131-15, 9° of the PHC).

Article L. 3131-15 of the PHC also provides that those measures "shall be strictly proportionate to the health risks incurred and appropriate to the circumstances of time and place. They shall be terminated without delay when they are no longer necessary".

Compensation for these requisitions is governed by Article L. 2234-1 of the French Defence Code.

The combination of paragraphs 7° and 9° of new Article L. 3131-15 of the PHC could be used to order the grant of a compulsory license on a patent (as well as on a patent application or on a supplementary certificate of protection) since it generally refers to "goods" and "all measures". Besides, paragraph 7° generally refers to the necessity to "fight against the sanitary disaster". Which means that it could apply to inventions related to the medical or pharmaceutical field, but also any other type of invention which can be of use to protect public health.

This law is completed by Decree No. 2020-293 of 23 March 2020 which was amended by successive decrees.

In the version of the Decree No. 2020-293 in force on April 27th, 2 articles on the conditions of requisition may be used to grant compulsory licenses to fight the COVID-19 pandemic:

- Article 12-1 I of the Decree No. 2020-293 provides that the State is empowered to order, if the health situation so warrants, the requisition of any good, service or person necessary for the proper functioning of health establishments.

- Article 12-1 VI of the Decree No. 2020-293 provides for the same right of requisition for the proper functioning of health agencies, in particular the National Agency for Medicines and Health Products and the National Public Health Agency. Notably, one of the missions of the National Public Health Agency is "At the request of the Minister responsible for health, [to] acquire, manufacture, import, store, transport, distribute and export products and services necessary for the protection of the population against serious health threats" (Article L. 1413-4 §1 of the PHC).

Therefore, the National Public Health Agency could have an instrumental role under the urgency provisions provided by Law No. 2020-290 and Decree No. 2020-293. In addition, the National Public Health Agency may also be granted a compulsory license under paragraph 2 of Article L. 1413-4 of the PHC.

Further, during one of the debates of the Senate regarding Law No. 2020-290, the Ministry of Health clearly stated that he didn't exclude the granting of compulsory licenses on the grounds of this law.

As a side note, before the promulgation of Law No. 2020-290 and Decree No. 2020-293, Articles L. 3131-8 and L.

3131-9 of the PHC already provided the possibility for (i) the State representative of the department, (ii) the prefects of defence zone. or (iii) the Prime Minister, to requisition goods or services if the influx of patients or victims or the health situation justified it. During the COVID-19 pandemic, the provisions of Article L. 3131-15 of PHC shall be applied instead of the provisions of Articles L. 3131-8 and L. 3131-9 of the PHC.

b Has this new law been used in the present COVID-19 pandemic?

We are not aware of any use of those provisions for the grant of a compulsory license.

Does your national patent law currently provide for the compulsory licensing of a patent by a third party, which is likely to be of relevance in a pandemic such as COVID-19 in particular by meeting a short term need to treat patients infected by COVID-19?

Two other articles of the French IP Code provide compulsory licence in case of:

– lack of exploitation of a patent by its holder (article L. 613-11 of the French IP Code);

– dependent inventions (article L. 613-15 of the French IP Code).

However, as described below, we don't think that it would be appropriate in the context of the COVID-19 pandemic.

a Describe in general terms the scope of the law and how it could be used by third parties to facilitate the treatment of patients infected by COVID-19.

Compulsory license for lack of exploitation

According to Article L. 613-11 of the IPC one may request a compulsory licence 3 years after the grant or 4 years after the filing of the patent application (and unless the patentee had a legitimate excuse) if:

1 the patentee has not started to exploit the invention or has not performed serious preliminary acts to do so; or

2 the patentee has not marketed the patented product in sufficient quantity to satisfy French market;

3 the patentee has stopped exploiting the invention or marketing the patented product as described in (i) or (ii) above for more than 3 years.

However, it would require several years of non-exploitation to obtain such a compulsory license, which is not compatible with the emergency of the COVID-19 crisis.

Compulsory license for dependant invention:

Article L. 613-15 of the IPC prevents the blocking of the exploitation of inventions for further development if:

– there is a lack of authorization from the dominant patent holder;

– the invention constitutes, in relation to the earlier patent, an important technical advance and is of considerable economic interest.

This compulsory license can only be used in limited cases since there needs to be an important technical advance on a basis invention. Besides, the process for obtaining such a compulsory license would be lengthy since it would be granted through a Court order.

b Has the compulsory licensing law been used in previous health emergencies and/or in the present COVID-19 pandemic?

We are not aware of any such use.

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Germany

Does your national patent law provide in the context of a health emergency such as a pandemic like COVID-19 for the state to do or authorise others to do acts which facilitate treatment of patients and which a patentee would otherwise have the right to prevent?

Yes

Sec. 13 of the German Patent Act ("GPA") in conjunction with Sec. 5(2) no. 5 of the German Act on the Prevention and Control of Infectious Diseases in Humans ("IfSG").

a Describe in general terms the scope of the law and how it could be used by the state or third parties to facilitate the treatment of patients infected by COVID-19.

Sec. 13(1) GPA authorizes the Federal Government to order that a "patent shall not have effect insofar as (...) the invention be used in the interest of public welfare or in the interest of the security of the Federation". The order stipulated in Sec. 13(1) GPA is hereafter referred to as "use order".

Primarily, a use order enables the government to use the patented teaching. However, third parties may also benefit from use orders. There is one known case decided in 1949 where use had been legally delegated by the government to a third party (Higher Regional Court of Frankfurt, BlPMZ 1949, 330).

The effect of a use order is such that covered patents have no exclusionary effect, i.e. acts such as import, manufacture, offer, putting on the market, use of a patented teaching, cannot be challenged. Due to the principle of territoriality a use order is generally limited to patents granted in Germany, e.g. German patents and German national parts of European patents.

The new legislation introduced in April 2020 in the wake of the COVID-19-pandemic, Sec. 5(2) no. 5 IfSG, is essentially a modification to Sec. 13(1) GPA in that it authorizes the Ministry of Health ("MoH") to make use orders within the context of an "epidemic situation of national importance". The MoH may alternatively instruct a subordinate. Use orders based on Sec. 5(2) no. 5 IfSG (in conjunction with Sec. 13 GPA) are limited to "an invention relating to one of the products mentioned in no. 4", which lists medicinal products, narcotics, active ingredients, starting materials and auxiliary materials for these products, medical devices, laboratory diagnostics, aids, personal protective equipment and products for disinfection.

Sec. 5(2) no. 5 IfSG does not replace Sec. 13(1) GPA meaning that the prerequisites of Sec. 13(1) GPA need to be satisfied in addition.

In the absence of a particular procedure, use orders are treated according to the general principles of administrative law. They are administrative acts ("Verwaltungsakt") that must comply with basic principles and be executed whilst taking into account dutiful discretion ("pflichtgemäßes Ermessen").

Though sometimes disputed in legal literature, use orders are to be considered acts of expropriation by the government permissible only in exceptional cases and if adequate compensation is paid (Art. 14 of the German Constitution, Grundgesetz).

b Has this law been used in previous health emergencies and/or in the present COVID-19 pandemic?

