Study Guidelines

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2025 – Study Question

Compulsory licensing

Introduction

1) A patent is an exclusive right granted to the inventor (or their assignee) for an invention in exchange for the disclosure of the invention. By providing public access to technical information about the invention through a patent application, the patent holder obtains the exclusive right to prohibit others from exploiting (e.g., by making, using, offering for sale, selling, and/or importing) the invention for a limited period of time in the territory in which the patent has been granted. Patent rights also benefit the public by providing individuals and companies with incentives to innovate and to develop new products, methods, and uses that can benefit the society.

2) Compulsory licenses represent an exception to the scope of the exclusive rights of the patent holder: Compulsory licensing system provides the public with access to a patented invention by enabling – in certain exceptional circumstances – a third party to exploit the patented invention without the consent of the patent holder.

3) Compulsory licensing has most often been linked to areas involving public health. However, a question has arisen as to whether compulsory licensing could be increasingly relevant also in relation to various other technology areas. In addition, recent global events and evolving circumstances (e.g., the COVID-19 pandemic) have prompted a conversation on whether the current modalities of the compulsory licensing regime, and principles governing its application, are sufficient and/or appropriate or whether the compulsory licensing regime should be re-visited.

4) This Study Question examines whether additional harmonization (whether through minimum standards or otherwise) of compulsory licensing is needed. Further, the purpose of the Study Question is to examine the interests that can justify the grant of a compulsory license (overriding interests) as well as the conditions for, and characteristics of, a

compulsory license as well as the supportive mechanisms for a functioning compulsory licensing system.

Why AIPPI considers this an important area of study

5) The patent system is based on a trade-off between the inventor (patentee) and the society: In exchange for the inventive contribution, the inventor is granted with a time-limited exclusive right. Society also has an interest in granting patents as patent rights promote technological progress and thereby increase global welfare. This is a long-term interest, which may become vulnerable when pressure is felt to provide for goods in the short term, for example for reasons of public health or security.

6) In view of balancing this trade-off, AIPPI has throughout its history studied extensively the different mechanisms that should be available to ensure that patent holders (and IP holders more broadly) can effectively protect and enforce their rights. AIPPI has also studied the balance between the interests of the rightsholders and third parties and the means available to ensure that the IP system itself comprises sufficient safeguards.

7) The overall legitimacy of the patent system relies on the patent system itself having the necessary checks and balances to ensure that the exploitation of the exclusive rights granted are proportional vis-à-vis the justification of the patent system – and that any exceptions to the right holders' rights are proportional in relation to the importance of providing those exceptions. Ensuring such proportionality requires assessing the special circumstances in which exceptions to patent holders' rights in the form of compulsory licenses may be applied and which conditions, mechanisms, and safeguards should be applied to ensure the appropriate balance.

8) While certain minimum standards for compulsory licensing have been laid out in the Paris Convention and in the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), different jurisdictions implement and enforce compulsory licensing within their own statutory frameworks. Therefore, there are also differences on the grounds for the granting of compulsory licenses as well as in the procedural aspects.

9) Compulsory licensing witnessed renewed interest in light of the COVID-19 pandemic. On one hand, the pandemic underscored the importance of innovation and incentivizing intellectual property protection. On the other hand, the pandemic also brought to surface issues of access to medicines and highlighted the need to ensure that life-saving medicines are widely available around the world. Some have postulated that patents impede access to medicine and that, therefore, the compulsory licensing regime should be considered in future global emergencies and/or other areas concerning public health, such as epidemics, bioterrorism, biologic threats, natural disasters, or environmental crises. Additionally, some have called for compulsory licensing in relation to various other technology areas in which inventions may have a high public interest potential such as green tech, technologies to combat climate change, environmental hazards, e-waste, natural disasters, clean energy/infra etc. which all may include innovations of greater public interest. However, others have argued that rather than impeding access, patents encourage development of medicines and other technologies and enable companies to collaborate and combine their different skills and expertise to develop such new medicines and technologies.

10) Further, compulsory licensing regimes have been traditionally predominantly considered to cater to the domestic markets. However, the cross-jurisdictional nature of emerging issues has prompted a conversation on possibility of regional, or even broader, compulsory licensing regimes. For instance, in 2023, the European Commission proposed establishment of a European Union level compulsory licensing framework for crisis management. As of 2024, there is a pending regulation proposal on the same.[1]

11) In view of the recent legislative initiatives, the divergence in implementation of the compulsory licensing regimes, the potential increased needs for compulsory licensing in different of fields of technology, and the topics of cross-jurisdictional impact, AIPPI considers that it is timely to examine the compulsory licensing framework more broadly.

