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The Compulsory Licensing E-Guide

An e-guide from the Global Intellectual Property Group
A legal roadmap of over 20 jurisdictions

February 2021

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Foreword

Intellectual property rights are critical for any economy that wants to foster a culture of innovation, risk taking, and entrepreneurship. Particularly in a medical context, pharmaceutical companies invest significant resources into researching, inventing, and gaining approval for new medicines to treat known and emerging diseases. Patents grant exclusive rights to the patent holders to exploit the patented product or process, enabling the pharmaceutical companies to recoup their investments and providing incentives for investing in new drugs.

However, such exclusive rights through patents can in some cases obstruct access to medicines, for example for low-income people in need of a medicine due to high prices. Particularly now, with potential COVID-19 vaccines racing through the development pipeline at dizzying speeds and some vaccines already being authorized for (emergency) use, pressure is mounting to ensure all countries have affordable access to any therapeutics or vaccines that emerge.

The COVID-19 outbreak has led to increased demand for several medicines around the world and many countries want to ensure that exclusive IP rights do not prevent them from producing enough medicine to combat COVID-19. Activists are calling for more attention to secure access to new medicines, putting pressure on lagging governments to act now so they will be able to immediately benefit from any advances in treating or preventing COVID-19. They refer to several mechanisms for guaranteeing affordable access to medicines, including issuing compulsory licenses, which allow parties to use an invention without the patent holder's consent in extraordinary circumstances. The COVID-19 pandemic has therefore once again put compulsory licensing into the spotlight.

Compulsory licensing provides a specific mechanism to bypass a patent owner's legal monopoly. However, compulsory licensing is a drastic measure, the last resort in extraordinary times or exceptional situations. So far, it has been put into practice only in rare individual cases. The analysis and implementation of *"better tools to facilitate access to critical IP in times of crisis"* is one goal of the EU Action Plan for IP (COM(2020), 760) and has put also compulsory licensing on the spot.

Even though compulsory licenses are only awarded under exceptional conditions, and where specific requirements are met, does the unprecedented scale and magnitude of the coronavirus crisis provide the right circumstances for applying this tool? Who can apply for such a compulsory license? Can the competent authority grant a compulsory licence without hearings under an urgent situation? And does the compulsory licensee have to pay a royalty to the right holder?

This guide provides a high-level overview of all such issues and requirements involving compulsory licensing over 20 jurisdictions.

We hope you find this edition of the CMS Compulsory Licensing Expert Guide an interesting read and if you would like any more detailed information and advice, please do not hesitate to get in touch with us or your named contact in the relevant country.



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Legal framework per jurisdiction

JURISDICTION: Austria

Compulsory licensing in general

1.	What is the definition of compulsory licensing?	A compulsory licence is a restriction of the effect of a patent right. The consequence of such a limitation is that the owner of the right cannot or can only to a limited extent assert his privileges from it.
2.	What are the applicable sources of law relating to compulsory licensing?	Sections 36 – 38 of the Austrian Patent Act, Sec 6 of the Austrian Plant Variety Protection Act.
3.	Types of products which compulsory licensing applies to: (a) What type(s) of products or technologies do compulsory licensing applies to? (b) Has any compulsory licence ever been issued in your jurisdiction? If yes, on what type of technology?	<p>(a) In principle, compulsory licences are possible for all patented inventions, but are only granted if the conditions set out in one of the Subsections of Sec 36 are fulfilled (see later). In Sec 36 and 37 of the Austrian Patent Act, plant variety rights and biotechnological inventions are explicitly mentioned (implementation of the Biotechnology Directive), as well as semiconductors. In Austria, compulsory licences can be granted in case of public interest. In connection with COVID-19, compulsory licences were therefore mentioned in connection with vaccines.</p> <p>(b) Compulsory licences may be recorded in the patent registry, but there is no obligation to record them and it is also not possible to search for them in the registry in a structured way. Because of this it is not possible to say with certainty if compulsory licences have ever been granted in Austria, but we have not found any indications of that in publicly available sources.</p>

Regulatory requirements on compulsory licensing

4.	Who can apply for a compulsory licence? Are foreigners or foreign companies allowed to apply for a compulsory licence?	Compulsory licences in the public interest or because of non-use are open to everyone for use in his business; the Federal Administration can request a compulsory licence in the public interest irrespective of any use in a business. Compulsory licences that are based on other grounds have more specific requirements, which are addressed in question 5. Foreigners or foreign companies are generally not excluded.
5.	What are the legal grounds to grant a compulsory licence under the local laws of your jurisdiction and any applicable international treaties?	<p>— If a patented invention cannot be commercialised without infringing an invention patented with a higher seniority (earlier patent), the owner of the later patent is entitled to a compulsory licence to the older patent if the invention protected by the later patent represents significant technical progress of considerable economic importance compared to the invention protected by the earlier patent. In case of granting a licence, the owner of the earlier patent is also entitled to a compulsory licence to the later patent.</p> <p>— If a plant breeder cannot obtain or commercialise a right to a plant variety without infringing an invention patented with a higher priority (earlier patent), he shall be entitled to a compulsory licence to the patent, provided that the plant</p>

	<p>variety represents significant technical progress of considerable economic interest compared with the invention protected by the patent and provided that this licence is necessary for commercialisation of the plant variety to be protected.</p> <ul style="list-style-type: none"> — If the holder of a patent for a biotechnological invention is granted a compulsory licence for a plant variety protected by a plant-variety right granted with a higher priority (earlier plant-variety right) because he cannot commercialise the biotechnological invention without infringing an earlier plant-variety right, the holder of the earlier plant-variety right shall be entitled to a compulsory licence to the later patent for the exploitation of the protected invention. — If a patented invention is not adequately exercised in Austria, whereby the exercise may also be effected by importing, and if the patent owner has not taken all steps necessary for such an exercise, any person shall be entitled to a compulsory licence to the patent for his business, unless the patent owner proves that the exercise of the invention in Austria is not reasonable or not reasonable to a greater extent than has been the case because of the difficulties involved in the exercise. — If the granting of a licence in respect to a patented invention is required for the public interest, any person shall be entitled to a compulsory licence in respect to the invention for his business. However, the claim of the Federal Administration in this respect is not bound to any business.
<p>6. Are there any preconditions to apply for a compulsory licence? For example:</p> <ul style="list-style-type: none"> (a) Any negotiation required between the applicant and the right holder before applying for a compulsory licence? (b) Any urgent situation required in order to grant a compulsory licence? (c) Any minimum number of years required for the patent to be granted and/or implemented in order to be subject to compulsory licensing? 	<p>Yes.</p> <ul style="list-style-type: none"> (a) The licensee must make every effort within a reasonable period of time to obtain a licence from the patent owner with reasonable terms and conditions customary in the business. If he is not successful, he can file an application with the Patent Office for the grant of a compulsory licence. (b) An urgent situation is not required to grant a compulsory licence. (c) A compulsory licence because of non-use may only be granted after four years from the application date or three years from the publication of the grant of the patent, whichever is later. For other compulsory licences, no such requirements apply.
<p>7. Are there any limits on the number of compulsory licensees?</p>	<p>No.</p>
<p>8. Will there be any limitation on the scope of the compulsory licence, for example limitations on the time and the territory?</p>	<p>Scope and duration are determined by the Austrian Patent Office and shall primarily enable supply of the Austrian market; in addition, scope and duration must be limited in accordance with the purpose for which the compulsory licence is granted.</p>
<p>9. Which authority has the competency to grant a compulsory licence?</p>	<p>The Austrian Patent Office.</p>

<p>10. Application procedure for compulsory licence:</p> <p>(a) What are the application procedures to get a compulsory licence?</p> <p>(b) What materials need to be submitted to the competent authority?</p> <p>(c) How long will it take to get a compulsory licence?</p>	<p>(a) At first, the licence applicant must attempt to reach an agreement with the patent owner. If this is not possible, the Austrian Patent Office decides on the grant of the licence and determines an appropriate remuneration.</p> <p>(b) There are no specific formal requirements. The general requirements for invalidity proceedings apply, i.e. the application must include a summary of the main facts, a sufficiently substantiated request as well as an account of the evidence to support the request.</p> <p>(c) Likely several months (in first instance), but there is an accelerated procedure available for urgent matters.</p>
<p>11. Can the competent authority grant a compulsory licence without hearings under an urgent situation?</p>	<p>In case of a national emergency or in an extremely urgent situation a compulsory licence may be granted without the need to have unsuccessfully tried to obtain the approval of the patent owner prior to filing the application. In this case, the Patent Office can only grant a preliminary approval to use the invention. Austrian law does not specify whether or not an oral hearing would take place in such proceedings and to our knowledge there is no precedent. However, from the fact that the applicant does not have to contact the patent owner to obtain approval and the preliminary nature of the decision, we would conclude that a hearing does not have to take place.</p>
<p>12. Revocation/termination of compulsory licence:</p> <p>(a) Can a compulsory licence be revoked/terminated or automatically revoked/terminated?</p> <p>(b) What are the conditions for the revocation/termination of a compulsory licence?</p> <p>(c) How should products made under a compulsory licence be treated if the compulsory licence is terminated/revoked?</p>	<p>(a) A compulsory licence may terminate automatically if its duration is limited. In addition, the Austrian Patent Office may order the termination of the licence upon request by the patent owner.</p> <p>(b) The Austrian Patent Office has to order the termination of the compulsory licence if the conditions that led to its grant have ceased to exist and are likely not to occur again. In deciding upon a request for termination, the Patent Office has to take into account the legitimate interests of the licensees.</p> <p>(c) Austrian law does not specify that. We would expect this to be addressed by a decision of the Patent Office that terminates the licence.</p>
<p>Rights and obligations of the right holders in relation to compulsory licensing</p>	
<p>13. Royalty:</p> <p>(a) Does the compulsory licensee have to pay a royalty to the right holder?</p> <p>(b) If the compulsory licensee is required to pay a royalty, how is the amount of royalty determined and who will decide the amount of the royalty?</p> <p>(c) Is there any remuneration available for the right holders other than royalty?</p>	<p>(a) Yes.</p> <p>(b) The patent owner is entitled to reasonable compensation taking into account the commercial value of the licence. It is determined by the Patent Office if no agreement with the patent owner can be reached.</p> <p>(c) The Austrian Patent Act does not specify the nature of the compensation, so it can be in form of a lump sum, a royalty or another form of compensation. In addition, the Patent Office may request a security deposit.</p>

14. Are there any legal remedies for the party who is not satisfied with the compulsory licensing decision of the competent authority?	The decision of the Austrian Patent Office is subject to appeal to the Vienna Higher Regional Court (and in some cases to the Supreme Court as a court of third instance).
15. Provision of know-how and support: (a) In order to implement the compulsory licence, for example, to manufacture the licenced product, is the right holder required to provide necessary support, such as know-how and training as in a voluntary agreed licence agreement? (b) Will this provision of know-how and support be compensated and how is the amount of such compensation determined?	(a) The Patent Office has to take into account the nature of the invention and the circumstances of the case. If warranted by specific circumstances, it may therefore order know-how and training. (b) The Patent Office has to provide reasonable compensation. If it would be reasonable to compensate for know-how and support. Such compensation would in our view have to include a component for know-how and support.
16. Confidentiality: (a) Is the compulsory licensee subject to any confidentiality obligation? (b) If the compulsory licensee discloses the confidential information in violation of its obligation, does the right holder have a basis of claim against the compulsory licensee?	(a) There are no specific provisions under Austrian law addressing confidentiality obligations in connection with compulsory licences. We assume that the Patent Office may provide for confidentiality obligations of the licensee in its decision if warranted by the nature of the invention and/or the circumstances of the case. (b) Generally, in Austria, legal action can be taken in case of a violation of a confidentiality agreement. This would also apply to the breach of a confidentiality obligation that is part of a compulsory licence grant.
17. Export of products under compulsory licence (a) Is the compulsory licensee allowed to export their products under the compulsory licence? (b) If the compulsory licensee is permitted to export products under the compulsory licence, are there any requirements and limitations on the export of such products?	(a) The Austrian Patent Act provides that the compulsory licence is primarily granted for the supply of the domestic market. It appears therefore, that export restrictions may be imposed. However, such restrictions must be in compliance with the rules governing the free movement of goods within the EU. (b) See (a) above.
Compulsory licensing in the present COVID-19 pandemic	
18. Have the laws on compulsory licensing been used in previous health emergencies and/or in the present COVID-19 pandemic in your jurisdiction?	They have not been used in the past or in the present situation, but compulsory licensing was discussed in the media in relation to COVID-19 medicines and vaccines.

19.	Is it possible for third parties to use the current laws on compulsory licensing in your jurisdiction to facilitate the treatment of patients infected by COVID-19?	Yes, if they are able to demonstrate that granting a compulsory licence is in the public interest.
20.	Are there any recent major regulatory exemptions and/or amendments made following COVID-19 to regulations governing compulsory licensing?	No.
Transactions and dealings of products under compulsory licences		
21.	Can a compulsory licence be transferred or assigned?	According to Sec 38 of the Austrian Patent Act, most compulsory licences may be transferred among the living without the consent of the patent owner only together with the part of the enterprise or business entitled to the licence and shall, in case of death, pass to the legal successors only if that part of the enterprise or business entitled to the licence is continued by them. A licence granted under Section 36 (1) in respect to an earlier patent is not transferable unless it is transferred together with the transfer of the later patent.
22.	Does the issuance of a compulsory licence have any impact on the previously agreed licence?	The Patent Act does not address this situation. This would be governed by the contract with the licensee.
23.	Is there any special labelling requirement for the products made under the compulsory licence?	No, but the Patent Office may order such requirements in its decision granting the compulsory licence.
24.	Is there any special distribution channel requirement for the products made under the compulsory licence?	No, but the Patent Office may order such requirements in its decision granting the compulsory licence.
25.	Is there any price requirement for the products made under the compulsory licence?	No, but the Patent Office may order such requirements in its decision granting the compulsory licence.

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JURISDICTION: Bosnia and Herzegovina

Compulsory licensing in general

1. What is the definition of compulsory licensing?	<p>The legislation of Bosnia and Herzegovina ("BiH") does not expressly define the compulsory licence.</p> <p>However, under the Patent Law of Bosnia and Herzegovina, if the right holder refuses to assign the right to the economic exploitation of a protected invention in BiH or imposes unreasonable conditions for such assignment without having made effective and serious preparations for the exploitation thereof in BiH, the Court of BiH may grant a compulsory licence at the request of an interested party. Additionally, the Council of Ministers of BiH may grant a compulsory licence if the exploitation of the invention protected by a patent is necessary for the benefit of national emergencies as prescribed by the competent law.</p> <p>In relation to the Law on Protection of New Plant Varieties in BiH, the Administration of Bosnia and Herzegovina for Plant Health Protection, based on the request of an interested party, may grant a compulsory licence when the usage of breeding rights is in the public interest.</p>
2. What are the applicable sources of law relating to compulsory licensing?	<ul style="list-style-type: none"> — Patent Law (2010); — Law on Protection of New Plant Varieties in BiH (2010, 2013) ("LPNPV"); — Rulebook on the procedure for awarding a patent and consensual patent (2010, 2016).
3. Types of products which compulsory licensing applies to: (a) What type(s) of products or technologies do compulsory licensing applies to? (b) Has any compulsory licence ever been issued in your jurisdiction? If yes, on what type of technology?	<p>(a) Under the Patent Law, compulsory licensing applies to a protected invention in Bosnia and Herzegovina, without specifying the products or technologies.</p> <p>The LPNPV does not specify the products or technologies to which the compulsory licence applies.</p> <p>(b) No.</p>

Regulatory requirements on compulsory licensing

4. Who can apply for a compulsory licence? Are foreigners or foreign companies allowed to apply for a compulsory licence?	<p>Any person, both legal and natural, can apply for a compulsory licence upon fulfilling the conditions (i.e. as a party with interest for obtaining such right). In regard to foreign persons, they also can apply for the subject licence. However, they may perform its activities only through the representative (i.e. natural persons and legal entities registered in the Register of Patent Representatives before the BiH's Institute for Intellectual Property or respectively in the Register of Representatives before the Administration of Bosnia and Herzegovina for Plant Health Protection).</p>
5. What are the legal grounds to grant a compulsory licence under the local laws of your jurisdiction and any applicable international treaties?	<p>Patent Law</p> <p>If the right holder refuses to grant the right of usage of protected invention or imposes unreasonable conditions without effective and serious preparations for the exploitation thereof in BiH, an interested party requesting the compulsory licence, upon expiration of the four-year period from the filing date of a patent application or after the expiration of the three-year time limit from</p>

	<p>the date of granting a patent, whichever of these two time periods expires later if unsuccessfully attempted, within a reasonable period of time, to obtain authorisation from the patent holder for the exploitation of the protected invention on reasonable commercial terms and conditions, can submit a request for granting a compulsory licence. However, the compulsory licence may not be granted if the patent holder proves the existence of legitimate reasons justifying non-exploitation or insufficient exploitation of the protected invention.</p> <p>Furthermore, the compulsory licence may be grant for somebody else's patent to the patent holder who cannot exploit his protected invention without infringing someone else's patent, provided that:</p> <ul style="list-style-type: none"> (a) a patent held by the person filing the request for a compulsory licence, in addition to fulfilling the condition stated in above paragraph, involves an important technological advance, which is of considerable economic significance in relation to the invention protected by the patent for which the grant of a compulsory licence is requested; and (b) the holder of the patent for which the grant of a compulsory licence is requested is entitled to a cross licence on reasonable terms and conditions. <p>In addition to the above conditions, the Council of Ministers of BiH may grant a compulsory licence if the exploitation of the invention protected by a patent is necessary due to national emergencies for the purpose of:</p> <ul style="list-style-type: none"> (a) state security; (b) protection of public interest in the field of health and nutrition; (c) protection and improvement of human environment; (d) special interest in a particular branch of economy or where it is necessary to correct practices determined in a judicial or administrative process to be uncompetitive. <p>LPNPV</p> <p>The compulsory licence can be granted when the usage of the breeding right is in the public interest if the interested party prove that he has at his disposal the reproductive material, professional, production-technical and financial conditions for complete usage of the breeding right.</p>
<p>6. Are there any preconditions to apply for a compulsory licence? For example:</p> <ul style="list-style-type: none"> (a) Any negotiation required between the applicant and the right holder before applying for a compulsory licence? (b) Any urgent situation required in order to grant a compulsory licence? (c) Any minimum number of years required for the patent to be granted and/or implemented in order to be subject to compulsory licensing? 	<ul style="list-style-type: none"> (a) Yes. A compulsory licence under the Patent Law may be granted only if the person filing the request for a compulsory licence unsuccessfully attempted, within a reasonable period of time, to obtain authorisation from the patent holder for the exploitation of the protected invention on reasonable commercial terms and conditions. <p>Under the LPNPV, the obligation of a negotiation between the applicant and the right holder is not specified.</p> <ul style="list-style-type: none"> (b) The urgent situation is not expressly prescribed under the Patent Law. However, the Council of Ministers of BiH may grant a compulsory licence, if the exploitation of the invention protected by a patent is necessary for the benefit of national emergencies in the prescribed cases. <p>The LPNPV does not specify the matter relating to any urgent situation required in order to grant a compulsory licence.</p>

	<p>(c) For a patent to be subject to compulsory licensing, the request for such a compulsory licence may be filed after the expiration of the four-year period from the filing date of a patent application or after the expiration of the three-year time limit from the date of the grant of a patent, whichever of these two time periods expires later.</p> <p>Under the LPNPV, for a breeding right to be subject to a compulsory licence, an interested party can submit a request for such a compulsory licence only after expiration of the five years period from the acquisition of the breeding right.</p>
7. Are there any limits on the number of compulsory licensees?	The limits on the number of compulsory licensees are not specified under the Patent Law or LPNPV.
8. Will there be any limitation on the scope of the compulsory licence, for example limitations on the time and the territory?	<p>Under the Patent Law, a compulsory licence may not be exclusive, and the scope and duration thereof shall be related exclusively to the purpose for which it was granted.</p> <p>Additionally, the compulsory licence shall be authorised primarily for the purpose of supply in the domestic market, unless it is necessary to correct practices determined in a judicial or administrative process to be uncompetitive.</p> <p>In the case of semi-conductor technology, a compulsory licence may be granted only in case of national emergencies (i.e. in the public interest).</p> <p>In relation to the LPNPV, the compulsory licence shall be granted for a period of three years, with the possibility of an extension if it is determined that there are conditions for its re-acquisition.</p>
9. Which authority has the competency to grant a compulsory licence?	<p>Under the Patent Law, the Court of Bosnia and Herzegovina has the competency in procedure of granting a compulsory licence. Exceptionally, in the case of granting a compulsory licence due to public interest, (i.e. a national emergency), the Council of Ministers of BiH shall be the competent authority.</p> <p>Under the LPNPV, the Administration of Bosnia and Herzegovina for Plant Health Protection has competence over granting a compulsory licence.</p>
<p>10. Application procedure for compulsory licence:</p> <p>(a) What are the application procedures to get a compulsory licence?</p> <p>(b) What materials need to be submitted to the competent authority?</p> <p>(c) How long will it take to get a compulsory licence?</p>	<p>(a) Under the Patent Law and LPNPV, an interested party who requests that a compulsory licence to be granted must submit a request for the same to the competent authority.</p> <p>(b) Materials needed to be submitted to the competent authority for granting a compulsory licence are not expressly specified by the Patent Law or LPNPV.</p> <p>However, under the Rulebook on the procedure for awarding a patent and consensual patent, the following information/documents are required to change the entry in the patent registry (i.e. applicable to the registration of a licence):</p> <ul style="list-style-type: none"> — an explicit indication that a change in the registry is requested; — number of the patent application or patent; — information on the requester (last name, first name and residence of the natural person, or company name and registered seat of the legal entity, unique identification number of natural persons or identification number of the legal entity);

	<ul style="list-style-type: none"> — information on the applicant (i.e. patent holder, last name, first name and residence of natural person, or company name and registered seat of the legal entity); — signature of the requester or a representative; — indication on the type of subject change; — proof of legal basis in relation to change for which the registration is requested (contract, public document, statement) if there has been a change in the person who is the applicant and the patent holder; — proper power of attorney if the procedure for changes is initiated through a representative. <p>(c) The period for obtaining the compulsory licence is not specified under the Patent Law or LPNPV, nor is any information from the case law available as no compulsory licence has been issued.</p>
11. Can the competent authority grant a compulsory licence without hearings under an urgent situation?	<p>BiH's legislation does not expressly prescribe the urgent situation in relation to the compulsory licence.</p> <p>However, under the Patent Law, the Council of Ministers of BiH may grant a compulsory licence if the exploitation of an invention protected by a patent is necessary for the benefit of national emergencies in prescribed cases, and such a situation is not subject of prior negotiations with the patent holder.</p>
<p>12. Revocation/termination of compulsory licence:</p> <p>(a) Can a compulsory licence be revoked/terminated or automatically revoked/terminated?</p> <p>(b) What are the conditions for the revocation/termination of a compulsory licence?</p> <p>(c) How should products made under a compulsory licence be treated if the compulsory licence is terminated/revoked?</p>	<p>(a) Compulsory licence can be terminated automatically if the time period for which it was granted expires.</p> <p>(b) In addition to the condition outlined under item (a), under the Patent Law the compulsory licence can be cancelled by the competent authority based on the reasoned request of an interested party if and when the circumstances which led to the authorisation thereof cease to exist and are unlikely to recur, but provided that the legitimate rights of the licensee are protected.</p> <p>Under the LPNPV, the matter regarding the revocation/termination of a compulsory licence, in addition to item (a) above, is not expressly specified.</p> <p>(c) The matter treating the products made under a compulsory licence if such is terminated/revoked is not specified under the Patent Law or LPNPV.</p>
Rights and obligations of the right holders in relation to compulsory licensing	
<p>13. Royalty:</p> <p>(a) Does the compulsory licensee have to pay a royalty to the right holder?</p> <p>(b) If the compulsory licensee is required to pay a royalty, how is the amount of royalty determined and who will decide the amount of the royalty?</p>	<p>(a) Yes.</p> <p>(b) The patent holder shall be entitled to remuneration taking into account the economic value of a licence and the need for correcting uncompetitive practices. The Patent Law does not specify who will determine the amount of the royalty.</p> <p>Under the LPNPV, the holder of a compulsory licence has the obligation to pay a fair fee to the holder of the breeding right determined by an agreement of both parties, and if no agreement is reached, the amount of the fee and the method of payment shall be determined by the competent court.</p>

(c) Is there any remuneration available for the right holders other than royalty?	(c) The matter relating to any additional remuneration other than royalty is not specified under the Patent Law or LPNPV.
14. Are there any legal remedies for the party who is not satisfied with the compulsory licensing decision of the competent authority?	This is not expressly specified under the Patent Law or LPNPV, but discretionary remedies may be issued depending on the competent authority.
15. Provision of know-how and support: (a) In order to implement the compulsory licence, for example, to manufacture the licenced product, is the right holder required to provide necessary support, such as know-how and training as in a voluntary agreed licence agreement? (b) Will this provision of know-how and support be compensated and how is the amount of such compensation determined?	Not specified under the Patent Law or LPNPV.
16. Confidentiality: (a) Is the compulsory licensee subject to any confidentiality obligation? (b) If the compulsory licensee discloses the confidential information in violation of its obligation, does the right holder have a basis of claim against the compulsory licensee?	The provisions regarding the obligation of confidentiality are not specified under the Patent Law or LPNPV.
17. Export of products under compulsory licence (a) Is the compulsory licensee allowed to export their products under the compulsory licence? (b) If the compulsory licensee is permitted to export products under the compulsory licence, are there any requirements and limitations on the export of such products?	(a) A compulsory licence shall be authorised primarily for the purpose of supply in domestic market, unless it is necessary to correct the practices determined in a judicial or administrative process to be uncompetitive. Export of products under compulsory licences is not specified under the LPNPV. (b) Regarding the permit to export products and its potential limitations under the compulsory licence, this matter is not specified under the Patent Law or LPNPV.
Compulsory licensing in the present COVID-19 pandemic	
18. Have the laws on compulsory licensing been used in previous health emergencies and/or in the present COVID-19 pandemic in your jurisdiction?	No.

<p>19. Is it possible for third parties to use the current laws on compulsory licensing in your jurisdiction to facilitate the treatment of patients infected by COVID-19?</p>	<p>Generally, such a situation is possible.</p> <p>Under the Patent Law, the Council of Ministers of BiH may grant a compulsory licence if the exploitation of the invention protected by a patent is necessary due to national emergencies for the purpose of:</p> <ul style="list-style-type: none"> (a) state security; (b) protection of the public interest in the field of health and nutrition; (c) protection and improvement of the human environment; (d) special interest in a particular branch of the economy or where it is necessary to correct practices determined in a judicial or administrative process to be uncompetitive. <p>In this case, the provisions regarding the obligation of prior negotiations with the patent holder shall not apply.</p> <p>Moreover, under the LPNPV, the Administration of Bosnia and Herzegovina for Plant Health Protection may grant the compulsory licence when the usage of breeding rights is in the public interest and upon fulfilling the prescribed requirements.</p>
<p>20. Are there any recent major regulatory exemptions and/or amendments made following COVID-19 to regulations governing compulsory licensing?</p>	<p>No.</p>
<p>Transactions and dealings of products under compulsory licences</p>	
<p>21. Can a compulsory licence be transferred or assigned?</p>	<p>In relation to the transfer of a compulsory licence under the Patent Law, the same may be transferred only together with the production plant or the part thereof in which the invention for which it was granted is exploited.</p> <p>If the compulsory licence is granted based on the dependable patent (i.e. if the patent holder cannot exploit his protected invention without infringing somebody else's patent as described under the question no. 5 above), the licence is not transferrable, except in the case of simultaneous transfer of the patent for which it was granted.</p> <p>Under the LPNPV, transfer or assignment of a compulsory licence is not specified.</p>
<p>22. Does the issuance of a compulsory licence have any impact on the previously agreed licence?</p>	<p>The impact of the issuance of a compulsory licence on the previously agreed licence is not specified under the Patent Law or LPNPV.</p>
<p>23. Is there any special labelling requirement for the products made under the compulsory licence?</p>	<p>The matter relating to the special labelling requirement for the products made under the compulsory licence is not specified under the Patent Law or LPNPV.</p>
<p>24. Is there any special distribution channel requirement for the products made under the compulsory licence?</p>	<p>Under the Patent Law, a compulsory licence shall be authorised primarily for the purpose of supply in the domestic market, unless it is necessary to correct the practices determined in a judicial or administrative process to be uncompetitive.</p> <p>In relation to LPNPV, the special distribution channel requirement for the products made under the compulsory licence is not specified.</p>

<p>25. Is there any price requirement for the products made under the compulsory licence?</p>	<p>There is no price requirement for the products made under the compulsory licence specified under the Patent Law or LPNPV.</p>
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JURISDICTION: Bulgaria

Compulsory licensing in general

1.	What is the definition of compulsory licensing?	Compulsory licensing refers to the legal mechanism that the Bulgarian Patent Office authorises others to implement a patent without the permission of the patent holder according to the law under certain circumstances.
2.	What are the applicable sources of law relating to compulsory licensing?	<ul style="list-style-type: none"> — Patents and Utility Models Registration Act (1993) ("PUMRA"); — Ordinance for consideration of disputes under the Patents Act and registration of utility models. (2011) ("Ordinance")
3.	Types of products which compulsory licensing applies to: (a) What type(s) of products or technologies do compulsory licensing applies to? (b) Has any compulsory licence ever been issued in your jurisdiction? If yes, on what type of technology?	<p>(a) Compulsory licensing applies to any invention patent and utility model patent, varieties of plants.</p> <p>(b) N/A.</p>

Regulatory requirements on compulsory licensing

4.	Who can apply for a compulsory licence? Are foreigners or foreign companies allowed to apply for a compulsory licence?	<ul style="list-style-type: none"> — Any interested person or patent owner has a right to submit a request for granting or termination of a compulsory licence. The exception is that a compulsory licence shall not be granted in favour of the infringer of the patent. — Bilateral and multilateral agreements to which the Republic of Bulgaria is a party may provide for other conditions for granting a compulsory licence for patent holders by the states participating in such agreements.
5.	What are the legal grounds to grant a compulsory licence under the local laws of your jurisdiction and any applicable international treaties?	<ul style="list-style-type: none"> — Under any of the following circumstances, the Bulgarian Patent Office, based on the application of any entity or individual that is qualified to exploit an invention patent or utility model patent, grants a compulsory licence to any such entity or individual: <ul style="list-style-type: none"> (a) Where the invention has not been used for four years from the filing of the patent application or for three years from the grant of the patent, whichever is the later; (b) Within the terms under item (a), the invention has not been used to a sufficient extent to satisfy the national market, unless the holder proves a valid reason. (c) The applicant under the preceding paragraph must prove that he is able to use the invention within the framework of the requested compulsory licence. — A compulsory licence may be granted in favour of a holder whose invention is the subject of a later patent and falls within the scope of an earlier patent, and the holder of the earlier patent refuses to grant a licence on fair terms. This could be done where the invention, which is the subject of

	the later patent, constitutes important technical progress of substantial economic importance compared to the invention, which is the subject of the earlier patent. The holder of the earlier patent is entitled to a cross-licence under reasonable conditions for the use of the invention claimed in the later patent.
<p>6. Are there any preconditions to apply for a compulsory licence? For example:</p> <p>(a) Any negotiation required between the applicant and the right holder before applying for a compulsory licence?</p> <p>(b) Any urgent situation required in order to grant a compulsory licence?</p> <p>(c) Any minimum number of years required for the patent to be granted and/or implemented in order to be subject to compulsory licensing?</p>	<p>(a) It depends. A negotiation is required if the compulsory licensing is based on:</p> <ul style="list-style-type: none"> – the patentee's failure to exploit or fully exploit the patent without any legitimate reason 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; or – the exploitation of the later invention or utility model where the later patent represents a major technological advancement of remarkable economic significance compared with an earlier patent, and the exploitation of the later patent is directly dependent upon the exploitation of the earlier patent. <p>(b) No, but if public interest requires it, the Patent Office may grant a compulsory licence to exploit the patent for an invention or utility model without negotiating with the holder of the patent-protected invention.</p> <p>(c) It depends. For compulsory licensing based on an insufficient degree of exploitation to satisfy the national market, the patent has to be granted four years as of the date of filing the application for the patent.</p>
7. Are there any limits on the number of compulsory licensees?	No.
8. Will there be any limitation on the scope of the compulsory licence, for example limitations on the time and the territory?	Yes. The scope of the compulsory licence shall be determined by the purpose for which it was granted.
9. Which authority has the competency to grant a compulsory licence?	Bulgarian Patent Office
<p>10. Application procedure for compulsory licence:</p> <p>(a) What are the application procedures to get a compulsory licence?</p> <p>(b) What materials need to be submitted to the competent authority?</p> <p>(c) How long will it take to get a compulsory licence?</p>	<p>(a) The request for granting or termination of a compulsory licence shall be submitted in writing in Bulgarian, accompanied by a document for the paid fee, and with a power of attorney, when submitted through a representative. The request for granting a compulsory licence must be accompanied by evidence in support of the stated circumstances, as well as by evidence that the applicant is able to use the invention within the framework of the requested compulsory licence.</p> <p>(b) The following materials need to be submitted to the Patent Office:</p> <ul style="list-style-type: none"> – name and address of the applicant; – identification data (number and name) of the patent, for which the granting or termination of a compulsory licence is requested, as well as the name of the patent owner when he is not an applicant; – name and address of the representative when the request is submitted through a representative;

	<ul style="list-style-type: none"> – the legal interest of the applicant; – motives; – signature of the applicant and seal when the applicant is a sole trader or a legal entity. <p>(c) The Disputes department is responsible for considering requests for the granting and termination of a compulsory licence. It has nine months from the collection of all evidence in the dispute to decide on whether to grant a compulsory licence.</p>
11. Can the competent authority grant a compulsory licence without hearings under an urgent situation?	<p>Yes. Hearings are not required in the event a request for a compulsory licence is to be granted in the following circumstances:</p> <ul style="list-style-type: none"> — for the public interest; — to a proprietor of a patent whose invention is the subject of a later patent and within the extent of another earlier patent, in a case where the invention that is the subject of the later patent constitutes important technical progress of essential economic significance.
<p>12. Revocation/termination of compulsory licence:</p> <p>(a) Can a compulsory licence be revoked/terminated or automatically revoked/terminated?</p> <p>(b) What are the conditions for the revocation/termination of a compulsory licence?</p> <p>(c) How should products made under a compulsory licence be treated if the compulsory licence is terminated/revoked?</p>	<p>(a) Yes. The compulsory licence shall be terminated:</p> <ul style="list-style-type: none"> – under all circumstances if within two years of its granting the licensee has not begun to use the invention. – when the grounds for it cease to exist. <p>(b) The compulsory licence may be terminated if the licensee, within one year of its granting, has not commenced preparation for the use of the invention.</p> <p>(c) No specific provisions exist in the law.</p>
Rights and obligations of the right holders in relation to compulsory licensing	
<p>13. Royalty:</p> <p>(a) Does the compulsory licensee have to pay a royalty to the right holder?</p> <p>(b) If the compulsory licensee is required to pay a royalty, how is the amount of royalty determined and who will decide the amount of the royalty?</p> <p>(c) Is there any remuneration available for the right holders other than royalty?</p>	<p>(a) Yes.</p> <p>(b) It is not explicitly provided for in the law. However, the royalty should be market-based and agreed between the patent holder and the patent owner. In case of dispute, the royalty shall be determined by the Sofia City Court.</p> <p>(c) N/A.</p>
14. Are there any legal remedies for the party who is not satisfied with the compulsory licensing decision of the competent authority?	<p>Yes. The interested persons can submit an appeal to the Disputes Department within three months from the receipt of the decision regarding the compulsory licensing, and a document for a paid fee should be attached to it.</p>

<p>15. Provision of know-how and support:</p> <p>(a) In order to implement the compulsory licence, for example, to manufacture the licenced product, is the right holder required to provide necessary support, such as know-how and training as in a voluntary agreed licence agreement?</p> <p>(b) Will this provision of know-how and support be compensated and how is the amount of such compensation determined?</p>	<p>(a) The present law does not address this point.</p> <p>(b) The present law does not address this point.</p>
<p>16. Confidentiality:</p> <p>(a) Is the compulsory licensee subject to any confidentiality obligation?</p> <p>(b) If the compulsory licensee discloses the confidential information in violation of its obligation, does the right holder have a basis of claim against the compulsory licensee?</p>	<p>(a) The present law does not address this point.</p> <p>(b) The present patent law does not address this point, but the provisions of the Trade Secret Law should be taken into account, if applicable.</p>
<p>17. Export of products under compulsory licence</p> <p>(a) Is the compulsory licensee allowed to export their products under the compulsory licence?</p> <p>(b) If the compulsory licensee is permitted to export products under the compulsory licence, are there any requirements and limitations on the export of such products?</p>	<p>(a) Yes. For the purpose of public health, an entity satisfying the conditions for patent exploitation may request a compulsory licence for the manufacture of a generic medicine exported to:</p> <ul style="list-style-type: none"> — the world's least developed countries; — those that have informed the World Trade Organization of their intention to do so; — those listed in the OECD development assistance committee list of low-income countries. <p>(b) Yes. The following requirements will be specified in the compulsory licence-granting decision by the Patent Office:</p> <ul style="list-style-type: none"> — The amount of product manufactured under the licence shall not exceed what is necessary to meet the needs of the importing country or countries cited in the application, taking into account the amount of product manufactured under other compulsory licences granted elsewhere. — The duration of the licence shall be indicated. — The licence shall be strictly limited to all acts necessary for the purpose of manufacturing the product in question for export and distribution in the country or countries cited in the application. No product made or imported under the compulsory licence shall be offered for sale or put on the market in any country other than that cited in the application. — Products made under the licence shall be clearly identified through specific labelling or marking as manufactured under a compulsory licence.