The provision has not been applied by the Federal Government in the past.

In view of the COVID-19 pandemic, has your country enacted any new patent law intended to facilitate the treatment of patients infected by COVID-19?

The new provision of Sec. 5(2) no. 5 IfSG in connection with Sec. 13 GPA authorizes the Ministry of Health and instructed subordinate authorities to make use orders within a specific scope within the context of an "epidemic

situation of national importance".

a Describe in general terms the scope of the new law and how it could be used by third parties to facilitate the treatment of patients infected by COVID-19.

A use order according to Sec. 5(2) no. 5 IfSG, Sec. 13(1) GPA has to be made "within the context of an epidemic situation of national importance" and only if "an invention relating to one of the products mentioned in no. 4" is concerned.

Sec. 5(2) no. 4 IfSG relates to

- medicinal products, including narcotics,
- active ingredients,
- starting materials and auxiliary materials for these products,
- medical devices,
- laboratory diagnostics,
- aids,
- personal protective equipment and
- products for disinfection.

The new provision Sec. 5(2) no. 5 IfSG does not replace Sec. 13(1) GPA, but expressly refers to it, meaning that the prerequisites of Sec. 13(1) GPA (inter alia, use in the interest of public welfare) still need to be satisfied.

b Has this new law been used in the present COVID-19 pandemic?

We are not aware of any case where this new law has been used.

Does your national patent law currently provide for the compulsory licensing of a patent by a third party, which is likely to be of relevance in a pandemic such as COVID-19 in particular by meeting a short term need to treat patients infected by COVID-19?

Sec. 24 GPA provides for a possibility to obtain a (non-exclusive) compulsory license given that, inter alia:

- the patent proprietor is unwilling to grant a license and
- that "the public interest" "requires" the grant of a compulsory license.

a Does your national patent law currently provide for the compulsory licensing of a patent by a third party, which is likely to be of relevance in a pandemic such as COVID-19 in particular by meeting a short term need to treat patients infected by COVID-19?

Sec. 24 allows for compulsory licenses to be granted in cases where (i) the patent proprietor is unwilling to grant a license and where (ii) "the public interest" "requires" (or "calls for", in German: gebietet) a grant.

The first prerequisite, "unwillingness" requires that serious negotiations have taken place.

There is no settled case law on the second prerequisite ("the public interest requires the grant of a compulsory licence"). The legal literature sometimes delimits the term "public interest" from the term "public welfare" in Sec. 13 GPA (on use orders) arguing that the term "public interest" is broader. Case law on interpretation of that term is scarce. However, despite that legal discussion, the public interest needs to actually "require" ("call for) the "grant of compulsory license". This prerequisite cannot simply be satisfied by the existence of a pandemic situation. Rather, there need to be additional circumstances in the individual case in order to justify the grant of a compulsory license. For example, there could be a situation where a compulsory license is necessary to overcome

an otherwise acute and possibly life-threatening shortage of supply of medical equipment.

Generally, the threshold for the grant of a compulsory license must be high since the grant of a compulsory licence is a serious interference with the patentee's fundamental right of ownership.

Sec. 85 GPA allows for compulsory licenses according to Sec. 24 GPA to be granted on a provisional basis by way of a preliminary proceeding.

b Has the compulsory licensing law been used in previous health emergencies and/or in the present COVID-19 pandemic?

In 2016 the Federal Patent Court ("FPC") granted a compulsory licence for the use of an HIV active ingredient by way of a preliminary measure in a proceeding on the merits. The measures (Sec. 24 and 85 GPA) had been requested in defence to preliminary injunction proceedings the patentee had initiated at the Regional Court Düsseldorf.

The decisive factor for the FPC to provisionally grant a compulsory licence was that there was (i) no viable alternative to the patented active ingredient on the German market since (ii) certain patient groups existed which were dependent on the administering of said active ingredient and for which a switch to other drugs would have been practically impossible.

The compulsory license was later confirmed by the Federal Supreme Court both for the preliminary proceeding as well as for the proceeding on the merits.

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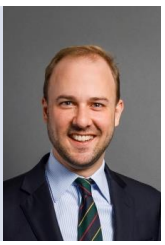

Hungary

Does your national patent law provide in the context of a health emergency such as a pandemic like COVID-19 for the state to do or authorise others to do acts which facilitate treatment of patients and which a patentee would otherwise have the right to prevent?

No. In the context of health emergencies, the Hungarian Patent Act contained provisions for compulsory licensing relating only to the manufacture of pharmaceuticals for export to countries with public health problems. However, see below for details of a new governmental decree resulting from the COVID-19 pandemic.

In view of the COVID-19 pandemic, has your country enacted any new patent law intended to facilitate the treatment of patients infected by COVID-19?

Yes, a governmental decree - Governmental Decree 212/2020 - was published in the Hungarian Official Journal which contains provisions on health emergency related compulsory licensing. This decree entered into force on 17 May 2020.

Further, recently enacted non-patent laws can provide for the possibility of the State introducing compulsory licensing provisions or requesting patent holders to provide licenses due to COVID-19. These laws are in particular, but not limited to the followings:

- Government Decree No. 40/2020 on declaration of state of emergency;
- Act XII of 2020 on Protection against Coronavirus;
- Act CXXVIII of 2011 on Disaster Management.

a Describe in general terms the scope of the new law and how it could be used by third parties to facilitate the treatment of patients infected by COVID-19.

The key provisions of Governmental Decree 212/2020 (Hungarian language version here) are as follows:

1. A compulsory license is issued by the HIPO based on the communication of the Hungarian pharma regulator (OGYÉI) in relation to domestic needs to tackle health emergency situation.
2. The subject of a compulsory license can be any of the followings:
    a. use of *medicinal product* or *active ingredient* being subject to a patent or a Supplementary Protection Certificate (SPC), or *medical device* or *investigational medicinal product* subject to a patent (referred jointly as "*health product*"); or
    b. use of *process, equipment or device necessary for manufacturing of health product*.
3. The scope of a compulsory license is limited to supply domestic needs mentioned in point 1. above.
4. The license is not exclusive and the licensor cannot issue a sub-license [note: the decree is silent on transfer of a license].
5. The period of the compulsory license is defined by the HIPO based on the information of the OGYÉI according to the needs to tackle the health emergency, but the final date of a compulsory license shall be 31 March 2021.
6. The licensor is entitled to *"appropriate" remuneration* for the compulsory license. The amount of such remuneration shall reflect the economic value of the compulsory license, in particular it shall be proportionate with a license fee which would have to paid under a normal license agreement. The remuneration is determined by the HIPO.

7. A compulsory license terminates once
    a. the licensee waives it;
    b. it expires; or
    c. the subject matter patent or SPC expires.

8. A compulsory license does not terminate if the licensee obtains a new compulsory license before the expiry of an earlier compulsory license.

9. If there is a pending litigation matter based on the relevant patent or SPC then this shall be stayed until the HIPO's decision on the compulsory license. The same applies for a pending preliminary injunction.

10. Decisions on a compulsory license shall be entered into the HIPO's patent/SPC registers and should be published in the Official Gazette of the HIPO.