Relevant treaty provisions

12) Article 30 of the TRIPS Agreement sets forth the possibility, in general, to provide limited exceptions to the rights conferred by a patent subject to balancing the interests of rights holders and those third parties:

> *"Article 30*
>
> *Exceptions to Rights Conferred*
>
> *Members may provide **limited exceptions to the exclusive rights** conferred by a patent, provided that such exceptions **do not unreasonably conflict** with a **normal exploitation** of the patent and **do not unreasonably prejudice the legitimate interests** of the patent owner, taking account of the legitimate interests of third parties."* [emphasis added]

13) However, with respect to compulsory licensing, Article 31 of the TRIPS Agreement[2] enlists the detailed principles on which a patent may be used without an authorisation by the patent right holder:

> *"Article 31*
>
> *Other Use Without Authorization of the Right Holder*
>
> *Where the law of a Member allows for other use of the subject matter of a patent without the authorization of the right holder, including use by the government or third parties authorized by the government, the following provisions shall be respected:*
>
> *(a) authorization of such use shall be considered on its individual merits;*

[1] European Parliament legislative resolution of 13 March 2024 on the proposal for a regulation of the European Parliament and of the Council on compulsory licensing for crisis management and amending Regulation (EC) No 816/2006.

[2] See Article 31 ibid

(b) *such use may only be permitted if, prior to such use, the proposed user has made **efforts to obtain authorization** from the right holder on **reasonable commercial terms and conditions** and that such efforts have not been successful within a **reasonable period of time**. This requirement may be **waived by a Member in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use**. In situations of national emergency or other circumstances of extreme urgency, the right holder shall, nevertheless, be **notified** as soon as reasonably practicable. In the case of public non-commercial use, where the government or contractor, without making a patent search, knows or has demonstrable grounds to know that a valid patent is or will be used by or for the government, the right holder shall be informed promptly;*

(c) *the **scope and duration** of such use shall be **limited to the purpose** for which it was authorized, and in the case of semi-conductor technology shall only be for public non-commercial use or to remedy a practice determined after judicial or administrative process to be anti-competitive;*

(d) *such use shall be **non-exclusive**;*

(e) *such use shall be **non-assignable**, except with that part of the enterprise or goodwill which enjoys such use;*

(f) *any such use shall be authorized predominantly for the **supply of the domestic market** of the Member authorizing such use;*

(g) *authorization for such use shall be liable, subject to **adequate protection of the legitimate interests of the persons so authorized**, to be **terminated if and when the circumstances which led to it cease to exist** and are **unlikely to recur.** The competent authority shall have the authority to review, upon motivated request, the continued existence of these circumstances;*

(h) *the right holder shall be paid **adequate remuneration** in the circumstances of each case, taking into account the economic value of the authorization;*

(i) *the legal validity of any decision relating to the authorization of such use shall be subject to judicial review or other independent review by a distinct higher authority in that Member;*

(j) *any decision relating to the remuneration provided in respect of such use shall be subject to judicial review or other independent review by a distinct higher authority in that Member;*

(k) *Members are not obliged to apply the conditions set forth in subparagraphs (b) and (f) where such use is permitted to remedy a practice determined after judicial or administrative process to be anti-competitive. The need to correct anti-competitive practices may be taken into account in determining the amount of remuneration in such cases. Competent authorities shall have the authority to refuse termination of authorization if and when the conditions which led to such authorization are likely to recur;*

(l) *where such use is authorized to permit the exploitation of a patent ("the second patent") which cannot be exploited without infringing another patent ("the first patent"), the following additional conditions shall apply:*

   i. *the invention claimed in the second patent shall involve an important technical advance of considerable economic significance in relation to the invention claimed in the first patent;*

ii. *the owner of the first patent shall be entitled to a cross-licence on reasonable terms to use the invention claimed in the second patent; and*

iii. *the use authorized in respect of the first patent shall be non-assignable except with the assignment of the second patent."* [emphasis added]

14) Moreover, in the specific context of pharmaceutical products, Article 31 *bis*[3] of the amended TRIPS Agreement provides a special procedure for eligible countries to seek the aid of another country to fulfil demands of pharmaceutical products by way of grant of a special compulsory license for export purposes by the other country.

15) In addition to the provisions of the TRIPS Agreement, aspects of compulsory licensing are set forth in the Partis Convention: Article 5A of the Paris Convention lays out a baseline requirement for member states to provide for a compulsory licensing regime. The compulsory licensing regime under the Paris Convention is targeted to *prevention of abuse* of the exercise of the exclusive rights provided by patents, e.g., in the event of failure to work the patented invention:

> *"[---] (2) Each country of the Union shall have the right to take legislative measures providing for the **grant of compulsory licenses to prevent the abuses** which might result from the exercise of the exclusive rights conferred by the patent, for example, failure to work. [---]*
>
> *(4) A compulsory license may not be applied for on the ground of failure to work or insufficient working before the expiration of a period of four years from the date of filing of the patent application or three years from the date of the grant of the patent, whichever period expires last; it shall be refused if the patentee justifies his inaction by legitimate reasons."* [emphasis added]