	<ul style="list-style-type: none"> — The products shall be distinguished from those made by the rights-holder through special packaging and/or special colouring/shaping, provided that such distinction is feasible and does not have a significant impact on price. — The packaging and any associated literature shall bear an indication that the product is subject to a compulsory licence, giving the name of the competent authority and any identifying reference number, and specifying clearly that the product is exclusively for export to and distribution in the importing country or countries concerned. — Details of the product characteristics shall be made available to the customs authorities of the member states. — Before shipment to the importing country or countries, the licensee shall post on a website, communicated to the competent authority, the following information: <ul style="list-style-type: none"> – the quantities being supplied under the licence and the importing countries to which they are supplied; – the distinguishing features of the product or products concerned.
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Compulsory licensing in the present COVID-19 pandemic

18. Have the laws on compulsory licensing been used in previous health emergencies and/or in the present COVID-19 pandemic in your jurisdiction?	No.
19. Is it possible for third parties to use the current laws on compulsory licensing in your jurisdiction to facilitate the treatment of patients infected by COVID-19?	Yes, any person may apply to the Patent Office if the conditions for granting a compulsory licence, set out in Question 5, have been complied with.
20. Are there any recent major regulatory exemptions and/or amendments made following COVID-19 to regulations governing compulsory licensing?	No.

Transactions and dealings of products under compulsory licences

21. Can a compulsory licence be transferred or assigned?	Yes. It may be transferred only together with the undertaking in which the invention is the subject of such a licence.
22. Does the issuance of a compulsory licence have any impact on the previously agreed licence?	The present law does not address this point. However, compulsory licensing may only be non-exclusive, so the granting of it may not affect previously agreed upon non-exclusive licences by default.

23.	Is there any special labelling requirement for the products made under the compulsory licence?	Yes, primarily for pharmaceutical drugs. Specific labels or marks shall be indicated on the drugs manufactured under a compulsory licence clearly indicating that they are manufactured according to the compulsory licence; and the drugs shall be distinguished from those made by the rights-holder through special packaging and/or special colouring/shaping, provided that such distinction is feasible and does not have a significant impact on price.
24.	Is there any special distribution channel requirement for the products made under the compulsory licence?	Yes. At least for drugs produced under the compulsory licence, the distribution channel should be published on the relevant website of WTO. The patented pharmaceutical product, which is imported to Bulgaria under the licence, shall not be exported from Bulgaria.
25.	Is there any price requirement for the products made under the compulsory licence?	Not specified.

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JURISDICTION: Mainland China

Compulsory licensing in general

1. What is the definition of compulsory licensing?	Compulsory licensing refers to the legal mechanism enabling the China National Intellectual Property Administration (“ CNIPA ”) to authorise others to implement a patent without the permission of the patentee according to the law under certain circumstances.
2. What are the applicable sources of law relating to compulsory licensing?	<ul style="list-style-type: none"> — Patent Law of the People’s Republic of China (2008); — Implementing Rules of the Patent Law of the People’s Republic of China (2010); — Measures on Compulsory Licence of Patent Exploitation (2012); — Opinions of the General Office of the State Council on Reforming and Improving Policies on the Guaranteed Supply and Use of Generic Drugs (2018); — Seed Law of the People’s Republic of China (2015).
3. Types of products which compulsory licensing applies to: (a) What type(s) of products or technologies do compulsory licensing applies to? (b) Has any compulsory licence ever been issued in your jurisdiction? If yes, on what type of technology?	(a) Compulsory licensing applies to any invention patent, utility model patent and new varieties of plants although limitations exist under certain circumstances. For example, for a patent directed to semi-conductors, the compulsory licence shall only be granted for the public interest and be limited to the circumstance 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. (b) No.

Regulatory requirements on compulsory licensing

4. Who can apply for a compulsory licence? Are foreigners or foreign companies allowed to apply for a compulsory licence?	<ul style="list-style-type: none"> — Any entity or individual that is qualified to exploit an invention patent or utility model patent can apply for a compulsory licence. — Yes. A foreigner, a foreign enterprise or any other foreign organisation that has no regular residence or place of business in China shall entrust a legally formed patent agency to handle the compulsory licensing relevant matters.
5. What are the legal grounds to grant a compulsory licence under the local laws of your jurisdiction and any applicable international treaties?	<ul style="list-style-type: none"> — Under any of the following circumstances, the CNIPA, based on the application of any entity or individual that is qualified to exploit an invention patent or utility model patent, grant a compulsory licence to any such entity or individual: <ul style="list-style-type: none"> – where, within three years of the date when the patent right is granted and within four years 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 – 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.

	<ul style="list-style-type: none"> — If a national emergency or an extraordinary state of affairs occurs, or if the public interest requires it, the CNIPA may grant a compulsory licence to exploit the patent for an invention or utility model. — For the purposes of public health, the CNIPA may grant a compulsory licence in order to facilitate the manufacture of patented medicines and their export to countries or regions, which comply with the provisions of the relevant international treaties to which the People's Republic of China has acceded. — In the event that an invention or utility model for which a patent right has been granted 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, if the exploitation of the later invention or utility model is directly dependent upon the exploitation of the earlier invention or utility model, then the CNIPA may, upon a request from the patentee of the earlier invention or utility model, grant a compulsory licence to exploit the later invention or utility model. — Under the circumstance where a compulsory licence for exploitation is granted in accordance with the provisions of the preceding paragraph, the CNIPA may, upon the request from the patentee of an earlier invention or utility model, also grant a compulsory licence to exploit the later invention or utility model.
<p>6. Are there any preconditions to apply for a compulsory licence? For example:</p> <p>(a) Any negotiation required between the applicant and the right holder before applying for a compulsory licence?</p> <p>(b) Any urgent situation required in order to grant a compulsory licence?</p> <p>(c) Any minimum number of years required for the patent to be granted and/or implemented in order to be subject to compulsory licensing?</p>	<p>(a) It depends. A negotiation is required if the compulsory licensing is based on:</p> <ul style="list-style-type: none"> — the patentee's failure to exploit or fully exploit the patent without any legitimate reason within three years of the date when the patent right is granted and within four years of the date of filing the application for a patent; or — the exploitation of the later invention or utility model where the later patent represents a major technological advancement of remarkable economic significance, compared with an earlier patent, and the exploitation of the later patent is directly dependent upon the exploitation of the earlier patent. <p>(b) No. But If a national emergency or an extraordinary state of affairs occurs, or if the public interest requires it, the CNIPA may grant a compulsory licence to exploit the patent for an invention or utility model.</p> <p>(c) It depends. For compulsory licensing based on no exploitation or no full exploitation by the patentee without any legitimate reason, the patent has to be granted three years from the date of grant and four years from the date of filing the application for the patent.</p>
7. Are there any limits on the number of compulsory licensees?	No.
8. Will there be any limitation on the scope of the compulsory licence, for example limitations on the time and the territory?	Yes. The decision to grant a compulsory licence shall stipulate the scope and time of implementation based on the reasons for the compulsory licence.

9. Which authority has the competency to grant a compulsory licence?	“CNIPA”-China National Intellectual Property Administration.
10. Application procedure for compulsory licence: (a) What are the application procedures to get a compulsory licence? (b) What materials need to be submitted to the competent authority? (c) How long will it take to get a compulsory licence?	<p>(a) Anyone who requests a compulsory licence shall submit a written request for the compulsory licence to CNIPA and explain why, together with relevant supporting documents.</p> <p>(b) In order to qualify for the compulsory licence, a written request including the following information is required:</p> <ul style="list-style-type: none"> — Name of a contact person for the requesting party including an address, postal code, and phone number. — Nationality of the requesting party or the country or region where the registration is to be made. — Name, patent number, date of application and date of official announcement of the invention patent or utility model patent for which the compulsory licence is being requested, and the name of the patentee. — Reasons and circumstances for the request of a compulsory licence and the period for which the licence is being requested. — Name and code of the appointed agency, as well as the name, practice certificate number and phone contact of the agent designated by said agency if appointed. — The signature or seal of the requesting party, and the seal of a patent agency if such an agency is appointed. — A list of annexed documents. — Details of other relevant matters. — The request and documents pertaining to the request shall be delivered in duplicate. <p>(c) Unclear. The present law does not specify how long the CNIPA shall make its decision.</p>
11. Can the competent authority grant a compulsory licence without hearings under an urgent situation?	<p>Yes. Hearings are not required in the event a request for a compulsory licence is to be granted:</p> <ul style="list-style-type: none"> — under a national emergency or an extraordinary state of affairs, or for the public interest; or — for the purposes of public health, in order to facilitate the manufacture of patented medicines and their export to countries or regions, which comply with the provisions of the relevant international treaties to which the People's Republic of China has acceded.
12. Revocation/termination of compulsory licence: (a) Can a compulsory licence be revoked/terminated or automatically revoked/terminated? (b) What are the conditions for the revocation/termination of a compulsory licence?	<p>(a) Yes. A compulsory licence will terminate automatically if:</p> <ul style="list-style-type: none"> — the term of the compulsory licence prescribed in the decision on granting the compulsory licence expires; or — the patent for which a compulsory licence has been granted has been terminated or declared invalid. <p>(b) Besides the conditions delineated under item (a), the patentee may request CNIPA to make a decision on terminating the compulsory licence where the reasons justifying the compulsory licence cease to exist and are</p>

<p>(c) How should products made under a compulsory licence be treated if the compulsory licence is terminated/revoked?</p>	<p>unlikely to recur prior to the expiration of the valid term of the compulsory licence as specified in the decision on granting the compulsory licence.</p> <p>(c) The present law does not specify how to treat the products made under a compulsory licence if the compulsory licence is terminated/revoked.</p>
<p>Rights and obligations of the right holders in relation to compulsory licensing</p>	
<p>13. Royalty:</p> <p>(a) Does the compulsory licensee have to pay a royalty to the right holder?</p> <p>(b) If the compulsory licensee is required to pay a royalty, how is the amount of royalty determined and who will decide the amount of the royalty?</p> <p>(c) Is there any remuneration available for the right holders other than royalty?</p>	<p>(a) Yes.</p> <p>(b) Any entity or individual that obtains a compulsory licence shall pay reasonable royalties to the relevant patentee or address the issue of royalties in accordance with the provisions of the relevant international treaties to which the People's Republic of China has acceded. In the event that royalties are to be paid, the specific amount to be paid shall be subject to consultation between the two parties. In the event of failure to reach an agreement between the two parties, the CNIPA shall make a ruling.</p> <p>(c) No.</p>
<p>14. Are there any legal remedies for the party who is not satisfied with the compulsory licensing decision of the competent authority?</p>	<p>Yes. Where a patentee is dissatisfied with the decision of the CNIPA on granting a compulsory licence for exploitation, it may, within three months of receipt of the notification bring a lawsuit to the People's court.</p>
<p>15. Provision of know-how and support:</p> <p>(a) In order to implement the compulsory licence, for example, to manufacture the licenced product, is the right holder required to provide necessary support, such as know-how and training as in a voluntary agreed licence agreement?</p> <p>(b) Will this provision of know-how and support be compensated and how is the amount of such compensation determined?</p>	<p>(a) The present law does not address this point.</p> <p>(b) The present law does not address this point.</p>
<p>16. Confidentiality:</p> <p>(a) Is the compulsory licensee subject to any confidentiality obligation?</p> <p>(b) If the compulsory licensee discloses the confidential information in violation of its obligation, does the right holder have a basis of claim against the compulsory licensee?</p>	<p>(a) The present law does not address this point.</p> <p>(b) The present law does not address this point. But the right holder has a claim on the basis of trade-secrets infringement.</p>

<p>17. Export of products under compulsory licence</p> <p>(a) Is the compulsory licensee allowed to export their products under the compulsory licence?</p> <p>(b) If the compulsory licensee is permitted to export products under the compulsory licence, are there any requirements and limitations on the export of such products?</p>	<p>(a) Yes. For the purpose of public health, an entity satisfying the conditions for patent exploitation may request a compulsory licence for the manufacture of a patented drug exported to:</p> <ul style="list-style-type: none"> — a less developed country or region; or — a developed or developing country that is a WTO member, which notifies the WTO and expresses its desire to be an importer in accordance with the relevant international treaty. <p>(b) Yes. The following requirements will be specified in the compulsory licence granting decision by the CNIPA:</p> <ul style="list-style-type: none"> — the amount of drugs manufactured based on a compulsory licence shall not exceed the amount needed by the importer, and all drugs must be exported to the importer; — specific labels or marks shall be indicated on the drugs manufactured under a compulsory licence clearly indicating that they are manufactured according to the compulsory licence; — the drugs shall have specific colours or shapes, or be packed in a particular manner if it is feasible and the price of drugs will not be significantly affected; — before the shipment of drugs, the entity that has obtained the compulsory licence shall publish on its website or the relevant WTO website the amount of drugs shipped to the importer and the special production characteristics of the drugs referred to in the items above.
<p style="text-align: center;">Compulsory licensing in the present COVID-19 pandemic</p>	
<p>18. Have the laws on compulsory licensing been used in previous health emergencies and/or in the present COVID-19 pandemic in your jurisdiction?</p>	<p>No.</p>
<p>19. Is it possible for third parties to use the current laws on compulsory licensing in your jurisdiction to facilitate the treatment of patients infected by COVID-19?</p>	<p>Yes. This is feasible in theory, but difficult in practice. Historically, a compulsory licence has been used as leverage by the government to negotiate with drug companies in granting a licence. During 2005 and 2006, Roche granted two licences in China to produce a generic form of Tamiflu, an anti-viral medicine that could be used in treating bird flu. Shanghai Pharmaceutical Group was the first licensee. Shenzhen-based HEC Group was the second licensee. Guangzhou Baiyunshan Pharmaceutical Co. Ltd. applied for a compulsory licence but failed to get either the compulsory licence from CNIPA or the licence from Roche.</p>
<p>20. Are there any recent major regulatory exemptions and/or amendments made following COVID-19 to regulations governing compulsory licensing?</p>	<p>Not yet.</p>

Transactions and dealings of products under compulsory licences	
21. Can a compulsory licence be transferred or assigned?	No.
22. Does the issuance of a compulsory licence have any impact on the previously agreed licence?	The present law does not address this point.
23. Is there any special labelling requirement for the products made under the compulsory licence?	Yes, primarily for drugs. Specific labels or marks shall be indicated on the drugs manufactured under a compulsory licence clearly indicating that they are manufactured according to the compulsory licence; and the drugs shall have specific colours or shapes, or be packed in a particular manner if it is feasible and the price of drugs will not be significantly affected.
24. Is there any special distribution channel requirement for the products made under the compulsory licence?	Yes. At least for drugs produced under the compulsory licence, the distribution channel should be published on the relevant website of WTO.
25. Is there any price requirement for the products made under the compulsory licence?	The present law does not address this point.

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JURISDICTION: Czech Republic

Compulsory licensing in general

1.	What is the definition of compulsory licensing?	There is no legal definition of compulsory licence under Czech legislation.
2.	What are the applicable sources of law relating to compulsory licensing?	<p>Act No. 527/1990 Coll., on Inventions, Industrial Designs and Rationalisation Proposals;</p> <p>Act. No. 478/1992 Coll., on Utility Designs;</p> <p>Decree No. 550/1990 Coll.;</p> <p>Act No. 206/2000 Coll., on protection of biotechnological inventions;</p> <p>Act No. 408/2000 Coll., on plant variety rights protection;</p> <p>Act No. 89/2012 Coll., the Civil Code;</p> <p>Regulation (EC) No 816/2006 on compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems;</p> <p>Paris Convention for the Protection of Industrial Property;</p> <p>The Agreement on Trade-Related Aspects of Intellectual Property Rights.</p>
3.	<p>Types of products which compulsory licensing applies to:</p> <p>(a) What type(s) of products or technologies do compulsory licensing applies to?</p> <p>(b) Has any compulsory licence ever been issued in your jurisdiction? If yes, on what type of technology?</p>	<p>(a) No specific limitation on the types of products or technologies to which compulsory licensing is applicable on top of the limitations according to the subject matter of the individual legal acts.</p> <p>(b) No.</p>

Regulatory requirements on compulsory licensing

4.	Who can apply for a compulsory licence? Are foreigners or foreign companies allowed to apply for a compulsory licence?	In relation to patents, utility designs, biotechnology patents, plant variety rights, and patents and supplementary protection certificates concerning the manufacture of pharmaceutical products for export to countries with public health problems (" pharmaceutical patents "), any individual or entity who meets the legal requirements can apply for a compulsory licence, including foreigners.
5.	What are the legal grounds to grant a compulsory licence under the local laws of your jurisdiction and any applicable international treaties?	The compulsory licence to patent and utility design might be granted by the Industrial Property Office (" IPO ") upon justified request if the patent or utility design holder does not use the invention or the utility design without due reason at all or uses it insufficiently and it has not accepted a proper offer for concluding a licensing agreement. It might also be granted in case of an immediate threat to the public interest. A compulsory licence won't be granted within the first four years from the filing the patent or utility design application or within the first three years from the granting of the patent or utility design (whichever period expires later).

	<p>The compulsory licence to a biotechnology patent might be granted by the IPO to a plant or animal variety right holder who unsuccessfully negotiated with the patent holder about a licence and if the plant or animal variety is considered a technical advance of considerable economic significance compared to the biotechnological invention protected by the patent. The patent holder is entitled to a cross-licence of the plant or animal variety right of the licensee.</p> <p>The compulsory licence to a plant variety right might be granted by the Ministry of Agriculture ("MA") if the plant variety right holder refuses to grant the licence and the use of the protected plant variety is in the public interest. The compulsory licence might be also granted to the biotechnology patent holder in case the biotechnology patent cannot be used without infringement of the plant variety right and the patent holder unsuccessfully negotiated with the plant variety right holder about a licence and if the invention is considered a technical advance of considerable economic significance compared to the protected plant variety. The plant variety right holder is in the latter case entitled to cross-licence the biotechnology patent of the licensee.</p> <p>The compulsory licence to pharmaceutical products might be granted by the IPO upon a justified request when such products are intended for export to eligible importing countries in need of such products in order to address public health problems and if the applicant has made efforts to obtain authorisation from the rights holder and that such efforts have not been successful within a period of thirty days before submitting the application.</p>
<p>6. Are there any preconditions to apply for a compulsory licence? For example:</p> <p>(a) Any negotiation required between the applicant and the right holder before applying for a compulsory licence?</p> <p>(b) Any urgent situation required in order to grant a compulsory licence?</p> <p>(c) Any minimum number of years required for the patent to be granted and/or implemented in order to be subject to compulsory licensing?</p>	<p>(a) In most cases, it is required that the applicant unsuccessfully negotiated with the right holder about a contractual licence on reasonable commercial terms and conditions.</p> <p>(b) In relation to patents, utility designs and biotechnology patents, in case of threat to the public interest, the requirement of prior unsuccessful negotiations between the applicant and the right holder might be waived.</p> <p>(c) In relation to patents and utility designs, the compulsory licence won't be granted within the first four years from filing of the patent application or within the first three years from the grant of the patent (whichever period expires later). This does not apply in case of a threat to the public interest.</p>
<p>7. Are there any limits on the number of compulsory licensees?</p>	<p>No.</p>
<p>8. Will there be any limitation on the scope of the compulsory licence, for example limitations on the time and the territory?</p>	<p>Yes.</p> <p>The compulsory licence for patents, utility designs, biotechnology patents and pharmaceutical patents will be limited by the IPO.</p> <p>In addition, in relation to patents and utility designs, it shall be used primarily for deliveries to the Czech market.</p> <p>In relation to pharmaceutical patents, the amount of products manufactured under the compulsory licence shall not exceed what is necessary to meet the needs of the importing country or countries cited in the application. The duration of the licence shall be indicated. The licence shall be strictly limited to all acts</p>

	<p>necessary for the purpose of manufacturing the product in question for export and distribution in the country or countries cited in the application.</p> <p>The MA will limit the compulsory licence to plant variety rights.</p>
9. Which authority has the competency to grant a compulsory licence?	The Industrial Property Office (for patents, utility designs, biotechnology patents and pharmaceutical patents) and the Ministry of Agriculture (for plant variety rights).
<p>10. Application procedure for compulsory licence:</p> <p>(a) What are the application procedures to get a compulsory licence?</p> <p>(b) What materials need to be submitted to the competent authority?</p> <p>(c) How long will it take to get a compulsory licence?</p>	<p>The application procedure for compulsory licences is regular administrative proceedings with varying procedures for patents, utility designs, biotechnology patents and pharmaceutical patents:</p> <p>(a) The proceedings for granting a compulsory licence is initiated upon the request of the potential compulsory licensee – the application can be in electronic or paper form. Subsequently, the relevant authority will assess the request and allow both parties to provide their statements in the matter and afterwards, the relevant authority will decide on the matter;</p> <p>(b) The potential compulsory licensee must submit relevant evidence to prove that the conditions for the granting of the compulsory licence are fulfilled – any document can serve as evidence in the proceedings;</p> <p>(c) In relation to plant variety rights, the competent authority must decide within 30 days after receiving the request; in relation to patents, utility designs, biotechnology patents and pharmaceutical patents, there is no time limitation for the proceedings and there is also no prior practice that would indicate the duration.</p>
11. Can the competent authority grant a compulsory licence without hearings under an urgent situation?	No.
<p>12. Revocation/termination of compulsory licence:</p> <p>(a) Can a compulsory licence be revoked/terminated or automatically revoked/terminated?</p> <p>(b) What are the conditions for the revocation/termination of a compulsory licence?</p> <p>(c) How should products made under a compulsory licence be treated if the compulsory licence is terminated/revoked?</p>	<p>(a) Yes.</p> <p>(b) In relation to patents, utility designs and biotechnology patents, the holder might submit a request to revoke the compulsory licence if: (i) the circumstances for granting the compulsory licence have changed and are unlikely to recur; or (ii) the licensee has not used the compulsory licence for a period of one year, or the licensee does not respect the conditions required by the compulsory licence. The IPO might decide to either revoke the compulsory licence completely or amend the conditions, duration or scope of the compulsory licence.</p> <p>In relation to plant variety rights, after one year from the granting of the licence, each of the parties might submit a request to revoke or change the decision on granting the compulsory licence to the MA. The sole ground for such a request is a change of circumstances.</p> <p>In relation to pharmaceutical patents, the compulsory licence may be terminated by a decision of the IPO if the conditions of the licence are not respected by the licensee. The IPO shall review upon reasoned request by the licensor or the licensee whether the licence conditions have been respected. This review shall be based on the assessment made in the importing country where appropriate.</p>

	(c) There is no specific regulation in this regard. Therefore, general conditions on licensing shall apply.
Rights and obligations of the right holders in relation to compulsory licensing	
<p>13. Royalty:</p> <p>(a) Does the compulsory licensee have to pay a royalty to the right holder?</p> <p>(b) If the compulsory licensee is required to pay a royalty, how is the amount of royalty determined and who will decide the amount of the royalty?</p> <p>(c) Is there any remuneration available for the right holders other than royalty?</p>	<p>(a) Yes</p> <p>(b) In relation to patents, utility designs and biotechnology patents, the licensor and the licensee might reach an agreement regarding the royalty amount. If they are unable to reach an agreement, a competent court will determine the amount.</p> <p>In relation to plant variety rights, the MA will determine the amount of the royalty.</p> <p>In relation to pharmaceutical patents, the IPO shall determine the adequate remuneration as follows: (i) in cases of national emergency or other circumstances of extreme urgency or in cases of public non-commercial use under Article 31(b) of the TRIPS Agreement, the remuneration shall be in a maximum amount of 4 % of the total price paid by the importing country or on its behalf; (ii) remuneration shall be determined taking into account the economic value of the use authorised under the licence to the importing country or countries concerned, as well as humanitarian or non-commercial circumstances relating to the issue of the licence.</p> <p>(c) In relation to biotechnology patents and plant variety rights, the licensor is entitled to cross-licence the biotechnology patent or the plant variety right of the licensee.</p>
<p>14. Are there any legal remedies for the party who is not satisfied with the compulsory licensing decision of the competent authority?</p>	<p>In general, it is possible to submit an appeal against the decision of the IPO or the MA.</p> <p>Should the appeal be unsuccessful, it is possible to submit lawsuit against the decision to the relevant administrative court.</p>
<p>15. Provision of know-how and support:</p> <p>(a) In order to implement the compulsory licence, for example, to manufacture the licenced product, is the right holder required to provide necessary support, such as know-how and training as in a voluntary agreed licence agreement?</p> <p>(b) Will this provision of know-how and support be compensated and how is the amount of such compensation determined?</p>	<p>(a) Czech legislation does not explicitly specify any such rule. However, both the IPO in relation to patents, utility designs and biotechnology patents and the MA in relation to plant variety rights can specify conditions for compulsory licences.</p> <p>(b) Czech legislation does not explicitly specify any such rule. Nevertheless, we assume that it would have to be included in the royalty.</p>
<p>16. Confidentiality:</p> <p>(a) Is the compulsory licensee subject to any confidentiality obligation?</p> <p>(b) If the compulsory licensee discloses the confidential information in violation of its obligation, does the right</p>	<p>(a) Yes. Generally, the licensee shall conceal from third persons documents and information received from the licensor, unless the agreement or the nature of the underlying documents and communications indicate that the licensor has no interest in concealing them. After the termination of the licence, the licensee shall return the underlying documents; the licensee shall keep the information confidential until it becomes generally known.</p>

holder have a basis of claim against the compulsory licensee?	(b) Yes.
<p>17. Export of products under compulsory licence</p> <p>(a) Is the compulsory licensee allowed to export their products under the compulsory licence?</p> <p>(b) If the compulsory licensee is permitted to export products under the compulsory licence, are there any requirements and limitations on the export of such products?</p>	<p>(a) In relation to patents, utility designs, biotechnology patents and plant variety rights, this will depend on the individual conditions of the compulsory licence.</p> <p>In relation to pharmaceutical patents, the scope of the licence is to all acts necessary for the purpose of manufacturing the product in question for export and distribution in the country or countries specified in the application. No product made or imported under the compulsory licence shall be offered for sale or put on the market in any country other than that cited in the application (exception applies).</p> <p>(b) In relation to patents, utility designs, biotechnology patents and plant variety rights, this will depend on the individual conditions of the compulsory licence.</p>
Compulsory licensing in the present COVID-19 pandemic	
18. Have the laws on compulsory licensing been used in previous health emergencies and/or in the present COVID-19 pandemic in your jurisdiction?	No.
19. Is it possible for third parties to use the current laws on compulsory licensing in your jurisdiction to facilitate the treatment of patients infected by COVID-19?	Yes, it is possible since facilitating the treatment of patients infected by COVID-19 might be considered in the public interest, which is a legal ground on which a compulsory licence might be granted. However, currently there is no special legal regulation in connection to the COVID-19 outbreak. The third parties must, therefore, follow the standard procedure.
20. Are there any recent major regulatory exemptions and/or amendments made following COVID-19 to regulations governing compulsory licensing?	No.
Transactions and dealings of products under compulsory licences	
21. Can a compulsory licence be transferred or assigned?	In relation to patents, utility designs, biotechnology patents and pharmaceutical patents, the compulsory licence may be assigned or transferred only within the enterprise (or its part) where the compulsory licence is being used.
22. Does the issuance of a compulsory licence have any impact on the previously agreed licence?	No.
23. Is there any special labelling requirement for the products made under the compulsory licence?	<p>In relation to patents, utility designs, biotechnology patents and plant variety rights, there is no such obligation to products made under the compulsory licence.</p> <p>In relation to pharmaceutical patents, the products made under the compulsory licence shall be clearly identified, through specific labelling or marking, as being produced pursuant to the EU Regulation. The products shall be distinguished from those made by the rights holder through special packaging and/or special colouring/shaping, provided that this distinction is feasible and does not have a significant impact on price. The packaging and</p>

	any associated literature shall bear an indication that the product is subject to a compulsory licence under the EU Regulation, giving the name of the IPO and any identifying reference number, and specifying clearly that the product is exclusively for export to and distribution in the importing country or countries concerned.
24. Is there any special distribution channel requirement for the products made under the compulsory licence?	No.
25. Is there any price requirement for the products made under the compulsory licence?	No.

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Compulsory licensing in general

1. What is the definition of compulsory licensing?	There is no specific definition of compulsory licensing. However, section 48 of The Patents Act 1977 provides that “at any time after the expiration of three years, or of such other period as may be prescribed, from the date of the grant of a patent, any person may apply to the comptroller on one or more of the relevant grounds: (a) for a licence under the patent; (b) for an entry to be made in the register to the effect that licences under the patent are to be available as of right; or (c) where the applicant is a government department, for the grant to any person specified in the application of a licence under the patent”.
2. What are the applicable sources of law relating to compulsory licensing?	The Patents Act 1977 (sections 46 – 54).
3. Types of products which compulsory licensing applies to: (a) What type(s) of products or technologies do compulsory licensing applies to? (b) Has any compulsory licence ever been issued in your jurisdiction? If yes, on what type of technology?	(a) Any product that is not in the field of “semi-conductor technology” (Section 48A(3) of The Patents Act 1977). (b) Yes, the most recent compulsory licence issued was in Swansea Imports Limited and Carver Technology Limited on 10 June 2004 (https://www.ipo.gov.uk/p-challenge-decision-results/o17004.pdf). The technology concerned was different aspects of heater units. Details can be found in the following article: https://e-courses.epo.org/wbts_int/CompulsoryLicensing/CL_GB.pdf]

Regulatory requirements on compulsory licensing

4. Who can apply for a compulsory licence? Are foreigners or foreign companies allowed to apply for a compulsory licence?	Any person may apply to the IPO for a compulsory licence (section 48(1) of The Patents Act 1977).
5. What are the legal grounds to grant a compulsory licence under the local laws of your jurisdiction and any applicable international treaties?	<p>In the case of an application made in respect to a patent with a WTO proprietor, a licence may be granted under the grounds of (i) where the patented invention is a product, that a demand in the UK for that product is not being met on reasonable terms; (ii) refusal to grant licences on reasonable terms that lead to the exploitation in the UK of any other patented invention, which involves an important technical advance of considerable economic significance or unfairly prejudices the establishment or development of commercial or industrial activities in the UK; (iii) that by reason of conditions imposed by the proprietor of the patent concerned on the grant of licences under the patent, or on the disposal or use of the patented product or on the use of the patented process, the manufacture, use or disposal of materials not protected by the patent, or the establishment or development of commercial or industrial activities in the UK is unfairly prejudiced.</p> <p>(Section 48A of The Patents Act 1977)</p> <p>In any other case, a compulsory licence may be granted under the grounds of:</p> <p>(a) the patented invention is capable of being commercially worked in the UK, that it is not being so worked or is not</p>

	<p>being so worked to the fullest extent that is reasonably practicable;</p> <p>(b) where the patented invention is a product, that a demand for the product in the UK (a) is not being met on reasonable terms, or (b) is being met to a substantial extent by importation from a country, which is not a member state;</p> <p>(c) where the patented invention is capable of being commercially worked in the UK, that it is being prevented or hindered from being so worked (a) where the invention is a product, by the importation of the product from a country, which is not a member state, and (b) where the invention is a process, by the importation from such a country of a product obtained directly by means of the process or to which the process has been applied;</p> <p>(d) that by reason of the refusal of the proprietor of the patent to grant a licence or licences on reasonable terms: (a) a market for the export of any patented product made in the UK is not being supplied; (b) the working or efficient working in the UK of any other patented invention, which makes a substantial contribution to the art is prevented or hindered; or (c) the establishment or development of commercial or industrial activities in the UK is unfairly prejudiced;</p> <p>(e) that by reason of conditions imposed by the proprietor of the patent on the grant of licences under the patent, or on the disposal or use of the patented product or on the use of the patented process, the manufacture, use or disposal of materials not protected by the patent, or the establishment or development of commercial or industrial activities in the UK is unfairly prejudiced.</p> <p>Furthermore, where: (a) an application is made on the grounds that the patented invention is not being commercially worked in the UK or is not being so worked to the fullest extent that is reasonably practicable; and (b) it appears to the comptroller that the time, which has elapsed since the publication in the journal of a notice of the grant of the patent has for any reason been insufficient to enable the invention to be so worked, he may by order adjourn the application for such a period as will – in his opinion – give sufficient time for the invention to be so worked.</p> <p>(Section 48B The Patents Act 1977)</p> <p>[Note: the term “member state” in this part of the legislation means EEA states. It is unclear whether this part of the legislation will be amended after the Brexit transition period ends on 1 January 2021 and the UK will no longer be part of the EU or EEA.]</p>
<p>6. Are there any preconditions to apply for a compulsory licence? For example:</p> <p>(a) Any negotiation required between the applicant and the right holder before applying for a compulsory licence?</p>	<p>(a) In respect to an application made relating to a patent with a WTO Proprietor: Yes. No order shall be made unless the applicant has made efforts to obtain a licence from the proprietor on reasonable commercial terms and conditions and his efforts have not been successful within a reasonable period. (Section 48A(2) The Patents Act 1977)</p> <p>In any other case: No negotiation required. However, no licence shall be granted unless the comptroller is satisfied that the proprietor of the patent for the other invention is</p>

<p>(b) Any urgent situation required in order to grant a compulsory licence?</p> <p>(c) Any minimum number of years required for the patent to be granted and/or implemented in order to be subject to compulsory licensing?</p>	<p>willing and able to grant the proprietor of the patent concerned and his licensees a licence.</p> <p>(b) No.</p> <p>(c) The applicant must wait until the expiration of three years from when the patent was granted before being able to apply for a compulsory licence. (Section 48(1) The Patents Act 1977)</p>
7. Are there any limits on the number of compulsory licensees?	Not specified.
8. Will there be any limitation on the scope of the compulsory licence, for example limitations on the time and the territory?	The licence shall be limited in scope and in duration to the purpose for which the licence was granted. The licence shall also be predominantly for the supply of the market in the UK. (Section 48A(6) The Patents Act 1877)
9. Which authority has the competency to grant a compulsory licence?	Intellectual Property Office (IPO)
<p>10. Application procedure for compulsory licence:</p> <p>(a) What are the application procedures to get a compulsory licence?</p> <p>(b) What materials need to be submitted to the competent authority?</p> <p>(c) How long will it take to get a compulsory licence?</p>	<p>(a) An application can be made to the IPO after three years from the date when the notice of the grant of a patent appears in the journal. The application will be advertised in the journal and a copy of the application and statement of grounds will be sent to the proprietor of the patent in order to give an opportunity for opposition.</p> <p>(b) Any application should be made by filing Patents Form 2 accompanied by a copy thereof and a statement of grounds (in duplicate). It is not necessary to file evidence verifying the statement. The statement should set out the grounds on which the application is made, which should be one or more of those specified in s.48A(1) (if the proprietor is a WTO proprietor) or s.48B(1) otherwise. (Guidance note 48.08 The Patents Act 1977 https://www.gov.uk/guidance/manual-of-patent-practice-mopp/section-48-compulsory-licences-general)</p> <p>(d) Not specified.</p>
11. Can the competent authority grant a compulsory licence without hearings under an urgent situation?	<p>Under section 55 of The Patents Act 1977, any government department or person authorised in writing by a government department may, for the services of the Crown, perform certain acts in the UK without the consent of the proprietor of the patent. Such acts consist of: (i) making, using, importing/ keeping the product or selling or offering to sell the product where doing so would be ancillary to making, using importing or keeping it; or (ii) selling or offering to sell the product for foreign defence purposes or for the production or supply of specified drugs and medicines.</p> <p>Section 59 of The Patents Act 1977 provides for Crown use during a period of emergency and extends the powers provided under Section 55 to include the power to use the invention for any purpose necessary: (a) for the efficient prosecution of war; (b) for the maintenance of supplies and services essential to the life of the community; (c) for securing a sufficiency of supplies essential to the well-being of the community; (d) for promoting the productivity of industry, commerce and agriculture; (e) for fostering and directing exports and reducing imports, or imports of any classes, from all or any countries and for redressing the balance of trade; (f) generally for ensuring that the whole</p>

	<p>resources of the community are available for use, and are used, in a manner best calculated to serve the interests of the community; or (g) for assisting the relief of suffering and the restoration and distribution of essential supplies and services in any country or territory outside the UK, which is in grave distress as the result of war; and any reference in this Act to the services of the Crown shall, as respects any period of emergency, include a reference to those purposes.</p> <p>A “period of emergency” is defined as “any period beginning with such date as may be declared by Order in Council to be the commencement, and ending with such date as may be so declared to be the termination, of a period of emergency for the purposes of this section”.</p> <p>The abovementioned provisions could lead to government authorisation of certain medical equipment or the manufacture of certain medicines and the Crown use defence could then act as a defence to potential patent infringement claims.</p>
<p>12. Revocation/termination of compulsory licence:</p> <p>(a) Can a compulsory licence be revoked/terminated or automatically revoked/terminated?</p> <p>(b) What are the conditions for the revocation/termination of a compulsory licence?</p> <p>(c) How should products made under a compulsory licence be treated if the compulsory licence is terminated/revoked?</p>	<p>(a) Yes, it can be revoked or terminated under section 52(3) of The Patents Act 1977 upon appeal to the Patents Court.</p> <p>(b) A WTO proprietor can apply to the comptroller to have the order revoked or terminated on the grounds that the circumstances, which led to the making of the order or entry have ceased to exist and are unlikely to recur.</p> <p>(c) Not specified, but when the comptroller decides to terminate a licence granted to a person he will do so subject to such terms and conditions as he thinks necessary for the protection of the legitimate interests of that person (Section 52(3)(b) of The Patents Act 1977)</p>
<h3>Rights and obligations of the right holders in relation to compulsory licensing</h3>	
<p>13. Royalty:</p> <p>(a) Does the compulsory licensee have to pay a royalty to the right holder?</p> <p>(b) If the compulsory licensee is required to pay a royalty, how is the amount of royalty determined and who will decide the amount of the royalty?</p> <p>(c) Is there any remuneration available for the right holders other than royalty?</p>	<p>(a) Under Section 48A(6)(d) of The Patents Act 1977, a licence granted to a person in respect to a patent with a WTO proprietor shall include conditions entitling the proprietor of the patent concerned to remuneration adequate in the circumstances of the case, taking into account the economic value of the licence. Under Section 50(1)(b) of The Patents Act 1977, the inventor or person beneficially entitled to a patent shall receive reasonable remuneration having regard to the nature of the invention.</p> <p>(b) Guidance note 48.18 of The Patents Act 1977 (https://www.gov.uk/guidance/manual-of-patent-practice-mopp/section-48-compulsory-licences-general) sets out that the royalty should be negotiated between a willing licensor and willing licensee. Even though section 50(1)(b) requires the patentee to receive “reasonable remuneration”, the royalty should not be such that the applicants could not bear it and were thus put out of the market.</p> <p>(c) Not specified.</p>
<p>14. Are there any legal remedies for the party who is not satisfied with the compulsory licensing decision of the competent authority?</p>	<p>Under Section 52(6) of The Patents Act 1977, where the proceedings are referred to an arbitrator or arbiter (under section 52(5)(b)), an appeal of the award shall go to the court.</p>

<p>15. Provision of know-how and support:</p> <p>(a) In order to implement the compulsory licence, for example, to manufacture the licenced product, is the right holder required to provide necessary support, such as know-how and training as in a voluntary agreed licence agreement?</p> <p>(b) Will this provision of know-how and support be compensated and how is the amount of such compensation determined?</p>	Not specified.
<p>16. Confidentiality:</p> <p>(a) Is the compulsory licensee subject to any confidentiality obligation?</p> <p>(b) If the compulsory licensee discloses the confidential information in violation of its obligation, does the right holder have a basis of claim against the compulsory licensee?</p>	Not specified.
<p>17. Export of products under compulsory licence</p> <p>(a) Is the compulsory licensee allowed to export their products under the compulsory licence?</p> <p>(b) If the compulsory licensee is permitted to export products under the compulsory licence, are there any requirements and limitations on the export of such products?</p>	This is not expressly provided for, but Section 48A(6)(c) states that the licence shall be predominantly for the supply of the UK market.
Compulsory licensing in the present COVID-19 pandemic	
<p>18. Have the laws on compulsory licensing been used in previous health emergencies and/or in the present COVID-19 pandemic in your jurisdiction?</p>	N/A
<p>19. Is it possible for third parties to use the current laws on compulsory licensing in your jurisdiction to facilitate the treatment of patients infected by COVID-19?</p>	It is possible. However, the pre-conditions that have to be met (noted in point 6 above), such as requiring the patent to be granted at least three years prior to the application for a compulsory licence, may limit the effectiveness of the current regime in the present environment. The applicant must also have sought a licence from the patentee (on reasonable terms), which was refused. This means that it is perhaps more likely that the "Crown use" defence available under Section 55 of The Patents Act 1977 will be relied upon in these circumstances.