11. The HIPO's decision on a request for a compulsory license is appealable according to the general rules of the Patent Act but a granted compulsory license is immediately applicable/enforceable regardless of an appeal. Practically the same applies to OGYÉI's decisions in relation compulsory licenses.

Additionally, Art 2(1) of Act XII of 2020 on Protection against Coronavirus authorizes the State to suspend the application of laws or to deviate from provisions by taking emergency measures.

This Act allows the government to limit the fundamental rights beyond what is allowed by the necessity test of the Fundamental Law of Hungary: the government may adopt laws and regulations only which are proportionate and necessary to prevent, manage and eliminate the COVID-19 pandemic and prevent or fend off its harmful effects.

Act CXXVIII of 2011 on Disaster Management regulates emergency measures in case of disasters such as COVID-19.

Art 47(4) of this Act provides the possibility of imposing obligations to conclude contracts to ensure production, supply and service obligations. Further the provisions on emergency measures can now be expanded by government decrees on the basis of the above mentioned authorization or the government may take emergency measures directly.

b Has this new law been used in the present COVID-19 pandemic?

We are not aware of any expropriation of patents based on these provisions.

Does your national patent law currently provide for the compulsory licensing of a patent by a third party, which is likely to be of relevance in a pandemic such as COVID-19 in particular by meeting a short term need to treat patients infected by COVID-19?

Art 31-33/A of the Hungarian Patent Act provides for a compulsory license in the following cases:

1 failure to commence exploitation;

2 dependency of patents;

3 to address public health problems (under the conditions set out in Regulation (EC) No. 816/2006).

We consider that case 1) and 2) are unlikely to be of relevance, but in theory it may be referred to under certain circumstances in the context of a pandemic such as COVID-19.

We consider that case 3) may only be relevant in the context of COVID-19, in case the State prohibits the exporting of certain pharmaceutical products or active substances by decree; as such a license is generally listed as an exemption. As this is the case for the prohibition of exporting hydroxychloroquine sulphate and pharmaceutical products containing that substance from Hungary.

a Describe in general terms the scope of the law and how it could be used by third parties to facilitate the

treatment of patients infected by COVID-19.

In case of "failure to commence exploitation" pursuant to Art 31 the Metropolitan Court shall decide on the grant of a compulsory license if:

- the holder of the patent did not exploit the invention, made any effective and genuine arrangements therefor, or did not license the exploitation to others
- within Hungary
- in the interest of satisfying domestic demand
- during the four (4) years from the application date or - if this period is longer - during the three (3) years from the grant of the patent.

In case of "dependency of patents" as per Article 32 of the Hungarian Patent Act the Metropolitan Court may grant a compulsory licence to the holder of a pending patent for the exploitation of the impeding patent if:

- the patented invention cannot be exploited without infringing the impeding patent, and
- the invention of the dependent patent constitutes significant technical progress of considerable economic interest compared with the invention claimed in the impeding patent.

In both cases the applicant must demonstrate that:

- the conditions for granting such license exist
- the holder of the patent was not willing to grant a license voluntarily within a reasonable time in spite of the fact all requirements are satisfied
- he has the ability to exploit the invention to the extent required.

In both cases, a compulsory license is a non-exclusive license and may be granted predominantly for serving domestic demand.

The patent holder is entitled to appropriate remuneration for granting such license. Failing an agreement, this fee is set by the court. Similarly the extent, scope and time limit of such license is established by the court.

The holder of a compulsory license cannot grant a further license for exploitation, also there is a prohibition on assignment or transfer.

Compulsory licenses must be registered in the patent register.

b Has the compulsory licensing law been used in previous health emergencies and/or in the present COVID-19 pandemic?

We are not aware of any such use.

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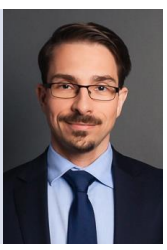

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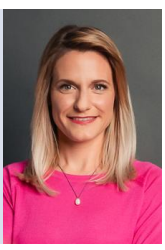

Italy

Does your national patent law provide in the context of a health emergency such as a pandemic like COVID-19 for the state to do or authorise others to do acts which facilitate treatment of patients and which a patentee would otherwise have the right to prevent?

Yes. Article 141 of the Italian IP Code provides that the State may expropriate a patent for reasons of public utility.

a Describe in general terms the scope of the law and how it could be used by the state or third parties to facilitate the treatment of patients infected by COVID-19.

The State may expropriate a patent right (even a patent not granted yet) for reasons of public utility through:

- the forced transfer of the ownership of the right; or
- a forced grant of a licence.

The right to health, endangered by a pandemic such as COVID-19, could be invoked by the State as a reason of public utility to justify the expropriation.

Expropriation is ordered by a decree of the President of the Republic, under proposal from the relevant Minister, in coordination with the Ministries of Productive Activities and of Economy and Finance, and after having heard the opinion of the Board of Appeal of the Italian Trademark and Patent Office.

The patent proprietor has the right to receive an indemnity calculated on the market value of the invention.

The decree of the President of the Italian Republic ordering the expropriation may be challenged before the Administrative Court, and the amount of the indemnity may be challenged in front of an arbitration panel.

b Has this law been used in previous health emergencies and/or in the present COVID-19 pandemic?

We are not aware of any expropriation of patents.

In view of the COVID-19 pandemic, has your country enacted any new patent law intended to facilitate the treatment of patients infected by COVID-19?

Yes.

a Describe in general terms the scope of the new law and how it could be used by third parties to facilitate the treatment of patients infected by COVID-19.

Art 6 of Law Decree no. 18/2020 may be interpreted as also affecting patents and, in particular, patented products.

Indeed this rule provides that until the end of the state of emergency declared because of COVID-19, the Head of the Department of Civil Defence can order the requisition in use or in property of medical and surgical products, as well as of movable property of any kind whatsoever, needed to cope with the health emergency.

The proprietor has the right to receive compensation in an amount calculated at the current market values that the goods had at December 31, 2019 and without taking account any variation in price or demand due to the emergency.

b Has this new law been used in the present COVID-19 pandemic?

We are not aware of any case providing the requisition of patented products.

Does your national patent law currently provide for the compulsory licensing of a patent by a third party, which is likely to be of relevance in a pandemic such as COVID-19 in particular by meeting a short term need to treat patients infected by COVID-19?

Art 70 and 71 of the Italian IP Code provides that a compulsory license may be granted for:

- failure to work/insufficient working;
- "dependent invention".

In the context of COVID-19, these rules could be invoked, even if not easily, in particular:

- for insufficient working, submitting that the patent has not been exploited sufficiently to satisfy the Country's needs to supply medicinal products/medical devices necessary to treat/ save the lives of patients affected by the virus;
- for "dependent" invention in case someone infringes the invention to implement another subsequent patent claiming devices, kits, drugs or vaccines or relevant uses to treat patients affected by COVID-19.

a Describe in general terms the scope of the law and how it could be used by third parties to facilitate the treatment of patients infected by COVID-19.