16) Moreover, Article 5A(4) of the Paris Convention specifies certain characteristics for compulsory licenses:

> "*(4) [---] Such a compulsory license shall be **non-exclusive** and shall **not be transferable**, even in the form of the grant of a sub-license, except with that part of the enterprise or goodwill which exploits such license."*

Scope of this Study Question

17) This Study Question focuses on the general regime of compulsory licenses for patents. The purpose of this Study Question is to examine the additional need for harmonization of compulsory licensing regimes in changing circumstances. Additionally, this Study Question focuses on examining interests that may justify the grant of a compulsory license (overriding interests) as well as the conditions and characteristics related to compulsory licensing and, in particular, the procedural aspects relating to compulsory licenses.

[3] Article 31 *bis* at https://www.wto.org/english/res_e/publications_e/ai17_e/trips_art31_bis_oth.pdf

18) Questions relating to potential compulsory licensing of intellectual property rights other than patents, utility models, and supplementary protection certificates are out of the scope of this Study Question.

19) Questions related to standard essential patents (SEPs) and FRAND obligations arising therefrom, as well as questions relating to anti-trust, are also outside the scope of this Study Question.

Previous work of AIPPI

20) AIPPI has studied in the past certain aspects of compulsory licensing. For instance, in Q3 "Restrictions of the Rights of the Patentee for Reasons of Public Interest" (Washington, 1956) AIPPI suggested as potential clarifications to the then-current Paris Convention that: *"Compulsory licences will only be granted to qualified applicants. These licences shall be subject to equitable compensation to the patentee. In the absence of agreement, this equitable compensation shall be determined by the competent authority, and should, at least as a last resort, be considered by a court. Compulsory licences will be non-exclusive and can only be transferred, even as grant of sublicences, together with the portion of the business concerned with the application of these compulsory licences."*

21) In Q39 *Reasons for Which the Rights of the Patentee Can be Restricted* (Berlin, 1963; Salzburg, 1964; Tokyo, 1966) AIPPI emphasized that if patentee's rights are subject to restrictions which are not strictly required by public interest, it will undermine the principles for which a patent is granted. It was further resolved in relation to Article 5 of the Paris Convention that restrictions ought to be directed towards individual patents and not generally and only in limited circumstances where an agreement has proved to be impossible.

22) In Q128 *Patents and protection of the environment* (Montreal, 1995) AIPPI noted that if a country has a compulsory licensing provision, it should be applicable to patents related to the environment.

23) In Q137 *The future of the Patent System in Europe* (Sorrento, 2000) further emphasizing the limited nature of compulsory licenses AIPPI resolved in relation to Community Patents that: *"That compulsory licences should be granted on the bases permitted by TRIPS only and should, in the case of a compulsory licence granted on a Community Patent under national law, be effective in the country of grant only; since the licence was not granted with the express consent of the proprietor, the doctrine of international exhaustion should not apply. However, in the case of Community Patents use in any part of the Community should suffice to overcome an application for compulsory licence based on non-use."*

24) In Q150 *Patentability Requirements and Scope of Protection of Expressed Sequence Tags (ESTs), Single Nucleotide Polymorphisms (SNPs) and Entire Genomes*, (Sorrento, 2000) AIPPI noted that it is not in favour of special provisions, such as compulsory licensing, for the use of inventions related to Expressed Sequence Tags (ETS), Single Nucleotide Polymorphisms (SNPS) and Entire Genomes.

25) In Q202 *The Impact of Public Health issues on Exclusive Patent Rights*, (Boston, 2008) AIPPI considered that compulsory licensing is a more appropriate and proportionate means of providing access to patented medicines and other medical products than expropriation of patent rights. In addition, AIPPI further resolved, with respect to public health, that the patent law should provide that a compulsory license can only be granted in exceptional and strictly defined circumstances and further that the law should not permit expropriation of patent rights.

26) Finally, during the COVID-19 pandemic, AIPPI's released its *position paper on the waiver for certain provisions of the TRIPS agreement for the prevention, containment and treatment of COVID-19 proposed by some countries within the WTO (2021),* AIPPI supported existing flexibilities present under Article 31, 31bis, and the Doha Declaration to resolve any concerns with respect to access to health technologies during the pandemic. AIPPI also stated that *"intellectual property rights should not be viewed a priori [---] as a barrier to the development, manufacturing, distribution and provision of supplies and services of any kind"*. AIPPI also noted that IP rights "*contribute to the promotion of technological innovation [---] to the mutual advantage of producers and users of technological knowledge [---]*".

