

Q293

Compulsory licensing

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Respondent

9

Anonymous

157:16

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Contact details

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I. Current law and practice

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

5. 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 below. If you answered NO to question above, please move to section II below.

☒ Yes

☐ No

6. 1) (continued) Please add brief explanation

YES, in Hungarian Act XXXIII of 1995 on the Protection of Inventions by Patents (hereinafter referred to as the "Patent Act") provides for compulsory licensing with respect to patents. Chapter IV of the Patent Act contains the regime for compulsory licensing of patents, namely the four types of compulsory licensing of patents: (I) Compulsory licenses for lack of exploitation; (II) Compulsory licenses in respect of dependent patents; (III) Compulsory licences falling within the scope of Regulation (EC) No 816/2006; and (IV) Public health compulsory licences.

7. 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.

☒ Yes

☐ No

8. 2) (continued) Please add brief explanation

YES, Section 33/A of the Patent Act contains the provisions on Compulsory Licensing Governed Under Regulation 816/2006/EC, i.e., it is based on the legal basis of Articles 31 and 31bis TRIPS. The objective of Section 33/A is to establish a harmonised procedures for the granting of compulsory licenses of patents relating to the production of pharmaceutical products intended for export to countries with public health problems. In Hungary, Section 33/A of the Patent Act has been in force since May 1, 2007.

Furthermore, Sections 33/B and 33/C of the Patent Act contains the provisions of Public Health Compulsory Licensing. Sections 33/B and 33/C of the Patent Act have been in force since June 18, 2020 (during COVID, similar provisions were adopted on 16 May 2020 in a governmental decree which were implemented into the Patent Act). The legal basis of this amendment is, on the one hand, Article 31 TRIPS, and, on the other hand, the public interest related to the fight against certain public health emergencies, such as the COVID. Although Sections 33/B and 33/C have been amended in response to the COVID pandemic, the TRIPS COVID-19 Vaccines Decision (MC12) has not been implemented into the Patent Act.

9. 3) Practice on compulsory licenses:

3) 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.

10. **3) b)** If your answer to subpoint (a) was YES:

3) b) i) for which industries the compulsory licenses have been applied or granted for:

3) b) i) 1) Pharmaceuticals? Please add brief explanation below

- ☐ Applied: YES
- ☐ Applied: No
- ☒ Granted: Yes
- ☐ Granted: NO

11. **3) b) i) 1) (continued)** Please add brief explanation

3)a)ii): YES, compulsory licenses have been applied for and granted. The legal basis for compulsory license, in relation to which the decision is publicly available, was Public Health Compulsory Licensing. This case involved three patents, each covering the same pharmaceutical active ingredient. In 2020 the Hungarian Intellectual Property Office (HIPO) granted compulsory licenses for the three patents, the patentee filed a request for review (appeal). While lower and appeal courts, including the Curia (the Supreme Court of Hungary, in Hungarian: Kúria), rejected the appeals, the Constitutional Court annulled all decisions, including the HIPO's decisions, and confirmed that the right for fair trial as basic constitutional principle must apply when granting public health compulsory licenses. This means that the patentee shall not be deprived of its right to participate in the compulsory licensing procedure as client and comment on the request for a public health compulsory license. The cases are still ongoing, so said compulsory licenses are not final.

3)b)i)1): Granted: YES. As for compulsory licenses in the pharmaceutical field, the decisions are not final. The subject of the patents affected by the compulsory license is remdesivir (Veklury®).

12. **3) b) i) 2)** Biotech or other life sciences fields (excluding pharma)? Please add brief explanation below

- ☐ Applied: Yes
- ☒ Applied: No
- ☐ Granted: Yes
- ☐ Granted: No

13. **3) b) i) 2) (continued)** Please add brief explanation

14. **3) b) i) 3)** Semiconductors? Please add brief explanation below

- ☐ Applied: Yes
- ☒ Applied: No
- ☐ Granted: Yes
- ☐ Granted: No

15. **3) b) i) 3) (continued)** Please add brief explanation

16. **3) b) i) 4)** Technologies relating to protection of the environment or the climate? Please add brief explanation below

☐ Applied: Yes

☒ Applied: No

☐ Granted: Yes

☐ Granted: No

17. **3) b) i) 4) (continued)** Please add brief explanation

18. **3) b) i) 5)** Cybersecurity? Please add brief explanation below

☐ Applied: Yes

☒ Applied: No

☐ Granted: Yes

☐ Granted: No

19. **3) b) i) 5) (continued)** Please add brief explanation

20. **3) b) i) 6)** National security? Please add brief explanation below

☐ Applied: Yes

☒ Applied: No

☐ Granted: Yes

☐ Granted: No

21. **3) b) i) 6) (continued)** Please add brief explanation

22. **3) b) i) 7) Others?** Please add brief explanation below

- ☐ Applied: Yes
- ☒ Applied: No
- ☐ Granted: Yes
- ☐ Granted: No

23. **3) b) i) 7) (continued)** Please add brief explanation

24. **3) ii)** have the compulsory licenses been applied for or granted based on:

3) b) ii) 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.