A non-exclusive compulsory license for failure to work/insufficient working may be granted by the Italian Patent and Trademark Office if:

- the patent proprietor has not implemented the invention or has implemented it to an extent that is gravely disproportionate to the Country's needs;
- three years since the grant of a patent or four years since the filing of the patent application pass, whichever comes last, or the implementation of the invention has been suspended or reduced for more than three years;
- failure to work/insufficient working is not due to causes outside the control of the patent proprietor.

A non-exclusive compulsory license for "dependent invention" may be granted:

- if the invention protected by the patent cannot be used without infringing an earlier patent;
- to the extent necessary to exploit the invention, provided that with respect to the subject of the earlier patent, the "dependent invention" represents an important technical progress of considerable economic importance.

In both cases, the applicant must:

- prove they have contacted the patent proprietor first and have been unable to obtain from him a license at fair conditions;
- not have infringed the patent, unless he can demonstrate good faith;
- pay a fair compensation to the patent proprietor and give the necessary guarantees in relation to a satisfactory implementation of the invention in accordance with the conditions set in the license.

The compulsory license is granted by decree of the Ministry of Productive Activities at the end of a procedure before the Italian Patent and Trademark Office. This procedure also provides for the exchange of written pleadings by the applicant and by the patent proprietor and should last 180 days.

b Has the compulsory licensing law been used in previous health emergencies and/or in the present COVID-19 pandemic?

We are not aware of any such use.

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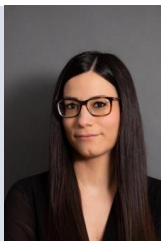

Netherlands

Does your national patent law provide in the context of a health emergency such as a pandemic like COVID-19 for the state to do or authorise others to do acts which facilitate treatment of patients and which a patentee would otherwise have the right to prevent?

Article 57 of the Dutch Patent Act ("DPA") provides for compulsory licensing in the common interest.

Apart from this provision on compulsory licensing, there are no other provisions in the law that would achieve a similar effect.

The standard remedy in patent infringement cases is an injunction. Article 3(2) of the Enforcement Directive provides that measures for enforcement should be proportionate. Article 12 provides that pecuniary compensation could take the place of other measures (such as an injunction), but this requires inter alia that the infringer acted unintentionally, which wouldn't apply if the infringer willingly infringed a patent in the interest of public health. In the Netherlands the patentee has a right to an injunction under article 3:296 of the Civil Code, unless this would constitute an abuse of its right. So far, injunctions have not been refused in full proceedings on the merits on the basis of proportionality, but a public health emergency might qualify. Proportionality is applied in preliminary injunction proceedings. However, this approach of course carries a large risk for the alleged infringer, since the court will only decide later on whether invoking proportionality was warranted.

a Describe in general terms the scope of the law and how it could be used by the state or third parties to facilitate the treatment of patients infected by COVID-19.

Article 57(1) of the DPA enables the Minister of Economic Affairs to impose a compulsory license for the "common interest". Based on the legislative history of the Dutch Patent Act, the definition of "common interest" should be understood broadly. Matters of national health will be considered in the common interest.

Except in the case of very urgent matters, the Minister must first ask the patentee whether he is willing to grant a license on reasonable terms. This means that a compulsory license can be imposed if the patentee refuses to license, or if the patentee wants to impose unreasonable terms. The law doesn't provide guidance for the content of such a license.

In case of a pandemic such as COVID-19, the Minister of Economic Affairs can take the position that taking measures is urgent and therefore there is no time for negotiations. As such, a compulsory license can be granted immediately. This decision can be appealed in the administrative court, but the Minister can decide that such appeal doesn't have suspensive effect because of the urgency.

The scope of the license will be determined by the Minister. The patentee and the licensee will have to negotiate the license fee. If no agreement is reached, each party (patentee and licensee) can request that the District Court The Hague determine the license fee.

b Has this law been used in previous health emergencies and/or in the present COVID-19 pandemic?

No. However, in a COVID-19 debate in the Dutch House of Representatives on 8 April 2020, a motion was accepted for the Netherlands to join and support a COVID-19 patent pool governed by the World Health Organisation. If the Netherlands joins the pool, it might be enforced by compulsory licensing, but so far neither has happened.

In view of the COVID-19 pandemic, has your country enacted any new patent law intended to facilitate the treatment of patients infected by COVID-19?

No

Does your national patent law currently provide for the compulsory licensing of a patent by a third party, which is likely to be of relevance in a pandemic such as COVID-19 in particular by meeting a short term need to treat patients infected by COVID-19?

The Dutch Patent Act provides for compulsory licensing at the request of a third party in the event that a patented invention is not put into practice by the patentee and in the event of the exploitation of a dependent patent, which may be used in the case of a pandemic. However, it is unlikely that these provisions can be used in preliminary injunction proceedings and therefore it would not be a timely solution. There is no case law.

a Describe in general terms the scope of the law and how it could be used by third parties to facilitate the treatment of patients infected by COVID-19.

The Dutch Patent Act ("DPA") provides for two grounds for the grant of a compulsory license at the request of a third party:

- Article 57(2) and (3) DPA: Compulsory license in the case of non-use by the patentee; and
- Article 57 (4) DPA: Compulsory license in the case of "dependency".

It is possible to obtain a compulsory license on the basis of "non-use" under articles 57(2) and 57(3) DPA if neither the patentee nor a licensee has used the patented invention in the three years after grant in the European Economic Area (or in any WTO Member State, provided that the product is made available in the Netherlands). A compulsory license will not be granted if the patentee has a valid reason not to use the invention. However, the three year period makes it unlikely that this will be suitable in the COVID-19 scenario.

The other possibility is obtaining a compulsory license in the case of "dependency", as laid down in article 57(4) DPA. This compulsory license aims to prevent the situation in which patentees of a later granted patent are unable to use the technology protected therein because of an earlier granted patent. This license is only granted in the event that the earlier patent hinders the general development of technology, or more specifically, hinders technical progress of considerable economic significance. However, since this requires that a dependent patent has been granted, it is unlikely to work in the COVID-19 scenario.

b Has the compulsory licensing law been used in previous health emergencies and/or in the present COVID-19 pandemic?

No

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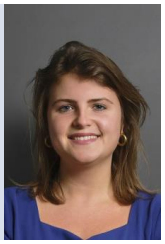

Poland

Does your national patent law provide in the context of a health emergency such as a pandemic like COVID-19 for the state to do or authorise others to do acts which facilitate treatment of patients and which a patentee would otherwise have the right to prevent?

Yes – Article 69 (1) (2) of the Industrial Property Law of 30 June 2000 (as amended).

a Describe in general terms the scope of the law and how it could be used by the state or third parties to facilitate the treatment of patients infected by COVID-19.

Article 69 (1) (2) IPL provides that a patent is not infringed upon by using the invention for state purposes to the extent necessary, without exclusivity, if such use is necessary to prevent or remove danger or threat to important interests of the State, in particular in the field of safety (including public health) and/or public order.

This provision can be invoked by a relevant minister or province governor (wojewoda), by means of an administrative decision, only in case it is not possible to prevent or remove danger or threat to important interests of the State by other means or if use of a third party patent for such purposes will enable much quicker and more effective action.

The patentee should be informed about the decision immediately. The decision should define the scope of use of the patent(s) in question as well as period during which the use will take place.