Discussion

27) The search for balance between incentives for innovation and the wider public interests is innate in the patent system. Hence, as early as in 1925, the Paris Convention exemplified non-working of a patent as a factor conferring its members the right to take corrective measures by way of granting compulsory licenses in certain situations.[4]

28) Since then, in addition to the work of AIPPI having led to amendments in the Paris Convention, the compulsory licensing regime has been much refined by way of the provisions of the TRIPS Agreement. However, the basic principle underlying the regime has remained unchanged, i.e. compulsory licensing is seen as an exceptional provision triggered only by specific grounds as determined by domestic legislation.

29) Article 31 of the TRIPS Agreement enlists the detailed principles on which a patent may be used without authorisation of the patent holder. It requires that usually such non-authorised use can only be considered if the applicant has made efforts to "*obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time*". This clause indicates that a compulsory licensing regime cannot be used to undermine the patentee's rights and that the right to commercialise the innovation (at the patentee's pace) is an inherent right afforded to the patentee.

30) While the TRIPS Agreement and its implementation has set certain minimum standards around the globe for compulsory licensing, there remains great divergence in the criteria for and application of compulsory licensing. For example, Canada, China, the United Kingdom, Australia, Singapore, India, Brazil, South Africa, Japan, and many other WTO members each provide diverse grounds for the grant of compulsory licenses such as

[4] Article 5, A, (2) – Paris Convention

unmet needs, dependent patents, government use, public interest and public health, prohibitive pricing, non-working, and remedies to anti-competitive practices.

31) Similarly, while India, Israel, and the UK provide for a compulsory license for dependant patents, the same is not available in many other jurisdictions. In the same vein, jurisdictions such as, China, Brazil, and Russia incorporate 'non-working' of a patent as a ground to grant a compulsory license, while the same is not recognized in some other large jurisdictions.

32) There is also variance in the various procedural aspects such as on the authority who may grant compulsory licenses as well as on lock in periods.

33) This divergence has often led to concerns regarding the manner of implementation (or non-implementation) of the compulsory licensing laws. The concerns have been voiced both from the side of patentees and the compulsory licensees alike. Such examples include, e.g., the grant of government-use compulsory licenses for life saving HIV/AIDs treatment in the early 2000s.

34) Furthermore, the COVID-19 pandemic in the early 2020s and the increasing global concerns on, e.g., climate change have resurfaced the question on compulsory licenses and in particular the availability of compulsory licenses in connection with cross-jurisdictional crises and events as well as more broadly with longer term, broader impact global challenges.

35) One of the key questions with respect to any compulsory license is determining the reasonable scope of the license. Finding a balance on the scope of the license is of utmost importance so as to minimize the restrictions on the patentee's exclusive rights, while at the same time providing a reasonable scope for the compulsory license in a manner through which the goals for which the compulsory license has been granted can be reasonably met. Aside from determining reasonable limits to assignability, sublicensing, and (non-)exclusiveness, this applies in particular in relation to determining the temporal and territorial scope of the license as well as the intended use and activities (and volumes) for which the compulsory license is granted.

36) From the perspective of ensuring continued incentives for innovation, the reasonableness of remuneration also in relation to compulsory licensing may be argued to be a key factor in striking the desired balance. Despite the importance of remuneration, the principles of compensation and the suggested approaches vary significantly across jurisdictions. For example, in connection with the recent EU proposal, there has been a debate on whether it would be reasonable or not to cap remuneration on compulsory licenses.

37) Accordingly, this Study Question will focus on examining the competing perspectives on compulsory licenses and assessing further needs for global harmonization.

You are invited to submit a Report addressing the questions below. Please refer to the 'Protocol for the preparation of Reports'. Please also note that references to patents in the questions below include also utility models and supplementary protection certificates unless otherwise expressly stated otherwise.

Questions

I) Current law and practice

Please answer all questions in Part I on the basis of your Group's current law.

Availability and use of compulsory licensing regime

1) Availability of compulsory licenses. Does the law of your jurisdiction provide for a regime for compulsory licensing with respect to patents? *Please answer YES or NO and add a brief explanation.*

If you answered YES to question 1) above, please continue answering to questions ***Error! Reference source not found.****-> below. If you answered NO to question* ***Error! Reference source not found.*** *above, please move to section II below.*

2) Implementation of TRIPS. Have the provisions of the TRIPS Agreement concerning compulsory licensing (Articles 31 and 31bis TRIPS and TRIPS COVID-19 Vaccines Decision, MC12, June 2022) been implemented in your jurisdiction? *Please answer YES or NO and add a brief explanation.*

3) Practice on compulsory licenses:

   a. Have compulsory licenses been applied for or granted in your jurisdiction? *[Please select the alternative that represents your jurisdiction and provide a brief explanation for your choice.]*
      i. Yes, compulsory licenses have been applied for, but not granted.
      ii. Yes, compulsory licenses have been applied for and granted.
      iii. No, there have been no applications for, or grants of, compulsory licenses.
      iv. Not applicable as compulsory licenses are not available in our jurisdiction.