- ☒ Yes
- ☐ No

25. **3) b) ii) 1) (continued)** Please add brief explanation

The public health compulsory licenses mentioned in Q3(a) above were based on public health emergency due to the COVID epidemic. Such health emergency was declared by a Governmental Decree.

26. **3) b) ii) 2)** other circumstances? Please answer YES or NO and add a brief explanation.

- ☐ Yes
- ☒ No

27. **3) b) ii) 2) (continued)** Please add brief explanation

28. Overriding interests and grounds for granting a compulsory license

4) (a - d) What are the conditions for the grant of a compulsory license? Please provide a brief explanation. In more specific:

Please answer YES or NO and add a brief explanation.

- ☒ 4) a) Have the requirements for granting a compulsory license been clearly or expressly specified in the law of your jurisdiction?
- ☒ 4) 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?
- ☐ 4) c) What kind of interests constitute an overriding interest giving rise to compulsory licensing?
- ☐ 4) c) i) Are there any technical fields, industries, or applications for which compulsory licensing is not available?
- ☒ 4) d) Are there any technical fields, industries, or applications for which there are special conditions or other special considerations for granting a compulsory license?

29. 4) a - d) (continued) Please add brief explanation

In Hungary, there are the four types of compulsory licensing of patents: (I) Compulsory licenses for lack of exploitation; (II) Compulsory licenses in respect of dependent patents; (III) Compulsory licences falling within the scope of Regulation (EC) No 816/2006; and (IV) Public health compulsory licences. Below we will refer to each of the compulsory licenses as (I)-(IV).

4a): Requirements are specified in the Patent Act.

Re (I)

The requirement is that if the patentee did not exploit his invention, in the interest of satisfying domestic demand, within the territory of the country, or did not make any effective and genuine arrangements therefore, and did not grant license to others during the four years from the date of the patent application or - if this period is longer - during the three years from granting the patent.

Re (II)

The requirement is that if the patented invention cannot be exploited without infringing another patent (hereinafter referred to as "blocking patent"), the holder of the dependent patent shall be granted a compulsory license upon request, to the extent necessary, for the exploitation of the blocking patent, provided that the invention of the dependent patent constitutes significant technical progress of considerable economic interest relative to the invention claimed in the blocking patent.

The meaning of "significant technical progress of considerable economic interest" is not defined in the Patent Act.

Re (III)

The cases and the requirements set out in Regulation (EC) No. 816/2006 of the European Parliament and of the Council of 17 May 2006.

Re (IV)

A Public Health Compulsory License can be ordered for both domestic and foreign needs. For domestic needs, the main requirement is that a public health emergency has been ordered according to the conditions set out in the Act on Health. For foreign needs the main precondition is that in that foreign country a public health compulsory license has been granted.

However, the Patent Act does not clearly define the circumstances of public health emergency, including the underlying cause of domestic supply need, assessment criteria of existing stock and potential future demand, and the involvement of the patentee in the granting procedure.

4b): Re (I)-(III), the applicant for the compulsory license needs to demonstrate that the patentee was not willing to license voluntarily the exploitation of the invention within a reasonable time in spite that all requirements are satisfied.

However, in case (IV), the applicant for the public health compulsory license does not need to request a prior voluntary license.

4c):

Re (I): the purpose of granting a compulsory license is to exploit the patented invention during the protection period.

Re (II): the purpose of granting a compulsory license is to exploit the invention of a dependent patent, if the invention constitutes significant technical progress of considerable economic interest relative to the invention claimed in the blocking patent.

Re (III): the purpose of granting a compulsory license is to ensure that countries struggling with a health crisis can obtain medicine through import.

Re (IV): the purpose of granting a public health compulsory license is to satisfy a domestic or foreign need for a healthcare product based on public health interest.

4ci): Re (IV): the public health compulsory license is limited to medical products, active substances or medical devices. Other inventions are not available for public health compulsory licensing.

4d): Re (IV): the public health compulsory license may be granted for medical products, active substances or medical devices, if it is required for managing the public health emergency. For this reason, in the context of public health emergency, the regulatory authority for pharmaceutical products analyses the information on the available stock of medical products and carries out a risk assessment considering the projected demand.

30. **5) Who can apply for a compulsory license?**

- ☒ 5) i) Any person?
- ☒ 5) ii) Only a specified category of persons/parties
- ☒ 5) ii) 1) Person with specific interest?
- ☐ 5) ii) 2) Government?
- ☒ 5) ii) 3) Commercial operators?
- ☒ 5) ii) 4) Other?

31. **5) i) & ii) (continued)** Please add brief explanation

5)i): YES, in case (I) and (III), any person can apply for a compulsory license.
5)ii)1): YES, in case (II), only the applicant of the dependent patent can apply for a compulsory license.
5)ii)2): NO, but a company owned by the state can apply for any kind of compulsory license.
5)ii)3): YES.
5)ii)4): YES. In case (IV), the applicant for public health compulsory license needs to prove that that the applicant is able to meet the domestic or foreign need.

32. **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.

- ☒ Yes
- ☐ No

33. **6) (continued)** Please add brief explanation

YES, the specific scopes / characteristics are explained below.

a) Territory

All types of compulsory licenses can be granted only for Hungary.

b) Duration:

In cases (I) and (II): the court establishes the duration which cannot be longer than the expiry date of the patent.