20.	Are there any recent major regulatory exemptions and/or amendments made following COVID-19 to regulations governing compulsory licensing?	N/A
Transactions and dealings of products under compulsory licences		
21.	Can a compulsory licence be transferred or assigned?	Under Section 48A(6)(b) of The Patents Act 1977 a compulsory licence granted to someone in respect to a patent with a WTO proprietor shall not be assigned except to a person to whom there is also assigned the part of the enterprise that enjoys the use of the patented invention, or the part of the goodwill that belongs to that part.
22.	Does the issuance of a compulsory licence have any impact on the previously agreed licence?	Not specified.
23.	Is there any special labelling requirement for the products made under the compulsory licence?	Not specified.
24.	Is there any special distribution channel requirement for the products made under the compulsory licence?	Not specified.
25.	Is there any price requirement for the products made under the compulsory licence?	Not specified.

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JURISDICTION: France

Compulsory licensing in general

1.	What is the definition of compulsory licensing?	Compulsory licensing refers to a legal mechanism by which a judicial court or the government grants a third party with a licence, without the prior consent of the patent owner, under certain circumstances and certain conditions.
2.	What are the applicable sources of law relating to compulsory licensing?	<p>TRIPS agreements (Accords ADPIC) (Article 31)</p> <p>EU "Biotech" Directive 98/44/EC on the legal protection of biotechnological inventions (article 12)</p> <p>EU Regulation (CE) 816/2006 on compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems</p> <p>Articles L.613-11 to L.613-22-1 et seq. of the French Intellectual Property Code.</p>
3.	Types of products which compulsory licensing applies to: (a) What type(s) of products or technologies do compulsory licensing applies to? (b) Has any compulsory licence ever been issued in your jurisdiction? If yes, on what type of technology?	<p>(a) A compulsory licence could apply to any invention covered by a patent (including patent directed to semi-conductors), any new varieties of plant and could apply to any type of products or technologies.</p> <p>(b) There are very limited cases of compulsory licence in France. One compulsory licence has been granted on 1983 for a patent on "a coupling head intended to air brake systems on motor vehicles" and another one has been granted on 1997 for a patent on a machine for the automatic production of skewers.</p>

Regulatory requirements on compulsory licensing

4.	Who can apply for a compulsory licence? Are foreigners or foreign companies allowed to apply for a compulsory licence?	<p>Such a compulsory license may be requested by any public or private entity or any qualified person who/which would be able to exploit the patent concerned.</p> <p>Yes, foreigners or foreign companies can apply for such compulsory licence, there is no specific restriction as to the nationality of the entity or the person.</p>
5.	What are the legal grounds to grant a compulsory licence under the local laws of your jurisdiction and any applicable international treaties?	<p>There are different legal grounds depending on the type of the licence:</p> <ul style="list-style-type: none"> – Compulsory licence due to the lack of exploitation of the patent by its holder: Such licence is granted if the patent owner has not been exploiting or seriously preparing the exploitation of the patent, or has not been commercialising its patent enough in the EU for 3 years following the grant of the patent or 4 years following the publication of the patent application (Article L.613-12 of the French Intellectual Property Code). – Compulsory licence in respect of dependent patents: Such licence is granted when a person owns a patent that cannot be exploited without infringing a prior patent. If the authorisation of the prior patent owner is impossible to obtain amicably, the Court may grant a licence if the invention would bring significant technical progress and is

	<p>of great economic interest (Articles L.613-15 and L.613-15-1 of the French Intellectual Property Code).</p> <ul style="list-style-type: none"> – Compulsory licence in the interest of public health: Such licence can be granted, on any patent for: a) a drug, a medical device, an in vitro diagnostic medical device, a related therapeutic product; b) a process for obtaining them, a product necessary for obtaining them or a process for manufacturing such a product; c) an ex vivo diagnostic method, when the exploitation of this patent is contrary to the interest of public health or if the quality of quantity of the products based on this patent offered to the public are not sufficient or too expensive or if such exploitation constitutes anticompetitive behaviour (Articles L.613-16 and L.613-17 of the French Intellectual Property Code). – Compulsory licence in the interest of the national economy: Such licence is granted if the patent owner does not exploit (or not sufficiently exploit) the patent. The Ministry in charge of industrial property matters (Minister of Economy) can order the patent owner to exploit the patent in order to “satisfy the needs of the national economy” and if after 1 year the exploitation is not done or not sufficiently, then an order can be issued to grant compulsory licences to third parties. (Article L.613-18 of the French Intellectual Property Code) – Compulsory licence in the interest of the national defence: Such licence can cover any patent or patent application and is granted if the French State claim it for itself or for an exploitation on its behalf in the interest of national defence. (Article L.613-19 of the French Intellectual Property Code)
<p>6. Are there any preconditions to apply for a compulsory licence? For example:</p> <ul style="list-style-type: none"> (a) Any negotiation required between the applicant and the right holder before applying for a compulsory licence? (b) Any urgent situation required in order to grant a compulsory licence? (c) Any minimum number of years required for the patent to be granted and/or implemented in order to be subject to compulsory licensing? 	<ul style="list-style-type: none"> – Compulsory licence due to the lack of exploitation of the patent by its holder: Such licence is granted if the patent owner has not been exploiting or seriously preparing the exploitation of the patent, or has not been commercialising its patent enough in the EU for 3 years following the grant of the patent or 4 years following the publication of the patent application. Any party able to prove both its ability to exploit seriously the patent and the impossibility to obtain a negotiated licence from the patent owner may claim for a licence (Article L.613-12 of the French Intellectual Property Code). – Compulsory licence in respect of dependent patents: Such license is granted if the authorisation of the prior patent owner is impossible to obtain amicably, so the Court may grant such licence. The part requesting the licence must prove both its ability to exploit the invention in a serious and effective manner and the impossibility of obtaining a negotiated licence from the patent owner. The owner of the prior patent is automatically granted a licence back on the dependent patent of its licensee (Article L.613-15 of the French Intellectual Property Code). – Compulsory licence in the interest of public health: Such licence is granted if the Ministry failed to obtain an amicable agreement with the patent owner, but no

	<p>minimum duration of exploitation is required. The exploitation of the patent must be contrary to the interest of public health or the quality/quantity of the products based on this patent offered to the public must be insufficient or too expensive or such exploitation must constitute anticompetitive behaviour (Article L.613-16 of the French Intellectual Property Code).</p> <ul style="list-style-type: none"> – Compulsory licence in the interest of the national economy: Such licence is granted if the patent owner failed to comply, after more than 1 year, with the order issued by the Ministry to operate its patent in a way sufficient to satisfy the interest of the national economy. (Articles L.613-18 and L.613-26 of the French Intellectual Property Code) – Compulsory licence in the interest of the national defence: Such licence is granted at any time if the French State claim for it in the interest of national defence without further justification. The license is granted at the request of the minister in charge of defense by order of the minister in charge of industrial property. (Article L.613-19 of the French Intellectual Property Code).
7. Are there any limits on the number of compulsory licensees?	There are no limits on the number of compulsory licensees. Moreover, any compulsory licence is granted a non-exclusive basis.
8. Will there be any limitation on the scope of the compulsory licence, for example limitations on the time and the territory?	Regardless of the type of compulsory licence, such a licence should be granted according to specific conditions, particularly with respect to duration/territory/scope of application. Any compulsory license is granted on a non-exclusive basis.
9. Which authority has the competency to grant a compulsory licence?	Only a judicial court or the government are competent to grant such compulsory license depending on the type of licence to be granted.
10. Application procedure for compulsory licence: (a) What are the application procedures to get a compulsory licence? (b) What materials need to be submitted to the competent authority? (c) How long will it take to get a compulsory licence?	(a) It depends on the type of compulsory license. The application procedure can take place before a judicial court as part of a standard civil procedure but summons and pleadings must be sent to the French National Institute of the Industrial Property (INPI) within 15 days of the day of their notification to the court. For the applications taking place before the government, the applicant must request the licence to the competent ministry depending of the type of licence requested. After a consultation procedure of few months, the Ministry decides or not to issue a decision submitting the patent to compulsory licence. Then, any third party may require to be granted a licence and the Ministry will issue other decisions determining the specific conditions. (b) Depending on the type of licence to be granted, it can be required to submit pre negotiations documents proving that the applicant did not succeed obtaining amicably a licence from the patent owner, documents proving the ability of the party requesting this licence to exploit the patent invention, documents proving the lack of exploitation of the patent owner etc. (c) It is difficult to assess but we assume at least few months depending on the application process.

<p>11. Can the competent authority grant a compulsory licence without hearings under an urgent situation?</p>	<p>A compulsory license can be granted without hearings but only under specific circumstances.</p> <ul style="list-style-type: none"> – in the interest of public health: Such licence is granted when the exploitation of the patent is contrary to the interest of public health or if the quality of quantity of the products based on this patent offered to the public are not sufficient or too expensive or if such exploitation constitutes anticompetitive behaviour. This licence is granted if the Ministry failed to obtain an amicable agreement, but this amicable phase is not required in case of urgent situation (Article L.613-16 of the French Intellectual Property Code). – In the interest of National defence: The French State may claim and obtain, at any time, for the needs of national defence and without providing further justification, a license for the exploitation of an invention that is the subject of a patent application or a patent, whether such exploitation is made by itself or on its behalf. The license is granted at the request of the Minister in charge of defence by order of the Minister in charge of industrial property. This decree sets the conditions of the license with the exception of those relating to the royalties to which it gives rise. In the absence of an amicable agreement, the amount of the royalties is fixed by the judicial court (Article L.613-19 of the French Intellectual Property Code)
<p>12. Revocation/termination of compulsory licence:</p> <p>(a) Can a compulsory licence be revoked/terminated or automatically revoked/terminated?</p> <p>(b) What are the conditions for the revocation/termination of a compulsory licence?</p> <p>(c) How should products made under a compulsory licence be treated if the compulsory licence is terminated/revoked?</p>	<p>(a) Yes</p> <p>(b) The compulsory license can be terminated or revoked if the licensee does not comply with the conditions under which the licence was granted, the owner of the patent and, where applicable, the other licensees, may obtain the withdrawal of the licence from a Judicial Court (Article L.613-14 of the French Intellectual Property Code).</p> <p>(c) These issues must be determined in the court decision declaring the withdrawal of the compulsory license.</p>
<p>Rights and obligations of the right holders in relation to compulsory licensing</p>	
<p>13. Royalty:</p> <p>(a) Does the compulsory licensee have to pay a royalty to the right holder?</p> <p>(b) If the compulsory licensee is required to pay a royalty, how is the amount of royalty determined and who will decide the amount of the royalty?</p> <p>(c) Is there any remuneration available for the right holders other than royalty?</p>	<p>(a) Yes</p> <p>(b) The compulsory license may provide the amount of the royalties involved. Otherwise, in the absence of an amicable agreement between the patent owner and the licensee, the amount of the royalties is determined by a Judicial Court</p> <p>(c) Not provided by law.</p>

14. Are there any legal remedies for the party who is not satisfied with the compulsory licensing decision of the competent authority?	<p>The terms of the compulsory license may be amended by the Court at the request of either the patent owner or the licensee. (Article L.613-12 of the French Intellectual Property Code).</p> <p>Decisions granting a compulsory licence may be appealed following the regular civil appeal procedure (i.e. within one month).</p> <p>Decisions of the government (any Ministry for example) may be appealed pursuant to the relevant public law provisions.</p>
15. Provision of know-how and support:	<p>(a) Not provided by law.</p> <p>(b) Not provided by law.</p>
<p>(a) In order to implement the compulsory licence, for example, to manufacture the licenced product, is the right holder required to provide necessary support, such as know-how and training as in a voluntary agreed licence agreement?</p> <p>(b) Will this provision of know-how and support be compensated and how is the amount of such compensation determined?</p>	
16. Confidentiality:	<p>(a) The law does not provide for confidentiality obligations except if required by the granted license and for the compulsory license granted in the interest of the national defence where all the proceedings and hearings are confidential. If obtained, a confidentiality obligation will obey to the same regime than a "normal" confidential obligation.</p> <p>(b) No specific remedies applicable to compulsories licenses.</p>
17. Export of products under compulsory licence	<p>(a) Not provided by law.</p> <p>(b) No specific requirements or limitations on the export.</p>
<p>(a) Is the compulsory licensee allowed to export their products under the compulsory licence?</p> <p>(b) If the compulsory licensee is permitted to export products under the compulsory licence, are there any requirements and limitations on the export of such products?</p>	
Compulsory licensing in the present COVID-19 pandemic	
18. Have the laws on compulsory licensing been used in previous health emergencies and/or in the	No. There are currently no reported cases of compulsory licensing being used in previous health emergencies or in the present COVID-19 pandemic in France.

present COVID-19 pandemic in your jurisdiction?	
19. Is it possible for third parties to use the current laws on compulsory licensing in your jurisdiction to facilitate the treatment of patients infected by COVID-19?	The law of 23 March 2020 n°2020-90 has introduced a new article L 3131-15 in the French public health code allowing to the Prime Minister to order the requisition of all goods and services necessary to fight against the sanitary disaster as well as any person necessary for the operation of these services or the use of these goods but also to take all measures allowing the provision of patients with appropriate medicines for the eradication of the sanitary disaster. The COVID-19 pandemic could obviously lead to recourse to the compulsory license mechanism.
20. Are there any recent major regulatory exemptions and/or amendments made following COVID-19 to regulations governing compulsory licensing?	A bill n°2808 proposed by deputies on 7 April 2020 suggests a relaxation of the conditions for granting these licenses, subject however to respecting the framework established by the TRIPS agreement.
Transactions and dealings of products under compulsory licences	
21. Can a compulsory licence be transferred or assigned?	The rights attached to compulsory licenses are personal and non-transferable, except in the case of an assignment of the business of the company or the part of the company to which the license is attached. For the compulsory license granted on dependant patents, the license granted to the licensee (with the posterior patent) can only be transferred with the prior patent.
22. Does the issuance of a compulsory licence have any impact on the previously agreed licence?	No legal provision as to the impact of compulsory licenses on pre-existing licensees. The compulsory license can be terminated or revoked if the licensee does not comply with the conditions under which the licence was granted, the owner of the patent and, but also the other licensees, may obtain the withdrawal of the licence from a Judicial Court (Article L.613-14 of the French Intellectual Property Code).
23. Is there any special labelling requirement for the products made under the compulsory licence?	There is no special labelling requirement for the products made under the compulsory license.
24. Is there any special distribution channel requirement for the products made under the compulsory licence?	There is no special distribution channel requirement for the products made under the compulsory license.
25. Is there any price requirement for the products made under the compulsory licence?	There is no price requirement for the products made under the compulsory license.

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Compulsory licensing in general

<p>1. What is the definition of compulsory licensing?</p>	<p>Section 24 (1) German Patent Act (<i>Patentgesetz</i> – "GPA") contains a definition of compulsory license. It reads as follows:</p> <p><i>"The non-exclusive authorisation to commercially use an invention shall be granted by the Federal Patent Court in an individual case in accordance with the following provisions (compulsory licence)..."</i></p> <p>Accordingly, the compulsory license is a non-exclusive right of use granted by the Federal Patent Court (<i>Bundespatentgericht</i>) if further pre-conditions are met.</p>
<p>2. What are the applicable sources of law relating to compulsory licensing?</p>	<p>The basic common source is Section 24 GPA which specifies the compulsory licenses with respect to granted patents. This provision applies on German patents and the German national part of European patents. Further statutory provisions regarding compulsory licenses under various registered intellectual property rights:</p> <ul style="list-style-type: none"> • Section 16a (2) GPA refers to the application of Section 24 GPA also with respect to supplementary protection certificates. • Section 20 German Utility Model Act (<i>Gebrauchsmustergesetz</i>) refers to the application of certain provisions of the GPA regarding compulsory licenses. • Further provisions regarding compulsory licenses are contained in Sections 12 and 12a German Plant Varieties Protection Act (<i>Sortenschutzgesetz</i>) and Section 42a German Copyright Act (<i>Urheberrechtsgesetz</i>). • Section 13 GPA provides: <i>"The patent shall have no effect in a case where the Federal Government orders that the invention is to be used in the interest of public welfare. Further, it shall not extend to a use of the invention which is ordered in the interest of the security of the Federal Republic of Germany by the competent highest federal authority or by a subordinate authority acting on its instructions."</i> This provision has been put into the focus at the beginning of the COVID-19 pandemic, instead of the "normal" compulsory license provision in Section 24 GPA, but so far no order has been made yet pursuant to Section 13 GPA.
<p>3. Types of products which compulsory licensing applies to:</p> <p>(a) What type(s) of products or technologies do compulsory licensing applies to?</p> <p>(b) Has any compulsory licence ever been issued in your jurisdiction? If yes, on what type of technology?</p>	<p>(a) In principle, compulsory licenses are possible for all patented inventions if the preconditions for granting are met. However, in fact applications for compulsory licenses under Section 24 GPA have been made only in relation to pharmaceutical patents with respect to specific medicinal products so far. Furthermore, the special compulsory license provisions in Sections 12 and 12a German Plant Varieties Protection Act (<i>Sortenschutzgesetz</i>) relate to plant varieties and biotechnological inventions.</p> <p>(b) There were three cases in which a pharmaceutical company applied for a compulsory license for its medicinal product under Section 24 (1) GPA:</p>

	<ul style="list-style-type: none"> • In the first case relating to the marketing of the pharmaceutical product <i>Polyferon</i> (IFN-gamma as active pharmaceutical ingredient) the Federal Patent Court (<i>Bundespategericht</i>) granted a compulsory license that, however, was cancelled by the Federal Court of Justice (<i>Bundesgerichtshof</i>) in the appeal. • The second case relates to the HIV drug <i>Isentress</i> (Raltegravir as active pharmaceutical ingredient). After request for a compulsory license by way of interim decision the Federal Patent Court (<i>Bundespategericht</i>) ordered the compulsory license and the Federal Court of Justice (<i>Bundesgerichtshof</i>) maintained the decision. The patent at issue was cancelled later, but nonetheless the royalty had be paid for the compulsory license for the period from the order until cancellation of the patent. • Just recently the request for a compulsory license for the cholesterol lowering drug <i>Praluent</i> (Alirocumab as active pharmaceutical ingredient) was refused by the Federal Patent Court (<i>Bundespategericht</i>) and the Federal Court of Justice (<i>Bundesgerichtshof</i>). Again, the applicant requested an interim decision for a compulsory license, but made a first license offer to the patentee only three weeks before filing the law suit for the compulsory license although patent infringement proceedings were pending already for around two years.
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Regulatory requirements on compulsory licensing

4. Who can apply for a compulsory licence? Are foreigners or foreign companies allowed to apply for a compulsory licence?	Applications for compulsory licenses may be made by everyone. Foreigners or foreign companies are generally not excluded.
5. What are the legal grounds to grant a compulsory licence under the local laws of your jurisdiction and any applicable international treaties?	<p>The main provision for compulsory patent licenses in Section 24 GPA foresees the license grant in five different scenarios:</p> <p>(a) Section 24 (1) GPA: If a licence seeker has, within a reasonable period of time, unsuccessfully attempted to obtain permission from the patent owner to use the invention on reasonable commercial terms and conditions, and the public interest calls for the grant of a compulsory licence. These requirements set out in Section 24 (1) GPA are included by reference in the cases described in the following paragraphs.</p> <p>(b) Section 24 (2) GPA: If a patented invention cannot be commercialized without infringing an invention patented with a higher seniority (earlier patent), the owner of the later patent is entitled to a compulsory license to the older patent if the invention protected by the later patent represents significant technical progress of considerable economic importance compared to the invention protected by the earlier patent. In case of granting a license, the owner of the earlier patent is also entitled to a compulsory license to the later patent.</p> <p>(c) Section 24 (3) GPA: If a plant breeder cannot obtain or commercialize a plant varieties protection right without infringing an invention patented with a higher priority (earlier patent), he shall be entitled to a compulsory license to the patent, provided that the plant variety represents significant technical progress of considerable economic</p>

	<p>interest compared with the invention protected by the patent and provided that this compulsory license is necessary for commercialization of the plant variety to be protected.</p> <p>(d) Section 24 (4) GPA: If the holder of a patent for a biotechnological invention is granted a compulsory license for a plant variety protected by a plant varieties protection right granted with a higher priority (earlier plant variety right) because he cannot commercialize the biotechnological invention without infringing an earlier plant varieties protection right, the holder of the earlier plant varieties protection right shall be entitled to a compulsory license to the later patent for the exploitation of the protected invention.</p> <p>(e) Section 24 (5) GPA: If a patented invention is not adequately exercised in Germany, whereby the exercise may also be effected by import, and if the patent owner has not taken all steps necessary for such exercise, any person shall be entitled to a compulsory licence to the patent for his business, unless the patent owner proves that the exercise of the invention in Germany is not reasonable or not reasonable to a greater extent than has been the case because of the difficulties involved in the exercise.</p>
<p>6. Are there any preconditions to apply for a compulsory licence? For example:</p> <p>(a) Any negotiation required between the applicant and the right holder before applying for a compulsory licence?</p> <p>(b) Any urgent situation required in order to grant a compulsory licence?</p> <p>(c) Any minimum number of years required for the patent to be granted and/or implemented in order to be subject to compulsory licensing?</p>	<p>Yes, the basic conditions are set forth in Section 24 (1) GPA.</p> <p>(a) The licence seeker has, within a reasonable period of time, unsuccessfully attempted to obtain permission from the proprietor of the patent to use the invention on reasonable commercial terms and conditions. The Federal Court of Justice (<i>Bundesgerichtshof</i>) has emphasized in its decision regarding the cholesterol lowering drug <i>Praluent</i> that this requirement must be applied strictly and, particularly, the mere tactical (first) license request in light of pending patent infringement proceedings close before the scheduled oral hearing is not sufficient.</p> <p>(b) No. However, it is possible to request an interim decision ordering a compulsory license in urgent situations. Such requests will be handled in expedited proceedings according to Section 85 (1) GPA.</p> <p>(c) No. The patent must be granted and in force. There will not be ordered compulsory licenses under patent applications.</p>
<p>7. Are there any limits on the number of compulsory licensees?</p>	<p>No. However, it is clear that the license seeker may be granted only one compulsory license under the same patent. Moreover, any granted compulsory license under a specific patent will – at least implicitly – be considered in the context to the pre-conditions of the subsequent compulsory license request of another license seeker, particularly with respect to the pre-conditions of whether <i>"the grant of the compulsory license is required in the public interest"</i> (Section 24 (1) No. 2 GPA) or whether the <i>"patentee does not uses the patented invention in Germany"</i> and <i>"grant of the compulsory license is necessary to ensure sufficient supply of the patented product in the German market"</i> (Section 24 (5) GPA).</p>

<p>8. Will there be any limitation on the scope of the compulsory licence, for example limitations on the time and the territory?</p>	<p>In general, the compulsory license ordered by decision of the Federal Patent Court (<i>Bundespatentgericht</i>) does not have a retrospective effect since it is directed to a use of the patented technology in the future. The scope of the compulsory license depends on the request of the license seeker and, furthermore, will be limited to the extent necessary for the license seeker's purpose justified by the public interest. The compulsory license is limited to patent protected activities to be conducted in Germany.</p>
<p>9. Which authority has the competency to grant a compulsory licence?</p>	<p>The compulsory patent license according to Section 24 GPA will be granted by decision of the Federal Patent Court (<i>Bundespatentgericht</i>) in the first instance and the Federal Court of Justice (<i>Bundesgerichtshof</i>) in the second (appellate) instance.</p> <p>Use orders under Section 13 GPA (<i>Benutzungsanordnung</i>) are made by the German Federal Government (<i>Bundesregierung</i>); the competency has been delegated to the Ministry of Health under Section 5 (2) No. 5 German Infection Protection Act (<i>infektionsschutzgesetz</i>) for certain products specified in the act at the beginning of the COVID-19 pandemic (and the ministry is entitled to further delegate its competency to subordinated administrative authorities).</p> <p>Compulsory licenses with respect to Plant Varieties Protection Rights according to Sections 12 and 12a German Plant Varieties Protection Act (<i>Sortenschutzgesetz</i>) are ordered by the Federal Plant Variety Office (<i>Bundessortenamt</i>).</p> <p>Actions for compulsory licenses according to Section 42a German Copyright Act (<i>Urheberrechtsgesetz</i>) must be filed before the ordinary courts competent at the author's seat; or if the author does not have a seat in Germany, before the ordinary court in Munich.</p>
<p>10. Application procedure for compulsory licence:</p> <p>(a) What are the application procedures to get a compulsory licence?</p> <p>(b) What materials need to be submitted to the competent authority?</p> <p>(c) How long will it take to get a compulsory licence?</p>	<p>(a) At first, the license seeker must attempt to reach an agreement with the patent owner. If this is not possible, the license seeker may file a law suit at the Federal Patent Court (<i>Bundespatentgericht</i>) for ordering the compulsory license for specific product(s). The Federal Patent Court will decide on the grant of the license on the merits and determines an appropriate remuneration.</p> <p>(b) There are no specific formal requirements. The general requirements for nullity proceedings apply, i.e. the application must include a summary of the main facts, a sufficiently substantiated request (i.e. why the legal requirements for ordering a compulsory license are met) as well as an account of the evidence to support the request.</p> <p>(c) Likely several months up to one to two years in main proceedings (in first instance). However, there is the possibility to file an additional request for an interim order of the compulsory license handled in preliminary proceedings in urgent matters; Section 85 GPA. The Federal Patent Court (<i>Bundespatentgericht</i>) decides about such request for an interim order usually in two to three months and the Federal Court of Justice (<i>Bundespatentgericht</i>) the appeal usually within eight to ten months after first instance decision.</p>
<p>11. Can the competent authority grant a compulsory licence without hearings under an urgent situation?</p>	<p>No. The Federal Patent Court (<i>Bundespatentgericht</i>) decides on the basis of an oral hearing according to Section 85 (3) GPA</p>

<p>12. Revocation/termination of compulsory licence:</p> <p>(a) Can a compulsory licence be revoked/terminated or automatically revoked/terminated?</p> <p>(b) What are the conditions for the revocation/termination of a compulsory licence?</p> <p>(c) How should products made under a compulsory licence be treated if the compulsory licence is terminated/revoked?</p>	<p>(a) A compulsory licence may be ordered by the Federal Patent Court (<i>Bundespatentgericht</i>) with limitation in time and will automatically terminate if the ordered maximum period of time expires. The patentee or its legal successor is entitled to request revocation of the compulsory licence if the circumstances upon which the order of the compulsory licence was based no longer apply and if their recurrence is improbable; Section 24 (6) sent. 6 GPA. The patentee may file a respective law suit for revocation at the Federal Patent Court (<i>Bundespatentgericht</i>); Section 81 GPA. The patentee and the compulsory licensee may further terminate the compulsory licence by agreement. The compulsory licence is automatically terminated if the relevant patent is cancelled, expires or becomes invalid.</p> <p>(b) The circumstances upon which the order of a compulsory licence was based no longer apply and their recurrence is improbable; Section 24 (6) sent. 6 GPA.</p> <p>(c) The products already sold are covered by the compulsory licence. If the manufacturing is covered by the compulsory licence and the royalty obligation became due and payable already with the manufacturing of the product, the licensee must still pay such royalty.</p>
<p>Rights and obligations of the right holders in relation to compulsory licensing</p>	
<p>13. Royalty:</p> <p>(a) Does the compulsory licensee have to pay a royalty to the right holder?</p> <p>(b) If the compulsory licensee is required to pay a royalty, how is the amount of royalty determined and who will decide the amount of the royalty?</p> <p>(c) Is there any remuneration available for the right holders other than royalty?</p>	<p>(a) Yes, the compulsory licensee must pay the royalty determined by the Federal Patent Court (<i>Bundespatentgericht</i>) to the patentee.</p> <p>(b) The royalty obligation is determined by the Federal Patent Court (<i>Bundespatentgericht</i>) which decides also on the structure of the royalty (e.g. one-time lump sum; running royalty per piece or per turnover). When determining the royalty, the court will consider particularly the economic power of the compulsory licensee and the reasonableness of the compensation for the patentee. Typically, a turnover-based royalty at a rate between 1-10% is to be expected.</p> <p>(c) No. However, the patentee might have a damages claim for the compulsory licensee's patent infringing use before the order of the compulsory licence.</p>
<p>14. Are there any legal remedies for the party who is not satisfied with the compulsory licensing decision of the competent authority?</p>	<p>Either party may file an appeal against the first instance decision of the Federal Patent Court (<i>Bundespatentgericht</i>) which will be finally and legally decided by the Federal Court of Justice (<i>Bundesgerichtshof</i>). Moreover, the patentee is entitled to file a law suit for revocation of the compulsory licence according to Section 81 GPA at any time if the requirements of Section 24 (6) sent. 6 GPA are met.</p>
<p>15. Provision of know-how and support:</p> <p>(a) In order to implement the compulsory licence, for example, to manufacture the licenced product, is the right holder required to provide necessary support, such as know-how and training as in a voluntary agreed licence agreement?</p>	<p>(a) No.</p> <p>(b) n/a</p>

<p>(b) Will this provision of know-how and support be compensated and how is the amount of such compensation determined?</p>	
<p>16. Confidentiality:</p> <p>(a) Is the compulsory licensee subject to any confidentiality obligation?</p> <p>(b) If the compulsory licensee discloses the confidential information in violation of its obligation, does the right holder have a basis of claim against the compulsory licensee?</p>	<p>(a) No, not in general. The accounting and royalty reports provided by the compulsory licensee might be covered by a statutory duty of confidentiality, particularly according to the German Trade Secrets Protection Act (<i>Geschäftsgeheimnisgesetz</i>).</p> <p>(b) n/a</p>
<p>17. Export of products under compulsory licence</p> <p>(a) Is the compulsory licensee allowed to export their products under the compulsory licence?</p> <p>(b) If the compulsory licensee is permitted to export products under the compulsory licence, are there any requirements and limitations on the export of such products?</p>	<p>(a) The compulsory license does not cover the export of any product manufactured and/or distributed in Germany to another country where a parallel patent covering the relevant product is granted. Particularly, the rights of the patentee under a parallel national part of a European Patent are not exhausted through the putting the relevant product on the German market under the compulsory license.</p> <p>(b) The compulsory licensee is free to export the products manufactured and/or distributed under the compulsory licensee to countries where the products are not covered by a parallel patent of the patentee.</p>
<p style="text-align: center;">Compulsory licensing in the present COVID-19 pandemic</p>	
<p>18. Have the laws on compulsory licensing been used in previous health emergencies and/or in the present COVID-19 pandemic in your jurisdiction?</p>	<p>No. Although the competence for use orders under Section 13 GPA (<i>Benutzungsanordnung</i>) has been delegated to the Ministry of Health for specific products under Section 5 (2) No. 5 German Infection Protection Act (<i>Infektionsschutzgesetz</i>)</p>
<p>19. Is it possible for third parties to use the current laws on compulsory licensing in your jurisdiction to facilitate the treatment of patients infected by COVID-19?</p>	<p>Yes. In principle, this is possible, but it is open whether a third party would file a request for a compulsory license under Section 24 GPA. The current (political) discussion in Germany is rather focused on ministerial use orders under Section 13 GPA (<i>Benutzungsanordnung</i>) in light of the slow start of the supply with vaccines against COVID-19.</p>
<p>20. Are there any recent major regulatory exemptions and/or amendments made following COVID-19 to regulations governing compulsory licensing?</p>	<p>No major regulatory exemptions have been made. Only the competency for use orders under Section 13 GPA (<i>Benutzungsanordnung</i>) have been delegated from the German Federal Government (<i>Bundesregierung</i>) to the Ministry of Health under Section 5 (2) No. 5 German Infection Protection Act (<i>infektionsschutzgesetz</i>) for certain products specified in the act at the beginning of the COVID-19 pandemic (and the ministry is entitled to further delegate its competency to subordinated administrative authorities).</p>

Transactions and dealings of products under compulsory licences

21. Can a compulsory licence be transferred or assigned?	<p>According to Section 24 (7) GPA the compulsory patent license may be transferred only together with business, where the compulsory license is used, i.e. where the patented invention is used.</p> <p>In case of a compulsory patent license according to Section 24 (2) GPA (license under an older patent necessary to enable use of a dependent patented invention), such license can be assigned only together with the (dependent) patent with earlier priority date.</p>
22. Does the issuance of a compulsory licence have any impact on the previously agreed licence?	No, unless there is a specific provision in the previously concluded license agreement with respect to subsequent grant of a compulsory license.
23. Is there any special labelling requirement for the products made under the compulsory licence?	The statutory provisions in Section 24 GPA do not provide explicitly for such labelling requirement. However, the Federal Patent Court (<i>Bundespatentgericht</i>) might order such labelling in its decision if this is deemed necessary in the interest of the patentee.
24. Is there any special distribution channel requirement for the products made under the compulsory licence?	This is not explicitly provided in the statutory provisions in Section 24 GPA, but limitations for distribution may be ordered by the Federal Patent Court (<i>Bundespatentgericht</i>) in its decision under which the compulsory license is granted if this is deemed necessary in the interest of the patentee.
25. Is there any price requirement for the products made under the compulsory licence?	This is not explicitly provided in the statutory provisions in Section 24 GPA, but minimum sales prices may be ordered by the Federal Patent Court (<i>Bundespatentgericht</i>) in its decision under which the compulsory license is granted if this is deemed necessary in the interest of the patentee, or price ceiling with respect to the grounds on which the compulsory license is granted (i.e. public interest requires such pricing regime in order to ensure availability of the patented products on German market at affordable prices).