The decision can be appealed by the patentee to the Provincial Administrative Court (WSA) within 30 days of receipt of the copy of the decision.

The patentee is entitled to remuneration from the Treasury of the State for the use of his patent for the aforementioned purposes which shall be indicated in the decision and should be at the market level of licence fees for such use.

b Has this law been used in previous health emergencies and/or in the present COVID-19 pandemic?

We are not aware of any cases where this provision has been invoked in the context of COVID-19 as of 27 April 2020 or has been used in the past in health emergencies.

In view of the COVID-19 pandemic, has your country enacted any new patent law intended to facilitate the treatment of patients infected by COVID-19?

No.

Does your national patent law currently provide for the compulsory licensing of a patent by a third party, which is likely to be of relevance in a pandemic such as COVID-19 in particular by meeting a short term need to treat patients infected by COVID-19?

Yes - Articles 82 - 88 of the Industrial Property Law of 30 June 2000 (as amended).

a Describe in general terms the scope of the law and how it could be used by third parties to facilitate the treatment of patients infected by COVID-19.

The Patent Office may grant permission to use third party's patented invention (compulsory licence) among others when it is necessary to prevent or remove danger or threat to the security of the State, in particular in the field of defense, public order, protection of human life and health and/or protection of the natural environment.

In the case of such compulsory licence (contrary to other cases in which a compulsory licence can be applied for) the applicant is not required to demonstrate that he had previously made good faith efforts to obtain a licence from the patentee.

Grant of a compulsory licence is decided by the Patent Office by means of an administrative decision after the contentious proceedings between the applicant and the patentee on the motion of the applicant. Generally a hearing should be held in such proceedings, but in urgent cases, it is possible to have a decision on compulsory licence issued at a closed session.

The compulsory licence is a non-exclusive licence.

The decision should define the scope of use of the patent(s) in question, the period for which the licence is granted, the detailed conditions of the licence and indication of the licence fees due to the patentee as well as method and dates of payment.

The decision can be appealed to the Provincial Administrative Court (WSA) within 30 days of receipt of the copy of the decision.

On request the compulsory licence can be registered in the patent register of the Patent Office.

The compulsory licence can be transferred to another party only jointly with the enterprise or its part to which it is related to and used.

b Has the compulsory licensing law been used in previous health emergencies and/or in the present COVID-19 pandemic?

We are not aware of any such use.

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Singapore

Does your national patent law provide in the context of a health emergency such as a pandemic like COVID-19 for the state to do or authorise others to do acts which facilitate treatment of patients and which a patentee would otherwise have the right to prevent?

Yes – section 56 to 62 of the Patents Act (cap 221, Rev Ed 2005).

a Describe in general terms the scope of the law and how it could be used by the state or third parties to facilitate the treatment of patients infected by COVID-19.

Section 56 of the Patents Act allows the Government and any party authorized in writing by the Government to do anything in relation to a patented invention (a) for a public non-commercial purpose, or (b) for or during a national emergency or other circumstances of extreme urgency, without such acts amounting to an infringement of the patent. These acts should be limited to the supply of the patented invention predominantly in Singapore (s 60(1)(c)).

In particular, the Patents Act explicitly allows the Government or a party authorised by the Government to import a relevant health product, and do anything in relation to that health product , as long as notification has been given to the Council for TRIPS (s 56(1A)). The provisions do not extend to the re-export of such health product (s 60 (1A)).

The current COVID-19 crisis is likely to qualify as a situation of national emergency or a circumstance of extreme urgency.

Although the Act itself does not expressly define these terms, the Doha declaration on the TRIPS Agreement and Public Health (of which Singapore is part of) interprets the same terms to include public health crises, relating to HIV/AIDS, tuberculosis, malaria and other epidemics. Further, the Infectious Diseases Act (Cap 137, Rev Ed 2003) authorizes the Minister to declare a public health emergency where there is an (imminent) outbreak of an infectious disease that poses a substantial risk of a significant number of human fatalities or incidents of serious disability in Singapore.

Should a vaccine be developed and patented in Singapore, the Government can do such acts as required to supply the treatment to COVID-19 patients. The Government must inform the patentee of its acts as soon as reasonably practicable (s 61(2)), and provide remuneration at a sum to be agreed or determined by the court (s 62(1)).

Should a patented vaccine become available overseas, the Government can import and use such treatment on COVID-19 patients. No remuneration is payable, as long as the patentee has received or will receive any other remuneration for that vaccine (s 62(2)).

The right to Government use may be terminated on application of any interested party, where the circumstances that gave rise to the right have ceased to exist and are unlikely to recur (s 60(2)) – i.e. when the public health threat posed by the COVID-19 virus is eliminated.

Any disputes relating to Government use may be brought before the court by either party to the dispute (s 58(1)). The court has the discretion to refer such proceedings to arbitration (s 58(5)).

b Has this law been used in previous health emergencies and/or in the present COVID-19 pandemic?

We are not aware of any cases of Government use in the context of the present COVID-19 crisis or any other pandemic, as of 22 April 2020.

In view of the COVID-19 pandemic, has your country enacted any new patent law intended to facilitate the treatment of patients infected by COVID-19?

No

Does your national patent law currently provide for the compulsory licensing of a patent by a third party, which is likely to be of relevance in a pandemic such as COVID-19 in particular by meeting a short term need to treat patients infected by COVID-19?

Yes – section 55 of the Patents Act (cap 221, Rev Ed 2005) relates to compulsory licenses.

a Describe in general terms the scope of the law and how it could be used by third parties to facilitate the treatment of patients infected by COVID-19.

Section 55 of the Patents Act is drafted broadly and enables the court to grant a license under a patent to "remedy an anti-competitive practice" (s 55(1)).

An example of such "anti-competitive practice" is provided in section 55(2) – where there is a market for the patented invention in Singapore, and that market is not being supplied or is not being supplied on reasonable terms, and the proprietor has no reason for failing to supply this market (whether directly or through a license). There is no further guidance on section 55, absent any reported cases applying the provision in Singapore.

Since the compulsory licensing provision is worded broadly, it may be invoked to meet a short-term need to treat patients infected by the COVID-19 virus. A possible situation could be when the patent proprietor does not have enough quantities to supply a COVID-19 vaccine in Singapore, or the COVID-19 vaccine is too expensive.

The inventor or other person beneficially entitled to the patent shall receive reasonable remuneration, having regard to the economic value of the license (s 55(7)).

The license is only meant to satisfy a short-term need, since it may be terminated by the application of any interested party when the ground upon which the license was granted has ceased to exist and is unlikely to recur (s 55(5)).

b Has the compulsory licensing law been used in previous health emergencies and/or in the present COVID-19 pandemic?

We are not aware of any cases of compulsory licensing in the context of the present COVID-19 crisis or any other pandemic, as of 22 April 2020.

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Slovakia

Does your national patent law provide in the context of a health emergency such as a pandemic like COVID-19 for the state to do or authorise others to do acts which facilitate treatment of patients and which a patentee would otherwise have the right to prevent?