In case (III): the Hungarian Intellectual Property Office (HIPO) establishes the duration.

In case (IV): the HIPO establishes the duration:

- for use in the domestic market, based on what is required to manage the public health emergency at least six months (can be extended), maximum the expiry date of the patent or supplementary protection based on the revocation of the patent or supplementary protection,
- in the case of exportation, for the same term as the foreign compulsory license.

c) Field of use:

In cases (I) and (II): the field of use is not limited.

In case (III): such compulsory license can be granted in relation of patents on pharmaceutical products. The term of "pharmaceutical products" is defined in Article 2 (1) of the Regulation as any product of the pharmaceutical sector, including medicinal products as defined in Article 1(2) of Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use, active ingredients and diagnostic kits *ex vivo*.

In case (IV): a public health compulsory license can be granted for (a) patent or SPC protected pharmaceutical products and active substances, (b) patent protected medical devices, and (c) patent protected procedures, equipment or devices required for the production pharmaceutical products, active substances and medical devices.

d) Intended purpose:

See answer to Q4(c). In general, the intended purpose is public interest or satisfying domestic demand.

Case (III): a compulsory license covers only activities necessary for manufacture of the product in question, export to the country or countries indicated in the application.

Case (IV): meeting domestic demand triggered by a public health crisis, or the exportation to another country addressing public health concerns.

e) Transferability:

In cases (I) and (II): a compulsory license cannot be transferred unless the licensee is going through corporate restructuring or the licensee transfers the dependent patent.

In case (III) and (IV): a compulsory license cannot be transferred.

f) Sublicensability:

In cases (I)-(IV): it is not permitted to sub-license a compulsory license.

g) Non-exclusivity:

In cases (I)-(IV): a compulsory license is not exclusive.

34. **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.

☒ Yes

☐ No

35. **7) (continued)** Please add brief explanation

a) YES to SPCs:

Cases (I)-(II): the Patent Act does not address that Supplementary Protection Certificates (SPC) can be the basis of a compulsory license. However, as the provisions of the Patent Act shall apply to SPC, the Hungarian group is of the view that compulsory licenses per cases (I)-(II) can be granted on SPCs too.

Cases (III) and (IV): the Patent Act addresses that Supplementary Protection Certificates (SPC) can be the basis of a compulsory license.

b) YES to patent applications:

Cases (I): the Patent Act addresses patent applications.

Cases (II)-(IV): the Patent Act does not address patent applications, but as in Hungary there is a temporary patent protection for patent applications, the Hungarian Group is of the view that compulsory licenses per cases (II)-(IV) can be granted on patent applications.

36. **8) a) b)** Does the current law provide for other mandatory obligations (if any) for the patentee vis-à-vis the licensee? E.g.:

- ☐ 8) a) Is the patent holder required to provide further information on the implementation of the patent to the compulsory licensee? YES
- ☒ 8) a) Is the patent holder required to provide further information on the implementation of the patent to the compulsory licensee? NO
- ☐ 8) 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? YES
- ☐ 8) 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? NO

37. **8) a) b) (continued)** Please add brief explanation

8)a): NO.
8)b): NO.

38. **Authority to decide on compulsory licenses.**

9) a) Who has the power to decide on grant a compulsory license in your jurisdiction? **i)** Patent authority (e.g., patent office)? **ii)** Court? **iii)** Other governmental body? **iv)** Arbitration?

- ☒ i) Yes
- ☐ i) No
- ☒ ii) Yes
- ☐ ii) No
- ☐ iii) Yes
- ☒ iii) No
- ☐ iv) Yes
- ☒ iv) No
- ☐ v) Other?

39. **9) a) (continued)** Please add brief explanation

9)a)i): YES, in cases (III) and (IV) the HIPO shall decide on the grant, respectively.
9)a)ii): YES, in cases (I) and (II) the court shall decide on the grant.

40. **9) b)** Does the same body decide on remuneration? Please answer YES or NO and add a brief explanation

- ☒ Yes
- ☐ No

41. **9) b) (continued)** Please add brief explanation

In cases (I) and (II), in the absence of agreement between the patentee and the licensee, the court shall set the fee.

In cases (III) and (IV) the HIPO shall set the fee to be paid to the patentee.

42. **9) c)** Can the decision on compulsory license be appealed and to whom? *Please answer YES or NO and add a brief explanation*

☒ Yes

☐ No

43. **9) c) (continued)** Please add brief explanation

Cases (I) and (II): the decision of the court can be appealed to the Metropolitan Appeal Court (in Hungarian: Fővárosi Ítéltábla).

Cases (III) and (IV): the decision of the HIPO can be appealed to the Metropolitan Court (in Hungarian: Fővárosi Törvényszék).

44. **Rights of patentees**

10) 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).

☒ Yes

☐ No

45. **10) a) (continued)** Please add brief explanation

In cases (I) and (II): as these types of compulsory licenses have to be requested at courts, by commencing civil procedures against the rights-holder, the general provisions of procedural law apply, including that the court will send a copy of the request (the complaint) to the rights-holder which can comment on it. The Patent Act itself does not require the rights-holder to be contacted before submitting the complaint to the court.