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JURISDICTION: Hong Kong

Compulsory licensing in general

1.	What is the definition of compulsory licensing?	Declaration by the Director of Health (" Director ") allowing a product that is necessary or expedient in connection with an extreme urgency to be imported/exported, put on the market, stocked, or used. This applies to a product, and/or any other act, which would apart from compulsory licensing, amount to an infringement of the patent concerned.
2.	What are the applicable sources of law relating to compulsory licensing?	Compulsory licences for standard patents (sections 64-67 of the Cap. 514 Patents Ordinance (" PO ")); Government use of patented inventions (sections 68-72 of the PO); Import compulsory licences for patented pharmaceutical products (sections 72A-72J of the PO); and Export compulsory licences for patented pharmaceutical products (sections 72K-72R of the PO).
3.	Types of products which compulsory licensing applies to: (a) What type(s) of products or technologies do compulsory licensing applies to? (b) Has any compulsory licence ever been issued in your jurisdiction? If yes, on what type of technology?	(a) No limitation on the type(s) of products or technologies to which compulsory licensing is applicable. (b) No.

Regulatory requirements on compulsory licensing

4.	Who can apply for a compulsory licence? Are foreigners or foreign companies allowed to apply for a compulsory licence?	Any person, including foreigners or foreign companies, can apply for a licence under the patent.
5.	What are the legal grounds to grant a compulsory licence under the local laws of your jurisdiction and any applicable international treaties?	Pursuant to the PO, a compulsory licence may be granted under the grounds of (i) non-working or insufficient working of the patented invention; (ii) refusal to grant licences on reasonable terms; (iii) public health; (iv) national emergency and/or extreme urgency; and (v) dependent patents. Under the Agreement on Trade-Related Aspects of Intellectual Property Rights (" TRIPS "), no such grounds are specified, instead giving a freedom to determine grounds in domestic patent laws, though widely recognised grounds are specified as a patentee abusing his exclusive right, excessive prices, market demand not sufficiently satisfied, public interest (health, national security issues), dependent patents, and government non-commercial use, etc.
6.	Are there any preconditions to apply for a compulsory licence? For example: (a) Any negotiation required between the applicant and the right holder before applying for a compulsory licence?	Preconditions for standard patents: — Application can be filed after the expiration of three years from the date of grant of a standard patent. — One of the application grounds listed under section 64(2) of the PO (a)-(e). — Applicant has made reasonable efforts to obtain authorisation from the proprietor on reasonable commercial

<p>(b) Any urgent situation required in order to grant a compulsory licence?</p> <p>(c) Any minimum number of years required for the patent to be granted and/or implemented in order to be subject to compulsory licensing?</p>	<p>terms and conditions and that such efforts have not been successful within a reasonable period of time.</p> <p>Preconditions for dependent patents:</p> <ul style="list-style-type: none"> — The proprietor of the patent has refused to grant a licence on reasonable terms and as a result, the working or efficient working of any other patented invention is prevented or hindered. — The dependent patent must involve an important technical advance of considerable economic significance in relation to the patent that is the subject matter of the compulsory licence (section 64(2)(d) of the PO). <p>Preconditions for government use of patents:</p> <ul style="list-style-type: none"> — A period of extreme urgency from the perspective of the Chief Executive in Council that it is necessary or expedient in the public interest to grant a compulsory licence (e.g. public health problems resulting from HIV/AIDS, tuberculosis, malaria and other epidemics). — Hong Kong has no or insufficient capacity to manufacture a patented pharmaceutical product to meet the needs for the product in Hong Kong. — In relation to export compulsory licences, the notification from the importing member to TRIPs Council that it is facing a national emergency or other circumstances of extreme urgency. — In case of a lack of such notification, the proposed compulsory licensee must make reasonable efforts to obtain authorisation from the proprietor of the patent concerned prior to submitting his application for an export compulsory licence (section 72L of the PO).
<p>7. Are there any limits on the number of compulsory licensees?</p>	<p>Not specified</p>
<p>8. Will there be any limitation on the scope of the compulsory licence, for example limitations on the time and the territory?</p>	<p>For the duration of the licence, the patented pharmaceutical product, which is imported to Hong Kong under the licence, shall not be exported out of Hong Kong.</p>
<p>9. Which authority has the competency to grant a compulsory licence?</p>	<p>The court: for standard patents.</p> <p>The Chief Executive in Council: for government use of patents during a period of extreme urgency.</p> <p>The Director: for import/export compulsory licences during a period of extreme urgency declared by Chief Executive in Council.</p>
<p>10. Application procedure for compulsory licence:</p> <p>(a) What are the application procedures to get a compulsory licence?</p> <p>(b) What materials need to be submitted to the competent authority?</p> <p>(c) How long will it take to get a compulsory licence?</p>	<p>Application for export compulsory licences for patented pharmaceutical products shall be:</p> <p>(a) made in writing and specifying the name/amount of the patented product to be made and sold for export, the name of the eligible importing member, the duration of the export compulsory licence, and/or the proposed labelling, marking, packaging, colouring or shaping of the patented product (for more information, please refer to section 72(L)(2)(a) of the PO)</p> <p>(b) accompanied by a copy of the written request from the eligible importing member or non-governmental organisation authorised by the eligible importing member to the applicant for the patented product and the amount of</p>

	<p>the product requested; and a copy of the notification made by the eligible importing member to the TRIPS Council (for the separate procedure in case of no such notification, please refer to section 72(L)(4) of the PO).</p> <p>(c) No time limit specified for the granting of an application.</p>
11. Can the competent authority grant a compulsory licence without hearings under an urgent situation?	Yes, in the discretion of the Director during a period of extreme urgency declared by Chief Executive in Council (section 72(B)&(C) of the PO)
<p>12. Revocation/termination of compulsory licence:</p> <p>(a) Can a compulsory licence be revoked/terminated or automatically revoked/terminated?</p> <p>(b) What are the conditions for the revocation/termination of a compulsory licence?</p> <p>(c) How should products made under a compulsory licence be treated if the compulsory licence is terminated/revoked?</p>	<p>(a) A compulsory licence can be revoked/terminated if the proprietor of the patent applies to the court for an order to terminate on the ground that any term or condition of the licence imposed has been contravened (and/or any information, document or documentary evidence specified in or accompanying the licence application is false, incorrect or incomplete in any material way for an export compulsory licence) and the court, on an application, makes an order to terminate the licence. (section 72J & 72R of the PO)</p> <p>(b) The Director (and/or court upon application by the patent owner) may terminate a compulsory licence by giving notice in writing to the compulsory licensee if he is satisfied that any term or condition of the licence imposed has been contravened; or any information, document or documentary evidence specified in or accompanying the licence application is false, incorrect or incomplete in any material way. (section 72G/72Q of the PO)</p> <p>(c) On the termination of the period of extreme urgency, the importing compulsory licensee shall take reasonable steps to recall or cause the recall of any patented pharmaceutical product imported under the compulsory licence; surrender to the Director any patented pharmaceutical product in his possession or recalled; dispose of the product in such a way as may be agreed with the proprietor of the patent (section 72H of the PO). Stocking of any such patented pharmaceutical products may amount to an infringement of the patent concerned. After the import, the compulsory licensee surrenders the product to the Director or disposes of the product from the effective date of the termination of the period of extreme urgency (section 72H of the PO). A person to whom a patented pharmaceutical product is disposed of in accordance with an import compulsory licence shall not export or cause to export the product out of Hong Kong (section 72I of the PO).</p>
Rights and obligations of the right holders in relation to compulsory licensing	
<p>13. Royalty:</p> <p>(a) Does the compulsory licensee have to pay a royalty to the right holder?</p> <p>(b) If the compulsory licensee is required to pay a royalty, how is the amount of royalty determined and who will decide the amount of the royalty?</p>	<p>(a) Royalty shall be paid to the proprietor of a patent granted in an exporting member for the export of a patented pharmaceutical product to Hong Kong in accordance with the relevant instrument (i.e. an agreement) or legislation, but only to the extent that such a contract could have been fulfilled from existing manufacturing or another capacity of the proprietor or licensee; but is payable notwithstanding the existence of circumstances rendering him ineligible for the award of such a contract. If remuneration has been paid, no remuneration shall be paid to the proprietor of the patent concerned granted in Hong Kong for the import compulsory licence in relation to the product (section 72E of the PO).</p>

<p>(c) Is there any remuneration available for the right holders other than royalty?</p>	<p>(b) Where government use is made of an invention, the government shall pay (i) to the proprietor of the patent; or (ii) if there is an exclusive licence in force to the exclusive licensee, compensation for any loss resulting from his not being awarded a contract to supply the patented product or to perform the patented process or supply a thing made by means of the patented process (in default of agreement, to be determined by the court).</p> <p>(c) The Director determines the amount of remuneration for the export compulsory licence in relation to the product (section 72N of the PO). The total amount of remuneration determined by the Director shall not exceed 4% of the total purchase price for the product payable by the import compulsory licensee to the seller of the product in the exporting member; or (ii) if the remuneration cannot be agreed upon, either party may apply to the court for determination of the amount payable. In determining the amount, the court will take into account all factors relevant to the circumstances, including the economic value to Hong Kong of the use of the relevant patented pharmaceutical product; humanitarian or non-commercial factors relevant to the grant of the licence (section 72E&72P of the PO).</p> <p>(d) Normally such other remuneration is to be determined by the court or the Director to the extent it fits.</p>
<p>14. Are there any legal remedies for the party who is not satisfied with the compulsory licensing decision of the competent authority?</p>	<p>If the private right holder fails to reach an agreement with the Director on the amount of remuneration or is not satisfied with the decision by the Director on matters including, but not limited to the grant of compulsory licence, any term or condition of a compulsory licence imposed (including government use of an invention), the right of any person to receive any part of a payment and the apportionment thereof, and/or termination of the compulsory licence, he may apply to the court for a review of or an order to decide on such matters (section 72 of the PO). The government shall provide to the private right holder any legal remedies that the court determines necessary (section 75E(2) of the PO).</p>
<p>15. Provision of know-how and support:</p> <p>(a) In order to implement the compulsory licence, for example, to manufacture the licenced product, is the right holder required to provide necessary support, such as know-how and training as in a voluntary agreed licence agreement?</p> <p>(b) Will this provision of know-how and support be compensated and how is the amount of such compensation determined?</p>	<p>(a) Required if such acts authorised or agreed to be provided in relation to the patented pharmaceutical product under the terms and conditions of the licence; otherwise, required if the Director still thinks this is necessary in regard to the public health needs in Hong Kong in a period of extreme urgency (section 72D of the PO).</p> <p>(b) The provision of know-how and support will be compensated if the Director and the private right holder agree to do so and/or if the court determines to do so on an application submitted by the private right holder or any other person who is entitled to claim this – subject to a 4% royalty restrictions under Q38 (section 72E&72(F) of the PO).</p>

16. Confidentiality: (a) Is the compulsory licensee subject to any confidentiality obligation? (b) If the compulsory licensee discloses the confidential information in violation of its obligation, does the right holder have a basis of claim against the compulsory licensee?	(a) The compulsory licensee is obliged to a duty of confidentiality, even in the case of government use of the invention (section 69(11) of the PO & Article 39.3 of the TRIPS Agreement). (b) In this case, the right holder has a basis of a claim against the compulsory licensee under common law duty of confidentiality.
17. Export of products under compulsory licence (a) Is the compulsory licensee allowed to export their products under the compulsory licence? (b) If the compulsory licensee is permitted to export products under the compulsory licence, are there any requirements and limitations on the export of such products?	(a) Yes, upon acceptance of application by the Director (section 72L(1) of the PO). (b) The patented pharmaceutical product made under the licence shall be exported only to the eligible importing member specified in the licence; and if the patented pharmaceutical product is also patented in the eligible importing member, the product shall be exported to the eligible importing member after it has granted a compulsory licence for importation of the product.
Compulsory licensing in the present COVID-19 pandemic	
18. Have the laws on compulsory licensing been used in previous health emergencies and/or in the present COVID-19 pandemic in your jurisdiction?	N/A
19. Is it possible for third parties to use the current laws on compulsory licensing in your jurisdiction to facilitate the treatment of patients infected by COVID-19?	Yes, any person may apply to the court at any time after the expiration of three years from the date a standard patent has been granted (sections 64-67 of the PO).
20. Are there any recent major regulatory exemptions and/or amendments made following COVID-19 to regulations governing compulsory licensing?	N/A
Transactions and dealings of products under compulsory licences	
21. Can a compulsory licence be transferred or assigned?	The compulsory licence is non-assignable (except for that part of the enterprise or goodwill organisation, which enjoys the use of the patent under the licence) and is also not exclusive (section 72N of the PO), but any provisions/regulations on assignment are of no effect in relation to any government use of an invention so far as those provisions restrict or regulate the working of the invention.

22. Does the issuance of a compulsory licence have any impact on the previously agreed licence?	Where an application for compulsory licence is made in respect to a patent by a person who holds a licence under the patent, the court may (i) if it orders the grant of a licence to the applicant, order the existing licence to be cancelled; or (ii) instead of ordering the grant of a licence to the applicant, order the existing licence to be amended (section 65 of the PO).
23. Is there any special labelling requirement for the products made under the compulsory licence?	The patented pharmaceutical product shall be (i) clearly identified as being imported under the licence through specific labelling or marking; and (ii) distinguished from the same product made by or under authorisation of the proprietor of the patent concerned through special packaging, colouring or shaping (section 72D/72N of the PO).
24. Is there any special distribution channel requirement for the products made under the compulsory licence?	The patented pharmaceutical product, which is imported to Hong Kong under the licence, shall not be exported out of Hong Kong.
25. Is there any price requirement for the products made under the compulsory licence?	N/A (to be determined by the Director and/or court if necessary).

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JURISDICTION: Italy

Compulsory licensing in general

1.	What is the definition of compulsory licensing?	The Industrial Property Code (the “ Code ”) does not contain any specific definition of compulsory licensing. However, it provides a set of rules governing compulsory licences related to patents, utility models, biotechnological inventions and plant varieties.
2.	What are the applicable sources of law relating to compulsory licensing?	<p>The main rules for compulsory licensing provided for by the Code are those concerning patents, laid down in Articles 70 to 74, Article 76 and Article 199.</p> <p>In particular:</p> <ul style="list-style-type: none"> — Article 70 regulates compulsory licences due to lack of implementation by the owner of the patent or his successor in title; — Article 71 regulates compulsory licences for dependent patent; — Article 76, paragraph 4, provides that if the conversion of an invalid patent into a different patent entails the extension of its original duration, the licensees and those who in view of the upcoming expiration had made serious and actual investments to use the invention shall have the right to obtain a free and non-exclusive compulsory licence for the extended period; — Articles 72, 73 and 74 regulate respectively the granting of compulsory licences, their withdrawal and the relationship between compulsory licences and military inventions; — Article 199 establishes the procedure to obtain compulsory licences. <p>The rules provided for compulsory licensing relating to patents apply also to utility models, biotechnological inventions and plant varieties as far as they are compatible with the regulation of said IP rights and unless special provisions apply.</p> <p>The answers below are based essentially on the provisions concerning compulsory licensing related to patents.</p>
3.	<p>Types of products which compulsory licensing applies to:</p> <p>(a) What type(s) of products or technologies do compulsory licensing applies to?</p> <p>(b) Has any compulsory licence ever been issued in your jurisdiction? If yes, on what type of technology?</p>	<p>(a) The Code does not provide the types of products or technologies, which compulsory licensing applies to. However, Article 74 expressly provides that the provisions relating to compulsory licensing do not apply to patented inventions belonging to military agencies or to patented inventions subject to a confidentiality obligation by military agencies.</p> <p>(b) There are no official information relating to compulsory licensing in Italy. However, from an informal inquiry with the PTO, we know that compulsory licensing is an unused tool.</p>

Regulatory requirements on compulsory licensing

<p>4. Who can apply for a compulsory licence? Are foreigners or foreign companies allowed to apply for a compulsory licence?</p>	<p>According to Article 70 of the Code, a compulsory licence due to lack of implementation may be requested by any interested party.</p> <p>According to Article 71 of the Code, a compulsory licence for a dependent patent may be requested by the owner of a later patent, if the requirements laid down in the same Article 71 are met (refer to the answer to question 5).</p> <p>The Code does not prevent (or limit) foreigners or foreign companies from applying for a compulsory licence.</p>
<p>5. What are the legal grounds to grant a compulsory licence under the local laws of your jurisdiction and any applicable international treaties?</p>	<p>Compulsory licence due to lack of implementation.</p> <p>According to Article 70, paragraphs 1 and 2, of the Code, a compulsory licence due to lack of implementation may be granted if:</p> <ul style="list-style-type: none"> — Within three years from the issue of the patent or within four years from the filing of the relevant application if it comes last, the owner of the patent (or his successor in title) has not implemented the patented invention (directly or through licensees), or has implemented it to an extent that is seriously disproportionate to the Country's needs. — The implementation of the invention has been suspended or reduced for more than three years in such a manner to be seriously disproportionate to the country's needs. <p>More specifically, the implementation of the invention means either the production in the territory of the Country, or the importation of products manufactured in a state belonging to the EU, to the European Economic Area or to the WTO.</p> <p>Furthermore, according to Article 70, paragraph 3, of the Code, the compulsory licence is not granted if the lack of or the insufficient implementation is due to causes out of control of the owner of the patent or his successor in title. The same Article 70 specifies, however, that the lack of financial means or the lack of demand in the national market (when the product is marketed abroad) cannot justify the lack of or insufficient implementation.</p> <p>Compulsory licence for dependent patent.</p> <p>According to Article 71 of the Code, a compulsory licence for dependent patent may be granted if:</p> <ul style="list-style-type: none"> — The invention protected by the later patent cannot be used without harm to the rights related to the patent granted on a previous application; and — The later patent represents important technical progress of considerable economic importance in respect to the object of the previous patent. <p>The "technical progress" and "economic importance" mentioned in Article 71 are assessed on a discretionary manner by the administrative authority issuing the compulsory licence. However, as suggested by the authors, the "economic importance" should consist either in an advantage for the society or in a saving of costs compared to the already known production processes.</p>

<p>6. Are there any preconditions to apply for a compulsory licence? For example:</p> <p>(a) Any negotiation required between the applicant and the right holder before applying for a compulsory licence?</p> <p>(b) Any urgent situation required in order to grant a compulsory licence?</p> <p>(c) Any minimum number of years required for the patent to be granted and/or implemented in order to be subject to compulsory licensing?</p>	<p>In addition to the requirements described in the answer to question 5, consider the following:</p> <p>(a) In order to obtain a compulsory licence, the applicant must prove that he has asked the owner of the patent first and has been unable to obtain a contractual licence at fair conditions (Article 72, paragraph 1, of the Code);</p> <p>(b) The Code does not refer to any urgency requirement regarding the granting of a compulsory licence.</p> <p>(c) As pointed out in the answer to question 5, the compulsory licence due to lack of implementation may be requested within three years from the issue of the patent or within four years from the filing of the relevant application, if it comes last. On the contrary, no minimum-years requirements are provided for compulsory licences for dependent patents.</p> <p>Furthermore:</p> <p>(a) The applicant must be able to give appropriate guarantees regarding his ability to satisfactorily implement the invention (Article 72, paragraph 2, of the Code);</p> <p>(b) The applicant must not have infringed the patent, unless he can prove his good faith (Article 72, paragraph 3, of the Code).</p>
<p>7. Are there any limits on the number of compulsory licensees?</p>	<p>No, the Code does not provide any limits on the number of compulsory licensees.</p>
<p>8. Will there be any limitation on the scope of the compulsory licence, for example limitations on the time and the territory?</p>	<p>According to Article 72, paragraph 7, of the Code, the scope and duration of the compulsory licence, the relative methods of implementation, the guarantees and the other terms to which the granting of the licence is subject in relation to its scope, as well as the amount and method of payment of the compensation are determined by the decree granting the licence. The decree is subject to amendments at request of each of the interested parties.</p> <p>In any case, according to the same Article 72, paragraphs 4 and 5, a compulsory licence may be granted:</p> <ul style="list-style-type: none"> — For exploitation of the invention aimed mainly at supplying the national market; — For a period not exceeding the remaining duration of the patent. <p>With specific reference to compulsory licences for dependent patent, Article 71, paragraph 1, of the Code, provides that they may be granted only to the extent necessary to exploit the inventions of the dependent patents.</p>
<p>9. Which authority has the competency to grant a compulsory licence?</p>	<p>The Ministry of Economic Development.</p>
<p>10. Application procedure for compulsory licence:</p> <p>(a) What are the application procedures to get a compulsory licence?</p> <p>(b) What materials need to be submitted to the competent authority?</p>	<p>(a) According to Article 199 of the Code, the application for the granting of a compulsory licence must be submitted before the PTO. The Office shall promptly give notice of the request to the owner of the patent and to those who have rights on the patent (based on acts that have been registered or annotated). These subjects are entitled to oppose the application or the amount and method of payment of the compensation proposed by the applicant within 60 days. In case of opposition, the PTO, within 45 days from the expiration of the above term, shall summon</p>

<p>(c) How long will it take to get a compulsory licence?</p>	<p>the parties to attempt at conciliation. The applicant may file a brief by the fifth day prior to the date of the meeting scheduled for the conciliation attempt. Within 45 days after the meeting the Ministry of Economic Development will decide whether to grant the compulsory licence or reject the application.</p> <p>(b) The applicant must file a grounded request to the Italian PTO, indicating the amount and method of payment of the offered compensation.</p> <p>(c) The proceeding shall be concluded within 180 days from the filing of the application (Article 199, paragraph 7, of the Code).</p>
<p>11. Can the competent authority grant a compulsory licence without hearings under an urgent situation?</p>	<p>The procedure described in the answer to question 11 applies also in case of urgency.</p>
<p>12. Revocation/termination of compulsory licence:</p> <p>(a) Can a compulsory licence be revoked/terminated or automatically revoked/terminated?</p> <p>(b) What are the conditions for the revocation/termination of a compulsory licence?</p> <p>(c) How should products made under a compulsory licence be treated if the compulsory licence is terminated/revoked?</p>	<p>(a) A compulsory licence automatically terminates with the expiry of the patent.</p> <p>Furthermore, according to Article 73 of the Code, a compulsory licence shall be revoked by decree of the Ministry of Economic Development:</p> <ul style="list-style-type: none"> — On joint request of the parties; or — Upon request of the licensor, when the requirements indicated under letter b) below are met (in such a case a procedure governed by the same rules explained under the answer to question 10 shall commence). <p>(b) A compulsory licence shall be revoked if:</p> <ul style="list-style-type: none"> — The conditions established for the implementation of the invention have not been fulfilled; — The licensee has not paid the compensation in the amount or by the methods set; and — In case the circumstances that have led to the granting of the licence ceased to exist and it is unlikely that they will recur. <p>(c) Pursuant to Article 73, paragraph 4, of the Code, in the event of revocation, the party who obtained the licence may still implement the invention at the same conditions, within the limits of previous use or the limits that are determined by serious and actual preparations. For example, the revocation of the licence will have no effect on the products manufactured under it by the licensee.</p>
<p>Rights and obligations of the right holders in relation to compulsory licensing</p>	
<p>13. Royalty:</p> <p>(a) Does the compulsory licensee have to pay a royalty to the right holder?</p> <p>(b) If the compulsory licensee is required to pay a royalty, how is the amount of royalty determined and who will decide the amount of the royalty?</p>	<p>(a) According to Article 72, paragraph 2, of the Code, a compulsory licence may be granted only against the payment of fair compensation by the licensee. Note that the Code does not specify if the compensation shall consist in a lump-sum payment or in royalties; therefore, both kinds of compensation seem to be possible.</p> <p>(b) The amount and the method of payment of the compensation are determined in the decree granting the licence on a case-by-case basis.</p> <p>In the event of opposition to the amount and/or method of payment of the compensation, the decision shall be issued</p>

<p>(c) Is there any remuneration available for the right holders other than royalty?</p>	<p>by an Arbitration Board, consisting of three members (any party will appoint one member, while the third member will be appointed by the two appointed members or, in case of disagreement, by the President of the Board of Appeal of the PTO). The Arbitration Board shall decide on the basis of a fair assessment. If one of the parties does not appoint its arbitrator, or the determination of the board is clearly unfair or erroneous, the decision will be issued by the competent court.</p> <p>(c) Refer to the explanation under letter a) of this answer.</p>
<p>14. Are there any legal remedies for the party who is not satisfied with the compulsory licensing decision of the competent authority?</p>	<p>The decision of the Ministry of Economic Development is an administrative order, which can consequently be challenged before the competent Administrative Court.</p>
<p>15. Provision of know-how and support:</p> <p>(a) In order to implement the compulsory licence, for example, to manufacture the licenced product, is the right holder required to provide necessary support, such as know-how and training as in a voluntary agreed licence agreement?</p> <p>(b) Will this provision of know-how and support be compensated and how is the amount of such compensation determined?</p>	<p>(a) The Code does not provide for the obligation of the licensor of a compulsory licence to support the licensee in the implementation of the licence. However, in principle such an obligation could be provided by the decree of the Ministry of the Economic Development granting the licence.</p> <p>(b) Should the decree expressly provide for such obligations, it could also determine compensation and the relevant amount.</p>
<p>16. Confidentiality:</p> <p>(a) Is the compulsory licensee subject to any confidentiality obligation?</p> <p>(b) If the compulsory licensee discloses the confidential information in violation of its obligation, does the right holder have a basis of claim against the compulsory licensee?</p>	<p>(a) The Code does not provide for any obligation of confidentiality for the licensee of a compulsory licence. However, in principle such an obligation could be provided by the decree of the Ministry of the Economic Development granting the licence.</p> <p>(b) Should the decree expressly provide for such obligation, it could also determine the relative consequences in the event of a violation. In any case, the violation of the confidentiality obligation, if provided in the decree, could justify a request of revocation of the licence.</p>
<p>17. Export of products under compulsory licence</p> <p>(a) Is the compulsory licensee allowed to export their products under the compulsory licence?</p> <p>(b) If the compulsory licensee is permitted to export products under the compulsory licence, are there any requirements and limitations on the export of such products?</p>	<p>(a) Although, in principle, the export of products under the compulsory licence is not forbidden, according to Article 72, paragraph 4, of the Code, the compulsory licence must be aimed mainly at supplying the national market. In this regard, some authors argue that only the unexpected production surpluses may be exported.</p> <p>(b) There are no specific limitations, except for the main purpose indicated above.</p>

Compulsory licensing in the present COVID-19 pandemic

18. Have the laws on compulsory licensing been used in previous health emergencies and/or in the present COVID-19 pandemic in your jurisdiction?	To the best of our knowledge, laws on compulsory licensing have not been used in previous health emergencies or in the present COVID-19 pandemic in Italy.
19. Is it possible for third parties to use the current laws on compulsory licensing in your jurisdiction to facilitate the treatment of patients infected by COVID-19?	In principle, the current provisions on compulsory licensing can be used by third parties to facilitate the treatment of patients infected by COVID-19. However, in our opinion, the particularly strict requirements and burdensome procedure provided for by the Code may prove ineffective to grant solutions in emergency situations.
20. Are there any recent major regulatory exemptions and/or amendments made following COVID-19 to regulations governing compulsory licensing?	No regulatory exemptions and/or amendments have been made following COVID-19 to regulations governing compulsory licensing.

Transactions and dealings of products under compulsory licences

21. Can a compulsory licence be transferred or assigned?	<p>According to Article 72, paragraph 5, of the Code, except whether there is an express consent of the patent owner or his successor in title, the compulsory licence may only be transferred with the licensee's business or with the business unit in which the licence is used.</p> <p>Furthermore, according to Article 71, paragraph 2, the compulsory licence for the dependent patent may be transferred only accompanied by the patent on the dependent invention.</p>
22. Does the issuance of a compulsory licence have any impact on the previously agreed licence?	The Code does not provide specific provisions in this regard; it only establishes that any previous licensee is not relieved by the obligation to implement the invention.
23. Is there any special labelling requirement for the products made under the compulsory licence?	Italian rules on compulsory licensing do not provide for any specific labelling, distribution channels and/or price requirements. However, in principle such requirements could be provided by the Decree of the Ministry of the Economic Development granting the licence.
24. Is there any special distribution channel requirement for the products made under the compulsory licence?	Refer to the answer to question 23.
25. Is there any price requirement for the products made under the compulsory licence?	Refer to the answer to question 23.

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JURISDICTION: The Netherlands

Compulsory licensing in general

1. What is the definition of compulsory licensing?	<p>There is no specific legal definition for compulsory licensing under Dutch law. However, the Dutch Patents Act 1995 contains a number of requirements for obtaining a compulsory licence.</p> <p>The Dutch Patent Act 1995 states that “The Minister may, if he considers it in the public interest, grant a licence under a patent, the contents of which shall be described precisely by him, to a party designated by him.”</p>
2. What are the applicable sources of law relating to compulsory licensing?	<p>The Dutch Patents Act 1995 (<i>Rijksoctrooiwet</i> 1995, “ROW”); The Seeds and Planting Materials Act 2005 (Plant Variety Rights); the Dutch Copyright Act; and the General Administrative Law Act (<i>Algemene wet bestuursrecht</i>, “<i>Awb</i>”);</p> <p>Other sources are international agreements such as the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs). In addition, the Dutch Competition Act (<i>Mededingingswet</i>) may also be applicable. The information below will focus on the Patent Act (ROW).</p>
<p>3. Types of products which compulsory licensing applies to:</p> <p>(a) What type(s) of products or technologies do compulsory licensing applies to?</p> <p>(b) Has any compulsory licence ever been issued in your jurisdiction? If yes, on what type of technology?</p>	<p>(a) There is no limitation on the types of products or technologies, which compulsory licensing is applicable or potentially applicable to.</p> <p>(b) Other than two old cases (in 1936 and 1945 under the previous Dutch Patent Act) in which a compulsory licence was granted, no compulsory licences have been issued in the Netherlands. These two old cases related to a “low frequency amplifier” and technology related to the manufacture of “blueprint paper” respectively.</p>

Regulatory requirements on compulsory licensing

4. Who can apply for a compulsory licence? Are foreigners or foreign companies allowed to apply for a compulsory licence?	<p>Foreign companies are allowed to apply for a compulsory licence, as long as they are qualified as an interested party.</p> <p>A compulsory licence on the grounds of public interest is granted by ministerial order of the Minister of Economic Affairs and Climate Policy. The compulsory licence can only be granted to a party specifically designated by the Minister.</p> <p>According to Article 1:2 (3) <i>Awb</i>, the interested party needs to be a legal entity. In principle, ‘legal entity’ means a legal person within the meaning of Book 2 of the Dutch Civil Code (BW), although legal persons under foreign law may also be interested parties.</p>
5. What are the legal grounds to grant a compulsory licence under the local laws of your jurisdiction and any applicable international treaties?	<p>Article 57(1) ROW: public interest. According to the intention of the legislator, this concept must be interpreted broadly. According to the Minister of Economic Affairs and Climate Policy, this generally includes all of the government’s policy objectives. According to the Secretary of State, an example might be in the case of combatting an epidemic where the patent holder has insufficient production capacity to meet the demands for his effective drug (for which there are no equivalent alternatives).</p> <p>Article 57(2) ROW: non-use for three years</p> <p>Article 57(4) ROW: dependency of a younger patent</p>

	<p>Article 57(5&6) ROW: dependency in plant breeders' rights</p> <p>Article 59(1) ROW: (national) defence purposes</p> <p>Article 60(1) ROW: under the Euratom Treaty</p>
<p>6. Are there any preconditions to apply for a compulsory licence? For example:</p> <p>(a) Any negotiation required between the applicant and the right holder before applying for a compulsory licence?</p> <p>(b) Any urgent situation required in order to grant a compulsory licence?</p> <p>(c) Any minimum number of years required for the patent to be granted and/or implemented in order to be subject to compulsory licensing?</p>	<p>For a compulsory licence on the grounds of public interest (article 57(1) ROW), the granting of the licence is entrusted to the Ministry of Economic Affairs and Climate Policy (with the possibility of an appeal to the administrative court). A request for a compulsory licence must be addressed to the Minister. The law provides for the possibility that the Minister grants a compulsory licence "to itself" in case the government feels a public-interest need to be able to exploit an invention.</p> <p>(a) No negotiations between stakeholders and the holder of the patent are required for the Minister to grant the licence. However, before making its decision, the Minister shall, unless the urgency of the matter dictates otherwise, examine whether the patent holder is willing to grant the licence voluntarily on reasonable terms. The patent holder will be allowed to put forward its objections in writing and orally. There is no minimum number of years required for the patent to be granted and/or implemented in order to be subject to compulsory licensing.</p> <p>(b) Urgency is not a formal requirement. However, regarding the most important category of compulsory licences for reasons of "public interest", such public-interest cases will likely involve an element of urgency.</p> <p>(c) For compulsory licences based on public interest, there is no minimum number of years required in order to be subject to compulsory licensing. As for the other grounds, only a compulsory licence for non-use requires three years of non-usus for it to be applicable.</p>
<p>7. Are there any limits on the number of compulsory licensees?</p>	<p>None. Article 58a(1) ROW states that a licence granted on the basis of Article 57 ROW is not exclusive. Furthermore, when public interest is the grounds for being granted, only a person designated by the Minister can be granted it. This may be several persons, but not an unspecified generalisation.</p>
<p>8. Will there be any limitation on the scope of the compulsory licence, for example limitations on the time and the territory?</p>	<p>Compulsory licences by their nature give the licensee the right to apply the patent within the limits of the compulsory licence. The compulsory licence granted by Minister of Economic Affairs and Climate Policy will be limited to the Netherlands.</p> <p>The provision does not further regulate how the terms of the compulsory licence are to be determined. The parties are expected to agree on this themselves.</p> <p>However, the compulsory licence is strictly 'personal': the licensee may only apply the acts reserved to the patent holder himself under the compulsory licence. Please note that pursuant to Art. 58(a)(3) ROW, a compulsory licence may be revoked if, taking into consideration a reasonable protection of the licensee's justified interests, the circumstances that led to the licence being granted have ceased to exist and it is unlikely that they will be revived. On the grounds of a substantiated request, the authority that granted the licence shall investigate whether the aforementioned circumstances continue to apply.</p> <p>Note that the Minister may impose upon the licensee the obligation to provide security within a certain term.</p>