   b. If your answer to subpoint (a) was YES:
      i. for which industries the compulsory licenses have been applied or granted for:
         1. Pharmaceuticals? [Applied: YES / NO; Granted: YES / NO] *Please answer YES or NO and add a brief explanation.*
         2. Biotech or other life sciences fields (excluding pharma)? [Applied: YES / NO; Granted: YES / NO] *Please answer YES or NO and add a brief explanation.*
         3. Semiconductors? [Applied: YES / NO; Granted: YES / NO] *Please answer YES or NO and add a brief explanation.*
         4. Technologies relating to protection of the environment or the climate? [Applied: YES / NO; Granted: YES / NO] *Please answer YES or NO and add a brief explanation.*
         5. Cybersecurity? [Applied: YES / NO; Granted: YES / NO] *Please answer YES or NO and add a brief explanation.*

6. National security? [Applied: YES / NO; Granted: YES / NO] *Please answer YES or NO and add a brief explanation.*
7. Others? [Applied: YES / NO; Granted: YES / NO] *Please answer YES or NO and add a brief explanation.*

ii. have the compulsory licenses been applied for or granted based on:

1. circumstances referred to in Article 31 of the TRIPS Agreement (e.g., national emergency or other circumstances of extreme urgency or in cases of public non-commercial use or in any other scenario)? *Please answer YES or NO and add a brief explanation.*
2. other circumstances? *Please answer YES or NO and add a brief explanation.*

Overriding interests and grounds for granting a compulsory license

4) What are the conditions for the grant of a compulsory license? *Please provide a brief explanation.* In more specific:
   a. Have the requirements for granting a compulsory license been clearly or expressly specified in the law of your jurisdiction? *Please answer YES or NO and add a brief explanation.*
   b. Does the grant of a compulsory license require that the applicant for the compulsory license has made attempts to seek voluntary licensing prior to seeking a compulsory license? *Please answer YES or NO and add a brief explanation.*
   c. What kind of interests constitute an overriding interest giving rise to compulsory licensing? *Please add a brief explanation.*
      i. Are there any technical fields, industries, or applications for which compulsory licensing is not available? *Please answer YES or NO and add a brief explanation.*
   d. Are there any technical fields, industries, or applications for which there are special conditions or other special considerations for granting a compulsory license? *Please answer YES or NO and add a brief explanation.*

5) Who can apply for a compulsory license?
   i. Any person? *Please answer YES or NO and add a brief explanation.*
   ii. Only a specified category of persons/parties *Please answer YES or NO and add a brief explanation.*
      1. Person with specific interest? *Please answer YES or NO and add a brief explanation.*
      2. Government? *Please answer YES or NO and add a brief explanation.*
      3. Commercial operators? *Please answer YES or NO and add a brief explanation.*
      4. Other? *Please add a brief explanation*

Scope and characteristics of a compulsory license

6) Does your current law specify mandatory scope or characteristics for a compulsory license? (E.g., territory (i.e., internal market only or including export), duration, field of use

/ intended purpose, (non-)transferability, (non-)exclusivity, (non-)sublicensability, the period of time that has passed since the date of the grant of the patent or the filing of the patent application, etc.? *Please answer YES or NO and add a brief explanation.*

7) Does a compulsory license also cover patent applications (i.e. prior to grant) and/or patent term extensions (e.g., supplementary protection certificates)? *Please answer YES or NO and add a brief explanation.*

8) Does the current law provide for other mandatory obligations (if any) for the patentee vis-à-vis the licensee? E.g.:
    a. Is the patent holder required to provide further information on the implementation of the patent to the compulsory licensee? *Please answer YES or NO and add a brief explanation.*
    b. Is the patent holder required to provide to the compulsory licensee trade secrets or other know-how for the purposes of the compulsory licensee to work the invention effectively? *Please answer YES or NO and add a brief explanation.*

Procedural considerations

9) Authority to decide on compulsory licenses.
    a. Who has the power to decide on the grant of a compulsory license in your jurisdiction?
        i. Patent authority (e.g., patent office)? *Please answer YES or NO and add a brief explanation.*
        ii. Court? *Please answer YES or NO and add a brief explanation.*
        iii. Other governmental body? *Please answer YES or NO and add a brief explanation.*
        iv. Arbitration? *Please answer YES or NO and add a brief explanation.*
        v. Other? *Please add a brief explanation*
    b. Does the same body decide on remuneration? *Please answer YES or NO and add a brief explanation.*
    c. Can the decision on compulsory license be appealed and to whom? *Please answer YES or NO and add a brief explanation.*

10) Rights of patentees.
    a. Does the patentee have a right to receive prior notification of compulsory licensing? *Please answer YES or NO and add a brief explanation (in particular of any exceptions and of any distinction made between situations of extreme urgency and other situations).*
    b. Does the patentee have a right to be heard in cases of compulsory licensing? *Please answer YES or NO and add a brief explanation (in particular of any exceptions and of any distinction made between situations of extreme urgency and other situations).*
    c. What defences/grounds are available to a patentee against applications for a compulsory license? *Please add a brief explanation.*

d. Are there any special provisions for independent inventor or small entity patentees? *Please answer YES or NO and add a brief explanation.*