In case (III): according to Article 9 of Regulation (EC) 816/2006 prior negotiations with the rightsholder are required, unless there is national emergency or other circumstances of extreme urgency or in cases of public non-commercial use under Article 31(b) of the TRIPS Agreement.

In case (IV): the HIPO shall notify the patentee about the application within 8 days from the reception of the application. The precondition of a public health compulsory license is that the Government has ordered a public health emergency in a Governmental Decree. In such case it is not required to enter into prior negotiations with the rightsholder.

46. **10) 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).

☒ Yes

☐ No

47. **10) b) (continued)** Please add brief explanation

In cases (I) and (II): the patentee is the defendant in the civil proceedings. This means that the patentee can comment on the application.

In case (III): Article 7 of Regulation (EC) 816/2006 sets forth that the patentee must be heard before a compulsory license is granted.

Case (IV): according to the Patent Act the HIPO must notify the patentee of the fact that an application for public health compulsory license was filed; likewise the HIPO must notify the patentee within 8 days of the decision made on such application for compulsory licence. The Patent Act does not provide an explicit opportunity for the patentee to comment on the application, while general administrative law on client rights shall apply. According to the decision of the Constitutional Court this means that the patentee shall not be deprived of its right to participate in the compulsory licensing procedure as client and comment on the request for a public health compulsory license.

48. **10) c)** What defences/grounds are available to a patentee against applications for a compulsory license? Please add a brief explanation.

Case (I): the patentee may prove that it was willing to provide a voluntarily license within 'reasonable' period of time, or provide evidence that it has exploited the patent or had 'serious' preparatory arrangements within the territory of the country.

Case(II): the patentee may prove that it was willing to provide a voluntarily license within 'reasonable' period of time or the invention of the dependent patent does not constitute significant technical progress of considerable economic interest compared with the invention claimed in the blocking patent. Furthermore, the patentee may prove that the invention of the alleged dependent patent is not dependent on the invention in the rights-holder's patent.

Case (III): The patentee can submit comments during the written part of the proceedings.

Case (IV): the Patent Act does not provide an explicit opportunity for the patentee to comment on the application, while general administrative law on client rights shall apply. According to the decision of the Constitutional Court this means that the patentee shall not be deprived of its right to participate in the compulsory licensing procedure as client and comment on the request for a public health compulsory license. This means that the patentee can potentially argue that there is no unmet supply need, or the period of time for which the public health compulsory license is sought is too long, or the unmet need indicated in the application is excessive.

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

☐ Yes

☒ No

50. **10) d) (continued)** Please add brief explanation

51. **Remuneration**

11) How is the remuneration for the patentee determined?

11) a) Is the patentee always entitled to receive remuneration for the compulsory license? Please answer YES or NO

☒ Yes

☐ No

52. **11) b)** How and when is the adequacy of the remuneration and the economic value of the compulsory license assessed?

11)a): YES, pursuant to the provisions of the Patent Act the patent holder is entitled to receive remuneration for all types of compulsory licenses.

11)b):

In cases (I) and (II): the patent holder shall be entitled to appropriate remuneration for the compulsory license as agreed with the licensee. Failing such agreement, the fee is set by the court. The fee shall reflect the economic value of the compulsory license and it has to be consistent, in particular, with the amount which would have to be paid by the holder of the compulsory license, with regard to the licensing requirements prevailing in the field to which the invention pertains, under a license concluded with the patentee.

In case (III): According to the Article 10 (9) of Regulation (EC) 816/2006 the licensee shall be responsible for the payment of adequate remuneration to the patentee as determined by the HIPO:

(a) in the 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 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.

In case (IV): The fee shall be established by the HIPO. The fee shall reflect the economic value of the public health compulsory license and it shall be consistent, in particular, with the amount which would have to be paid by the holder of the compulsory license, with regard to the licensing requirements prevailing in the field to which the invention pertains, under a license with the patentee. In determining the fee the followings shall be taken into account, in particular, (a) the common ratio in specific industries between royalties and net sales, and (b) the ratio that any economic advantage generated in a given healthcare product, or in the procedures, equipment or devices required for the production of healthcare products represent in using a patent affected by the public health compulsory license (overlap ratio).

53. **11) c)** Does the patentee have the opportunity to participate in setting the remuneration level? Please answer YES or NO

☒ Yes

☐ No

54. **11) d)** Is there a cap on the level of remuneration? Please answer YES or NO

☐ Yes

☒ No

55. **11) (continued)** Please add brief explanation

11)c): YES.

In cases (I) and (II): YES, the patent holder may comment on the remuneration level suggested by the potential licensee and agree with the licensee on the fee to be paid. If there is no agreement, the decision on remuneration level is at the court's discretion.

In case (III): as set forth in Article 10(9)(a) of Regulation (EC) 816/2006, in 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, a cap of 4 % of the total price to be paid, so there is no need for prior negotiation. Otherwise, the rights-holder can comment on the remuneration level.

In case (IV): while the Patent Act does not provide an explicit opportunity for the patentee to comment on the application, according to the decision of the Constitutional Court, the HIPO must provide an opportunity to patentee to comment on the application, including commenting on the remuneration level.

11)d): NO.

In cases (I) and (II): no cap.