The Slovak Act No. 435/2001 Coll. as amended ("Patent Act") allows for compulsory licences (in Slovak: "nútená licencia") to be granted in the event that the essential (serious) public interest is threatened (for example, in the case of a war, a natural disaster or an epidemic) – Art. 27 of the Patent Act.

Please see Q3 for detailed information.

a Describe in general terms the scope of the law and how it could be used by the state or third parties to facilitate the treatment of patients infected by COVID-19.

Please see Q3 for detailed information.

b Has this law been used in previous health emergencies and/or in the present COVID-19 pandemic?

We are not aware of this law having been used in the context of the present COVID-19 crisis.

In view of the COVID-19 pandemic, has your country enacted any new patent law intended to facilitate the treatment of patients infected by COVID-19?

No

Does your national patent law currently provide for the compulsory licensing of a patent by a third party, which is likely to be of relevance in a pandemic such as COVID-19 in particular by meeting a short term need to treat patients infected by COVID-19?

The Art. 27 and foll. of the Patent Act sets out the legal criteria and options for obtaining compulsory licences (in Slovak: "nútená licencia"), as further outlined below.

Under Art. 27 (1) of the Patent Act, upon receiving a request, the court is entitled to grant a compulsory licence of a patent to any person/entity able to prove that they have the capability of exploiting an invention which is a subject-matter of a granted patent, within the territory of the Slovak Republic, provided that:

- 4 years have expired since the filing of the patent application or 3 years have expired from the grant of the patent (whichever is later);
- the person/entity requesting the grant of a compulsory licence has, prior to filing a request, offered to the patent owner a licence agreement, and this offer was not accepted by the patent owner within 3 months from its filing; and
- the invention has not been exploited within the territory of the Slovak Republic (without an appropriate reason) by the patent owner, or it has been exploited insufficiently, and the subject matter of the patented invention has not been supplied to the market of the Slovak Republic in sufficient quantities. There is a presumption that there is no appropriate reason for an invention not to have been exploited within the territory by the patent owner unless proven otherwise.

Art. 27 (4) of the Patent Act sets out an exception to the above conditions by stating that a compulsory licence may be granted in the event of an essential (serious) public interest threat notwithstanding paragraph (a) and (b) above.

In our view, as also mentioned in our response to Q1, this essential (serious) public interest could be potentially be relevant in connection with COVID-19.

a Describe in general terms the scope of the law and how it could be used by third parties to facilitate the treatment of patients infected by COVID-19.

A compulsory licence may be granted only as a non-exclusive licence, whilst its duration and scope shall be limited to the purpose for which it has been granted, on the condition that the domestic market needs shall be satisfied preferentially.

Assignment or transfer of right of a compulsory licence holder shall be possible exclusively as a part of an assignment or transfer of a company or of part of a company within which an invention is being used that is the subject of a compulsory licence.

In granting a compulsory licence, the right of a patent owner to adequate compensation shall remain unaffected.

In the event of a substantial change in the circumstances which led to the grant of a compulsory licence, the court shall be entitled, on a request of one of the parties of the licence relationship, to cancel a decision on granting a compulsory licence, providing that the re-occurrence of reasons for granting a compulsory licence is improbable or the compulsory licence rights have not been used during 1 year.

b Has the compulsory licensing law been used in previous health emergencies and/or in the present COVID-19 pandemic?

We are not aware of any such use.

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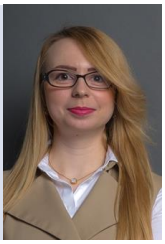

Spain

Does your national patent law provide in the context of a health emergency such as a pandemic like COVID-19 for the state to do or authorise others to do acts which facilitate treatment of patients and which a patentee would otherwise have the right to prevent?

Yes. The Spanish Act 24/2015, of 24 July, of Patents (hereinafter "Sp. PA") provides for two different legal situations that enable the State to authorise a third party to do such acts on behalf of the State in situations of emergency, such as the COVID-19 pandemic:

- Article 95 Sp. PA provides for compulsory licensing due to public interest. This regulation is developed in the Spanish Royal Decree 316/2017, of 31 March, that develops the Sp. PA in Article 86 and ff.
- In addition, Article 81 Sp.PA provides for patent expropriation.

a Describe in general terms the scope of the law and how it could be used by the state or third parties to facilitate the treatment of patients infected by COVID-19.

Compulsory licensing due to public interest

Article 95 SP. PA explicitly establishes that public interest situations include:

- Where the initiation of, increase in or generalisation of the exploitation of the invention, or the improvement of the conditions under which such exploitation takes place, is of primary importance for public health or national defence.
- Where a lack of exploitation or insufficiency in quality or quantity of the exploitation carried out would seriously harm the economic or technological development of the country.
- Where national supply needs demand it.

The Government can, at any time, submit a patent application or a patent already granted to the system of Compulsory Licenses due to public interest. This shall be approved by Royal Decree of the Government at the proposal of the Ministry of Industry, Energy and Tourism jointly with the Ministry of Health (in a case that impacts health). The Royal Decree shall establish the scope, duration and royalties or, alternatively, refer the setting of such conditions to the Spanish PTO. Once the Royal Decree is in force, the Spanish PTO will publish it in the Intellectual Property Gazette and, after that, any interested party may request the Compulsory License according to the Royal Decree before the Spanish PTO. There is an administrative procedure for this purpose. See Article 95 of the Sp. PA and Articles 86 and 87 of the Royal Decree 326/2017 that develops the Sp. PA.

Patent expropriation

Pursuant to Article 81 Sp. PA, any patent application or patent already granted may be expropriated by the State due to public utility or social interest subject to fair compensation.

A specific Act must authorize the expropriation. This Act shall state whether the invention falls into the public domain or whether the State is the one who acquires the ownership of the patent or the patent application. In the event that the patent or the patent application falls into the public domain, it may be freely exploited by anyone without the need to apply for a license. In case the patent or patent application is acquired by the State, the State acquires the ownership of the patent and the right to exploit it directly or indirectly -through third parties- and, therefore, to grant licenses.

The procedure and compensation shall be determined in accordance with the general procedure laid down in the Spanish Act of Compulsory Expropriation, of 16 December 1954 (Sp. Expropriation Act). In the event of any disagreement regarding fair compensation, the compensation shall be decided by a specific expropriation jury, in accordance with the Sp. Expropriation Act. The decision of the expropriation jury may be appealed before the administrative courts.

b Has this law been used in previous health emergencies and/or in the present COVID-19 pandemic?

We are not aware of any expropriation of patents in Spain.

In view of the COVID-19 pandemic, has your country enacted any new patent law intended to facilitate the treatment of patients infected by COVID-19?

No

Does your national patent law currently provide for the compulsory licensing of a patent by a third party, which is likely to be of relevance in a pandemic such as COVID-19 in particular by meeting a short term need to treat patients infected by COVID-19?