Remuneration

11) How is the remuneration for the patentee determined?
    a. Is the patentee always entitled to receive remuneration for the compulsory license? *Please answer YES or NO, you may add a brief explanation.*
    b. How and when is the adequacy of the remuneration and the economic value of the compulsory license assessed? *Please add a brief explanation.*
    c. Does the patentee have the opportunity to participate in setting the remuneration level? *Please answer YES or NO, you may add a brief explanation.*
    d. Is there a cap on the level of remuneration? *Please answer YES or NO, you may add a brief explanation.*

Measures for monitoring compliance with a compulsory license

12) Reporting and monitoring. Does your current law specify any mandatory monitoring or reporting requirements for compliance with the terms of the compulsory license? *Please answer YES or NO and add a brief explanation.*

13) Revocation of a compulsory license. Can a compulsory license be revoked or otherwise terminated during its term? *Please answer YES or NO and add a brief explanation.*
    a. If the answer to above was YES, what kind of reasons give rise to termination or revocation of a compulsory license under the law of your jurisdiction:
        i. End of the situation giving rise to the compulsory license? *Please answer YES or NO and add a brief explanation.*
        ii. Breach of the compulsory license? *Please answer YES or NO and add a brief explanation.*
        iii. Failure to pay remuneration for the compulsory license? *Please answer YES or NO and add a brief explanation.*
        iv. Other? *Please add a brief explanation.*
    b. Aside from potential termination of the compulsory license, are there any other remedies available for the patentee against breach of the compulsory license? *Please answer YES or NO and add a brief explanation.*

II) Policy considerations and proposals for improvements of your Group's current law

Please answer the questions of this Part II below.

14) According to the opinion of your Group, is your current law regarding compulsory licensing adequate and/or sufficient? *Please answer YES or NO and please explain your chosen view briefly.*

15) According to the opinion of your Group, what is or should be the policy rationale for compulsory licensing?

16) Is there any evidence in your jurisdiction to show that a compulsory license improved access, led to reduced prices, or increased availability of a product? *Please answer YES or NO and please explain your chosen view briefly.*

17) Are there any other policy considerations and/or proposals for improvement to your Group's current law falling within the scope of this Study Question?

III) Proposals for harmonisation

Please answer the questions of this Part III below.

Overall need for harmonization

18) Do you consider that there is a continued need to have harmonization regarding the compulsory licensing regime? *Please answer YES or NO and add a brief explanation.*

If your answer to question 18)18) was YES, please continue to answer the questions below. Even if you answered NO to question 18), please address the following questions to the extent your Group considers that the current law or practice could be improved.

19) Should the existing provisions of the TRIPS Agreement (e.g., Art. 31 and 31bis TRIPS) be considered sufficient for addressing harmonization? *Please answer YES or NO and add a brief explanation.*
    a. If you answered NO, what kind of issues/aspects should in general be subject to additional harmonization?

Overriding interests and grounds for granting a compulsory license

20) Overriding interests. Should the grant of compulsory licenses be limited to certain specific interests (overriding interests)? *Please answer YES or NO and add a brief explanation.*

In more specific, what kind of interests should constitute an overriding interest giving rise to compulsory licensing:

a. Public health (e.g., pandemics such as COVID-19, epidemics such HIV/AIDS, tuberculosis, other public health crises)? *Please answer YES or NO, you may add a brief explanation.*
b. Environmental circumstances and events (e.g., natural disasters, environmental protection, climate change)? *Please answer YES or NO, you may add a brief explanation with examples.*
c. Cybersecurity? *Please answer YES or NO, you may add a brief explanation.*
d. Security of national infrastructure (incl. biological threats)? *Please answer YES or NO, you may add a brief explanation.*
e. National defence? *Please answer YES or NO, you may add a brief explanation.*
f. Economic security? *Please answer YES or NO, you may add a brief explanation.*
g. Others? *Please answer YES or NO, you may add a brief explanation.*