<p>9. Which authority has the competency to grant a compulsory licence?</p>	<p>The Minister of Economic Affairs and Climate Policy is competent authority for granting a compulsory licence on the grounds of public interest. In other cases, interested parties can institute legal proceedings before the Hague Court. The Hague Court has jurisdiction to grant compulsory licences based on the ROW.</p>
<p>10. Application procedure for compulsory licence:</p> <p>(a) What are the application procedures to get a compulsory licence?</p> <p>(b) What materials need to be submitted to the competent authority?</p> <p>(c) How long will it take to get a compulsory licence?</p>	<p>For applications on the grounds of public interest:</p> <p>(a) The application for a decision shall be submitted in writing to the administrative body competent to decide on the application, which is in this case the Minister of Economic Affairs and Climate Policy (article 4:1 Awb).</p> <p>(b) The application shall be signed and contain the minimum information (article 4:2(1) Awb):</p> <ul style="list-style-type: none"> – the name and address of the applicant; – the date; – an indication of the decision, which is requested. <p>Article 4:2(2) stipulates: the applicant shall also provide such information and documents as may reasonably be obtained to enable him to take a decision on the application.</p> <p>(c) Article 4:13 Awb: An order must be given within the period prescribed by law or, in the absence of such a period, within a reasonable period of time after receipt of the application. The reasonable period shall in any case have expired if the administrative body has not issued a decision within eight weeks of receipt of the application, unless the administrative body informs the applicant of this within this period, stating a reasonable period within which the decision can be expected (article 4:14 (3) Awb).</p> <p>For other cases: The regular court procedures of the Hague Court apply.</p>
<p>11. Can the competent authority grant a compulsory licence without hearings under an urgent situation?</p>	<p>For the grounds of public interest:</p> <p>According to the TRIPS Treaty, it must be examined whether the patent holder is or is not willing to grant a licence voluntarily (as Article 31 TRIPs Treaty sub b prescribes). As discussed in sub 4, the patent holder will be allowed to put forward its objections to the Minister in writing and orally. According to Art. 57(1) RPOW, if there is urgency, the Minister is not obliged to examine whether the patent holder is willing to grant the licence voluntarily on reasonable terms. This would imply that under such circumstances of urgency, the compulsory licence could be granted without hearings.</p>
<p>12. Revocation/termination of compulsory licence:</p> <p>(a) Can a compulsory licence be revoked/terminated or automatically revoked/terminated?</p> <p>(b) What are the conditions for the revocation/termination of a compulsory licence?</p> <p>(c) How should products made under a compulsory licence be treated if the compulsory</p>	<p>(a) Article 58a(3) ROW stipulates that a granted compulsory licence may be revoked in certain circumstances.</p> <p>(b) The conditions for such revocation is when, after taking into account a reasonable protection of the legitimate interests of the licensee, the circumstances that led to the granting of the licence cease to exist and are unlikely to be revived. The authority that granted the licence shall, upon a well-reasoned request, investigate the circumstances above.</p> <p>(c) How products made under a compulsory licence should be treated if the compulsory licence is terminated/revoked is not specified in the ROW.</p>

licence is terminated/ revoked?	
Rights and obligations of the right holders in relation to compulsory licensing	
<p>13. Royalty:</p> <p>(a) Does the compulsory licensee have to pay a royalty to the right holder?</p> <p>(b) If the compulsory licensee is required to pay a royalty, how is the amount of royalty determined and who will decide the amount of the royalty?</p> <p>(c) Is there any remuneration available for the right holders other than royalty?</p>	<p>a/b/c. A compulsory licence will require payment of a licence fee by the licensee. Parties are expected to agree on this themselves. If they do not agree on the fee to be paid, article 58(6) ROW stipulates that the Hague Court will determine the fee.</p> <p>The court has jurisdiction for all compulsory licences except those pursuant to the Euratom Treaty for determining the fee to be paid by the licensee.</p> <p>The Minister may make the licence conditional upon the provision of security, but the determination of the fee to be paid is reserved to the court pursuant to article 58(6) ROW.</p>
<p>14. Are there any legal remedies for the party who is not satisfied with the compulsory licensing decision of the competent authority?</p>	<p>The applicant can within six weeks of the decision of the Minister lodge a notice of objection with the Minister. The applicant shall be obliged to state any new facts or changed circumstances (article 4:6 Awb). After this, the applicant can file an appeal with the court of The Hague. This objection has suspensive effect, unless the Minister has decided otherwise for reasons of urgency.</p> <p>For other grounds, the regular appeal procedure of the Hague Court of Appeal applies.</p>
<p>15. Provision of know-how and support:</p> <p>(a) In order to implement the compulsory licence, for example, to manufacture the licenced product, is the right holder required to provide necessary support, such as know-how and training as in a voluntary agreed licence agreement?</p> <p>(b) Will this provision of know-how and support be compensated and how is the amount of such compensation determined?</p>	<p>(a) There is no requirement under Dutch (patent) law for the right holder to provide know-how and support to the licensee.</p> <p>(b) N/A</p>
<p>16. Confidentiality:</p> <p>(a) Is the compulsory licensee subject to any confidentiality obligation?</p> <p>(b) If the compulsory licensee discloses the confidential information in violation of its obligation, does the right holder have a basis of claim against the compulsory licensee?</p>	<p>a/b. There is no such requirement under Dutch law. As a patent embodies technology that is made publicly available through publication in the respective patent registries, it is also not likely that any confidentiality obligations are violated by the mere use of a granted licence. Of course, as parties will usually negotiate contractual arrangements for the granting of a compulsory licence, such arrangement might well include (contractual) confidentiality obligations.</p>

17.	Export of products under compulsory licence (a) Is the compulsory licensee allowed to export their products under the compulsory licence? (b) If the compulsory licensee is permitted to export products under the compulsory licence, are there any requirements and limitations on the export of such products?	a/b. There are no express restrictions against the export of products produced under a compulsory licence granted under Article 57 of the ROW. However, as suggested above, the Minister, when granting a compulsory licence for reasons of public interest, can determine the scope and conditions of the licence.
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Compulsory licensing in the present COVID-19 pandemic

18.	Have the laws on compulsory licensing been used in previous health emergencies and/or in the present COVID-19 pandemic in your jurisdiction?	No.
19.	Is it possible for third parties to use the current laws on compulsory licensing in your jurisdiction to facilitate the treatment of patients infected by COVID-19?	<p>When third parties are interested parties, they could theoretically apply to the Ministry Economic Affairs and Climate Policy for a compulsory licence on the grounds of public interest.</p> <p>However, in the Netherlands as stated in legislative history, the compulsory licence is generally considered a drastic measure and a last resort option. However, one could argue that given the current COVID-19 crisis, public interest would constitute a valid reason for a compulsory licence for the use of patented inventions relating to the treatment and the diagnosis of COVID-19 in instances where the right holders do not make such inventions sufficiently available to the market.</p> <p>Note that granting of a compulsory licence does not mean that a patented treatment will become available to patients. Many other factors could hinder such availability, such as data-exclusivity and market-exclusivity periods and the fact that many patents require access to the know-how of the right holder to be able to efficiently produce the product.</p>
20.	Are there any recent major regulatory exemptions and/or amendments made following COVID-19 to regulations governing compulsory licensing?	On March 26, 2020, the Dutch parliament suggested that “all means, including a compulsory licence, should be used if necessary when fighting COVID-19”. All political parties agreed. A member of parliament (Ploumen) has also submitted on 5 June 2020 a legislative proposal amending the ROW to give special power to the Minister of Health, Welfare and Sport to grant a compulsory licence for combating the spread of COVID-19. However, no specific legislation or measures are in place yet.

Transactions and dealings of products under compulsory licences

21.	Can a compulsory licence be transferred or assigned?	Transfer of a compulsory licence is only possible to a limited extent, namely only together with the transfer of the company – or part of the company – in which the compulsory licence is applied, see 58(2) ROW.
22.	Does the issuance of a compulsory licence have any impact on the previously agreed licence?	There are no specific provisions in Dutch law that relate to the impact of a compulsory licence on a previously agreed licence.

23.	Is there any special labelling requirement for the products made under the compulsory licence?	There is no such special labelling requirement in the statutory provisions relating to compulsory licensing in the Netherlands.
24.	Is there any special distribution channel requirement for the products made under the compulsory licence?	There is no such special distribution channel requirement in the statutory provisions relating to compulsory licensing in the Netherlands.
25.	Is there any price requirement for the products made under the compulsory licence?	There are no express price requirements in the statutory provisions relating to compulsory licensing in the Netherlands.

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JURISDICTION: Republic of North Macedonia

Compulsory licensing in general

1. What is the definition of compulsory licensing?	Compulsory licensing is defined as granting the right of using a licence to a third person followed by payment of compensation to the holder of the patent (right holder) under the following cumulative conditions: (a) The right holder does not use the patent, or the usage of the patent does not satisfy the needs of the domestic market; (b) The right holder refuses to conclude an agreement on the licence or sets unfair conditions for using the patent.
2. What are the applicable sources of law relating to compulsory licensing?	Compulsory licensing is regulated in the Law on Industrial Property, Official Gazette of North Macedonia, nos. 21/2009, 24/2011, 12/2014, 41/2014, 152/2015, 53/2016 и 83/2018, and 31/2020 (" Law on IP Rights ") as well as in the Law on Ratification of the Protocol for Amending and Supplementing the Agreement on the Trade Aspects of the Intellectual Property Rights.
3. Types of products which compulsory licensing applies to: (a) What type(s) of products or technologies do compulsory licensing applies to? (b) Has any compulsory licence ever been issued in your jurisdiction? If yes, on what type of technology?	(a) The Law on IP Rights does not stipulate the products to which the compulsory licensing applies (i.e. there are no products or technologies excluded from its applicability). (b) There are no data on granted licences available online.

Regulatory requirements on compulsory licensing

4. Who can apply for a compulsory licence? Are foreigners or foreign companies allowed to apply for a compulsory licence?	Any person may apply for a compulsory licence. Namely, foreigners are not restricted to apply.
5. What are the legal grounds to grant a compulsory licence under the local laws of your jurisdiction and any applicable international treaties?	The Law on IP Rights stipulates that grounds for granting a compulsory licence include a court decision issued by the court that has jurisdiction to decide on IP rights. Such procedure is initiated upon a lawsuit submitted by the applicant for a compulsory licence against the right holder.
6. Are there any preconditions to apply for a compulsory licence? For example: (a) Any negotiation required between the applicant and the right holder before applying for a compulsory licence? (b) Any urgent situation required in order to grant a compulsory licence?	The following rules and obligations apply in the procedure for granting a compulsory licence: (a) The applicant must try to obtain consent from the right holder in the last 30 days before submitting the lawsuit for granting a compulsory licence with the competent court. (b) Urgent situations are not a mandatory pre-condition for issuance of a compulsory licence (in case all other statutory conditions are met). As an exemption of the standard conditions, the Law on IP Right stipulates that a compulsory licence may be granted in a situation in which using the patent is necessary due to state matters, protection of the public interest related to health, nutrition,

(c) Any minimum number of years required for the patent to be granted and/or implemented in order to be subject to compulsory licensing?	<p>protection and improvement of the environment, or in case the licence essentially benefits certain branches of the economy.</p> <p>(c) The request for granting a compulsory licence cannot be submitted prior to expiry of four years as of submitting the patent application, or prior to expiry of three years as of recognition of the patent (if this period expires later than the four-year period).</p>
7. Are there any limits on the number of compulsory licensees?	The regulations on compulsory licences do not stipulate any limitation of the number of licences.
8. Will there be any limitation on the scope of the compulsory licence, for example limitations on the time and the territory?	<p>Yes, the limitations on the scope of compulsory licences are as follows:</p> <p>(a) The compulsory licence is valid as long as the reasons for its issuance persist;</p> <p>(b) The compulsory licence cannot be exclusive;</p> <p>(c) It cannot be transferred to third persons, except in case of a transfer of the production unit in which the invention, subject to the compulsory licence, is used.</p>
9. Which authority has the competency to grant a compulsory licence?	The Macedonian court has an exclusive jurisdiction to decide on granting the compulsory licence in cases where the patent for which the compulsory licence is requested, is registered in North Macedonia.
<p>10. Application procedure for compulsory licence:</p> <p>(a) What are the application procedures to get a compulsory licence?</p> <p>(b) What materials need to be submitted to the competent authority?</p> <p>(c) How long will it take to get a compulsory licence?</p>	<p>(a) The application procedure is carried out by a competent court and is initiated by submitting a lawsuit. Such a lawsuit contains a request for granting a compulsory licence;</p> <p>(b) The Law on IP rights does not list the materials that need to be filed when applying for a compulsory licence, except for the following materials, which need to be filed when applying for a compulsory licence needed for public healthcare:</p> <ul style="list-style-type: none"> — Requests for issuance of compulsory licences submitted in other states for the same product; — Information on the applicant or its representative; — Name of the pharmaceutical product; — Quantity of the planned production; — Data on the state importer; — Proof that negotiations were carried out with the patent holder; — Proof of a request from an authorised representative from the importing country or other equivalent documentation. <p>(c) The duration of the issuance procedure is not regulated by law.</p>
11. Can the competent authority grant a compulsory licence without hearings under an urgent situation?	The issuance of a compulsory licence in an urgent situation represents an exception from ordinary procedures. However, the procedure that should be applied in urgent situations is not regulated.

<p>12. Revocation/termination of compulsory licence:</p> <p>(a) Can a compulsory licence be revoked/terminated or automatically revoked/terminated?</p> <p>(b) What are the conditions for the revocation/termination of a compulsory licence?</p> <p>(c) How should products made under a compulsory licence be treated if the compulsory licence is terminated/revoked?</p>	<p>(a) The compulsory licence terminates as soon as the reasons for its issuance cease. However, in practice such termination is not automatic (i.e. it should be initiated by submitting an elaborated request from an interested party). A revocation may also be claimed in a court procedure when the right holder or the holder of the compulsory licence initiates a lawsuit.</p> <p>(b) As stated in point a above, the compulsory licence shall be terminated as soon as the reasons for its issuance cease. Additionally, the court shall rule on revocation of the licence if it ascertains that the decision on granting a compulsory licence has not been followed.</p> <p>(c) In case of revocation of the compulsory licence, the court imposes an obligation for the licensee to:</p> <ul style="list-style-type: none"> — reallocate at its own expense all the products in its possession or jurisdiction; or — allow the importing country to reallocate the products; or — remove the products in any other manner agreed upon with the right holder.
<p>Rights and obligations of the right holders in relation to compulsory licensing</p>	
<p>13. Royalty:</p> <p>(a) Does the compulsory licensee have to pay a royalty to the right holder?</p> <p>(b) If the compulsory licensee is required to pay a royalty, how is the amount of royalty determined and who will decide the amount of the royalty?</p> <p>(c) Is there any remuneration available for the right holders other than royalty?</p>	<p>(a) Yes, the licensee is obliged to pay a royalty to the right holder.</p> <p>(b) The parties shall amicably determine the amount of the royalty. If such a settlement cannot be reached, the competent court shall determine the amount of the royalty.</p> <p>(c) There is no other remuneration available other than a royalty.</p>
<p>14. Are there any legal remedies for the party who is not satisfied with the compulsory licensing decision of the competent authority?</p>	<p>As a general procedural rule, the parties have a right to a second-instance ruling upon a submission of an appeal against the first-instance ruling.</p>
<p>15. Provision of know-how and support:</p> <p>(a) In order to implement the compulsory licence, for example, to manufacture the licenced product, is the right holder required to provide necessary support, such as know-how and training as in a voluntary agreed licence agreement?</p> <p>(b) Will this provision of know-how and support be compensated and how is the amount of such compensation determined?</p>	<p>No, the Law on IP rights does not stipulate obligations for the right holder to provide such support.</p>

16. Confidentiality: (a) Is the compulsory licensee subject to any confidentiality obligation? (b) If the compulsory licensee discloses the confidential information in violation of its obligation, does the right holder have a basis of claim against the compulsory licensee?	The Law on IP Rights does not regulate confidentiality obligations for the compulsory licensee. However, in terms of confidentiality in general, special rules apply for patents related to defence issues, which are within the competence of the Ministry of Defence.
17. Export of products under compulsory licence (a) Is the compulsory licensee allowed to export their products under the compulsory licence? (b) If the compulsory licensee is permitted to export products under the compulsory licence, are there any requirements and limitations on the export of such products?	<p>The compulsory licence is generally used for satisfying the needs of the domestic market.</p> <p>The Law on IP rights regulates only the export of pharmaceutical products. Namely, an export to other counties may be allowed for healthcare purposes. Pharmaceutical products may be exported only in:</p> <ul style="list-style-type: none"> — Less developed countries listed as such on the list of the UN; — Members of the WTO, which have sent a notification to the TRIPS council on the intention to use the system as an importing country; — Counties, which are not members of the WTO, but are listed as countries with low income (less than USD 745 per citizen) and have notified the Ministry of Economy of their intention to use the system as an importing country.
Compulsory licensing in the present COVID-19 pandemic	
18. Have the laws on compulsory licensing been used in previous health emergencies and/or in the present COVID-19 pandemic in your jurisdiction?	Such information has not been made publicly available.
19. Is it possible for third parties to use the current laws on compulsory licensing in your jurisdiction to facilitate the treatment of patients infected by COVID-19?	There is no restriction to use the current laws on compulsory licensing to facilitate such treatments.
20. Are there any recent major regulatory exemptions and/or amendments made following COVID-19 to regulations governing compulsory licensing?	There are no recent amendments to the compulsory licensing regulations made during the COVID-19 state of emergency.
Transactions and dealings of products under compulsory licences	
21. Can a compulsory licence be transferred or assigned?	In general, no. As an exception, the compulsory licence may be transferred in case of a transfer of the production unit in which the invention, subject to the compulsory licence, is used.
22. Does the issuance of a compulsory licence have any impact on the previously agreed licence?	No.

23.	Is there any special labelling requirement for the products made under the compulsory licence?	Yes, this requirement refers to pharmaceutical products made under a compulsory licence. The package of these products must contain a clear indication that the products were made under a compulsory licence, the name of the court that issued the licence, the court's file number, an indication that the products have been made for export and distribution to other importing countries, and all other data required by the customs authority in North Macedonia.
24.	Is there any special distribution channel requirement for the products made under the compulsory licence?	No. The compulsory licence does not influence distribution channels.
25.	Is there any price requirement for the products made under the compulsory licence?	No.

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JURISDICTION: Peru

Compulsory licensing in general

1. What is the definition of compulsory licensing?	<p>Peruvian law does not establish a definition of compulsory licences. However, Peruvian laws establish four types of compulsory licences:</p> <ul style="list-style-type: none"> — Compulsory licence for lack of exploitation. — Compulsory licence for reason of public interest, emergency or national security. — Compulsory Licences for Anti-competitive Practices. — Compulsory licence for dependency of the patent.
2. What are the applicable sources of law relating to compulsory licensing?	<p>The regulations applicable to Peru regarding compulsory licences are:</p> <ul style="list-style-type: none"> — Decision 486 of the Andean Community of Nations (CAN); — Legislative Decree No. 1075 issued by the Peruvian Government; — Resolution No. 2706-2019 / DIN-INDECOPI – Guidelines for the authorisation of compulsory licences of Patents issued by the National Institute for the Defence of Competition and Protection of Intellectual Property (INDECOPI); — Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) of the World Trade Organisation (WTO).
<p>3. Types of products which compulsory licensing applies to:</p> <p>(a) What type(s) of products or technologies do compulsory licensing applies to?</p> <p>(b) Has any compulsory licence ever been issued in your jurisdiction? If yes, on what type of technology?</p>	<p>(a) Compulsory licences can be requested for any kind of patent.</p> <p>(b) According to the public information of INDECOPI, no compulsory licence has been issued in Peru.</p>

Regulatory requirements on compulsory licensing

4. Who can apply for a compulsory licence? Are foreigners or foreign companies allowed to apply for a compulsory licence?	Any natural or legal person, regardless of their nationality, including foreign companies, can apply for a compulsory licence.
5. What are the legal grounds to grant a compulsory licence under the local laws of your jurisdiction and any applicable international treaties?	<p>The local regulations for the granting of a compulsory licence are:</p> <ul style="list-style-type: none"> — Legislative Decree No. 1075 issued by the Peruvian government; — Resolution No. 2706-2019/DIN-INDECOPI – Guidelines for the authorisation of compulsory licences of Patents issued by INDECOPI; — Decision 486 of CAN;

	<ul style="list-style-type: none"> — Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).
<p>6. Are there any preconditions to apply for a compulsory licence? For example:</p> <p>(a) Any negotiation required between the applicant and the right holder before applying for a compulsory licence?</p> <p>(b) Any urgent situation required in order to grant a compulsory licence?</p> <p>(c) Any minimum number of years required for the patent to be granted and/or implemented in order to be subject to compulsory licensing?</p>	<p>(a) Yes, the applicant for a compulsory licence must present satisfactory evidence to the Office of Inventions and New Technologies of INDECOPI that he has made an effort to obtain the authorisation of the rights holder and that such efforts have not been successful for a period of 30 days prior to submitting the application.</p> <p>(b) Compulsory licences can be granted for reasons of public interest, emergency or national security declared by the Peruvian state through a Supreme Decree.</p> <p>(c) After the expiration of three years from the granting of the patent or four years from its application, whichever is longer, the authority, at the request of any interested party, will grant a compulsory licence mainly for the industrial production of the product object of the patent or the integral use of the patented procedure, only if at the time of its request the patent has not been exploited, or if the exploitation of the invention has been suspended by more than a year.</p>
<p>7. Are there any limits on the number of compulsory licensees?</p>	<p>Peruvian laws establish four types of compulsory licences:</p> <ul style="list-style-type: none"> — Compulsory licence for lack of exploitation. — Compulsory licence for reason of public interest, emergency or national security. — Compulsory Licences for Anti-competitive Practices. — Compulsory licence for dependency of the patent.
<p>8. Will there be any limitation on the scope of the compulsory licence, for example limitations on the time and the territory?</p>	<p>The scope and duration of compulsory licences will be limited according to the purposes for which they were granted and solely to supply the national market. Likewise, at the request of the patent rights holder or licensee, the conditions of compulsory licences may be modified by the National Patent Office when new facts justify it and, in particular, when the patent rights holder grants another licence under more favourable conditions than those established in the compulsory licence.</p>
<p>9. Which authority has the competency to grant a compulsory licence?</p>	<p>The Office of Inventions and New Technologies of INDECOPI.</p>
<p>10. Application procedure for compulsory licence:</p> <p>(a) What are the application procedures to get a compulsory licence?</p> <p>(b) What materials need to be submitted to the competent authority?</p> <p>(c) How long will it take to get a compulsory licence?</p>	<p>(a) The application for a compulsory licence must follow the following procedure:</p> <ul style="list-style-type: none"> — Submit a written application to the Office of Inventions and New Technologies of INDECOPI that must contain i) the data that identifies the applicant and the address for notifications and POA, if necessary; ii) Patent registration number; iii) documents supporting the granting of the compulsory licence; and iv) the administrative fee. — Upon receipt of the application, the authority will assess whether it meets the requirements for its submission. If such requirements are not met, it will grant the applicant a non-extendable period of 30 working days to correct the omissions of the application. — After verifying the requirements for filing the application, the patent rights holder will be informed

	<p>so that he can present the documents he deems necessary, for a non-extendable period of 60 working days. The notification will be made at the last address indicated in the patent application file.</p> <ul style="list-style-type: none"> — The procedure before the Office of Inventions and New Technologies has a period of 180 working days. — The decision of the Office of Inventions and New Technologies can be appealed before the Specialised Chamber on Intellectual Property of INDECOPi within a period of 15 working days. — The procedure before the Specialised Intellectual Property Chamber has a period of 180 working days. — If at the end of the procedure, the compulsory licence is granted, the Economic Studies Department of INDECOPi will determine the amount of financial compensation that corresponds to the patent rights holder. — Both parties – the patent rights holder and the applicant for the compulsory licence – must submit the information requested by the Economic Studies Department, within ten working days. In the event of non-compliance with this request, INDECOPi may initiate a sanctioning procedure. — With the information available, the Economic Studies Department will issue a technical opinion on the amount of economic compensation for the patent rights holder within 30 working days. <p>(b) Any document or information that may support the application, including evidence that shows that a prior attempt was made to obtain a contractual licence from the patent rights holder without success.</p> <p>(c) The procedure lasts 180 working days. In the event of an appeal, the period is extended to another 180 additional working days.</p>
11. Can the competent authority grant a compulsory licence without hearings under an urgent situation?	No, the Peruvian authority must notify the patent rights holder of the compulsory licence application. However, the patent rights holder is not obliged to present a document opposing or supporting the application for a compulsory licence.
<p>12. Revocation/termination of compulsory licence:</p> <p>(a) Can a compulsory licence be revoked/terminated or automatically revoked/terminated?</p> <p>(b) What are the conditions for the revocation/termination of a compulsory licence?</p> <p>(c) How should products made under a compulsory licence be treated if the compulsory licence is terminated/revoked?</p>	<p>(a) Yes, a licence can be revoked or terminated.</p> <p>(b) The compulsory licence can be revoked or terminated when the patent expires or when the factual assumptions that justified it ends.</p> <p>(c) Peruvian law does not establish provisions for the treatment of products made under a compulsory licence that has been terminated or revoked.</p>

Rights and obligations of the right holders in relation to compulsory licensing

<p>13. Royalty:</p> <p>(a) Does the compulsory licensee have to pay a royalty to the right holder?</p> <p>(b) If the compulsory licensee is required to pay a royalty, how is the amount of royalty determined and who will decide the amount of the royalty?</p> <p>(c) Is there any remuneration available for the right holders other than royalty?</p>	<p>(a) Yes.</p> <p>(b) If at the end of the application procedure, the compulsory licence is granted, the Economic Studies Department will determine the amount of economic compensation that corresponds to the patent holder, as detailed in question 10.</p> <p>(c) No, there is not.</p>
<p>14. Are there any legal remedies for the party who is not satisfied with the compulsory licensing decision of the competent authority?</p>	<p>The party that is not satisfied with the result of the compulsory licence procedure can file an action with the Peruvian judiciary within a period of three months in order to request that a judge nullify the decision.</p>
<p>15. Provision of know-how and support:</p> <p>(a) In order to implement the compulsory licence, for example, to manufacture the licenced product, is the right holder required to provide necessary support, such as know-how and training as in a voluntary agreed licence agreement?</p> <p>(b) Will this provision of know-how and support be compensated and how is the amount of such compensation determined?</p>	<p>(a) Peruvian law does not address this matter.</p> <p>(b) Peruvian law does not address this matter.</p>
<p>16. Confidentiality:</p> <p>(a) Is the compulsory licensee subject to any confidentiality obligation?</p> <p>(b) If the compulsory licensee discloses the confidential information in violation of its obligation, does the right holder have a basis of claim against the compulsory licensee?</p>	<p>(a) Peruvian law does not address this matter.</p> <p>(b) Peruvian law does not address this matter.</p>
<p>17. Export of products under compulsory licence</p> <p>(a) Is the compulsory licensee allowed to export their products under the compulsory licence?</p> <p>(b) If the compulsory licensee is permitted to export products under the compulsory</p>	<p>(a) No.</p> <p>(b) No.</p>

licence, are there any requirements and limitations on the export of such products?	
Compulsory licensing in the present COVID-19 pandemic	
18. Have the laws on compulsory licensing been used in previous health emergencies and/or in the present COVID-19 pandemic in your jurisdiction?	No.
19. Is it possible for third parties to use the current laws on compulsory licensing in your jurisdiction to facilitate the treatment of patients infected by COVID-19?	Yes.
20. Are there any recent major regulatory exemptions and/or amendments made following COVID-19 to regulations governing compulsory licensing?	No.
Transactions and dealings of products under compulsory licences	
21. Can a compulsory licence be transferred or assigned?	Yes, the compulsory licence may only be transferred with a part of the company or with the company's intangible asset that allows for its industrial exploitation. Proof must be rendered in writing and registered with the Office of Inventions and New Technologies. Otherwise, the transfer will not have legal effect. Sub-licences are not granted.
22. Does the issuance of a compulsory licence have any impact on the previously agreed licence?	Peruvian law does not address this matter.
23. Is there any special labelling requirement for the products made under the compulsory licence?	Peruvian law does not address this matter.
24. Is there any special distribution channel requirement for the products made under the compulsory licence?	Peruvian law does not address this matter.
25. Is there any price requirement for the products made under the compulsory licence?	Peruvian law does address this matter.

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JURISDICTION: Poland

Compulsory licensing in general

1. What is the definition of compulsory licensing?	According to Article 82 of the Act of 30 June 2000 Industrial Property Law, a licence for exploiting a patented invention of another person is defined as a compulsory licence. This regulation applies to utility models, industrial designs and topographies.
2. What are the applicable sources of law relating to compulsory licensing?	<ul style="list-style-type: none"> — Act of 30 June 2000 Industrial Property Law; — Agreement on Trade-Related Aspects of Intellectual Property Rights, TRIPS; — Regulation (EC) No 816/2006 of the European Parliament and of the Council of 17 May 2006 on compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems.
3. Types of products which compulsory licensing applies to: (a) What type(s) of products or technologies do compulsory licensing applies to? (b) Has any compulsory licence ever been issued in your jurisdiction? If yes, on what type of technology?	(a) A compulsory licence applies to another person's patented invention, utility model, industrial design and topography. (b) We are not aware of any compulsory licence issued under Polish law.

Regulatory requirements on compulsory licensing

4. Who can apply for a compulsory licence? Are foreigners or foreign companies allowed to apply for a compulsory licence?	Any person, including foreigners or foreign companies, can apply for a compulsory licence.
5. What are the legal grounds to grant a compulsory licence under the local laws of your jurisdiction and any applicable international treaties?	<p>In accordance with Article 82 of the Act of 30 June 2000 Industrial Property Law, the Patent Office may grant a licence to exploit a patented invention of another person (compulsory licence) when:</p> <ul style="list-style-type: none"> (a) a threat to state security, particularly in respect to defence, public order, protection of human lives and health, and the natural environment must be prevented or remedied; (b) the patent is found to be abused; or (c) the proprietor of a patent granted with earlier priority (i.e. a prior patent) prevents, by refusing to make a licence agreement, domestic market demand from being satisfied through the exploitation of a patented invention (i.e. dependent patent), the exploitation of which would exceed the extent of the prior patent; in this case, the proprietor of the prior patent may request the granting of a licence for the exploitation of the invention that is the subject of a dependent patent (i.e. cross-l licence). <p>The above regulation applies also to utility models, industrial designs and topographies.</p> <p>Under Regulation (EC) No 816/2006 of the European Parliament and of the Council of 17 May 2006 on compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems: the granting of</p>

	compulsory licences in relation to patents and supplementary protection certificates concerning the manufacture and sale of pharmaceutical products is available when such products are intended for export to eligible importing countries in need of such products in order to address public health problems.
<p>6. Are there any preconditions to apply for a compulsory licence? For example:</p> <p>(a) Any negotiation required between the applicant and the right holder before applying for a compulsory licence?</p> <p>(b) Any urgent situation required in order to grant a compulsory licence?</p> <p>(c) Any minimum number of years required for the patent to be granted and/or implemented in order to be subject to compulsory licensing?</p>	<p>(a) A compulsory licence may be granted if an applicant proves that he has made, in good faith, previous efforts to obtain the licence. This requirement does not have to be met in order for a licence to be granted to prevent or remedy a threat to state security, or if an announcement is issued stating that applying for a compulsory licence is possible and the motion for a compulsory licence was submitted within one year from the date of this announcement.</p> <p>(b) One of the situations for granting a compulsory licence is the prevention or remedy of a threat to state security, in particular in respect to defence, public order, protection of human lives and health, and the natural environment.</p> <p>(c) Under Polish law, the time limit for a patent to be able to initiate a compulsory licence occurs only in relation to one of the conditions for establishing a compulsory licence (i.e. the patent is abused). According to Polish law, within three years of the patent being granted, the proprietor's action may not be considered an abuse of rights. Moreover, the three-year period begins the date the decision to grant the patent became final.</p>
7. Are there any limits on the number of compulsory licensees?	Not specified.
8. Will there be any limitation on the scope of the compulsory licence, for example limitations on the time and the territory?	There are no such limitations. However, the purpose of the compulsory licence and the duration of the patent (i.e. right to utility model, industrial design, topography) should be taken into account when granting such a compulsory licence.
9. Which authority has the competency to grant a compulsory licence?	Under Polish law, the Patent Office has the competence to grant a compulsory licence.
<p>10. Application procedure for compulsory licence:</p> <p>(a) What are the application procedures to get a compulsory licence?</p> <p>(b) What materials need to be submitted to the competent authority?</p> <p>(c) How long will it take to get a compulsory licence?</p>	<p>(a) The Patent Office grants or refuses to grant a compulsory licence to exploit an invention, utility model, industrial design or topography, in contentious proceedings, upon a written motion submitted by the applicant to the Patent Office.</p> <p>If the compulsory licence is granted, the Patent Office indicates in its decision the scope and term of a compulsory licence, the detailed requirements for the performance of the licence and the licence fee (according to the market value of the licence), as well as terms and methods for the payment of the licence fees.</p> <p>(b) The applicant shall submit a written motion to the Patent Office with the request for a compulsory licence to be granted.</p> <p>The motion will contain:</p> <ul style="list-style-type: none"> — an identification of the parties and their addresses; — a brief presentation of the case; — a clearly stated request; — the legal basis for the request;

	<ul style="list-style-type: none"> — an identification of evidence; — the signature of the applicant and the date. <p>The motion will be accompanied by:</p> <ul style="list-style-type: none"> — a power of attorney, if relevant; — copies of the motion in the number corresponding to the number of parties to the contentious proceedings; — proof of payment of the official fee. <p>(c) No time limit is specified for granting the compulsory licence.</p>
11. Can the competent authority grant a compulsory licence without hearings under an urgent situation?	Yes, only when it is necessary to prevent or remedy a threat to state security, particularly in respect to defence, public order, protection of human lives and health, and of the natural environment.
12. Revocation/termination of compulsory licence: <ul style="list-style-type: none"> (a) Can a compulsory licence be revoked/terminated or automatically revoked/terminated? (b) What are the conditions for the revocation/termination of a compulsory licence? (c) How should products made under a compulsory licence be treated if the compulsory licence is terminated/revoked? 	<ul style="list-style-type: none"> (a) Polish regulations do not provide for revocation/termination of a compulsory licence, but they regulate the possibility of the amendment of the compulsory licence. (b) The decision on granting a compulsory licence, in the part referring to the scope and term of the licence or the licence fee, may be amended at the request of the interested party, two years after the issuance of the decision. The circumstances justifying the change of a decision must be indicated in the written motion of the interested party. The decision may be amended in justified cases. Not every change of circumstances may in practice justify the motion – only significant changes that affect the content of the compulsory licence. The reasons justifying the amendment of the decision to grant the licence include the licensee's infringement of the conditions for using the compulsory licence specified in the administrative decision. The motion may be submitted by the proprietor whose patent (utility model, industrial design, topography) has been encumbered by a compulsory licence, and by the licensee. Moreover, the provision does not exclude the possibility of multiple changes to the decision on granting a compulsory licence. However, each time it is necessary to indicate the specific circumstances justifying this change. (c) There are no such specific requirements.
Rights and obligations of the right holders in relation to compulsory licensing	
13. Royalty: <ul style="list-style-type: none"> (a) Does the compulsory licensee have to pay a royalty to the right holder? (b) If the compulsory licensee is required to pay a royalty, how is the amount of royalty determined and who will decide the amount of the royalty? 	<ul style="list-style-type: none"> (a) Yes, a compulsory licence is always a paid licence. A person exploiting an invention (utility model, industrial design, topography) under a compulsory licence shall pay a licence fee to the proprietor of the patent (right to utility model, industrial design, topography). (b) The amount of the licence fees should be determined while taking into account the market value of the licence. Both the amount of the licence fee and the method and terms of payment are specified by the Patent Office in the decision on granting a compulsory licence. (c) Not specified.

(c) Is there any remuneration available for the right holders other than royalty?	
14. Are there any legal remedies for the party who is not satisfied with the compulsory licensing decision of the competent authority?	Yes, parties to the proceedings may appeal decisions of the Patent Office with the administrative court.
15. Provision of know-how and support: (a) In order to implement the compulsory licence, for example, to manufacture the licenced product, is the right holder required to provide necessary support, such as know-how and training as in a voluntary agreed licence agreement? (b) Will this provision of know-how and support be compensated and how is the amount of such compensation determined?	The regulations do not directly address these issues. These aspects may be agreed between the parties.
16. Confidentiality: (a) Is the compulsory licensee subject to any confidentiality obligation? (b) If the compulsory licensee discloses the confidential information in violation of its obligation, does the right holder have a basis of claim against the compulsory licensee?	The regulations do not directly address these issues. These aspects may be agreed between the parties.
17. Export of products under compulsory licence (a) Is the compulsory licensee allowed to export their products under the compulsory licence? (b) If the compulsory licensee is permitted to export products under the compulsory licence, are there any requirements and limitations on the export of such products?	(a) The allowed territorial scope of the export of products manufactured under the compulsory licence is specified in the decision of the Patent Office on granting the licence. (b) Such requirements and limitations on the export of such products may be specified in the decision of the Patent Office.
Compulsory licensing in the present COVID-19 pandemic	
18. Have the laws on compulsory licensing been used in previous health emergencies and/or in the present COVID-19 pandemic in your jurisdiction?	We are not aware of any such situations.

19.	Is it possible for third parties to use the current laws on compulsory licensing in your jurisdiction to facilitate the treatment of patients infected by COVID-19?	Yes.
20.	Are there any recent major regulatory exemptions and/or amendments made following COVID-19 to regulations governing compulsory licensing?	We are not aware of any major regulatory exemptions and/or amendments made following COVID-19 to regulations governing compulsory licensing.
Transactions and dealings of products under compulsory licences		
21.	Can a compulsory licence be transferred or assigned?	A compulsory licence may only be transferred jointly with an undertaking or the part of the undertaking where it is executed. A compulsory licence for an earlier patent may only be transferred to another person in conjunction with a dependent patent.
22.	Does the issuance of a compulsory licence have any impact on the previously agreed licence?	Not specified. Article 83 of the Industrial Property Law provides only that a compulsory licence is non-exclusive, which means that that the patent holder and persons to whom the licence to use the invention was granted may still use the invention. This regulation also applies to utility models, industrial designs and topographies.
23.	Is there any special labelling requirement for the products made under the compulsory licence?	There is no such special labelling requirement in the statutory provisions relating to compulsory licensing in Poland.
24.	Is there any special distribution channel requirement for the products made under the compulsory licence?	
25.	Is there any price requirement for the products made under the compulsory licence?	There is no such special distribution channel requirement in the statutory provisions relating to compulsory licensing in Poland.