Yes. Article 91 Sp. PA foresees five legal cases to grant Compulsory Licenses. All of them may be relevant in different COVID-19 situations. The most relevant one is the one based on public interest explained in the answer to Q1. The others are:

- Dependence between patents, or between patents and plant varieties, without undermining prior rights (developed in Article 93 Sp. PA).
- Manufacture of pharmaceutical products for export to countries with public health problems, pursuant to Regulation (EC) No. 816/2006 of the European Parliament and of the Council, of 17 May 2006 to countries with public health subject (developed in Article 96 Sp. PA).
- Need to terminate practices that have been declared contrary to the national or EU Competition Law by a final administrative or judicial decision (developed in Article 94 Sp. PA). Where the Government decides that there are public interest reasons to terminate an anti-competitive practice, the compulsory licensing regime can be established according to the procedure of cases of "public interest declared by the Government" explained in the answer to Q1(a).
- Lack or insufficiency of exploitation of a patent within four years of the publication of its application, or within three years of the publication of its granting in the Official Industrial Property Bulletin (developed in Article 92 Sp. PA).

a Describe in general terms the scope of the law and how it could be used by third parties to facilitate the treatment of patients infected by COVID-19.

Article 100 of the Sp. PA sets out the following general features and conditions of Compulsory Licenses:

- Non- exclusive.
- Proper compensation to the patent owner according to the circumstances of the case, given the economic relevance of the invention.
- Relationship between the patent owner and the licensee is based on the principle of good faith, this includes but it is not limited to the obligation of the patent owner to make available to the licensee the technical knowledge in his/her possession that might be necessary for the proper commercial exploitation of the licensed invention.
- Coverage of the licensed patent and any supplementary protection certificate ("SPC") where the basic patent is the licensed patent, including both the SPCs granted at the time of the license or later.
- In general, before the initiation of the procedure to request a Compulsory License before the Spanish PTO, the interested party should have tried to reach an agreement with the patentee, but this is not required in the following cases: national emergency, other circumstances of extreme urgency, public non-commercial use and need to terminate practices that have been declared contrary to the national or EU Competition Law by a final administrative or judicial decision (Article 97 Sp. PA).

b Has the compulsory licensing law been used in previous health emergencies and/or in the present COVID-19 pandemic?

We are not aware of any such use.

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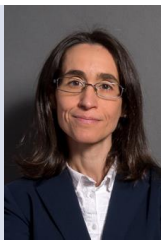

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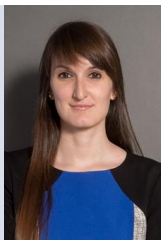

Sweden

Does your national patent law provide in the context of a health emergency such as a pandemic like COVID-19 for the state to do or authorise others to do acts which facilitate treatment of patients and which a patentee would otherwise have the right to prevent?

Yes – section 47 of chapter 6 of the Patents Act provides for compulsory licensing in cases of public interest of great importance, which covers situations of public emergency.

a Describe in general terms the scope of the law and how it could be used by the state or third parties to facilitate the treatment of patients infected by COVID-19.

The rules regarding compulsory licenses in sections 45-50 of chapter 6 of the Patents Act can be used by the authorities or by private entities to make use of patented inventions without the consent of the patent owner during periods when public interest of great importance demands it.

For Crown use to be granted, a number of prerequisites are necessary. An application for a Crown use license must be considered with regard to each and every emergency situation and the prevailing conditions of the situation, and an individual assessment must be made. In other words, the fact that there is an emergency is not sufficient in and of itself to invoke Crown use.

Furthermore, an application for a Crown use must be aimed at a specific drug and for a specified purpose. The patent owner must also first be given the opportunity to voluntarily license on reasonable commercial terms and within a reasonable time.

Therefore, before a compulsory license can be issued, attempts must be made to obtain a voluntary agreement.

What is meant by negotiating on reasonable business terms and within a reasonable time is subject to the circumstances at hand and to interpretation.

In cases where the state requires consent from the patent owner, on reasonable grounds, the state may take action against the patent owners without obtaining a license. The exclusive right is thus only revoked if the patent owner has not shown leniency and attempted negotiation.

In cases where there is a national crisis situation and/or an extreme emergency situation, such as the COVID-19 pandemic, exceptions are granted and Crown use can be used without prior negotiation, but the patent holder must then be informed within a reasonable time.

As for many other countries, the legal provisions above are motivated by the need to facilitate state action during a state emergency and prevent pharmaceutical companies from blocking access to vital medicines.

b Has this law been used in previous health emergencies and/or in the present COVID-19 pandemic?

We are not aware of any cases in the context of COVID-19.

In view of the COVID-19 pandemic, has your country enacted any new patent law intended to facilitate the treatment of patients infected by COVID-19?

No

But the legislature is very likely to pass, with great majority, new acts to facilitate Crown use of patents necessary for the prevention of, treatment of and research relating to the COVID-19 virus.

Does your national patent law currently provide for the compulsory licensing of a patent by a third party, which is likely to be of relevance in a pandemic such as COVID-19 in particular by meeting a short term need to treat patients infected by COVID-19?

Yes - a compulsory license may be granted in Sweden where:

1 it has been three years since the patent was granted and four years since the patent application was made;

2 the invention is not 'practiced' to a reasonable extent in Sweden; and

3 there is no acceptable reason why the invention is not practiced.

Applying point 2 above, the practice of an invention is equated with the import of the invention into Sweden from a State in the European Economic Area or a State affiliated to or an area affiliated to the World Trade Organization (WTO) Agreement.

a Describe in general terms the scope of the law and how it could be used by third parties to facilitate the treatment of patients infected by COVID-19.

A non-exclusive compulsory license for failure to work/insufficient working may be granted by the Stockholm District court.

However, the decisions of the European Court of Justice on 18.2.1992 in Cases C-30/90 and C-235/89 contravene national compulsory licensing rules if they provide for compulsory licensing when an invention is not exercised in a Member State but the need for the invention is met by imports from another Member State.

Nevertheless the preparatory legislative papers for the Swedish Patents Act state that if the patent holder sets conditions for third parties in order for those third parties to be given the opportunity to use the invention which are not acceptable and which limit access to the invention (such as requiring that patients need to send diagnostic samples abroad in an unmotivated way), this may be an important factor in the assessment of whether there is reasonable access to the invention. Thus, the fact that the invention is offered in any EEA state or WTO member does not necessarily mean that the requirement of reasonable exercise is met.

Since the question has arisen in relation to a pandemic the provisions above are not of any significant relevance.

b Has the compulsory licensing law been used in previous health emergencies and/or in the present COVID-19 pandemic?

We are not aware of any such use.