21) Should cross-jurisdictional compulsory licensing be available for any of the interests set forth in question 20) (or for any other interests)? *Please answer YES or NO*, *you may add a brief explanation.*
    a. If you answered YES to 21), should cross-jurisdictional compulsory licensing be categorically available for:
        i. Public health (e.g., pandemics such as COVID-19, epidemics such as HIV/AIDS, tuberculosis, other public health crises)? *Please answer YES or NO, you may add a brief explanation.*
        ii. Environmental circumstances and events (e.g., natural disasters, environmental protection, climate change)? *Please answer YES or NO, you may add a brief explanation.*
        iii. Cybersecurity? *Please answer YES or NO, you may add a brief explanation.*
        iv. Security of national infrastructure (incl. biological threats)? *Please answer YES or NO, you may add a brief explanation.*
        v. National defence? *Please answer YES or NO, you may add a brief explanation.*
        vi. Economic security? *Please answer YES or NO, you may add a brief explanation.*
        vii. Others? *Please answer YES or NO, you may add a brief explanation.*
    b. If you answered YES to 21), should there be a special organization or committee for operating such cross-jurisdictional compulsory licensing? *Please answer YES or NO, you may add a brief explanation.*
    c. If you answered YES to 21), should the modalities enshrined in Article 31bis of the TRIPS Agreement be extended to such other cases? *Please answer YES or NO, you may add a brief explanation.*

22) Grounds meriting the grant of a compulsory license. When an overriding interest is present, under what kind of grounds should a compulsory license be available? In more specific, should the following be categorically considered a justified ground for granting a compulsory license in the presence of an overriding interest:
    a. National emergency (or regional emergency as applicable). *Please answer YES or NO, you may add a brief explanation.*
    b. Other circumstances of extreme urgency. *Please answer YES or NO, you may add a brief explanation.*
    c. General public interest. *Please answer YES or NO, you may add a brief explanation.*
    d. Public non-commercial use. *Please answer YES or NO, you may add a brief explanation.*
    e. Unmet needs. *Please answer YES or NO, you may add a brief explanation.*
    f. Unreasonable pricing. *Please answer YES or NO, you may add a brief explanation.*
    g. Non-working/insufficient working. *Please answer YES or NO, you may add a brief explanation.*
    h. Related or dependant patent. *Please answer YES or NO, you may add a brief explanation.*
    i. To remedy anti-competitive practice(s). *Please answer YES or NO, you may add a brief explanation.*

j. Other. *Please answer YES or NO, you may add a brief explanation.*

Scope and conditions for a compulsory license

23) Should compulsory licenses be available for both patents and pending patent applications alike? *Please answer YES or NO, you may add a brief explanation.*

24) Should compulsory licenses also be extended to patent term extensions (e.g. supplementary protection certificates). *Please answer YES or NO, you may add a brief explanation.*

25) Provided that other criteria for the grant of a compulsory license are met, should compulsory licenses be available for any person: [*Please select the alternative that represents your Groups view the best and provide a brief explanation for your choice.]*
    a. Yes, to any (local or foreign) party.
    b. Yes, but to local parties only.
    c. No, only to certain categories of local compulsory licensees.
    d. No, only to certain categories of local or foreign compulsory licensees.
    e. No, to only to another specific group of compulsory licensees.

26) If your answer to question 25) was YES (answer a or b), please move forward to question 27). If your answer to question 25) was NO, should in general compulsory licenses be available for:
    a. Governmental bodies? *Please answer YES or NO, you may add a brief explanation.*
    b. Non-commercial research organizations? *Please answer YES or NO, you may add a brief explanation.*
    c. Other non-profit organizations? *Please answer YES or NO, you may add a brief explanation.*
    d. Commercial entities? *Please answer YES or NO, you may add a brief explanation.*
    e. Other? *Please answer YES or NO, you may add a brief explanation.*

27) Article 31 of the TRIPS Agreement lays out certain requirements (e.g., required effort to obtain a voluntary license for a reasonable period of time) for a compulsory license to be granted. Are there other or more detailed conditions that should be met prior to the grant of a compulsory license? E.g.:
    a. Should there continue to be a requirement of an effort to obtain a license on commercial terms (a voluntary license)? *Please answer YES or NO, you may add a brief explanation.*
        i. If your answer to subpoint a above was YES, what kind of efforts should be considered sufficient? E.g., what role should the express refusal or express willingness to license play in assessing whether compulsory license should be granted?
        ii. For how long period of time should voluntary licensing negotiations have been ongoing before a compulsory license could be applied for and subsequently granted?

iii. Should disagreement on the cost of a voluntary license in itself constitute a sufficient criterion for initiation of procedure of compulsory licensing? *Please answer YES or NO, you may add a brief explanation.*

b. Should there be any minimum requirements for working/non-working of the patent? E.g.:
   i. Compulsory license should be available irrespective of how the patent has been, or has not been, worked within the jurisdiction involved; *Please answer YES or NO, you may add a brief explanation.*
   ii. Compulsory license should not be available if the patent is currently being worked within the jurisdiction involved; *Please answer YES or NO, you may add a brief explanation.*
   iii. Compulsory license should not be available if the patent is currently not being worked within the jurisdiction involved but has in the past been worked within the jurisdiction involved. *Please answer YES or NO, you may add a brief explanation.*