In case (III): as set forth in Article 10(9)(a) of Regulation (EC) 816/2006, in 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, a cap of 4 % of the total price is to be paid.

In case (IV): no cap. In the single public health compulsory matter the HIPO applied the 4 % cap as set forth in Article 10(9)(a) of Regulation (EC) 816/2006 by analogy. As the Constitutional Court nullified the relevant decisions and the case is pending, there is no case law on this aspect.

56. **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.

☐ Yes

☒ No

57. **12) (continued)** Please add brief explanation

58. **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.

☒ Yes

☐ No

59. **13) a) i)** 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:

☐ 13) a) i) End of the situation giving rise to the compulsory license?

☒ 13) a) ii) Breach of the compulsory license?

☒ 13) a) iii) Failure to pay remuneration for the compulsory license?

☐ 13) a) iv) Other?

60. **13) a)** Please add a brief explanation.

13)a)i): NO.

In cases (I) and (II): there are no provisions for the termination of the compulsory license due to breach of its conditions. However, according to the Article 33 (6) of the Patent Act if the holder of the compulsory license fails to commence the exploitation of the invention within one year from the grant of the license, the patentee may request the amendment or termination of the compulsory license.

In case (III): according to Article 16(1) of Regulation (EC) 816/2006 a compulsory licence may be terminated by a decision of the HIPO if the licence conditions are not respected by the licensee.

In case (IV) there are no explicit provisions for termination if the licence conditions are not respected by the licensee.

13)a)ii): YES.

In cases (I) and (II): there are no provisions for the termination of the compulsory license due to breach of its conditions. However, according to the Article 33 (6) of the Patent Act if the holder of the compulsory license fails to commence the exploitation of the invention within one year from the grant of the license, the rights-holder may request the amendment or termination of the compulsory license.

In case (III): according to Article 16(1) of Regulation (EC) 816/2006 a compulsory licence may be terminated by a decision of the HIPO if the licence conditions are not respected by the licensee.

In case (IV) there are no provisions for termination if the licence conditions are not respected by the licensee.

13)a)iii): YES.

Cases (I), (II) and (IV): There are no specific provisions in the Patent Act for the termination of a compulsory license if the licensee fails to pay the fee.

Case (III): Article 16 (1) of Regulation (EC) 816/2006 can be interpreted in a way which covers this situation as well.

13)a)iv): NO.

61. **13) 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.

NO.

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

Please answer the questions of this Part II below.

62. **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.

☒ Yes

☐ No

63. **14) (continued)** Please add brief explanation

YES, the group considers that the current Hungarian law regarding compulsory licensing in general is sufficient and adequate. This being said the Hungarian Group expresses that the available case law on compulsory licensing regimes is scarce and the single known decision does not provide sufficient basis on whether the legal provisions are adequate or sufficient when applied.

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

The Hungarian Group is of the view that the policy rationale should be the ultima ratio characteristic of the compulsory licensing regimes; providing sufficient guarantees for the patentee while striking a fair balance with public interest.

65. **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?

NO. According to the case law history the Hungarian group has been able to identify, there has been only one case - not yet decided by final judgement - on the use of the compulsory licensing regimes. Based on these the Hungarian group cannot report that such cases would have proven to improve access, led to reduced process or increased availability of a product.

66. **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?

NO. No sufficient case law available in Hungary to evaluate the practical effect and identify considerations for improvement.

III) Proposals for harmonisation

Please answer the questions of this Part III below.

67. **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) 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.

☐ Yes

☒ No

68. **18) (continued)** Please add brief explanation

The Hungarian Group is of the opinion that the existing provisions of the TRIPS Agreement (i.e., Art. 31 and 31bis TRIPS) as well as Art 5A of the Paris Convention are considered sufficient to address necessary harmonization, notwithstanding the eventual need to have a coordinated approach on certain type of compulsory licenses on a regional level, such as European Union.

69. **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

☒ Yes

☐ No

70. **19) (continued)** Please add brief explanation

71. **19) a)** If you answered NO, what kind of issues/aspects should in general be subject to additional harmonization?

72. **Overriding interests and grounds for granting a compulsory license**

20) Overriding interests. Should the grant of compulsory licenses be limited to certain specific 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:

20) 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.

☐ 20) Yes

☐ 20) No

☒ 20) a) Yes

☐ 20) a) No

73. **20) (continued)** Please add brief explanation

20): YES, only if such overriding interests are proven to fulfil the prerequisites of the TRIPS provisions and benefit from the flexibilities Art 31 (b) TRIPS offers. In principle we do not consider that specific designation of a type of overriding interest is necessary, presupposing public interest is present.

74. **20) a) (continued)** Please add brief explanation

75. **20) 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.

☒ Yes

☐ No

76. **20) b) (continued)** Please add brief explanation

77. **20) c)** Cybersecurity? Please answer YES or NO, you may add a brief explanation.

☒ Yes

☐ No

78. **20) c) (continued)** Please add brief explanation

79. **20) d)** Security of national infrastructure (incl. biological threats)? Please answer YES or NO, you may add a brief explanation.

☒ Yes

☐ No

80. **20) d) (continued)** Please add brief explanation

81. **20) e)** National defence? Please answer YES or NO, you may add a brief explanation.