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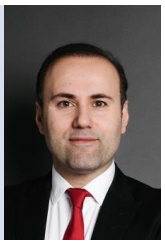

UAE

Does your national patent law provide in the context of a health emergency such as a pandemic like COVID-19 for the state to do or authorise others to do acts which facilitate treatment of patients and which a patentee would otherwise have the right to prevent?
Yes – Compulsory Licensing provisions are set out in Article 23 – 32 of the Federal Law No. 17/2002 on the Regulation and Protection of Industrial Property of Patents, Designs and Industrial Patterns (as amended) ("UAE Patent Law"). a Describe in general terms the scope of the law and how it could be used by the state or third parties to facilitate the treatment of patients infected by COVID-19. Under the UAE Patent Law, compulsory licenses can be granted by a decision of the Minister of Economy, if the said invention has a significant contribution to the public interest, however, this applies where the inventor "does not exploit sufficiently or at all the invention". It is unclear how this "exploitation" will be interpreted by a court, however it is likely that this requirement will be overlooked as the Patent Law provides for compulsory licensing during an emergency (which COVID-19 will undoubtedly fall under) (Article 27 and 29). The competent court may disregard the need for the applicant to show that attempts were made to obtain rights under reasonable commercial conditions if the application for the compulsory license has been dictated by a general emergency case or by a highly urgent public need. It should also be noted that the use of the patent is restricted to the licensee, however, multiple compulsory licenses can be issued. b Has this law been used in previous health emergencies and/or in the present COVID-19 pandemic? We are not aware of any cases in the context of COVID-19.
In view of the COVID-19 pandemic, has your country enacted any new patent law intended to facilitate the treatment of patients infected by COVID-19?
No.
Does your national patent law currently provide for the compulsory licensing of a patent by a third party, which is likely to be of relevance in a pandemic such as COVID-19 in particular by meeting a short term need to treat patients infected by COVID-19?
Yes - Article 24 of the UAE Patent Law sets out the conditions for obtaining a compulsory license. Under the law, "any interested party may obtain a compulsory license" providing the conditions are met. In the case of an emergency, there is no need for a lapse of at least 3 years to pass from the issuance of the patent or for the applicant to show that it made efforts to obtain a license from the patentee under reasonable commercial conditions. In the case of an emergency, some of the conditions that must be met for a compulsory license to be granted include the following: – License should not be absolute. – The license must be intended to satisfy the requirements of the local market. – The patentee should be granted fair compensation. The use of the patent is also restricted to the licensee. The license cannot be transferred to a third party except where the ownership (or part) of the licensee entity has been assigned. Such a transfer must be approved by the

competent court.

a Describe in general terms the scope of the law and how it could be used by third parties to facilitate the treatment of patients infected by COVID-19.

See response above.

b Has the compulsory licensing law been used in previous health emergencies and/or in the present COVID-19 pandemic?

We are not aware of any such use.

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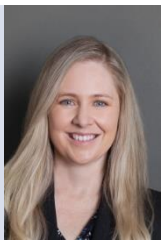

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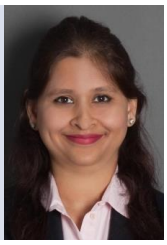

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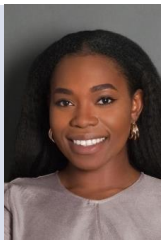

United Kingdom

Does your national patent law provide in the context of a health emergency such as a pandemic like COVID-19 for the state to do or authorise others to do acts which facilitate treatment of patients and which a patentee would otherwise have the right to prevent?

Yes – the Crown Use provisions set out in sections 55 – 59 of the UK Patents Act 1977.

a Describe in general terms the scope of the law and how it could be used by the state or third parties to facilitate the treatment of patients infected by COVID-19.

Section 55(1) of the Patents Act 1977 allows a government department or any person authorised in writing by a government department to make use of patented inventions for the services of the Crown without the consent of the patent proprietor. "Services of the Crown" include, inter alia, the production or supply of specified drugs and medicines.

Further, during periods of emergency, the definition of use for "services of the Crown" is widened (s59), for example to include the maintenance of supplies and services essential to the life of the community. This may make it easier to invoke Crown Use provisions during the COVID-19 pandemic.

Crown Use is relevant to "patented inventions", meaning an invention where a patent has already been granted or is subsequently granted. The patent proprietor is entitled to receive compensation for Crown Use, typically on terms agreed between the patent proprietor and the Government on a willing licensor/willing licensee basis. In some circumstances, loss of manufacturing profit can also be taken into account if the patent proprietor was in a position to supply the product or use the process concerned (s57A).

There is no particular procedure that needs to be followed for Crown Use. For example, the written authorisation from the Government can be given prior to the use of the patented invention, or retrospectively. The written authorisation also does not need to be directed towards specific patents; it can be a general authorisation to make use of a particular process or product. The Government should notify the patent proprietor as soon as practicable if Crown Use is relied on, but any compensation will usually be agreed later down the line.

A patent proprietor may challenge the following in court:

- the exercise by a government department, or a person authorised by a government department, of the Crown Use provisions;
- the terms for the use of an invention for the services of the Crown; and
- the compensation payable.

b Has this law been used in previous health emergencies and/or in the present COVID-19 pandemic?

Crown Use has been relied on in the past, but rarely and not in the same context as the current pandemic. Most recently, Crown Use was successfully relied on by way of a defence in a telecoms case relating to priority access to mobile phone networks for emergency services (IPCom v Vodafone [2020] EWHC 132 (Pat)). In another example, Crown Use was used to supply a patented drug (tetracycline) to the NHS (Pfizer Corp v Ministry of Health [1965] 2 WLR 387).

We are not aware of any cases on Crown Use in the context of COVID-19 as at 1 May 2020. However, with respect to the Rapidly Manufactured Ventilator System Project, we understand that the Government has indemnified suppliers for potential infringement of third-party IP rights. In order to mitigate the risk of infringement, Michael Gove pointed out, in a Departmental Minute of the Cabinet Office dated April 2020, that the Government can avail itself of the Crown Use provisions. Therefore Crown Use appears to be an option being considered by the Government in the present COVID-19 pandemic.

In view of the COVID-19 pandemic, has your country enacted any new patent law intended to facilitate the treatment of patients infected by COVID-19?
No.
Does your national patent law currently provide for the compulsory licensing of a patent by a third party, which is likely to be of relevance in a pandemic such as COVID-19 in particular by meeting a short term need to treat patients infected by COVID-19?
Yes, the UK Patents Act 1977 includes in section 46 – 54 provisions related to the grant of compulsory licences and licences of right. However, the criteria for the grant of a compulsory licence and the procedure that needs to be followed under the Patents Act 1977 are such that these provisions are unlikely to be of any relevance in the context of a pandemic such as COVID-19, and in particular the short-term need to obtain products (be they devices or therapeutic drugs or vaccines) to assist in the treatment of patients infected by COVID-19. a Describe in general terms the scope of the law and how it could be used by third parties to facilitate the treatment of patients infected by COVID-19. The Comptroller can grant a compulsory licence for use of a patent without the patent proprietor's consent in situations where, for example, the patent proprietor is not meeting demand for a patented product in the UK. However certain conditions must be met which reduce the usefulness of the compulsory licence provisions in the context of COVID-19. One requirement for compulsory licences is that the patent in question must have been granted at least 3 years prior. Further, where the patent owner is a WTO proprietor, the applicant must have unsuccessfully tried for a reasonable period of time to agree a licence with the patent owner on reasonable commercial terms. The procedural requirements for obtaining a compulsory licence at the UK IPO are also cumbersome and the process is likely to take at least several months. b Has the compulsory licensing law been used in previous health emergencies and/or in the present COVID-19 pandemic? We are not aware of any such use under the Patents Act 1977 and, as mentioned above, we do not consider it likely that compulsory licences will be relied on in the context of COVID-19.

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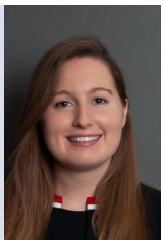

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