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JURISDICTION: Portugal

Compulsory licensing in general

1.	What is the definition of compulsory licensing?	Compulsory licensing is not defined in the Portuguese legislation.
2.	What are the applicable sources of law relating to compulsory licensing?	<p>The applicable sources of law in Portugal regarding compulsory licences are the following:</p> <ul style="list-style-type: none"> — Portuguese Industrial Property Code; — Regulation (EC) no 816/2006 of the European Parliament and of the Council of 17 May 2006 on compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems; — TRIPS Agreement (Agreement on trade related aspects of Intellectual Property Rights).
3.	<p>Types of products which compulsory licensing applies to:</p> <p>(a) What type(s) of products or technologies do compulsory licensing applies to?</p> <p>(b) Has any compulsory licence ever been issued in your jurisdiction? If yes, on what type of technology?</p>	<p>(a) Compulsory licensing applies to any invention patent and utility model patent.</p> <p>Though there are some limitations under certain circumstances. For example for patents directed to semi-conductors, the compulsory licence shall only be granted for public interest and not for commercial purposes.</p> <p>(b) No.</p>

Regulatory requirements on compulsory licensing

4.	Who can apply for a compulsory licence? Are foreigners or foreign companies allowed to apply for a compulsory licence?	<ul style="list-style-type: none"> — Any entity or individual that is interested in the application of a compulsory licence. — There are no restrictions on foreigners or foreign companies in relation to applying for a compulsory licence under the applicable Portuguese law.
5.	What are the legal grounds to grant a compulsory licence under the local laws of your jurisdiction and any applicable international treaties?	<p>The legal grounds for granting a compulsory licence are established in the Portuguese Industrial Property Code, and include the following:</p> <ul style="list-style-type: none"> — Lack or insufficiency of exploitation of the patented invention; — Dependency between patents; and — Public interest.
6.	<p>Are there any preconditions to apply for a compulsory licence? For example:</p> <p>(a) Any negotiation required between the applicant and the right holder before applying for a compulsory licence?</p> <p>(b) Any urgent situation required in order to grant a compulsory licence?</p>	<p>(a) According to the applicable Portuguese law, compulsory licences can only be granted where the prospective licensee has made efforts to obtain a contractual licence from the patent holder on acceptable commercial terms and such efforts have not been successful within a reasonable time.</p> <p>(b) No. But if the public interest so requires, INPI may grant a compulsory licence to exploit the patent for an invention or a utility model.</p> <p>(c) It depends. For compulsory licensing based on non-exploitation or non-full exploitation by the patentee without</p>

(c) Any minimum number of years required for the patent to be granted and/or implemented in order to be subject to compulsory licensing?	any legitimate reason, the patent has to be granted three years as of the date of the issuance and four years as of the date of filing the application for the patent.
7. Are there any limits on the number of compulsory licensees?	The applicable Portuguese law does not address this point.
8. Will there be any limitation on the scope of the compulsory licence, for example limitations on the time and the territory?	The Portuguese Code of Industrial Property does not provide rules in this regard. However, the TRIPS agreement provides in the article 31 (c) that: Where the law of a Member allows for other use of the subject matter of a patent without the authorisation of the right holder, including use by the government or third parties authorised by the government, the following provisions shall be respected: the scope and duration of such use shall be limited to the purpose for which it was authorised, and in the case of semiconductor technology shall only be for public non-commercial use.
9. Which authority has the competency to grant a compulsory licence?	The competent authority is the Portuguese Institute of Industrial Property (INPI). For compulsory licences on the grounds of public interest, the government is the competent authority.
10. Application procedure for compulsory licence: (a) What are the application procedures to get a compulsory licence? (b) What materials need to be submitted to the competent authority? (c) How long will it take to get a compulsory licence?	(a) Anyone who requests a compulsory licence shall submit a written request for a compulsory licence to INPI with the relevant supporting documents. (b) The Portuguese Code of Industrial Property does not address this point. (c) Unclear. The applicable Portuguese law does not provide specific deadlines for the Portuguese PTO to issue a final decision.
11. Can the competent authority grant a compulsory licence without hearings under an urgent situation?	Oral hearings are not required in order to grant a compulsory licence. However, upon receipt of the application for a compulsory licence, the INPI notifies and instructs the patent owner to submit its observations and relevant evidence within two months. According to the applicable Portuguese law, there are no exceptions even during an urgent situation.
12. Revocation/termination of compulsory licence: (a) Can a compulsory licence be revoked/terminated or automatically revoked/terminated? (b) What are the conditions for the revocation/termination of a compulsory licence? (c) How should products made under a compulsory licence be treated if the compulsory licence is terminated/revoked?	(a) The compulsory licence can be revoked. (b) The compulsory licence may be revoked, subject to adequate protection of the legitimate interests of the licensee, if and when the circumstances that substantiated the decision cease to exist and are not likely to recur. (c) The Portuguese applicable law does not specify how to treat the products made under a compulsory licence if the compulsory licence is terminated or revoked.

Rights and obligations of the right holders in relation to compulsory licensing

<p>13. Royalty:</p> <p>(a) Does the compulsory licensee have to pay a royalty to the right holder?</p> <p>(b) If the compulsory licensee is required to pay a royalty, how is the amount of royalty determined and who will decide the amount of the royalty?</p> <p>(c) Is there any remuneration available for the right holders other than royalty?</p>	<p>(a) Yes, the Portuguese Industrial Code determines that the right holder has a right to obtain a “remuneration”.</p> <p>(b) The patent holder will receive remuneration appropriate to each individual case, taking into account the economic value of the licence. Hence, if INPI decides to grant the compulsory licence, it notifies the parties to appoint an expert in order to reach an agreement on the compensation to pay to the patent owner.</p> <p>(c) No.</p>
<p>14. Are there any legal remedies for the party who is not satisfied with the compulsory licensing decision of the competent authority?</p>	<p>Yes. The Party who is not satisfied with the decision of INPI of granting or refusing the licence, or only the conditions under which it was granted, can file a judicial appeal to the competent court within three months of the date of notification.</p>
<p>15. Provision of know-how and support:</p> <p>(a) In order to implement the compulsory licence, for example, to manufacture the licenced product, is the right holder required to provide necessary support, such as know-how and training as in a voluntary agreed licence agreement?</p> <p>(b) Will this provision of know-how and support be compensated and how is the amount of such compensation determined?</p>	<p>(a) The Portuguese applicable law does not address this point.</p> <p>(b) The applicable Portuguese law does not specify on this point.</p>
<p>16. Confidentiality:</p> <p>(a) Is the compulsory licensee subject to any confidentiality obligation?</p> <p>(b) If the compulsory licensee discloses the confidential information in violation of its obligation, does the right holder have a basis of claim against the compulsory licensee?</p>	<p>(a) The applicable Portuguese law does not address this point.</p> <p>(b) The applicable Portuguese law does not address this point. However, the right holder may have a claim on the basis of trade-secrets infringement if the parties establish that the compulsory licence is subject to confidentiality obligations.</p>
<p>17. Export of products under compulsory licence</p> <p>(a) Is the compulsory licensee allowed to export their products under the compulsory licence?</p> <p>(b) If the compulsory licensee is permitted to export products under the compulsory</p>	<p>(a) Yes. According to Regulation (EC) no. 816/2006 of the European Parliament and of the Council of 17 May 2006, for the purpose of public health, any person may request a compulsory licence for the manufacture of a patented pharmaceutical product exported to:</p> <ul style="list-style-type: none"> — any less-developed country appearing as such in the UN list; — any member of the WTO, other than the less-developed country members referred to in the

licence, are there any requirements and limitations on the export of such products?	<p>previous point, that has made a notification to the Council for TRIPs of its intention to use the system as an importer, including whether it will use the system in its entirety or in a limited way;</p> <ul style="list-style-type: none"> — any country that is not a member of the WTO, but is listed on the OECD Development Assistance Committee's list of low-income countries with a gross national product per capita of less than USD 745, and has made a notification to the Commission of its intention to use the system as an importer, including whether it will use the system in its entirety or in a limited way. <p>(b) Yes. The following requirements regarding the export of pharmaceutical products are applicable under Portuguese Law:</p> <ul style="list-style-type: none"> — The amount of products manufactured based on a compulsory licence shall not exceed the amount needed by the importer, and all products must be exported to the importer; — No product made or imported under the compulsory licence shall be offered for sale or put on the market in any country other than that cited in the application; — Specific labels or marks shall be indicated on the products manufactured under a compulsory licence clearly indicating that they are manufactured according to the compulsory licence; — The products shall be distinguished from those made by the rights holder through special packaging and/or special colouring/shaping, provided that such distinctions are feasible and do not have a significant impact on price; — Before the shipment of products, the entity that has obtained the compulsory licence shall publish on a website the amount of products shipped to the importer and the special production characteristics of the products referred to in the above items.
Compulsory licensing in the present COVID-19 pandemic	
18. Have the laws on compulsory licensing been used in previous health emergencies and/or in the present COVID-19 pandemic in your jurisdiction?	No.
19. Is it possible for third parties to use the current laws on compulsory licensing in your jurisdiction to facilitate the treatment of patients infected by COVID-19?	In theory, yes. However, until the present date, no applications for compulsory licences related to Covid-19 have been filed.
20. Are there any recent major regulatory exemptions and/or amendments made following COVID-19 to regulations governing compulsory licensing?	Not yet.

Transactions and dealings of products under compulsory licences	
21. Can a compulsory licence be transferred or assigned?	Compulsory licences may only be transferred with that part of the business or establishment, which exploits them.
22. Does the issuance of a compulsory licence have any impact on the previously agreed licence?	The applicable law does not address this point.
23. Is there any special labelling requirement for the products made under the compulsory licence?	Yes, at least for pharmaceutical products. Specific labels or marks shall be indicated on the products manufactured under a compulsory licence clearly indicating that they are manufactured according to the compulsory licence; and the products shall have specific colours or shapes, or be packed in a particular manner if feasible, and the price of the products will not be significantly affected.
24. Is there any special distribution channel requirement for the products made under the compulsory licence?	Yes. At least for pharmaceuticals products produced under the compulsory licence, the importing countries to which they are supplied, must be mentioned on the relevant website.
25. Is there any price requirement for the products made under the compulsory licence?	<p>According to article 10 (9) of the Regulation (EC) no 816/2006 of the European Parliament and of the Council of 17 May 2006, the licensee shall be responsible for the payment of adequate remuneration to the rights holder as determined by the competent authority as follows:</p> <ul style="list-style-type: none"> (a) in cases referred to in Article 9(2), which are related to situations of national emergency or other circumstances of extreme urgency or in cases of public non-commercial use under Article 31 (b) of the TRIPS Agreement, the remuneration shall be a maximum of 4% of the total price to be paid by the importing country or on its behalf; (b) in all other cases, the remuneration shall be determined taking into account the economic value of the use authorised under the licence to the importing country or countries concerned, as well as humanitarian or non-commercial circumstances relating to the issue of the licence. <p>For general compulsory licences, the applicable Portuguese law provides that the patent holder will receive a remuneration appropriate to each individual case, taking into account the economic value of the licence. Hence, if INPI decides to grant the compulsory licence, it notifies the parties to appoint an expert in order to reach an agreement on the compensation to pay to the patent owner.</p>

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JURISDICTION: Russia

Compulsory licensing in general

1.	What is the definition of compulsory licensing?	<p>A court decision granting an interested party (i.e. an applicant) the right to use intellectual property owned by another party.</p> <p>Currently, there are three types of compulsory licences named as such by the law:</p> <ul style="list-style-type: none"> (a) Compulsory licence to the patented invention, utility model or industrial design in case of non-use or insufficient use by the patent holder. (b) Compulsory licence to the patented invention or utility model in favour of the owner of the dependent invention, who are not able to use its invention without licence. (c) Compulsory licence in respect to breeding achievement (e.g. plant variety or animal breed). <p>In addition, Russian law also provides for some additional cases of use without the direct consent of the patent holder, although it does not name this as a compulsory licence. These cases include:</p> <ul style="list-style-type: none"> (d) Use of the invention, utility model or industrial design for reason of force majeure (e.g. during natural disasters, accidents and emergencies) shall not be qualified as a patent infringement. (e) Government of the Russian Federation has the right to allow the use of invention, utility model and/or industrial design without the consent of the patent holder in the interests of defence and security.
2.	What are the applicable sources of law relating to compulsory licensing?	The Civil Code of the Russian Federation (Part 4).
3.	Types of products which compulsory licensing applies to: <ul style="list-style-type: none"> (a) What type(s) of products or technologies do compulsory licensing applies to? (b) Has any compulsory licence ever been issued in your jurisdiction? If yes, on what type of technology? 	<ul style="list-style-type: none"> (a) Generally, no limitation on the types of products or technologies to which compulsory licensing is applicable. However, in respect to semiconductor technologies, a compulsory licence under p. (A) above can be granted only for non-commercial use in state, social or any other public interest or to change the status quo that has been recognised as anti-competitive. (b) Yes, in respect to medicines under compulsory licence.

Regulatory requirements on compulsory licensing

4.	Who can apply for a compulsory licence? Are foreigners or foreign companies allowed to apply for a compulsory licence?	<p>Depending on the type of compulsory licence, described above:</p> <ul style="list-style-type: none"> (a) Any person, including foreigners or foreign companies, can apply for a licence under the patent, if this person can prove its wish and readiness to use the patent. (b) An owner, including a foreign person or entity, of the invention patent (i.e. dependent patent), which cannot be used without the use of the patent, owned by a third party and subject to a compulsory licence. (c) Any person, including foreigners or foreign companies, can apply for a licence under the patent, if this person can
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	<p>prove its wish and readiness to use the breeding achievement.</p> <p>(d) Any person, including foreigners or foreign companies, although there have been no cases in practice.</p> <p>(e) Any person, including foreigners or foreign companies, could apply to the Russian government, although the procedure is not regulated.</p>
<p>5. What are the legal grounds to grant a compulsory licence under the local laws of your jurisdiction and any applicable international treaties?</p>	<p>Depending on the type of compulsory licence, described above:</p> <p>(a) Failure of the patent holder to use or sufficiently use the invention or industrial design within four years, and utility model within three years, from the day of the granting of the patent, which results in the insufficient amount of goods or services on the market (unless the patent holder proves that such failure is justified by the legitimate excuse); and refusal of the patent holder to enter into the licence agreement on the general market conditions.</p> <p>(b) Impossibility of the owner of the dependent patent to use the invention without a licence; refusal of the patent holder to enter into the licence agreement on the general market conditions; and the dependent patent shall be proved to be an important technical development and to have significant economic advantages compared to the invention/utility model to be compulsory licensed.</p> <p>(c) After three years from the day of the granting of the patent to the breeding achievement, the patent owner refuses to enter into the licence agreement on the general market conditions.</p> <p>(d) Existence of force majeure (e.g. natural disasters, accidents and emergencies); notification of the patent owner regarding such use; and subject to payment of the adequate compensation.</p> <p>(e) Decision of the government made in the interests of defence and security; notification of the patent owner regarding such use; and subject to payment of adequate compensation.</p>
<p>6. Are there any preconditions to apply for a compulsory licence? For example:</p> <p>(a) Any negotiation required between the applicant and the right holder before applying for a compulsory licence?</p> <p>(b) Any urgent situation required in order to grant a compulsory licence?</p> <p>(c) Any minimum number of years required for the patent to be granted and/or implemented in order to be subject to compulsory licensing?</p>	<p>Negotiation requirement:</p> <ul style="list-style-type: none"> — Refusal to grant the licence is required for licences under p. (A) – (C). — Not required for cases under p. (D) and (E). <p>Urgent situation requirement:</p> <ul style="list-style-type: none"> — Not required for licences under p. (A) – (C). — Not explicitly required, but could be implied in certain cases, for p. (D) and (E). <p>Minimum number of years:</p> <ul style="list-style-type: none"> — Required for licences under p. (A) and (C), as indicated above. — Not required for cases under p. (B), (D) and (E).
<p>7. Are there any limits on the number of compulsory licensees?</p>	<p>Not specified.</p>

<p>8. Will there be any limitation on the scope of the compulsory licence, for example limitations on the time and the territory?</p>	<p>For licences under p. (A) – (C), the relevant scope of the licence shall be determined by the court, including limitations of the scope of use. Limitation of the term and territory are theoretically possible, but has not been indicated in practice.</p> <p>Not specified for cases under (D) and (E), but it is fair to assume that such limitations can be imposed.</p>
<p>9. Which authority has the competency to grant a compulsory licence?</p>	<p>The court for licences under p. (A) – (C).</p> <p>No decision is required under p. (D). The notification of the patent holder is required.</p> <p>The government of the Russian Federation under p. (E).</p>
<p>10. Application procedure for compulsory licence:</p> <p>(a) What are the application procedures to get a compulsory licence?</p> <p>(b) What materials need to be submitted to the competent authority?</p> <p>(c) How long will it take to get a compulsory licence?</p>	<p>For licences under p. (A) – (C):</p> <p>(a) Written application to the court requesting a compulsory licence.</p> <p>(b) Evidence confirming compliance with the requirements for the compulsory licence indicated above (e.g. confirmation of refusal to grant a licence from the patent owner, dependence of the applicant's patent under p. (B), etc.).</p> <p>(c) Not specified, but the first instance proceeding can take around one year with the possibility of appeal.</p> <p>For p. (D):</p> <p>(a) Notification of the patent holder regarding free use of the patent.</p> <p>(b) N/A.</p> <p>(c) N/A.</p> <p>For p. (E): the procedure is not regulated.</p>
<p>11. Can the competent authority grant a compulsory licence without hearings under an urgent situation?</p>	<p>No, for licences under p. (A) – (C).</p> <p>Not applicable for cases under p. (D), since a person/entity can start use without any decision.</p> <p>Not regulated under p. (E), but theoretically it is possible.</p>
<p>12. Revocation/termination of compulsory licence:</p> <p>(a) Can a compulsory licence be revoked/terminated or automatically revoked/terminated?</p> <p>(b) What are the conditions for the revocation/termination of a compulsory licence?</p> <p>(c) How should products made under a compulsory licence be treated if the compulsory licence is terminated/revoked?</p>	<p>For licence under p. (A):</p> <p>(a) Yes, under a written application to the court from the patent holder requesting a termination of the compulsory licence.</p> <p>(b) If the circumstances under which the compulsory licence has been granted have terminated and are unlikely to appear in future.</p> <p>(c) This should be specified in the court decision.</p> <p>For licence under p. (B):</p> <p>(a) Not specified in the law, but there is a general right of the patent holder to request the court to terminate the compulsory licence.</p> <p>(b) Not specified.</p> <p>(c) This should be specified in the court decision.</p> <p>For licence under p. (C):</p> <p>(a) Yes, under a written application to the court from the patent holder requesting a termination of the compulsory licence.</p>

	<p>(b) If the circumstances under which the compulsory licence has been granted have terminated or if the licensee breaches the compulsory licence.</p> <p>(c) This should be specified in the court decision.</p> <p>For p. (D):</p> <p>(a) Not specified by the law, but the patent owner is generally allowed to challenge the use of the patent by a third party under this case.</p> <p>(b) Not specified, but it can be assumed that the patent holder can try and prove that the use without consent is no longer justified.</p> <p>(c) Not specified.</p> <p>For p. (E):</p> <p>(a) Not specified by the law, but the patent owner is generally allowed to challenge the decision of the government granting the permission to use the patent.</p> <p>(b) Not specified, but it can be assumed that the patent holder can try and prove that the use without consent is no longer justified.</p> <p>(c) Not specified.</p>
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Rights and obligations of the right holders in relation to compulsory licensing

<p>13. Royalty:</p> <p>(a) Does the compulsory licensee have to pay a royalty to the right holder?</p> <p>(b) If the compulsory licensee is required to pay a royalty, how is the amount of royalty determined and who will decide the amount of the royalty?</p> <p>(c) Is there any remuneration available for the right holders other than royalty?</p>	<p>For licences under p. (A) – (C):</p> <p>(a) Yes.</p> <p>(b) The court shall indicate the amount of the royalty.</p> <p>(c) No.</p> <p>For p. (D) – (E):</p> <p>(a) Person/entity using the patent or the government shall pay adequate compensation.</p> <p>(b) Not specified how to determine adequate compensation.</p> <p>(c) No.</p>
<p>14. Are there any legal remedies for the party who is not satisfied with the compulsory licensing decision of the competent authority?</p>	<p>For licences under p. (A) – (C): the court decision granting the compulsory licence can be further appealed.</p> <p>Use of the patent under (D) and the decision of the government under (E) can be challenged through the court procedure.</p>
<p>15. Provision of know-how and support:</p> <p>(a) In order to implement the compulsory licence, for example, to manufacture the licenced product, is the right holder required to provide necessary support, such as know-how and training as in a voluntary agreed licence agreement?</p> <p>(b) Will this provision of know-how and support be compensated and how is the</p>	<p>For licences under p. (A), (B), (D) and (E): not specified in the law.</p> <p>For licence under (C): on the basis of a court decision the patent owner shall provide the samples of breeding achievement (e.g. seeds) to the licensee in order to allow the latter to use the compulsory licence.</p>

amount of such compensation determined?	
<p>16. Confidentiality:</p> <p>(a) Is the compulsory licensee subject to any confidentiality obligation?</p> <p>(b) If the compulsory licensee discloses the confidential information in violation of its obligation, does the right holder have a basis of claim against the compulsory licensee?</p>	<p>Not specified by the law.</p> <p>Theoretically, it is possible that the court will impose some confidentiality obligations, if any of the parties apply for this.</p> <p>If such obligations are included in the compulsory licence, the patent owner has the right to prosecute the breach of relevant obligations committed by the licensee.</p>
<p>17. Export of products under compulsory licence</p> <p>(a) Is the compulsory licensee allowed to export their products under the compulsory licence?</p> <p>(b) If the compulsory licensee is permitted to export products under the compulsory licence, are there any requirements and limitations on the export of such products?</p>	<p>For licences under p. (A) – (C): this could be indicated in the court decision, if the scope of compulsory licence demanded by the licensee includes the right to export.</p> <p>For cases under (D) and (E): theoretically, it is possible if export is necessary for the relevant purposes for which the patent is used (i.e. in case of force majeure and in the interest of defence and security).</p>
Compulsory licensing in the present COVID-19 pandemic	
18. Have the laws on compulsory licensing been used in previous health emergencies and/or in the present COVID-19 pandemic in your jurisdiction?	No.
19. Is it possible for third parties to use the current laws on compulsory licensing in your jurisdiction to facilitate the treatment of patients infected by COVID-19?	Use of the patent under p. (D) is theoretically possible, if the COVID-19 pandemic is duly recognised as force majeure and the use of the patent is properly justified for this purpose.
20. Are there any recent major regulatory exemptions and/or amendments made following COVID-19 to regulations governing compulsory licensing?	No, but during COVID-19 pandemic the government has tried to amend the provision of law related to p. (E) to allow the export of medical products under a government decision without consent of the patent owner. This initiative has not resulted in any actual amendments so far.
Transactions and dealings of products under compulsory licences	
21. Can a compulsory licence be transferred or assigned?	<p>For licences under p. (A), (C): not specified.</p> <p>For licence under p. (B): no, except for the case of assignment of the dependent patent, which is a basis for the compulsory licence.</p> <p>For cases under (D) and (E): not specified but given that this is the permission rather than the licence, it is unlikely that this can be transferred or assigned.</p>

22.	Does the issuance of a compulsory licence have any impact on the previously agreed licence?	Not specified.
23.	Is there any special labelling requirement for the products made under the compulsory licence?	Not specified.
24.	Is there any special distribution channel requirement for the products made under the compulsory licence?	Not specified. For licences under p. (A) – (C): the court can theoretically limit the scope of compulsory licences to some specific distribution channels.
25.	Is there any price requirement for the products made under the compulsory licence?	N/A

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JURISDICTION: Serbia

Compulsory licensing in general

1.	What is the definition of compulsory licensing?	Compulsory licensing refers to the legal mechanism whereby the competent government authority in accordance with the law authorises interested parties to implement a patent without the permission of the patentee. A similar mechanism is applicable to plant varieties and a statutory licence exists for copyright and related rights.
2.	What are the applicable sources of law relating to compulsory licensing?	Patent Law (Official Gazette of the Republic of Serbia no. 99/2011, 113/2017, 95/2018, and 66/2019); Law on Protection of Rights of Plant Variety Breeders (Official Gazette of the Republic of Serbia no. 41/2009 and 88/2011); Law on Copyright and Related Rights (Official Gazette of the Republic of Serbia no. 104/2009, 99/2011, 119/2012, 29/2016, and 66/2019).
3.	Types of products which compulsory licensing applies to: (a) What type(s) of products or technologies do compulsory licensing applies to? (b) Has any compulsory licence ever been issued in your jurisdiction? If yes, on what type of technology?	(a) The law does not exclude or provide specific types of products or technologies that can be subject to compulsory licensing, which can be granted for any patented invention if the legal requirements are met, although for certain products the legal grounds for granting a compulsory licence may be limited (see point 5 on semi-conductor technology and plant varieties). (b) No.

Regulatory requirements on compulsory licensing

4.	Who can apply for a compulsory licence? Are foreigners or foreign companies allowed to apply for a compulsory licence?	Any interested party can apply if it proves that it has the appropriate technological capacity and production facilities for the commercial use of the protected invention. If the protected invention is necessary for the commercial use of the subsequently protected invention of another person, only a dependent patent holder can apply. Foreigners or foreign companies are not prohibited from applying for a compulsory licence if they otherwise fulfil legal requirements.
5.	What are the legal grounds to grant a compulsory licence under the local laws of your jurisdiction and any applicable international treaties?	If the right holder refuses to licence the right of commercial use of a protected invention to other persons or sets unreasonable conditions for such licensing, the government authority competent in the field in which the invention shall be employed may, at the request of an interested party after considering the merits of each individual case, grant a compulsory licence, in the following cases: (a) if the right holder himself or a person authorised by him does not use the protected invention or uses it insufficiently in the Republic of Serbia; (b) if the commercial use of an invention that has been subsequently protected in the name of another person is not possible, without the use of the protected invention in whole or in part; (c) when it is necessary to remedy a practice determined after a judicial or administrative process to be anti-competitive.

	<p>In the case of semi-conductor technology, a compulsory licence may be granted only with the aim of public non-commercial use or when it is necessary to remedy a practice determined after a judicial or administrative process to be anti-competitive.</p> <p>In case of a plant variety, a compulsory licence can be granted only for reasons of general interest (national or other exceptional needs for the purpose of protection of health and nutrition of the population and protection of public interest in areas of vital importance for socio-economic and technological development).</p> <p>In case of copyright and similar rights, the law itself provides for a statutory licence permitting reproduction for educational purposes, reproduction of certain newspaper articles and reproduction of works displayed in the open space.</p>
<p>6. Are there any preconditions to apply for a compulsory licence? For example:</p> <p>(a) Any negotiation required between the applicant and the right holder before applying for a compulsory licence?</p> <p>(b) Any urgent situation required in order to grant a compulsory licence?</p> <p>(c) Any minimum number of years required for the patent to be granted and/or implemented in order to be subject to compulsory licensing?</p>	<p>(a) Before making the request for the grant of a compulsory licence, the interested person must prove that it has made efforts to obtain authorisation for the use of the protected invention from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time.</p> <p>(b) Urgency is not a requirement for granting a compulsory licence, but prior negotiations and the minimum period from the filing of the patent application/granting of the patent or petty patent, are not required for granting a compulsory licence when the public emergency endangers the survival of the state or its citizens or in cases of public non-commercial use.</p> <p>(c) The request for the grant of a compulsory licence cannot be filed before the expiration of a period of four years from the date of filing of the patent application or before the expiration of a period of three years from the grant of the patent or petty patent, whichever period expires last.</p> <p>(d) In case of non-use or insufficient use, an interested party must prove that it has the appropriate technological capacity and production facilities for the commercial use of the protected invention.</p> <p>(e) In case of a dependent patent, only the holder of the dependent patent can apply provided that the second invention involves a technical advancement of special economic significance in relation to the first protected invention, and that the owner of the first invention is entitled, on reasonable terms, to a cross-licence to use the second invention.</p> <p>(f) In case of compulsory licences for patents relating to the manufacture of pharmaceutical products for export to countries with public health problems, additional requirements have to be met.</p> <p>(g) In case of a plant variety, an interested party must prove that it has the possibilities and capacities necessary for the use of the protected plant variety.</p>
<p>7. Are there any limits on the number of compulsory licensees?</p>	No.
<p>8. Will there be any limitation on the scope of the compulsory licence, for example limitations on the time and the territory?</p>	<p>Yes.</p> <p>In case of patents, the scope and duration of a compulsory licence shall be limited to the purpose for which it has been granted.</p>

	<p>A compulsory licence shall predominantly be granted for the supply of the domestic market, and only exceptionally for the supply of the foreign market. The compulsory licence shall be non-exclusive and may be assigned only with the manufacturing plant that exploits the invention, or with the assignment of the dependent patent, respectively.</p> <p>In case of plant varieties, the compulsory licence is issued only for reasons of general interest, for the supply of the market of the Republic of Serbia, the scope and duration are limited to reasons of general interest for which a compulsory licence has been issued. A compulsory licence cannot be exclusive and can be transferred only together with the legal entity or part of the legal entity where it is used.</p>
9. Which authority has the competency to grant a compulsory licence?	A compulsory licence is granted by the government authority competent in the field in which the invention shall be employed (e.g. Ministry of Health for medicines, Ministry of Agriculture for plant varieties).
10. Application procedure for compulsory licence: <ul style="list-style-type: none"> (a) What are the application procedures to get a compulsory licence? (b) What materials need to be submitted to the competent authority? (c) How long will it take to get a compulsory licence? 	<ul style="list-style-type: none"> (a) An interested party initiates the administrative procedure by submitting a written request for a compulsory licence to the government authority competent in the field in which the invention shall be employed. The government authority shall conduct the proceedings, consider the evidence, and pass a decision granting a compulsory licence or refusing the request. (b) With the request, the interested party should submit the information and evidence necessary for the government authority to make a decision: details of the applicant, right holder, and patent, evidence related to the prior negotiations with the right holder, available technological capacity and production facilities for the commercial use of the protected invention, details of the subsequent invention and its dependence on the use of the invention for which the compulsory licence is requested, other evidence depending on a particular case (e.g. additional evidence in case of pharmaceutical products for export to countries with public health problems). (c) The Patent Law does not specify the deadlines in which the government authority should decide, so the general deadlines applicable in administrative procedure will apply (i.e. 30/60 days). It should be noted that deadlines are not binding for the authority and an applicant can only file an appeal after the expiry of the deadline. He will not acquire any other rights due to the failure of the government authority to decide within the deadline.
11. Can the competent authority grant a compulsory licence without hearings under an urgent situation?	<p>The Patent Law does not exclude hearing in an urgent situation, it only provides that the requirements related to the prior negotiations and minimum period from filing of a patent application/granting of the patent or petty patent do not have to be fulfilled.</p> <p>General rules applicable to the administrative procedure envisage the hearing when there are parties with opposing interest. Although the Law on General Administrative Procedure provides the conditions when oral hearings do not have to be conducted, it is unlikely that the authorities would grant the compulsory licence without obtaining the statement from the right holder.</p>

<p>12. Revocation/termination of compulsory licence:</p> <p>(a) Can a compulsory licence be revoked/terminated or automatically revoked/terminated?</p> <p>(b) What are the conditions for the revocation/termination of a compulsory licence?</p> <p>(c) How should products made under a compulsory licence be treated if the compulsory licence is terminated/revoked?</p>	<p>(a) Yes.</p> <p>(b) A compulsory licence may be revoked/terminated upon expiry of its term, if and when circumstances that have led to its grant cease to exist and are unlikely to recur. In case of compulsory licences for patents relating to the manufacture of pharmaceutical products for export to countries with public health problems, such a licence can be revoked/terminated if the importing country has failed to honour its obligations or if the opposing party does not comply with the decision on the granting of the compulsory licence. In case of plant varieties, if the conditions under which the mandatory licence is issued change or if the person to whom the mandatory licence is issued ceases to meet the requirements, the Minister may revoke the compulsory licence.</p> <p>(c) The Patent Law and the Law on Protection of Rights of Plant Variety Breeders do not specify how to treat the products made under a compulsory licence if the compulsory licence is terminated/revoked, except for compulsory licences for patents relating to the manufacture of pharmaceutical products for export to countries with public health problems, where the licensee shall at its expense, redirect all the products that are in his possession to the country having needs or otherwise dispose of them after consultation with the holder of right.</p>
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Rights and obligations of the right holders in relation to compulsory licensing

<p>13. Royalty:</p> <p>(a) Does the compulsory licensee have to pay a royalty to the right holder?</p> <p>(b) If the compulsory licensee is required to pay a royalty, how is the amount of royalty determined and who will decide the amount of the royalty?</p> <p>(c) Is there any remuneration available for the right holders other than royalty?</p>	<p>(a) Yes, but the statutory provisions related to the compulsory licensing refer to the payment of remuneration rather than royalties.</p> <p>(b) The holder of compulsory licence shall be required to pay to the right holder a mutually agreed remuneration. In the absence of an agreement on the amount and method of payment of such remuneration, the competent court shall decide, considering the merits of each individual case and the economic value of the compulsory licence. In case of compulsory licences for patents relating to the manufacture of pharmaceutical products for export to countries with public health problems, the decision on the grant of a compulsory licence shall require that the licensee shall pay the remuneration to the right holder that is to be determined as follows: 1) in the cases of national emergency or other circumstances of extreme urgency or in cases of public non-commercial use, the remuneration shall be a maximum of 4% of the total price to be paid by the importing country or on its behalf; 2) in all other cases, the remuneration shall be determined taking into account the economic value of the use authorised under the licence to the importing country or countries concerned, as well as humanitarian and non-commercial circumstances relating to the issue of the licence.</p> <p>(c) Only one type of remuneration is available; the law does not specify how it is calculated, except for the compulsory licences for patents relating to the manufacture of pharmaceutical products for export to countries with public health problems.</p>
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<p>14. Are there any legal remedies for the party who is not satisfied with the compulsory licensing decision of the competent authority?</p>	<p>Yes. The party who is not satisfied with the decisions of the government authority on the grant of a compulsory licence, the refusal of the request to grant a compulsory licence, the amendment and cancellation of the compulsory licence, may file an appeal to the government of the Republic of Serbia within 15 days from the receipt of the decision. The decision of the government is final and only an administrative dispute may be instituted against that decision concerning the appeal within 30 days from the date of the receipt of the government's decision.</p> <p>In the case of plant varieties, the only available remedy against the decision of the Minister of Agriculture is an administrative dispute.</p>
<p>15. Provision of know-how and support:</p> <p>(a) In order to implement the compulsory licence, for example, to manufacture the licenced product, is the right holder required to provide necessary support, such as know-how and training as in a voluntary agreed licence agreement?</p> <p>(b) Will this provision of know-how and support be compensated and how is the amount of such compensation determined?</p>	<p>(a) The Patent Law and Law on Protection of Rights of Plant Variety Breeders do not regulate this matter.</p> <p>(b) The Patent Law and Law on Protection of Rights of Plant Variety Breeders do not regulate this matter.</p>
<p>16. Confidentiality:</p> <p>(a) Is the compulsory licensee subject to any confidentiality obligation?</p> <p>(b) If the compulsory licensee discloses the confidential information in violation of its obligation, does the right holder have a basis of claim against the compulsory licensee?</p>	<p>(a) The Patent Law does not regulate this matter, but the compulsory licensee should comply with the confidentiality obligations under the Law on Protection of Trade Secrets.</p> <p>(b) The Patent Law does not regulate this matter, but the right holder has a claim on the basis of trade-secret infringement.</p>
<p>17. Export of products under compulsory licence</p> <p>(a) Is the compulsory licensee allowed to export their products under the compulsory licence?</p> <p>(b) If the compulsory licensee is permitted to export products under the compulsory licence, are there any requirements and limitations on the export of such products?</p>	<p>(a) Yes. Although a compulsory licence should predominantly be granted for the supply of the domestic market, the compulsory licences can also be granted for patents relating to the manufacture of pharmaceutical products for export to countries with public health problems.</p> <p>(b) Yes. The following requirements apply in case of compulsory licences for patents relating to the manufacture of pharmaceutical products for export to countries with public health problems:</p> <ul style="list-style-type: none"> — The importing country is considered as the country with public health problems; — The quantity of product does not exceed that notified to the WTO by an importing country that is a WTO member, or to the government by an importing country that is not a WTO member; — Taking into account other compulsory licences granted in other countries, the total amount of

	<p>product authorised to be produced for any importing country does not significantly exceed the amount notified by that country to the WTO, which are WTO members, or to the government body, in the case of importing countries that are not WTO members</p> <ul style="list-style-type: none"> — No product made or imported under the compulsory licence shall be offered for sale or put on the market in any country other than that cited in the application, except where an importing country avails itself of the possibilities to export to fellow members of a regional trade agreement that share the health problem in question. — The products made under the compulsory licence must be clearly identified, through specific labelling or marking, as being produced under a compulsory licence, must be distinguished from those made by the right holder through special packaging and/or special colouring or shaping, provided that such a distinction is feasible and does not have a significant impact on price; — The packaging and any associated text must bear an indication that the product is subject to a compulsory licence, giving the name of the authority that has granted the compulsory licence and any identifying reference number, and specifying clearly that the product is exclusively for export to and distribution in the importing country or countries concerned; — Details of the product characteristics shall be made available to the customs authorities of the Republic of Serbia; — Before shipment to the importing country, the licensee shall post on a website and notify the Ministry of Health the quantities being supplied under the compulsory licence, the importing countries to which they are supplied, and the distinguishing features of the product or products concerned. — If the product covered by the compulsory licence granted in the Republic of Serbia is protected by a patent or petty patent in the importing countries cited in the request, the product shall only be exported if those countries have issued a compulsory licence for the import, sale and/or distribution of the product. — The import of products manufactured under such a compulsory licence in the Republic of Serbia for the purposes of release for free circulation, re-export, placing under suspensive procedures or placing in a free zone or free warehouse is prohibited.
Compulsory licensing in the present COVID-19 pandemic	
18. Have the laws on compulsory licensing been used in previous health emergencies and/or in the present COVID-19 pandemic in your jurisdiction?	No.