☒ Yes

☐ No

82. **20) e) (continued)** Please add brief explanation

83. **20) f)** Economic security? Please answer YES or NO, you may add a brief explanation

☐ Yes

☒ No

84. **20) f) (continued)** Please add brief explanation

85. **20) g)** Others? Please answer YES or NO, you may add a brief explanation.

☐ Yes

☒ No

86. **20) g) (continued)** Please add brief explanation

87. **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.

☐ Yes

☒ No

88. **21) a)** If you answered YES to 21), should cross-jurisdictional compulsory licensing be categorically available for: **21) a) i)** 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.

☐ Yes

☐ No

89. **21) a) i) (continued)** Please add brief explanation

90. **21) a) ii)** Environmental circumstances and events (e.g., natural disasters, environmental protection, climate change)? Please answer YES or NO, you may add a brief explanation.

☐ Yes

☐ No

91. **21) a) ii) (continued)** Please add brief explanation

92. **21) a) iii)** Cybersecurity? Please answer YES or NO, you may add a brief explanation.

☐ Yes

☐ No

93. **21) a) iii) (continued)** Please add brief explanation

94. **21) a) iv)** Security of national infrastructure (incl. biological threats)? Please answer YES or NO, you may add a brief explanation.

☐ Yes

☐ No

95. **21) a) iv) (continued)** Please add brief explanation

96. **21) a) v)** National defence? Please answer YES or NO, you may add a brief explanation.

☐ Yes

☐ No

97. **21) a) v) (continued)** Please add brief explanation

98. **21) a) vi)** Economic security? Please answer YES or NO, you may add a brief explanation.

☐ Yes

☐ No

99. **21) a) vi) (continued)** Please add brief explanation

100. **21) a) vii)** Others? Please answer YES or NO, you may add a brief explanation.

☐ Yes

☐ No

101. **21) a) vii) (continued)** Please add brief explanation

102. **21) 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.

☐ Yes

☐ No

103. **21) b) (continued)** Please add brief explanation

104. **21) c)** If you answered YES to 18), 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.

☐ Yes

☐ No

105. **21) c) (continued)** Please add brief explanation

106. **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:

22) a) National emergency (or regional emergency as applicable). Please answer YES or NO, you may add a brief explanation.

☒ Yes

☐ No

107. **22) a) (continued)** Please add brief explanation

108. **22) b)** Other circumstances of extreme urgency. Please answer YES or NO, you may add a brief explanation.

☒ Yes

☐ No

109. **22) b) (continued)** Please add brief explanation

110. **22) c)** General public interest. Please answer YES or NO, you may add a brief explanation.

☐ Yes

☒ No

111. **22) c) (continued)** Please add brief explanation

The Hungarian Group considers the presence of public interest as a prerequisite, where "general public interest" cannot sufficiently serve as a categorical justified ground.

112. **22) d)** Public non-commercial use. Please answer YES or NO, you may add a brief explanation

☒ Yes

☐ No

113. **22) d) (continued)** Please add brief explanation

114. **22) e)** Unmet needs. Please answer YES or NO, you may add a brief explanation.

☐ Yes

☒ No

115. **22) e) (continued)** Please add brief explanation

NO, not categorically in itself.

116. **22) f)** Unreasonable pricing. Please answer YES or NO, you may add a brief explanation.

☐ Yes

☒ No

117. **22) f) (continued)** Please add brief explanation

NO, not categorically in itself.

118. **22) g)** Non-working/insufficient working. Please answer YES or NO, you may add a brief explanation

☒ Yes

☐ No

119. **22) g) (continued)** Please add brief explanation

120. **22) h)** Related or dependant patent. Please answer YES or NO, you may add a brief explanation.

☒ Yes

☐ No

121. **22) h) (continued)** Please add brief explanation

122. **22) i)** To remedy anti-competitive practice(s). Please answer YES or NO, you may add a brief explanation.

☐ Yes

☒ No

123. **22) i) (continued)** Please add brief explanation

Non-working/insufficient working should cover these scenarios.

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

☐ Yes

☒ No

125. **22) j) (continued)** Please add brief explanation

126. **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.

☒ Yes

☐ No

127. **23) (continued)** Please add brief explanation

YES, the compulsory licence should be available for both patents and patent applications because in case of the patent is granted the application can be infringed.

128. **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.

☒ Yes

☐ No

129. **24) (continued)** Please add brief explanation

YES, as an SPC can be infringed.

130. **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.

131. **25) (continued)** Please add brief explanation

132. **26)** If your answer to question 24) was YES (answer a or b), please move forward to question 26). If your answer to question 24) was NO, should in general compulsory licenses be available for: **25) a)** Governmental bodies? Please answer YES or NO, you may add a brief explanation

☐ Yes

☐ No

133. **26) a) (continued)** Please add brief explanation

134. **26) b)** Non-commercial research organizations? Please answer YES or NO, you may add a brief explanation.

☐ Yes

☐ No

135. **26) b) (continued)** Please add brief explanation

136. **26) c)** Other non-profit organizations? Please answer YES or NO, you may add a brief explanation.

☐ Yes

☐ No

137. **26) c) (continued)** Please add brief explanation

138. **26) d)** Commercial entities? Please answer YES or NO, you may add a brief explanation.