28) Procedural considerations:
   a. Who should bear the burden of proof of establishing that conditions for the grant of a compulsory license are met?
   b. Should the patentee always have a right to receive prior notification of a potential compulsory license before such is granted? *Please answer YES or NO and add a brief explanation (in particular of any exceptions).*
   c. Should the patentee always have a right to be heard in cases of compulsory licensing? *Please answer YES or NO and add a brief explanation (in particular of any exceptions).*

Scope and characteristics of a compulsory license

29) Should compulsory licenses be categorically:
   a. Non-exclusive / Exclusive / Depend on the case *[please choose one alternative, you may add a brief explanation]*
   b. Transferable / Non-transferable / Non-transferable except in the context of transfer of the relevant business/assets / Depend on the case *[please choose one alternative, you may add a brief explanation]*
   c. Sublicensable / Non-sublicensable / Non-sublicensable except as needed to effect the exploitation of the permitted license (e.g., sublicensing required within supply chain) / Depend on the case *[please choose one alternative, you may add a brief explanation]*
   d. Available for all activities (manufacturing, selling, using, etc.) within the scope of the patent. *Please answer YES or NO and add a brief explanation.*

30) How should the territorial scope of a compulsory license be determined?

31) How should the term of the compulsory license be determined? E.g., should the compulsory license be limited strictly for the period during which the overriding interest subsists or should it be available for a fixed term irrespective of the continuation of the existence of the overriding interest:
    a. For the duration of the existence of the overriding interest?
    b. For fixed term(s)?
    c. Other? *Please add a brief explanation.*

32) Should compulsory license be limited to:
    a. Specified products/processes? *Please answer YES or NO and add a brief explanation.*
    b. Specified quantities or volumes? *Please answer YES or NO and add a brief explanation.*
    c. Specified uses of the patented invention? *Please answer YES or NO and add a brief explanation.*

33) What kind of obligations (if any) should the patentee have vis-à-vis the licensee? E.g.:
    a. Should the patent holder be required to provide further information on the implementation of the patent to the compulsory licensee? *Please answer YES or NO and add a brief explanation.* In particular:
    b. Should the patent holder be required to provide to the compulsory licensee trade secrets or other know how for the purposes of the compulsory licensee to work the invention effectively? *Please answer YES or NO and add a brief explanation.*

Remuneration

34) How should the remuneration to the patentee be determined:
    a. Should the patentee be always entitled to a remuneration for the compulsory license? *Please answer YES or NO and add a brief explanation.*
    b. How and when should the adequacy of the remuneration be determined?
    c. Should remuneration be based on reasonable compensation comparable to a license fee. *Please answer YES or NO and add a brief explanation.*
        i. If you answered YES to c, how should the reasonable compensation be determined?
    d. Should there be a fixed cap on remuneration (e.g., a certain percentage of revenue)? *Please answer YES or NO and add a brief explanation.*
    e. Who should determine the remuneration?
    f. Should the method for calculating the remuneration be the same for compulsory licenses granted in situations of extreme urgency and of other nature? *Please answer YES or NO and add a brief explanation.*

Measures for monitoring compliance with a compulsory license

35) Reporting and monitoring.

a. What kind of reporting obligations should apply with respect to compulsory licenses:
    i. Should the compulsory licensee be required to provide periodic reporting of the exploitation of the license? *Please answer YES or NO and add a brief explanation.*
    ii. Should the patentee have the right to audit the compulsory licensee? *Please answer YES or NO and add a brief explanation.*
    iii. Other? *Please add a brief explanation.*
b. What kind of other measures should be in place to ensure that the use of the compulsory license remains within its permitted sphere? *Please add a brief explanation.*

36) Revocation of a compulsory license.
a. Should a compulsory license be revocable or otherwise capable of being terminated during its term? *Please answer YES or NO and add a brief explanation.*
b. What kind of reasons should give rise to termination or revocation of the compulsory license:
    i. circumstances having led to the compulsory license ceasing to exist or being unlikely to recur? *Please answer YES or NO and add a brief explanation.*
    ii. Breach of the compulsory license? *Please answer YES or NO and add a brief explanation.*
    iii. Failure to pay remuneration for the compulsory license? *Please answer YES or NO and add a brief explanation.*
    iv. Other? *Please add a brief explanation.*
c. Who should bear the responsibility of monitoring that the conditions for grant of a compulsory license continue to subsist during the term of the compulsory license?
d. Aside from potential termination of the compulsory license, should there be other remedies available for the patentee against breach of the compulsory license? *Please answer YES or NO and add a brief explanation.*
    i. Damages? *Please answer YES or NO and add a brief explanation.*
    ii. Fines? *Please answer YES or NO and add a brief explanation.*
    iii. Other remedies? *Please answer YES or NO and add a brief explanation.*

37) Please comment on any additional issues concerning any aspect of compulsory licensing that you consider relevant to this Study Question.

38) Please indicate which industry sector views provided by in-house counsels are included in your Group's answers to Part III.