19.	Is it possible for third parties to use the current laws on compulsory licensing in your jurisdiction to facilitate the treatment of patients infected by COVID-19?	Yes, the existing legal framework allows that possibility.
20.	Are there any recent major regulatory exemptions and/or amendments made following COVID-19 to regulations governing compulsory licensing?	No.
Transactions and dealings of products under compulsory licences		
21.	Can a compulsory licence be transferred or assigned?	<p>A compulsory licence may be assigned only with the manufacturing plant that exploits the invention for which the licence has been granted.</p> <p>Also, authorisation for the use of the earlier protected invention shall be non-assignable except with the assignment of the subsequent patent.</p> <p>In case of plant varieties, the compulsory licence can be transferred only together with the legal entity or part of the legal entity where it is used.</p>
22.	Does the issuance of a compulsory licence have any impact on the previously agreed licence?	It should not have any impact on the previously agreed upon licence (such a licence will continue), given that the compulsory licence cannot be exclusive.
23.	Is there any special labelling requirement for the products made under the compulsory licence?	There is a labelling requirement in case of compulsory licences for patents relating to the manufacture of pharmaceutical products for export to countries with public health problems. In this case, the products made under the compulsory licence must be clearly identified, through specific labelling or marking, as being produced under a compulsory licence, must be distinguished from those made by the right holder through special packaging and/or special colouring or shaping, provided that such a distinction is feasible and does not have a significant impact on price; the packaging and any associated text must bear an indication that the product is subject to a compulsory licence, giving the name of the authority that has granted the compulsory licence and any identifying reference number, and specifying clearly that the product is exclusively for export to and distribution in the importing country or countries concerned.
24.	Is there any special distribution channel requirement for the products made under the compulsory licence?	<p>No product made or imported under the compulsory licence shall be offered for sale or put on the market in any country other than that cited in the application, except where an importing country exports to fellow members of a regional trade agreement that share the health problem in question.</p> <p>The licence conditions are without prejudice to the method of distribution in the importing country.</p> <p>A government authority can access the books and records kept by the licensee, for the sole purpose of checking whether all obligations cited in the decision to grant the compulsory licence, and in particular those relating to the final destination of the products, have been met.</p>

25. Is there any price requirement for the products made under the compulsory licence?	The Patent Law does not regulate pricing of the products made under a compulsory licence. There may be other laws that regulate the prices of certain products, but this would not be related to the compulsory licence.
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JURISDICTION: Singapore

Compulsory licensing in general

1. What is the definition of compulsory licensing?	Compulsory licensing is not defined in Singapore legislation.
2. What are the applicable sources of law relating to compulsory licensing?	<ul style="list-style-type: none"> — Patents Act (Cap. 221); — Layout-Designs of Integrated Circuits Act (Cap. 159A) ("LDICA"); — Plant Varieties Protection Act (Cap. 232A) ("PVPA"); — Registered Designs Act (Cap. 266) ("RDA"); — Copyright Act (Cap. 63).
3. Types of products which compulsory licensing applies to: <ul style="list-style-type: none"> (a) What type(s) of products or technologies do compulsory licensing applies to? (b) Has any compulsory licence ever been issued in your jurisdiction? If yes, on what type of technology? 	<ul style="list-style-type: none"> (a) The statutory provisions relating to compulsory licensing in Singapore do not contain specific requirements/restrictions for the types of products or technologies which compulsory licensing may apply to. (b) There are currently no reported cases applying the statutory provisions relating to compulsory licensing in Singapore.

Regulatory requirements on compulsory licensing

4. Who can apply for a compulsory licence? Are foreigners or foreign companies allowed to apply for a compulsory licence?	<p>Patents Act</p> <p>Under section 55(1) of the Patents Act, "any interested person" may apply to the court for a compulsory licence under a patent.</p> <p>LDICA</p> <p>Under section 27(1) of the LDICA, any person may apply to the court for a compulsory licence in relation to a protected layout-design.</p> <p>PVPA</p> <p>Under 34(1) of the PVPA, any person may apply to the court for a compulsory licence to exploit a protected variety in Singapore.</p> <p>There are no restrictions on foreigners or foreign companies in relation to applying for a compulsory licence under the Patents Act, LDICA and PVPA.</p>
5. What are the legal grounds to grant a compulsory licence under the local laws of your jurisdiction and any applicable international treaties?	<p>Patents Act</p> <ul style="list-style-type: none"> — Under section 55(1) of the Patents Act, the court may grant a licence under a patent on the ground that the grant of licence is necessary <u>to remedy an anti-competitive practice</u>. Section 55(2) provides an example of such "anti-competitive practice", namely 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 licence). — Section 56(1) of the Patents Act allows the Singapore government and any party authorised in writing by the Singapore government to do anything in relation to a

patented invention for (a) public non-commercial purpose; or (b) during a national emergency or other circumstances of extreme urgency without these acts amounting to an infringement of the patent. Section 56(1)(a) further provides that the Singapore government may import any relevant health product, and do anything in relation to any relevant imported health product for or during a national emergency or other circumstances of extreme urgency, provided that the government first notifies the Council for TRIPS of its intention.

LDICA

- Under section 27(1) of the LDICA, the court may grant a licence in relation to a protected layout-design upon the ground that the grant of the licence is necessary to remedy an anti-competitive practice.
- Section 23 of the LDICA allows the Singapore government and any party authorised in writing by the Singapore government to do anything in relation to a protected layout-design if the act is done for a public non-commercial purpose, including acts done (a) for the defence or national security of Singapore; or (b) to assist in the exercise of powers and the implementation of civil defence measures during a state of emergency or state of civil defence emergency under the Civil Defence Act.

PVPA

Under section 34(2) of the PVPA, the court may grant a compulsory licence to exploit a protected variety in Singapore on the ground that the grant of a compulsory licence is in the public interest. Sections 34(5) and 34(6) further provide that a compulsory licence will only be granted to a person who (a) is able to demonstrate to the court that he will be able to exploit the protected variety in a manner acceptable to the court, and (b) has first taken all reasonable steps to obtain authorisation from the grantee on reasonable commercial terms and conditions and has failed to obtain such authorisation within a reasonable period of time.

RDA

Section 45 of the RDA allows the Singapore government and any party authorised in writing by the Singapore government to use any registered design for the services of the Singapore government, including use:

- (a) to avoid prejudice to the security or defence of Singapore;
- (b) for public non-commercial use;
- (c) to assist in the exercise of powers and the implementation of civil defence measures during a state of emergency or state of civil defence emergency under the Civil Defence Act;
- (d) for the supply to the government of any country or territory outside Singapore, in pursuance of any agreement or arrangement between the Singapore government and the government of that country, with articles, non-physical products, or devices for projecting non-physical products, required (i) for the defence of that country; or (ii) for the defence of any other country whose government is party to any agreement or arrangement with the Singapore government in respect to defence matters; or
- (e) for the supply to the United Nations, or to the government of any country belonging to that organisation, with articles,

	<p>non-physical products, or devices for projecting non-physical products, required for any armed forces operating in pursuance of a resolution of that organisation or any organ of that organisation.</p> <p>Copyright Act</p> <p>Compulsory licences are provided for in the Copyright Act as statutory licences, including statutory licences that permit:</p> <ul style="list-style-type: none"> (a) an educational institution to reproduce multiple copies of copyright works for educational purposes (section 52, 52A and 53); (b) an institution assisting disabled readers in reproducing copyrighted works in more accessible formats (section 54); (c) the making of records or adaptations of a musical work, subject to a duty to pay 5% royalty and conditions (sections 56 and 57); and (d) the use of copyright materials for the service of the Singapore government on agreed terms or as specified by the Copyright Tribunal (section 198).
<p>6. Are there any preconditions to apply for a compulsory licence? For example:</p> <ul style="list-style-type: none"> (a) Any negotiation required between the applicant and the right holder before applying for a compulsory licence? (b) Any urgent situation required in order to grant a compulsory licence? (c) Any minimum number of years required for the patent to be granted and/or implemented in order to be subject to compulsory licensing? 	<p>Please see the response to question 55 above.</p> <p>Furthermore, there is no requirement under the statutory provisions relating to compulsory licensing in Singapore for a certain minimum number of years to elapse after the relevant intellectual property right has been granted before it may be subjected to compulsory licensing.</p>
<p>7. Are there any limits on the number of compulsory licensees?</p>	<p>There are no express limits on the number of compulsory licensees in the statutory provisions relating to compulsory licensing in Singapore.</p>
<p>8. Will there be any limitation on the scope of the compulsory licence, for example limitations on the time and the territory?</p>	<p>Patents Act</p> <ul style="list-style-type: none"> — A compulsory licence granted under section 55 is: <ul style="list-style-type: none"> (a) non-exclusive, and (b) non-assignable, except where the assignment is in connection with the goodwill of the business in which the patented invention is used (section 55(4)). — The right to use a patented invention pursuant to section 56 is: <ul style="list-style-type: none"> (a) non-exclusive, (b) non-assignable, except where the assignment is in connection with the goodwill of the business in which the patented invention is used, and (c) limited to the supply of the patented invention, predominantly in Singapore (section 60(1)).

	<ul style="list-style-type: none"> — The right under section 56 to use a relevant health product, which is imported under section 56(1A), does not include a right to export the relevant health product (section 60(1A)). <p>LDICA</p> <ul style="list-style-type: none"> — A compulsory licence granted under section 27 is non-exclusive and non-assignable (section 28(1)(a)). — The right to do an action in relation to a protected layout-design under section 23: <ul style="list-style-type: none"> (a) is non-exclusive, (b) is non-assignable, (c) does not permit the sale of the layout-design, or an integrated circuit in which the layout-design is incorporated to the public, and (d) is limited to the performing of the act predominantly in Singapore (section 24(1)). <p>PVPA</p> <p>A compulsory licence granted under section 34 may only be assigned together with the business activity in connection with which the protected variety is exploited or is intended to be exploited (section 34(8)).</p> <p>Copyright Act</p> <p>The scope of the statutory licences under the Copyright Act are set out in the respective provisions for each statutory licence (see the response to question 55 above for the relevant provisions).</p>
9. Which authority has the competency to grant a compulsory licence?	The High Court of Singapore has the authority to grant compulsory licences, which are applied for under section 55 of the Patents Act, section 27 of the LDICA and section 34 of the PVPA.
10. Application procedure for compulsory licence: <ul style="list-style-type: none"> (a) What are the application procedures to get a compulsory licence? (b) What materials need to be submitted to the competent authority? (c) How long will it take to get a compulsory licence? 	<ul style="list-style-type: none"> (a) There are no specific procedures set out in the Patents Act, LDICA and PVPA for an application to a court for the grant of a compulsory licence. The general rules of procedure found in the Rules of Court and Supreme Court Practice Directions would apply. (b) The application for a court order for the grant of a compulsory licence is made by way of summons and supported by an affidavit, which contains information/evidence relating to the grounds relied upon for the grant of the compulsory licence. (c) The time required to obtain a court order for the grant of a compulsory licence would depend on factors such as how soon the application can be heard by the court and the complexity of the matter.
11. Can the competent authority grant a compulsory licence without hearings under an urgent situation?	The statutory provisions relating to compulsory licensing in Singapore do not provide the court with such power to grant a compulsory licence without a hearing.
12. Revocation/termination of compulsory licence: <ul style="list-style-type: none"> (a) Can a compulsory licence be revoked/terminated or automatically revoked/terminated? 	<ul style="list-style-type: none"> (a) Yes, it is possible to terminate compulsory licences. There are express provisions in the Patents Act, LDICA and PVPA relating to the termination of a compulsory licence. (b) A compulsory licence in relation to a patented invention, protected layout-design or protected plant variety may, on the application of any interested party, be terminated by the court where the court is satisfied that the ground upon which the licence was granted has ceased to exist (section

<p>(b) What are the conditions for the revocation/termination of a compulsory licence?</p> <p>(c) How should products made under a compulsory licence be treated if the compulsory licence is terminated/revoked?</p>	<p>55(5) of the Patents Act, section 34(9) of the PVPA and section 29 of the LDICA).</p> <p>(c) In addition, the right to government use of a patented invention may, on the application of any interested party, be terminated by the court where the court is satisfied that the circumstances that gave rise to the right to government use have ceased to exist and are unlikely to recur (section 60(2) of the Patents Act).</p> <p>(d) There are no specific requirements in the Patents Act, LDICA and PVPA, which relate to the treatment of products made under a compulsory licence upon the termination of the compulsory licence.</p>
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Rights and obligations of the right holders in relation to compulsory licensing

<p>13. Royalty:</p> <p>(a) Does the compulsory licensee have to pay a royalty to the right holder?</p> <p>(b) If the compulsory licensee is required to pay a royalty, how is the amount of royalty determined and who will decide the amount of the royalty?</p> <p>(c) Is there any remuneration available for the right holders other than royalty?</p>	<p>(a) Yes, but the statutory provisions relating to compulsory licensing generally refer to the payment of remuneration rather than royalties.</p> <p>(b) The statutory provisions relating to the determination of the amount of remuneration to be paid to right holders are as follows:</p> <p>Patents Act</p> <ul style="list-style-type: none"> - Section 55(6) of the Patents Act provides that a licensee who is granted a compulsory licence under section 55 shall pay such remuneration to the patentee as may be agreed, or as may be determined by a method agreed between the licensee and the patentee or, in default of agreement, as is determined by the court on the application of either party. Where an application is made to court under section 55(6), the powers of the court will be exercised with a view to enable the inventor or other person beneficially entitled to a patent to receive reasonable remuneration reflecting the economic value of the licence. - Similarly, where an act is done under section 56, section 62(1) requires the Singapore government to provide remuneration at a sum to be agreed, or as may be determined by a method agreed between the Singapore government and the patentee reflecting the economic value of the patented invention. If the parties are unable to come to an agreement, the court will determine the remuneration under section 58. - Section 62(2) clarifies that no remuneration will be payable to the patentee for the importation of health products under section 56(1A) if he has already received or will receive any other remuneration in respect to the relevant health product. <p>LDICA</p> <ul style="list-style-type: none"> - Where the court makes an order for the grant of a compulsory licence under section 27 of the LDICA, section 27(3) provides that the court shall specify in the order such remuneration to be paid by the licensee to the owner of the protected layout-design as the court considers reasonable. - For an act carried out under section 23, section 26 requires the Singapore government to provide
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	<p>remuneration at a sum to be agreed, or as may be determined by a method agreed between the Singapore government and the owner of the protected layout-design or, in default of agreement, as is determined by the court on the application of either party.</p> <p>PVPA</p> <p>Where the court makes an order for the grant of a compulsory licence under section 34 of the PVPA, section 34(4) provides that the court shall set out in the order the equitable remuneration, which the licensee shall pay to the grantee.</p> <p>RDA</p> <p>Section 46(2) of the RDA provides that government use of registered designs under section 45 shall be made on such terms (which may include terms relating to remuneration) as agreed between the Singapore government and registered owners or, in default of such agreements, as may be determined by the court.</p> <p>Copyright Act</p> <p>The provisions in the Copyright Act relating to statutory licences generally provide that equitable remuneration must be paid to the copyright owner if the copyright owner makes a request, in writing, for payment for the making of copies. The amount of remuneration may be agreed upon between the parties or, in default of the agreement, the remuneration may be determined by a Copyright Tribunal (see sections 52(11), 52(11C), 52(15), 54A(7) and 198(5) of the Copyright Act). Section 57 of the Copyright Act provides that the making of records or adaptations of a musical work under section 56 is subject to a duty to pay royalty equivalent to 5% of the retail selling price of the record.</p> <p>(c) See our response to question 13(b) above.</p>
14. Are there any legal remedies for the party who is not satisfied with the compulsory licensing decision of the competent authority?	In general, a party who is not satisfied with a decision made by the High Court of Singapore in relation to compulsory licensing may appeal to the Singapore Court of Appeal to set aside or vary the decision.
15. Provision of know-how and support:	<p>(a) There is no such requirement under the statutory provisions relating to compulsory licensing in Singapore.</p> <p>(b) Not applicable.</p>
<p>(a) In order to implement the compulsory licence, for example, to manufacture the licenced product, is the right holder required to provide necessary support, such as know-how and training as in a voluntary agreed licence agreement?</p> <p>(b) Will this provision of know-how and support be compensated and how is the amount of such compensation determined?</p>	
16. Confidentiality:	There are no express confidentiality obligations for compulsory licensees in the statutory provisions relating to compulsory licensing in Singapore.

<p>(a) Is the compulsory licensee subject to any confidentiality obligation?</p> <p>(b) If the compulsory licensee discloses the confidential information in violation of its obligation, does the right holder have a basis of claim against the compulsory licensee?</p>	
<p>17. Export of products under compulsory licence</p> <p>(a) Is the compulsory licensee allowed to export their products under the compulsory licence?</p> <p>(b) If the compulsory licensee is permitted to export products under the compulsory licence, are there any requirements and limitations on the export of such products?</p>	<p>(a) It may be possible for compulsory licensees in Singapore to export their products under certain compulsory licences, but only under limited circumstances.</p> <p>(b) Where a compulsory licensee is permitted to export products, there are generally limitations on the export of such products. The relevant provisions relating to exportation are as follows:</p> <p>Patents Act</p> <ul style="list-style-type: none"> – There are no express restrictions against the export of products produced under a compulsory licence granted under section 55 of the Patents Act. However, a licence will only be granted under section 55 if it is necessary to remedy an anti-competitive practice. – The right under section 56 of the Patents Act may extend to the export of products, but this right is limited to use of a patented invention for public non-commercial purposes or for a national emergency or other circumstances of extreme urgency. In addition, the right under section 56 to use a relevant health product, which is imported under section 56(1A), does not include a right to export the relevant health product (section 60(1A) of Patents Act). <p>LDICA</p> <ul style="list-style-type: none"> – There are no express restrictions against exportation in section 27 of the LDICA. However, a licence will only be granted under section 27 if it is necessary to remedy an anti-competitive practice. – The right under section 23 of the LDICA is unlikely to include the right to export. Section 24(d) expressly states that the right under section 23 does not permit the sale of the layout-design or an integrated circuit (in which the layout-design is incorporated) to the public. Furthermore, section 24(e) also states that the right under section 23 is limited to performing the act predominantly in Singapore. <p>PVPA</p> <p>There are no express restrictions against exportation in section 34 of the PVPA. However, a licence will only be granted under section 34 if the court is satisfied that this would be in the public interest.</p> <p>RDA</p> <p>The right under section 45 of the RDA may extend to the export of products, but this right is limited to use of a registered design to avoid prejudice to the security or defence of Singapore, or to assist in the exercise of powers and the implementation of civil defence measures during a</p>

	<p>state of emergency or state of civil defence emergency, or for public non-commercial use.</p> <p>Copyright Act</p> <p>The copying of certain work for the purpose of export may be possible under statutory licences set out in the Copyright Act, subject to conditions. For instance, section 54(5) permits the making, on a non-profit basis, of an accessible format copy in a physical form of a work for use by a person with a reading disability for the purpose of export, provided that the various conditions set out in section 54(6) are met.</p>
<p>Compulsory licensing in the present COVID-19 pandemic</p>	
<p>18. Have the laws on compulsory licensing been used in previous health emergencies and/or in the present COVID-19 pandemic in your jurisdiction?</p>	<p>There are currently no reported cases of compulsory licensing being used in previous health emergencies or in the present COVID-19 pandemic in Singapore.</p>
<p>19. Is it possible for third parties to use the current laws on compulsory licensing in your jurisdiction to facilitate the treatment of patients infected by COVID-19?</p>	<p>It may be possible for a third party to invoke section 55 of the Patents Act (which enables the court to grant a compulsory licence under a patent to remedy an anti-competitive practice) to facilitate the treatment of patients infected by COVID-19. A possible situation could arise when a patent proprietor does not have sufficient quantities to supply treatment for COVID-19 in Singapore. However, such a licence can be terminated once the grounds upon which the licence was granted has ceased to exist and is unlikely to recur (section 55(5) of the Patents Act).</p> <p>Section 56 to 62 of the Patents Act could also enable the Singapore government and any party authorised in writing by the Singapore government to facilitate the use of patentable treatments for COVID-19 patients, given that the COVID-19 pandemic is likely to qualify as a situation of national emergency or a circumstance of extreme urgency. If a patented vaccine becomes available overseas, section 56(1A) allows the Singapore government or a party authorised by the Singapore government to import and use such treatment on COVID-19 patients, provided that notification has been given to the Council for TRIPS.</p>
<p>20. Are there any recent major regulatory exemptions and/or amendments made following COVID-19 to regulations governing compulsory licensing?</p>	<p>None.</p>
<p>Transactions and dealings of products under compulsory licences</p>	
<p>21. Can a compulsory licence be transferred or assigned?</p>	<p>There are express restrictions on the assignment of compulsory licences in the Patents Act, LDICA and PVPA.</p> <p>Patents Act</p> <p>A compulsory licence granted under section 55 and the right to use a patented invention under section 56 are both non-assignable, except where the assignment is in connection with the goodwill of the business in which the patented invention is used (sections 55(4)(b) and 60(1)(b)).</p> <p>LDICA</p>

	<p>A compulsory licence granted under section 27 and the right to do an action in relation to a protected layout-design under section 23 are both non-assignable (sections 28(1)(a) and 24(1)(a)).</p> <p>PVPA</p> <p>A compulsory licence granted under section 34 may only be assigned together with the business activity in connection with which the protected variety is exploited or is intended to be exploited (section 34(8)).</p>
22. Does the issuance of a compulsory licence have any impact on the previously agreed licence?	<p>Yes, but only in relation to the use of patented inventions, registered designs and copyright materials for the services of the Singapore government.</p> <p>The relevant provisions are as follows:</p> <p>Patents Act</p> <p>If the patented product is used for the services of the Singapore government, provisions in any licences, assignments or agreement shall be of no effect to the extent that the provisions restrict or regulate the working of the invention (section 57(1) of the Patents Act).</p> <p>RDA</p> <p>In relation to any use of a registered design for the services of the Singapore government, provisions in any licence, assignment or agreement made between the registered owner and a third party shall be of no effect to the extent that the provisions restrict or regulate the use of the design or any model, document or information relating to it, or provide for the making of payments in respect to, or calculated by reference to, such use (section 47 of the RDA).</p> <p>Copyright Act</p> <p>Where copyright material is used for service of the Singapore government, an agreement or licence fixing the terms upon which a person other than the government may perform acts included in a copyright is inoperative with respect to the performance of those acts, unless the agreement or licence has been approved by the Minister (section 198(6) of the Copyright Act).</p>
23. Is there any special labelling requirement for the products made under the compulsory licence?	There is no such special labelling requirement in the statutory provisions relating to compulsory licensing in Singapore.
24. Is there any special distribution channel requirement for the products made under the compulsory licence?	There is no such special distribution channel requirement in the statutory provisions relating to compulsory licensing in Singapore.
25. Is there any price requirement for the products made under the compulsory licence?	There are no express price requirements in the statutory provisions relating to compulsory licensing in Singapore.

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JURISDICTION: Spain

Compulsory licensing in general

1. What is the definition of compulsory licensing?	<p>Spanish regulation does not provide a specific definition of compulsory licensing.</p> <p>In general terms, compulsory licensing refers to a special regime provided in Spanish regulation, through which there is a limitation of the patent right through which, in specific cases provided by law, the Spanish Patents and Trademarks Office ("SPTO") grants a licence over a patent, utility model or plant variety right, which is valid and owned by a third party (the right holder).</p>
2. What are the applicable sources of law relating to compulsory licensing?	<ul style="list-style-type: none"> — Spanish Patent Act no. 24/2015 ("SPA"); — Spanish Plant Variety Act no. 3/2000, of 7 January ("SPVA"); — Regulation (EC) no 816/2006 of the European Parliament and of the Council of 17 May 2006 on compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems.
<p>3. Types of products which compulsory licensing applies to:</p> <p>(a) What type(s) of products or technologies do compulsory licensing applies to?</p> <p>(b) Has any compulsory licence ever been issued in your jurisdiction? If yes, on what type of technology?</p>	<p>(a) Compulsory licensing applies to any invention protected by a patent or a utility model , or to new plant varieties protected by a plant variety right. However, there are some particularities for certain products, such as new plant varieties or pharmaceutical products aimed at countries with public health problems.</p> <p>(b) No.</p>

Regulatory requirements on compulsory licensing

4. Who can apply for a compulsory licence? Are foreigners or foreign companies allowed to apply for a compulsory licence?	<ul style="list-style-type: none"> — Any natural person or legal entity that fulfils the requirements of the application for a compulsory licence. — Spanish law does not prevent foreigners or foreign companies from applying for a compulsory licence.
5. What are the legal grounds to grant a compulsory licence under the local laws of your jurisdiction and any applicable international treaties?	<p>Compulsory licences can be granted for a given patent in one of the following cases:</p> <ul style="list-style-type: none"> — Lack or insufficiency of exploitation of the patented invention: Cases in which a right holder, without any legitimate reason, fails to have exploited the patent within three years since the publication date of the granting of the patent or within four years since the filing date, whichever period expires last. The patent will also be considered to be insufficiently exploited if, once these periods have elapsed, the exploitation is interrupted for over a year; — Dependent patents, or cases in which there is a dependency between patents and plant variety rights: Where it is not possible to exploit the invention protected by a patent or a plant variety right without infringing the rights conferred by a prior patent or by a prior plant variety right.

	<ul style="list-style-type: none"> — Need to put an end to practices, which have been declared contrary to national or EU antitrust law by a final administrative or judicial decision. — Existence of public interest grounds for the grant of the compulsory licence: Public interest shall be deemed to exist when: <ul style="list-style-type: none"> – The initiation, increase or generalisation of the exploitation of the invention, or the improvement of the conditions under which such exploitation takes place, are of primary importance for public health or national defence. – The lack of exploitation or the insufficient quality or quantity of the exploitation carried out entails serious prejudice to the economic or technological development of the country. – National supply demands require it. — Manufacture of pharmaceutical products for export pursuant to EU Regulation (EC) No 816/2006, through which compulsory licences may be granted over patents concerning manufacturing of pharmaceutical products, which will be destined to countries with public health issues.
<p>6. Are there any preconditions to apply for a compulsory licence? For example:</p> <p>(a) Any negotiation required between the applicant and the right holder before applying for a compulsory licence?</p> <p>(b) Any urgent situation required in order to grant a compulsory licence?</p> <p>(c) Any minimum number of years required for the patent to be granted and/or implemented in order to be subject to compulsory licensing?</p>	<p>(a) Yes. The applicant must prove that he has unsuccessfully attempted (within a reasonable time) to obtain from the right holder a contractual licence on reasonable commercial terms and conditions. However, there are certain situations where this attempt is not required (e.g. national emergency, non-commercial public use and cases in which there is a need to put an end to practices, which have been declared contrary to national or EU rules).</p> <p>(b) Not specifically. Urgent situations such as national defence or public health could lead to the existence of public interest grounds (as stated in question 5) but this is just one of the situations in which a compulsory licence can be granted.</p> <p>(c) No. The only scenario in which there is a minimum number of years is in cases in which the compulsory licence is requested due to lack or insufficiency of exploitation of the patented invention.</p>
<p>7. Are there any limits on the number of compulsory licensees?</p>	<p>There is no specific limit in this regard in Spanish legislation.</p>
<p>8. Will there be any limitation on the scope of the compulsory licence, for example limitations on the time and the territory?</p>	<p>Yes. The agreement between the parties or the decision of the SPTO granting the compulsory licence shall stipulate the scope of the licence, and particularly, the scope of the compulsory licence, the royalty, the duration, the guarantees to be provided by the licensee and any other clauses ensuring compliance by the licensee with the conditions that justify the granting of the licence.</p>
<p>9. Which authority has the competency to grant a compulsory licence?</p>	<p>The SPTO.</p>
<p>10. Application procedure for compulsory licence:</p>	<p>(a) The application for a compulsory licence shall be submitted with the SPTO through the specific standard form.</p> <p>The SPTO shall notify the application to the right holder and enable the right holder to file a brief of arguments</p>

<p>(a) What are the application procedures to get a compulsory licence?</p> <p>(b) What materials need to be submitted to the competent authority?</p> <p>(c) How long will it take to get a compulsory licence?</p>	<p>within the following month. If no allegations are submitted, the SPTO will grant the licence.</p> <p>If the right holder does file a brief of arguments, the SPTO will evaluate the arguments and evidence of both parties. If the SPTO considers that there are circumstances, which allow for the granting of a compulsory licence, the SPTO will request the parties to appoint a common mediator within a period of two months, or each party shall appoint an expert who, together with a third expert appointed by the SPTO, shall agree on the terms and conditions of the licence.</p> <p>In the absence of agreement on the appointment of a mediator or expert, or on the conditions of the licence within a period of two additional months, the SPTO shall decide accordingly.</p> <p>(b) The application shall be accompanied by proof of the previous attempt to obtain a contractual licence, except in those cases of (i) national emergency or other circumstances of extreme urgency, (ii) public non-commercial use, (iii) anti-competitive practices. The application shall include the receipt of payment of the official fee.</p> <p>The applicant shall provide evidence proving that a circumstance enabling the granting of a compulsory licence is met as well as evidence proving that he has sufficient means and guarantees to carry out a real and effective exploitation of the patented invention.</p> <p>(c) According to the above timelines, it could take around 5-6 months, although there are no precedents enabling an estimation of how long a decision by the SPTO would take.</p>
<p>11. Can the competent authority grant a compulsory licence without hearings under an urgent situation?</p>	<p>No.</p>
<p>12. Revocation/termination of compulsory licence:</p> <p>(a) Can a compulsory licence be revoked/terminated or automatically revoked/terminated?</p> <p>(b) What are the conditions for the revocation/termination of a compulsory licence?</p> <p>(c) How should products made under a compulsory licence be treated if the compulsory licence is terminated/revoked?</p>	<p>(a) Yes, the Spanish Patent Act expressly envisages the revocation/termination of the compulsory licence.</p> <p>(b) If the licensee seriously or repeatedly fails to comply with any of the obligations under the compulsory licence, the SPTO may, on its own initiative or at the request of an interested party, terminate the compulsory licence. Further from that, if there is a judicial decision declaring that the licensor has acted in bad faith, the licensee could request the termination of the compulsory licence to the SPTO.</p> <p>(c) There are no specific provisions in this regard in the Spanish legislation. Thus, parties of the compulsory licence agreement should carefully assess the conditions of the compulsory licence imposed by the SPTO in this regard (if any).</p>
<p>Rights and obligations of the right holders in relation to compulsory licensing</p>	
<p>13. Royalty:</p> <p>(a) Does the compulsory licensee have to pay a royalty to the right holder?</p> <p>(b) If the compulsory licensee is required to pay a royalty,</p>	<p>(a) Yes, the compulsory licensee has to pay a royalty to the owner of the patent.</p> <p>(b) The compulsory licence shall be accompanied by adequate remuneration according to the circumstances of each case, taking into account the economic importance of the invention. As mentioned, the SPTO shall invite the parties</p>

<p>how is the amount of royalty determined and who will decide the amount of the royalty?</p> <p>(c) Is there any remuneration available for the right holders other than royalty?</p>	<p>to appoint a joint mediator in order to reach an agreement on the terms and conditions of the compulsory licence. In any case, the SPTO's resolution granting the compulsory licence shall determine the content of the licence, including the amount of the royalty.</p> <p>(c) There are no specific provisions in this regard in the Spanish legislation.</p>
<p>14. Are there any legal remedies for the party who is not satisfied with the compulsory licensing decision of the competent authority?</p>	<p>Yes, the SPTO decision can be appealed (administratively/judicially) by any of the parties. However, the filing of the appeal does not suspend the execution of the resolution, although the SPTO may authorise the licensee, upon a justified request, to delay the exploitation of the patent until the granting decision becomes final.</p> <p>Moreover, both the licensee and the rights holder can request from the SPTO the modification of the royalty or other conditions if new facts justify such modification and, especially, if the right holder has granted contractual licences with conditions, which are unjustifiably more favourable to the conditions of the prior compulsory licence.</p>
<p>15. Provision of know-how and support:</p> <p>(a) In order to implement the compulsory licence, for example, to manufacture the licenced product, is the right holder required to provide necessary support, such as know-how and training as in a voluntary agreed licence agreement?</p> <p>(b) Will this provision of know-how and support be compensated and how is the amount of such compensation determined?</p>	<p>(a) Yes, the right holder has the obligation to provide the licensee with the technical knowledge needed to proceed to a suitable commercial exploitation of the invention.</p> <p>(b) This obligation falls under the principle of good faith. Accordingly, if a court decision finds that the right holder has breached this obligation and thus has violated this principle, the licensee may request that the SPTO reduce the royalty to be paid.</p>
<p>16. Confidentiality:</p> <p>(a) Is the compulsory licensee subject to any confidentiality obligation?</p> <p>(b) If the compulsory licensee discloses the confidential information in violation of its obligation, does the right holder have a basis of claim against the compulsory licensee?</p>	<p>(a) There are no statutory provisions in this regard in the Spanish legislation, although foreseeably the conditions of the compulsory licence would provide a confidentiality obligation covering all confidential information.</p> <p>(b) Probably yes, although this should be assessed on a case by case basis taking into account the conditions of the compulsory licence, the specific information disclosed and whether this information could be considered a trade secret.</p>
<p>17. Export of products under compulsory licence</p> <p>(a) Is the compulsory licensee allowed to export their products under the compulsory licence?</p> <p>(b) If the compulsory licensee is permitted to export products under the compulsory licence, are there any</p>	<p>(a) It may be possible for compulsory licensees in Spain to export pharmaceutical products to eligible importing countries in need of such products in order to address public health problems.</p> <p>(b) According to Regulation (EC) No. 816/2006, the patented pharmaceutical product made under the licence shall be exported only to the eligible importing country specified in the licence, and upon acceptance of an application by the national competent authority. The application may include evidence of prior negotiation with the rights holder within 30</p>

requirements and limitations on the export of such products?	<p>days prior to the submission of the application. It shall also include evidence of a specific request from:</p> <ul style="list-style-type: none"> — authorised representatives of the importing country or countries; or — a non-governmental organisation acting with the formal authorisation of one or more importing countries; or — UN bodies or other international health organisations acting with the formal authorisation of one or more importing countries.
Compulsory licensing in the present COVID-19 pandemic	
18. Have the laws on compulsory licensing been used in previous health emergencies and/or in the present COVID-19 pandemic in your jurisdiction?	There are currently no reported cases of compulsory licensing being used in Spain in previous health emergencies or in the present COVID-19 pandemic.
19. Is it possible for third parties to use the current laws on compulsory licensing in your jurisdiction to facilitate the treatment of patients infected by COVID-19?	Spanish legislation provides that the Spanish government may, at any time, impose the compulsory licensing regime to any patent or patent application on public interest grounds. Since treatment for people infected with COVID-19 could be considered to be of primary importance for public health, the Spanish government could use this provision to impose this regime on any patent or patent application.
20. Are there any recent major regulatory exemptions and/or amendments made following COVID-19 to regulations governing compulsory licensing?	None.
Transactions and dealings of products under compulsory licences	
21. Can a compulsory licence be transferred or assigned?	<p>Yes. A compulsory licence can be transferred or assigned although it must be transferred together with the company or the part of the company that exploits it. Further to that, the assignment shall be expressly noted by the SPTO. In case the compulsory licence has been granted due to the dependent patent circumstance explained above, it is also necessary for the compulsory licence to be transferred together with the dependent patent.</p> <p>In any case, the granting of sub-licences by the licensee is considered null and void.</p>
22. Does the issuance of a compulsory licence have any impact on the previously agreed licence?	There are no specific provisions in this regard in Spanish legislation.
23. Is there any special labelling requirement for the products made under the compulsory licence?	According to Regulation (EC) No. 816/2006, the patented pharmaceutical products made under the compulsory licence shall be clearly identified through specific labelling or marking, as being produced pursuant to this regulation. The products shall be distinguished from those made by the rights holder through special packaging and/or special colouring/shaping, provided that such distinction is feasible and does not have a significant impact on price. The packaging and any associated literature shall bear an indication that the product is subject to a compulsory licence under this regulation, providing the name of the competent

	authority and any identification reference number, and clearly specifying that the product is exclusively for export to and distribution in the importing country or countries concerned. Details of the product characteristics shall be made available to the customs authorities of the member states.
24. Is there any special distribution channel requirement for the products made under the compulsory licence?	There are no specific provisions in this regard in Spanish legislation.
25. Is there any price requirement for the products made under the compulsory licence?	There are no specific provisions in this regard in Spanish legislation.