☐ Yes

☐ No

139. **26) d) (continued)** Please add brief explanation

140. **26) e)** Other? Please answer YES or NO, you may add a brief explanation.

☐ Yes

☐ No

141. **26) e) (continued)** Please add brief explanation

142. **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.:

27) 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.

☒ Yes

☐ No

143. **27) a) (continued)** Please add brief explanation

YES, provided exceptions are available in justified situations respecting the ultima ratio nature of compulsory licenses. In addition, we believe that the court or competent authority shall have a discretion on the evaluation of the requirement of an effort to obtain a license on commercial terms.

144. **27) a) 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?

☐ Yes

☐ No

145. **27) a) i) (continued)** Please add brief explanation

At least credible proof of starting negotiations, with sufficient flexibility. No strict formal requirements are required.

146. **27) a) 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?

☐ Yes

☐ No

147. **27) a) ii) (continued)** Please add brief explanation

The court or competent authority shall have discretion on the evaluation of the requirement of an effort to obtain a license on commercial terms based on the individual circumstances of the case.

148. **27) a) 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.

☐ Yes

☒ No

149. **27) a) iii) (continued)** Please add brief explanation

Could be grounds for misuse of the compulsory licensing regimes.

150. **27)** Should there be any minimum requirements for working/non-working of the patent? E.g.:

27) b) 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.

☒ Yes

☐ No

151. **27) b) i) (continued)** Please add brief explanation

152. **27) b) 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.

☐ Yes

☒ No

153. **27) b) ii) (continued)** Please add brief explanation

154. **27) b) 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.

☐ Yes

☒ No

155. **27) b) iii) (continued)** Please add brief explanation

156. **28)** Procedural considerations:

a. Who should bear the burden of proof of establishing that conditions for the grant of a compulsory license are met?

Claimant.

157. **28) 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).

☒ Yes

☐ No

158. **28) b) (continued)** Please add brief explanation

YES, we believe that a simple notification should always be provided to the patentee in order for the patentee to exercise its rights to seek legal remedy, in particular to challenge the grant of the compulsory licence.

159. **28) 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).

☒ Yes

☐ No

160. **28) c) (continued)** Please add brief explanation

YES, except in case of extreme urgency, e.g. public health emergency and/or natural disaster and/or imminent threat of national security. Irrespective of these exceptions, the patentee should always have the right to be heard when seeking legal remedy in particular to challenge the grant of the compulsory licence.

161. **Scope and characteristics of a compulsory license**

29) a) Should compulsory licenses be categorically: [please choose one alternative, you may add a brief explanation]

☒ Non-exclusive - YES

☐ Non-exclusive - NO

☐ Exclusive - YES

☐ Exclusive - NO

☐ Depend on the case - YES

☐ Depend on the case - NO

162. **29) a) (continued)** Please add brief explanation

163. **29) 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]

☐ Yes

☐ No

164. **29) b) (continued)** Please add brief explanation

Non-transferable except in the context of transfer of the relevant business/assets

165. **29) 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]

☐ Yes

☐ No

166. **29) c) (continued)** Please add brief explanation

Non-sublicensable except as needed to effect the exploitation of the permitted license

167. **29) 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.

☒ Yes

☐ No

168. **29) d) (continued)** Please add brief explanation

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

Predominantly considered to cater for the domestic market affected by the authorization for such use, only.

170. **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.

171. **31) (continued)** Please add brief explanation

The Hungarian Group considers that in principle a shorter fixed term would provide the most predictable solution, with the possibility to request the extension of the compulsory license should the overriding interest subsist. In addition, the group finds it important to strike a balance between the patentee and the licensee by providing the patentee the right to seek termination of the compulsory license should the grounds/interest justifying the compulsory license cease to exist.

172. **32)** Should compulsory license be limited to:

- ☒ a. Specified products/processes? **YES** and add a brief explanation.
- ☐ a. Specified products/processes? **NO** and add a brief explanation.
- ☐ b. Specified quantities or volumes? **YES** and add a brief explanation.
- ☒ b. Specified quantities or volumes? **NO** and add a brief explanation.
- ☒ c. Specified uses of the patented invention? Please answer **YES** and add a brief explanation.
- ☐ c. Specified uses of the patented invention? **NO** and add a brief explanation.

173. **32) (continued)** Please add brief explanation

32)a): YES.

32)b): NO. In respect of public health related compulsory licenses some members of the Hungarian Group are of the opinion that quantities or volumes should be specified in said type of compulsory licenses, similar to the approach of Regulation 816/2006/EC. Should the case be that there is additional unmet need an opportunity could be provided to amend the compulsory license.

32)c): YES.

174. **33)** What kind of obligations (if any) should the patentee have vis-à-vis the licensee? E.g.:

- ☐ a. **YES** - Should the patent holder be required to provide further information on the implementation of the patent to the compulsory licensee? Add a brief explanation. In particular:
- ☒ a. **NO** - Should the patent holder be required to provide further information on the implementation of the patent to the compulsory licensee? Add a brief explanation. In particular:
- ☐ b. **YES** - 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? Add a brief explanation.
- ☒ b. **NO** - 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? Add a brief explanation.