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JURISDICTION: Switzerland

Compulsory licensing in general

1.	What is the definition of compulsory licensing?	Compulsory licensing refers to the mechanism that a competent court (in case of patents the Swiss Federal Patent Court) may grant in certain circumstances a compulsory licence to use certain or patent/copyright-protected inventions.
2.	What are the applicable sources of law relating to compulsory licensing?	<ul style="list-style-type: none"> — Swiss Federal Patents Act ("PatA", cf. question 5 below); — Swiss Federal Copyright Act ("CopA", cf. question 5 below); — Swiss Federal Act on Cartels and other Restraints of Competition ("CartA") provides for the possibility of compulsory licences in the event of a dominant position in the market and abusive practices or in the framework of merger controls. Though, the relationship to the above-mentioned sources of law with regard to compulsory licences ("PatA" and "CopA") is unclear. Compulsory licences based on the CarA should be viewed as separate remedies than core-IP-based remedies in the PatA and/or CopA.
3.	Types of products which compulsory licensing applies to: (a) What type(s) of products or technologies do compulsory licensing applies to? (b) Has any compulsory licence ever been issued in your jurisdiction? If yes, on what type of technology?	<p>(a) The provisions of the PatA are either linked to a certain circumstance (e.g. lack of exploitation or prevailing public interest) or to certain products (e.g. research tools, pharmaceutical products or semi-conductor products). For more detail see answer to question 5 below.</p> <p>(b) Compulsory licences are only of limited practical relevance in Switzerland. Up to now, Swiss courts have never granted a compulsory licence in the field of pharmaceutical products. Cases may have occurred on a settlement basis between parties, but such settlements are not accessible to the public.</p>

Regulatory requirements on compulsory licensing

4.	Who can apply for a compulsory licence? Are foreigners or foreign companies allowed to apply for a compulsory licence?	<ul style="list-style-type: none"> — Any entity or individual that is qualified to exploit a patent can apply for a compulsory licence. — Swiss patent law and practice does not provide for any restriction to Swiss entities or organisations. However, the compulsory licence under article 23 CopA (cf. question 5 below) is limited to Swiss entities. The Federal Council, however, may waive the requirement of a commercial establishment in Switzerland in the case of nationals of countries granting reciprocity.
5.	What are the legal grounds to grant a compulsory licence under the local laws of your jurisdiction and any applicable international treaties?	<p>The following article in the PatA and the CopA provide for compulsory licences:</p> <ul style="list-style-type: none"> — article 36 and 36a (in case of dependent inventions and dependent plant variety rights); — article 37 (in case of insufficient exploitation); — article 40 (in case of public interest); — article 40a (in the field of semi-conductor technology to remedy a practice held to be anti-competitive)

	<ul style="list-style-type: none"> — article 40b (in case of use of a patented biotechnological invention as an instrument or means for research); — article 40c (in case of inventions concerning a diagnostic product or procedure for humans to remedy a practice held to be anti-competitive); — article 40d (for the manufacture of patent-protected pharmaceutical products and for their export to a country that has insufficient or no production capacity of its own in the pharmaceutical sector and which requires these products to combat public health problems); — article 40e (common provisions for Articles 36–40d); — article 23 CopA (for the manufacture of phonograms if a musical work, with or without lyrics, has been fixed on a phonogram in Switzerland or abroad and has been offered, transferred or otherwise distributed in this form with the permission of the author); — Article 21 CopA (which provides for access rights to software interface data necessary to establish interoperability); — WTO/TRIPS Agreement; — Article 5 para 2 Paris Convention (PVÜ).
<p>6. Are there any preconditions to apply for a compulsory licence? For example:</p> <p>(a) Any negotiation required between the applicant and the right holder before applying for a compulsory licence?</p> <p>(b) Any urgent situation required in order to grant a compulsory licence?</p> <p>(c) Any minimum number of years required for the patent to be granted and/or implemented in order to be subject to compulsory licensing?</p>	<p>(a) A compulsory licence is granted only if efforts by the applicant to obtain a contractual licence on appropriate terms within a reasonable period of time have been unsuccessful; in the case of a licence in accordance with Article 40d (export of pharmaceutical products to combat public health problems in foreign countries), a period of 30 working days is considered reasonable. Such efforts are not required in situations of national emergency or other circumstances of extreme urgency or in cases of public non-commercial use. (article 40e para 1 PatA).</p> <p>(b) In general, an urgent situation is not required, but see question 11 below.</p> <p>(c) Not in general, but in the case of a request for a compulsory licence under article 37 PatA (lack of exploitation), three years from the date of the grant of the patent, or at the earliest four years after filing the patent application, any person with a legitimate interest may apply to the court for the grant of a non-exclusive licence to use the invention if the proprietor of the patent has not sufficiently exploited it in Switzerland by the time of the action and cannot justify such a failure. Importing is also considered. domestic exploitation.</p>
<p>7. Are there any limits on the number of compulsory licensees?</p>	<p>No, Swiss law does not provide for a statutory limitation on the number of compulsory licensees. However, if there are multiple compulsory licensees (enabling them to market knowledge or sub-licence), there may no longer be a need for patent holder to grant compulsory licences.</p>

<p>8. Will there be any limitation on the scope of the compulsory licence, for example limitations on the time and the territory?</p>	<ul style="list-style-type: none"> — The scope and term of a compulsory licence are limited to the purpose for which it has been granted and the licence may only be transferred with that part of the enterprise, which uses the licence. This also applies to sub-licences (article 40e para 2 and 3 PatA). — In addition, the licence is primarily granted for supplying the domestic market (article 40e para 4 PatA). Compulsory licences for the export of pharmaceutical products remain reserved. However, such licences may be limited to the production of the pharmaceutical product in the quantity that meets the requirements of the beneficiary country; the total quantity must be exported to the beneficiary country (article 40d para 3 PatA).
<p>9. Which authority has the competency to grant a compulsory licence?</p>	<p>The Swiss Federal Patent Court is the competent authority to grant compulsory licences under the PatA (with the exception of administrative antitrust-proceedings where a claim is based on anti-competitive behaviour). The compulsory licences under the CopA are granted by the competent, local Commercial Court dealing with a copyright dispute.</p>
<p>10. Application procedure for compulsory licence:</p> <ul style="list-style-type: none"> (a) What are the application procedures to get a compulsory licence? (b) What materials need to be submitted to the competent authority? (c) How long will it take to get a compulsory licence? 	<ul style="list-style-type: none"> (a) Compulsory licences are granted in Switzerland by the competent courts or administrative body (cf. question 9 above) based on a respective civil lawsuit. (b) Evidence that the preconditions set out in the respective laws are met (e.g. that efforts by the applicant to obtain a contractual licence on appropriate market terms within a reasonable period of time have been unsuccessful). (c) Depending on the circumstances of the case, it may take between a few weeks (if such licence is granted) and several months to obtain a compulsory licence (if such licence must be enforced via court proceedings).
<p>11. Can the competent authority grant a compulsory licence without hearings under an urgent situation?</p>	<p>No, but in the case of article 37 PatA (lack of exploitation) at the request of the plaintiff, the court may grant a licence immediately after the action has been filed without prejudice to the final judgment providing that, the plaintiff provides prima facie evidence that he has an interest in the immediate use of the invention and that he provides adequate security to the defendant; however, the defendant is given the opportunity to be heard beforehand.</p>
<p>12. Revocation/termination of compulsory licence:</p> <ul style="list-style-type: none"> (a) Can a compulsory licence be revoked/terminated or automatically revoked/terminated? (b) What are the conditions for the revocation/termination of a compulsory licence? (c) How should products made under a compulsory licence be treated if the compulsory licence is terminated/revoked? 	<ul style="list-style-type: none"> (a) The court may revoke an entitled person's licence on request. (b) A compulsory licence may be revoked if the circumstances that led to its issuance no longer applies and it is not expected that they will arise again. Appropriate protection of the legal interests of the entitled person remains reserved (article 40e para 6 PatA). (c) Swiss law does not provide for any specific provision on the question how products made under a compulsory licence should be treated if the compulsory licence is terminated/revoked. However, Art. 40e para 6 PatA provides that legal interests of the entitled person remain reserved, which should provide room to craft temporary solutions for products affected.

Rights and obligations of the right holders in relation to compulsory licensing

<p>13. Royalty:</p> <p>(a) Does the compulsory licensee have to pay a royalty to the right holder?</p> <p>(b) If the compulsory licensee is required to pay a royalty, how is the amount of royalty determined and who will decide the amount of the royalty?</p> <p>(c) Is there any remuneration available for the right holders other than royalty?</p>	<p>(a) Yes. The proprietor of the patent has a right to appropriate remuneration.</p> <p>(b) In assessing the remuneration, the circumstances of the individual case and the economic value of the licence are taken into account. In the case of a licence under Article 40d PatA (compulsory licences for the export of pharmaceutical products), the remuneration is determined by taking into account the economic value of the licence in the importing country, its level of development and the urgency in public health and humanitarian terms.</p> <p>(c) No.</p>
<p>14. Are there any legal remedies for the party who is not satisfied with the compulsory licensing decision of the competent authority?</p>	<p>Yes, decision of the Swiss Federal Patent Court and of Swiss Commercial Courts may be appealed to the Swiss Federal Supreme Court. However, the appeal grounds are limited.</p>
<p>15. Provision of know-how and support:</p> <p>(a) In order to implement the compulsory licence, for example, to manufacture the licenced product, is the right holder required to provide necessary support, such as know-how and training as in a voluntary agreed licence agreement?</p> <p>(b) Will this provision of know-how and support be compensated and how is the amount of such compensation determined?</p>	<p>(a) No. Swiss law does not provide for any explicit duty of the right holder to support the licensee with his know-how or with training. In principle, the patent claims and descriptions must be self-explanatory to meet the requirements of a patent (patents are only granted for new inventions "applicable in industry"; Art. 1 para. 1 PatA). However, such a duty could arise under competition law considerations, if critical know-how was withheld in the sphere of a market-dominant player;</p> <p>(b) There are no statutory provisions or case law available on this subject. Nevertheless, such a provision should be compensated as any use of knowledge provided under a compulsory licence is also compensated (both under patent and competition law considerations).</p>
<p>16. Confidentiality:</p> <p>(a) Is the compulsory licensee subject to any confidentiality obligation?</p> <p>(b) If the compulsory licensee discloses the confidential information in violation of its obligation, does the right holder have a basis of claim against the compulsory licensee?</p>	<p>(a) No. Swiss law does not provide for statutory confidentiality obligations. However, a compulsory licence granted still remains a contract <i>inter partes</i> and as such can be considered confidential information of each party. Thus, each party may stipulate or invoke that the contract remains confidential.</p> <p>(b) Yes, depending on the circumstances, breach of confidentiality obligations of a contract may constitute a breach of contract and unlawful behaviour under the Swiss Federal Act against Unfair Competition ("FAUC").</p>
<p>17. Export of products under compulsory licence</p> <p>(a) Is the compulsory licensee allowed to export their products under the compulsory licence?</p> <p>(b) If the compulsory licensee is permitted to export products under the compulsory</p>	<p>(a) The compulsory licence granted under article 23 CopA is limited to the Swiss market.</p> <p>The compulsory licence granted under article 40e para 4 PatA is primarily granted for supplying the domestic Swiss market. However, article 40d PatA remains reserved, which provides for a compulsory licence for the export of pharmaceutical products to a country that has insufficient or no production capacity of its own in the pharmaceutical sector and which requires these products to combat public</p>

licence, are there any requirements and limitations on the export of such products?	<p>health problems, in particular those related to HIV/AIDS, tuberculosis, malaria and other epidemics (beneficiary country).</p> <p>(b) A licence under article 40d PatA is limited to the production of the pharmaceutical product in the quantity that meets the requirements of the beneficiary country; the total quantity must be exported to the beneficiary country. In addition, the owner of the licence, as well as any manufacturer that produces products under the licence, must ensure that they are clearly identified as products that have been produced under a respective licence and that the products are distinguished by their packaging or by their special colouring or shape from patent-protected products, provided this does not have a significant impact on the price of the products in the beneficiary country.</p>
Compulsory licensing in the present COVID-19 pandemic	
18. Have the laws on compulsory licensing been used in previous health emergencies and/or in the present COVID-19 pandemic in your jurisdiction?	No. There is no respective precedence.
19. Is it possible for third parties to use the current laws on compulsory licensing in your jurisdiction to facilitate the treatment of patients infected by COVID-19?	Yes, a third party could in theory invoke article 40 PatA stating that where public interest so dictates, the person to whom the proprietor of the patent has, without sufficient reason, refused to grant the licence requested, may apply to the court for the grant of a licence to use the invention. To our knowledge, there is no such patented knowledge available yet on combatting COVID-19.
20. Are there any recent major regulatory exemptions and/or amendments made following COVID-19 to regulations governing compulsory licensing?	No. In fact, Switzerland officially supports initiatives that provide for the licensing of patents for the battle against COVID-19 on a voluntary basis, but fears that opening the door to automatic compulsory licences in this pandemic might weaken the institute of patent protection and be counterproductive.
Transactions and dealings of products under compulsory licences	
21. Can a compulsory licence be transferred or assigned?	According to article 40e para 3 PatA, the licence may only be transferred with that part of the enterprise using the licence. This also applies to sub-licences.
22. Does the issuance of a compulsory licence have any impact on the previously agreed licence?	Swiss law does not provide for statutory provisions on such impact. Indeed, the question arises whether the new compulsory licence would replace an previously agreed-upon licence or only complement it (which must be reviewed under each individual case).
23. Is there any special labelling requirement for the products made under the compulsory licence?	According to article 40d para 4 PatA, the owner of the licence for the export of pharmaceutical products to fight public health problems, as well as any manufacturer that produces products under licence, must ensure that they are clearly identified as products that have been produced under the compulsory licence and that the products are distinguished by their packaging or by their special colouring or shape from patent-protected products, provided this does not have a significant impact on the price of the products in the beneficiary country.

24.	Is there any special distribution channel requirement for the products made under the compulsory licence?	No, Swiss law does not provide for special distribution channels, but in the event of compulsory licences for the export to beneficiary countries of pharmaceutical products to fight public health problems in these countries, the licensee has to take care that the total quantity is exported to the beneficiary country (article 40d para 4 PatA).
25.	Is there any price requirement for the products made under the compulsory licence?	No, not to our knowledge. Generally, price fixation of end selling products is considered critical under competition law-statutes and should not be triggered by a compulsory licence. A compulsory licence must remain compliant with the rest of the law.

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JURISDICTION: Turkey

Compulsory licensing in general

1.	What is the definition of compulsory licensing?	The Turkish Law No 6769 on Intellectual Property (" IP Law ") does not contain a definition of compulsory licences.
2.	What are the applicable sources of law relating to compulsory licensing?	The applicable legal source for compulsory licensing is the IP Law.
3.	Types of products which compulsory licensing applies to: (a) What type(s) of products or technologies do compulsory licensing applies to? (b) Has any compulsory licence ever been issued in your jurisdiction? If yes, on what type of technology?	(a) The IP Law has not listed any specific products or technologies to which compulsory licensing applies. (b) According to the WIPO questionnaire on "Exceptions and Limitations to Patent Rights in Turkey", a compulsory licence has been granted in the field of mechanical engineering for an anchor device, which can be fixed to the wall (IPC class: F16B13). The compulsory licence was granted on the basis of non-use.

Regulatory requirements on compulsory licensing

4.	Who can apply for a compulsory licence? Are foreigners or foreign companies allowed to apply for a compulsory licence?	The only restriction laid down in the IP Law is that compulsory licences are granted mainly for the domestic market.
5.	What are the legal grounds to grant a compulsory licence under the local laws of your jurisdiction and any applicable international treaties?	According to Article 129 of the IP Law, a compulsory licence may be granted under one of the conditions listed below: (a) In case of non-use; (b) In case of questions concerning the dependence of the patent; (c) In accordance with the Agreement on Trade-Related Aspects of Intellectual Property Rights (" TRIPS "), to which Turkey has acceded if there is a public health problem with exported pharmaceutical products; (d) In the public interest; (e) Where a breeder cannot develop a new plant variety without infringing an earlier patent; and (f) If the patent holder engages in anti-competitive activities during the use of the patent.
6.	Are there any preconditions to apply for a compulsory licence? For example: (a) Any negotiation required between the applicant and the right holder before applying for a compulsory licence? (b) Any urgent situation required in order to grant a compulsory licence?	Conditions for non-use: (a) According to Article 130 of the Intellectual Property Law, a compulsory licence can be applied for at the court if the patent holder has not used the patent within three years after publication of a grant decision in the Trademark/Patent Bulletin or within four years after the date of the patent application (whichever date expires later). (b) In determining "use" (or lack thereof), the court will also take into account conditions beyond the control of the patentee, such as market conditions.

<p>(c) Any minimum number of years required for the patent to be granted and/or implemented in order to be subject to compulsory licensing?</p>	<p>(c) Non-use also applies to situations in which a patent proprietor has repeatedly paused in the use of his patent for more than three years without justified reasons.</p> <p>Conditions for questions relating to the dependence of the patent:</p> <p>(a) According to Article 131 of the Intellectual Property Law, the holder of the successor patent may apply for a compulsory licence for the successor patent if it is not possible to exploit a patented invention without infringing the rights of an earlier patent. When granting a compulsory licence, the court will examine whether the licence can bring significant technological and economic benefits.</p> <p>(b) If a compulsory licence is granted to the holder of the subsequent patent, the holder of the earlier patent may apply for a compulsory licence for the subsequent patent.</p> <p>(c) If one of the dependent patents becomes null and void or expires, the compulsory licence is also terminated.</p> <p>Public interest requirements under Article 132 of the IP Law:</p> <p>(a) If the use, dissemination or improvement of the patented invention is of crucial importance for public health or national security;</p> <p>(b) If the non-use/inadequate use of the patented invention causes serious technical or economic damage, whether qualitative or quantitative, the Council of Ministers may decide to grant a compulsory licence in the public interest; or</p> <p>(c) If the patented invention is vital for public health or national security, the competent ministry will seek the approval of the Ministry of Defence or the Ministry of Health.</p>
<p>7. Are there any limits on the number of compulsory licensees?</p>	<p>As a rule, a compulsory licence is not exclusive. However, there are exceptions. Accordingly, a compulsory licence granted in the public interest may be exclusive. Furthermore, a compulsory licence granted for reasons of national security may be limited to use by one or more undertakings.</p>
<p>8. Will there be any limitation on the scope of the compulsory licence, for example limitations on the time and the territory?</p>	<p>As mentioned in question 4, compulsory licences are mainly granted for the domestic market. In addition, the import of the patented invention is in principle prohibited. Exceptionally, however, the patented invention may be imported if the compulsory licence has been granted in the public interest and the licensee has been granted an explicit authorisation for a limited need and period of time.</p>
<p>9. Which authority has the competency to grant a compulsory licence?</p>	<p>As a rule, a compulsory licence is granted by the court. However, if a compulsory licence is requested because a patent holder engages in anti-competitive activities while using the patent, it is granted by the competition authority.</p>
<p>10. Application procedure for compulsory licence:</p> <p>(a) What are the application procedures to get a compulsory licence?</p> <p>(b) What materials need to be submitted to the competent authority?</p>	<p>(a) As a rule, compulsory licences are applied for before the court, with the exception of the exception described in question 9.</p> <p>(b) According to Article 129(2) of the IP Law, the individual/entity applying for a compulsory licence should prove that he has not obtained a contractual licence within a reasonable period of time, despite having requested reasonable conditions from the patent holder. This does not apply in emergency situations or in the cases referred to in the TRIPS Agreement, where public-health issues relating</p>

(c) How long will it take to get a compulsory licence?	<p>to exported pharmaceutical products are involved, and in cases where a patent holder has carried out activities restricting competition during the use of the patent.</p> <p>(c) The competent court will decide within one month whether or not to grant a compulsory licence.</p>
11. Can the competent authority grant a compulsory licence without hearings under an urgent situation?	The IP Law contains an emergency exception.
<p>12. Revocation/termination of compulsory licence:</p> <p>(a) Can a compulsory licence be revoked/terminated or automatically revoked/terminated?</p> <p>(b) What are the conditions for the revocation/termination of a compulsory licence?</p> <p>(c) How should products made under a compulsory licence be treated if the compulsory licence is terminated/revoked?</p>	<p>(a) A compulsory licence cannot be automatically revoked/terminated.</p> <p>(b) The court may terminate the compulsory licence if the licensee seriously infringes his obligations under the compulsory licence or systematically fails to fulfil them. The court may also annul a compulsory licence if the conditions under which the compulsory licence was granted expire.</p> <p>(c) This is not specified in the IP Law.</p>
Rights and obligations of the right holders in relation to compulsory licensing	
<p>13. Royalty:</p> <p>(a) Does the compulsory licensee have to pay a royalty to the right holder?</p> <p>(b) If the compulsory licensee is required to pay a royalty, how is the amount of royalty determined and who will decide the amount of the royalty?</p> <p>(c) Is there any remuneration available for the right holders other than royalty?</p>	<p>(a) Yes, the compulsory licensee must pay a royalty to the right holder.</p> <p>(b) The amount of the royalty is fixed by the authorised court taking into account the economic value of the patent, the duration of the compulsory licence and the field of use.</p> <p>(c) The parties may agree on remuneration other than a licence fee. However, it must be in line with the provisions on compulsory licensing.</p>
14. Are there any legal remedies for the party who is not satisfied with the compulsory licensing decision of the competent authority?	Yes, since compulsory licences are granted by civil courts, there is a right of appeal.
<p>15. Provision of know-how and support:</p> <p>(a) In order to implement the compulsory licence, for example, to manufacture the licenced product, is the right holder required to provide necessary support, such as know-how and training as in a voluntary agreed licence agreement?</p> <p>(b) Will this provision of know-how and support be</p>	This is not specified in the IP Law.

	compensated and how is the amount of such compensation determined?	
16.	<p>Confidentiality:</p> <p>(a) Is the compulsory licensee subject to any confidentiality obligation?</p> <p>(b) If the compulsory licensee discloses the confidential information in violation of its obligation, does the right holder have a basis of claim against the compulsory licensee?</p>	<p>(a) This is not specified in the IP Law.</p> <p>(b) The IP Law only recognises a mutual relationship of trust between the licensor and the licensee.</p>
17.	<p>Export of products under compulsory licence</p> <p>(a) Is the compulsory licensee allowed to export their products under the compulsory licence?</p> <p>(b) If the compulsory licensee is permitted to export products under the compulsory licence, are there any requirements and limitations on the export of such products?</p>	<p>(a) The compulsory licensee is not allowed to export the patented invention.</p> <p>(b) If the compulsory licence has been granted in the public interest, the licensee may exceptionally be allowed to export for a limited period of time on the basis of the licence.</p>
Compulsory licensing in the present COVID-19 pandemic		
18.	Have the laws on compulsory licensing been used in previous health emergencies and/or in the present COVID-19 pandemic in your jurisdiction?	No.
19.	Is it possible for third parties to use the current laws on compulsory licensing in your jurisdiction to facilitate the treatment of patients infected by COVID-19?	The Ministry of Health may authorise a compulsory licence in the public interest where the use, dissemination or improvement of the patented invention is of crucial importance for public health.
20.	Are there any recent major regulatory exemptions and/or amendments made following COVID-19 to regulations governing compulsory licensing?	No.
Transactions and dealings of products under compulsory licences		
21.	Can a compulsory licence be transferred or assigned?	Compulsory licences can only be transferred as part of the transfer of an undertaking to which the licence is linked. If the compulsory licence is granted because of problems of dependency, the licence is transferred with the dependent patent.

22.	Does the issuance of a compulsory licence have any impact on the previously agreed licence?	
23.	Is there any special labelling requirement for the products made under the compulsory licence?	This is not specified in the IP Law.
24.	Is there any special distribution channel requirement for the products made under the compulsory licence?	This is not specified in the IP Law.
25.	Is there any price requirement for the products made under the compulsory licence?	This is not specified in the IP Law.

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JURISDICTION: Ukraine

Compulsory licensing in general

1. What is the definition of compulsory licensing?	Compulsory licensing is a procedure under which it is permissible to use a patented IP object (inventions, utility models, industrial designs, integrated circuits, plants varieties) without the IP right holder's permission.
2. What are the applicable sources of law relating to compulsory licensing?	<p>The applicable sources of law are:</p> <ul style="list-style-type: none"> (a) Civil Code of Ukraine; (b) Law of Ukraine on the Protection of Rights to Inventions and Utility Models; (c) Law of Ukraine on the Protection of Rights to Integrated Circuits; (d) Law of Ukraine on the Protection of Rights to Industrial Designs; (e) Law of Ukraine on the Protection of Rights to Plant Varieties; (f) Cabinet of Ministers of Ukraine (the CMU) Resolution on the Procedure of Granting a Licence for the Use of a Patented Invention (Utility Model) or Registered Topography of Integrated Circuit by the Cabinet of Ministers of Ukraine; (g) Cabinet of Ministers of Ukraine Resolution on the Procedure of Granting a Compulsory Licence for the Use of Plant Varieties; (h) Cabinet of Ministers of Ukraine Resolution on the Procedure of Granting a Licence for the Use of a Patented Invention (Utility Model), related to a pharmaceutical by the Cabinet of Ministers of Ukraine.
<p>3. Types of products which compulsory licensing applies to:</p> <ul style="list-style-type: none"> (a) What type(s) of products or technologies do compulsory licensing applies to? (b) Has any compulsory licence ever been issued in your jurisdiction? If yes, on what type of technology? 	<p>Types of products to which compulsory licensing applies:</p> <ul style="list-style-type: none"> (a) inventions, utility models, industrial designs, integrated circuits and plant varieties; (b) not aware of any cases.

Regulatory requirements on compulsory licensing

4. Who can apply for a compulsory licence? Are foreigners or foreign companies allowed to apply for a compulsory licence?	Under current regulations, any person or legal entity can apply for or claim a compulsory licence. No exceptions are provided for regarding non-residents.
5. What are the legal grounds to grant a compulsory licence under the local laws of your jurisdiction and any applicable international treaties?	<p>Under Ukrainian legislation a compulsory licence may be granted:</p> <ul style="list-style-type: none"> (a) in the event of non-usage or insufficient usage of a patented (registered) IP object subject to compulsory licensing, provided that the IP right holder unreasonably refuses to grant licences to such objects;

	<p>(b) in the event of urgent social necessity provided that either martial law or state of emergency is in place (for plants varieties);</p> <p>(c) in a public health, state defence, environmental security or other social-interest matter (for inventions, utility models, integrated circuits);</p> <p>(d) for dependent patents (for inventions and utility models).</p>
<p>6. Are there any preconditions to apply for a compulsory licence? For example:</p> <p>(a) Any negotiation required between the applicant and the right holder before applying for a compulsory licence?</p> <p>(b) Any urgent situation required in order to grant a compulsory licence?</p> <p>(c) Any minimum number of years required for the patent to be granted and/or implemented in order to be subject to compulsory licensing?</p>	<p>— Preconditions for a court to grant a compulsory licence based on the “non-usage grounds”:</p> <p>(a) the patented or registered IP object is not used, is inefficiently used by the holder within three years after its registration, its last use is without objective grounds;</p> <p>(b) the IP rights holder unreasonably refuses to grant a licence under reasonable conditions to a person seeking such a permit;</p> <p>(c) for plant varieties: the person asking for a licence is capable, from the financial and any other aspect, of competently and effectively executing the right granted under the licence.</p> <p>— Preconditions for the CMU granting a compulsory licence:</p> <p>(a) before applying for a compulsory licence related to pharmaceuticals, an applicant must prove that the patent holder cannot satisfy the need for the relevant pharmaceutical by means usually used for the manufacturing of such pharmaceuticals; additionally, the applicant must show evidence that the right holder unreasonably refuses to grant the relevant licence;</p> <p>(b) before applying for a compulsory licence to use inventions, utility models or integrated circuits, an applicant must first ask the right holder to issue such licence, and only after the holder unreasonably refuses to issue the licence may the person seeking it apply for a compulsory licence;</p> <p>(c) a compulsory licence for a plant variety can only be issued if either martial law or a state of emergency is declared.</p>
<p>7. Are there any limits on the number of compulsory licensees?</p>	<p>Not specified.</p>
<p>8. Will there be any limitation on the scope of the compulsory licence, for example limitations on the time and the territory?</p>	<p>The scope of a compulsory licence is always limited and is defined by a competent authority (court or the CMU) in each case individually.</p> <p>If the CMU grants a compulsory licence for a plant variety on the grounds of urgent social necessity, the licensing period cannot exceed four years.</p>
<p>9. Which authority has the competency to grant a compulsory licence?</p>	<p>A compulsory licence on the grounds of non-usage or insufficient usage of a patented (registered) IP object subject to compulsory licensing is granted by courts of general jurisdiction.</p> <p>Under the other grounds, the competent authority to grant such licences is the CMU.</p>

<p>10. Application procedure for compulsory licence:</p> <p>(a) What are the application procedures to get a compulsory licence?</p> <p>(b) What materials need to be submitted to the competent authority?</p> <p>(c) How long will it take to get a compulsory licence?</p>	<p>(a) Application procedure for compulsory licence for pharmaceuticals with the CMU:</p> <ul style="list-style-type: none"> — The motion must include the international non-proprietary name of the pharmaceutical, the title of the invention (i.e. utility model), the patent number, information about its holder (or holders), its (their) address or location, the name of the applicant, and its location. — Materials attached to the motion must include a justification of the need to use the patented invention (utility model) indicating the specific circumstances of the case and the necessary term of the licence, a technical and economic justification of expediency, capacity, and conditions to use the patented invention (utility model), documentary confirmation of the groundless refusal of the patent holder to issue a licence to use the patented invention (utility model), and a calculation of the amount of compensation offered by an applicant to the patent. — The term for issuing a decision granting the licence is not specified. <p>(b) Application procedure for obtaining compulsory licences for inventions and utility models (other than pharmaceuticals) and integrated circuits with the CMU:</p> <ul style="list-style-type: none"> — The applicant must file a motion seeking the licence, which must include the name of the object, the number of the relevant patent (certificate), information about its holder, address (or location) as well as information about the groundless refusal of holder to issue a licence to use the object. — The materials filed must include a justification of the need to use the object in the interests of society, indicating specific circumstances; a technical and economic justification of expediency, capacity, and conditions to use the object, and capacity to compensate the holder of the relevant patent (certificate) for the use of the object. — The term for issuing a decision on the granting of the licence is not specified. <p>(c) Application procedure for obtaining a compulsory licence for plant varieties with the CMU:</p> <ul style="list-style-type: none"> — The application for a compulsory licence to use a plant variety must include the number of the patent, the name of the plant variety, the term for which the licence is requested, compensation details, and the motivation to obtain the licence. — The applicant may submit documents confirming the attempt to obtain the licence directly from the patent holder and the holder's refusal to grant the licence. — The term for issuing a decision granting the licence is not specified.
<p>11. Can the competent authority grant a compulsory licence without hearings under an urgent situation?</p>	<p>If a licence is being granted in court proceedings, the hearings are obligatory under civil procedural rules.</p> <p>No hearings are provided for when a licence is granted by the CMU.</p>

<p>12. Revocation/termination of compulsory licence:</p> <p>(a) Can a compulsory licence be revoked/terminated or automatically revoked/terminated?</p> <p>(b) What are the conditions for the revocation/termination of a compulsory licence?</p> <p>(c) How should products made under a compulsory licence be treated if the compulsory licence is terminated/revoked?</p>	<p>Compulsory licences are subject to both revocation and termination.</p> <p>(a) A compulsory licence is automatically terminated after the term set out by the court or by the CMU granting the licence expires. The granting of the licence can be objected to in court when granted by the CMU, or in the appeal court when granted by a court.</p> <p>(b) If a licence is granted by the CMU (regarding inventions, utility models and integrated circuits), it can be revoked by the CMU when the grounds (circumstances) on which it was granted cease to exist, or when the term set out by the CMU expires. It may also be revoked under a motion by the licensee or if the licensee fails to follow the licence conditions or requirements set by the law.</p> <p>(c) A compulsory licence for a pharmaceutical can also be revoked by the CMU if a legal entity (licensee) ceases to exist or if it is established that the licensee submitted misleading (inaccurate) information when filling for the licence to be granted.</p>
<p>Rights and obligations of the right holders in relation to compulsory licensing</p>	
<p>13. Royalty:</p> <p>(a) Does the compulsory licensee have to pay a royalty to the right holder?</p> <p>(b) If the compulsory licensee is required to pay a royalty, how is the amount of royalty determined and who will decide the amount of the royalty?</p> <p>(c) Is there any remuneration available for the right holders other than royalty?</p>	<p>(a) The compulsory licensee must pay a royalty to the rights' holder.</p> <p>(b) The amount is decided by the authority granting the licence (i.e. the court or the CMU). The legislation only provides a formula for determining the royalty for the use of inventions related to pharmaceuticals. This formula reflects the maximum amount of compensation and is calculated based on the Tiered Royalty Method.</p> <p>(c) No other remuneration is available for the right holders other than royalties.</p>
<p>14. Are there any legal remedies for the party who is not satisfied with the compulsory licensing decision of the competent authority?</p>	<p>The decision granting a licence can be objected to in court when granted by the CMU; the claimant may simultaneously claim damages caused by the granting of such a licence.</p>
<p>15. Provision of know-how and support:</p> <p>(a) In order to implement the compulsory licence, for example, to manufacture the licenced product, is the right holder required to provide necessary support, such as know-how and training as in a voluntary agreed licence agreement?</p> <p>(b) Will this provision of know-how and support be compensated and how is the amount of such compensation determined?</p>	<p>When the CMU grants a compulsory licence to use patented plant varieties, it may also require the patent holder to provide the licensee with the materials needed to propagate the variety in amounts sufficient for the proper exercise of the rights granted by the compulsory licence. No compensation is provided for in the current legislation.</p>

16. Confidentiality: (a) Is the compulsory licensee subject to any confidentiality obligation? (b) If the compulsory licensee discloses the confidential information in violation of its obligation, does the right holder have a basis of claim against the compulsory licensee?	No specific requirements. A licence for a secret invention (utility model) can only be granted to a person who has permission to access the invention (utility model) from a State expert.
17. Export of products under compulsory licence (a) Is the compulsory licensee allowed to export their products under the compulsory licence? (b) If the compulsory licensee is permitted to export products under the compulsory licence, are there any requirements and limitations on the export of such products?	Under the general rule, there are no limitations on the export/import of products under compulsory licences. However, the use of inventions, utility models (other than pharmaceuticals) and integrated circuits under a compulsory licence granted by the CMU is allowed primarily to meet the needs of the internal market. As for compulsory licences related to pharmaceuticals that are granted by the CMU, products under such licences cannot be exported, as the use of such inventions and utility models is only allowed to meet the needs of the internal market.
Compulsory licensing in the present COVID-19 pandemic	
18. Have the laws on compulsory licensing been used in previous health emergencies and/or in the present COVID-19 pandemic in your jurisdiction?	No.
19. Is it possible for third parties to use the current laws on compulsory licensing in your jurisdiction to facilitate the treatment of patients infected by COVID-19?	Yes, any third party may file for a compulsory licence based on the grounds and under the conditions specified above.
20. Are there any recent major regulatory exemptions and/or amendments made following COVID-19 to regulations governing compulsory licensing?	A draft law introducing changes related to the compulsory licensing of pharmaceuticals concerning COVID-19 was announced, but not yet introduced in the parliament.
Transactions and dealings of products under compulsory licences	
21. Can a compulsory licence be transferred or assigned?	Under a general rule, a compulsory licence cannot be transferred. The only exception relates to inventions, utility models and integrated circuits, when such a licence is being transferred along with the respective business as a whole (or its respective part).
22. Does the issuance of a compulsory licence have any impact on the previously agreed licence?	No.

23.	Is there any special labelling requirement for the products made under the compulsory licence?	No.
24.	Is there any special distribution channel requirement for the products made under the compulsory licence?	No.
25.	Is there any price requirement for the products made under the compulsory licence?	No.

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