175. **33) (continued)** Please add brief explanation

176. **Remuneration**

34) How should the remuneration to the patentee be determined:

34) a) Should the patentee be always entitled to a remuneration for the compulsory license? Please answer YES or NO and add a brief explanation.

- ☒ Yes
- ☐ No

177. **34) (continued)** Please add brief explanation

34)a): YES. By taking into account that the patentee is obliged always to cover the development costs of the patent based on which the compulsory license is granted. There cannot be a reason not to pay an adequate compensation to the patent holder. This is further supported by the fact that a compulsory license – although being a strictly non-exclusive one – is interfering with the monopolies the patentee would otherwise enjoy. This restriction of the patentee's monopolies – although being justified – is generating market losses for the patentee that should also be taken into account when adequate remuneration is being calculated.

178. **34) b)** How and when should the adequacy of the remuneration be determined?

In the group's view, if the parties cannot agree on the amount of the adequate remuneration, it should be determined at the time the decision is made by the court or a relevant other authority (like the Hungarian Intellectual Property Office in case of a public health compulsory licence).

The amount of the adequate license fee can be determined by the court based on the information supplied by the patent holder and the applicant.

179. **34) 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 i, how should the reasonable compensation be determined?

☒ Yes

☐ No

180. **34) c) (continued)** Please add brief explanation

YES. In the group's our view the reasonable compensation can be determined on the basis of the economic value of the license and can be commensurate with the royalty the holder of the license would have to pay under a license agreement in free market conditions.

181. **34) 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.

☐ Yes

☒ No

182. **34) d) (continued)** Please add brief explanation

NO. In our view, as the circumstances of the grant of a compulsory license and the licensing customs of the industries vary, any cap on the remuneration would unnecessarily limit the competence of the authority granting the compulsory license.

183. **34) e)** Who should determine the remuneration?

The competent authority granting the compulsory license.

184. **34) 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.

☒ Yes

☐ No

185. **34) f) (continued)** Please add brief explanation

YES. As a principle, the existence of extreme urgency and the value of the exploitation of a patent are different aspects and should not be conjoined. The fact that extreme urgency may exist does not make a patented technology less valuable, therefore the Hungarian Group believes that the method for calculating the remuneration should be the same as in situations of other nature.

186. **Measures for monitoring compliance with a compulsory license**

35) Reporting and monitoring.

35) a) What kind of reporting obligations should apply with respect to compulsory licenses:**34) a) 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.

☒ Yes

☐ No

187. **35) a) (continued)** Please add brief explanation

35)a)i): YES. The periodic reporting of the exploitation by the licensee should help to avoid further legal disputes between the patent owner and the licensee.

188. **35) a) ii)** Should the patentee have the right to audit the compulsory licensee? Please answer YES or NO and add a brief explanation.

☐ Yes

☒ No

189. **35) a) (continued)** Please add brief explanation

190. **35) iii)** Other? Please add a brief explanation.

☐ Yes

☐ No

191. **35) 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.

The Hungarian group is of the view that this issue does not differ from the situation when the patentee tries to establish whether the patent is used within its scope of protection by another party. Therefore same legal tools should be available for the patent owner.

192. **36) Revocation of a compulsory license**

36) 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.

☒ Yes

☐ No

193. **36) a)** Please add a brief explanation.

YES. The patentee should have the right to request modification or cancellation of the compulsory license if the circumstances on which it was based cease to exist and/or are unlikely to occur again. It can provide a proper balance between the interests of the patentee and the licensee. In our view, in case of modification or cancellation, the court should also take into account the legitimate interests of the holder of the compulsory license.

194. **36) b)** What kind of reasons should give rise to termination or revocation of the compulsory license:

☒ i. **YES** - circumstances having led to the compulsory license ceasing to exist or being unlikely to recur?

☐ i. **NO** - circumstances having led to the compulsory license ceasing to exist or being unlikely to recur?

☒ ii. **YES** - Breach of the compulsory license?

☐ ii. **NO** - Breach of the compulsory license?

☒ iii. **YES** - Failure to pay remuneration for the compulsory license?

☐ iii. **NO** - Failure to pay remuneration for the compulsory license?

☐ iv. Other?

195. **36) 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?

36)b)i): YES. For example, a compulsory license seems to be apt for withdrawal if the patentee exploits the licensed patent fully, or it can provide the required amount of the medicines in case of public health issue, or the public health urgency does not exist anymore. Another example could be if the licensed drug cannot be used anymore for the purpose disclosed in the compulsory license.

36)b)ii): YES. Compulsory license is a kind of license agreement and the breach of an agreement is unacceptable. The same is true in respect of the non-payment of remuneration.

36)b)iii): YES. see subsection ii) above.

36)c): Principally, the patent owner. In the cases where the compulsory license is granted only for a specific fixed term than it is the compulsory licensee's responsibility to monitor and prove that conditions prompting that the grounds and circumstances for a potential extension of the compulsory license are still present.

196. **36) d)** Aside from potential termination of the compulsory license, should there be other remedies available for the patentee against breach of the compulsory license?

☒ i. **YES** - Damages?

☐ i. **NO** - Damages?

☐ ii. **YES** - Fines?

☒ ii. **NO** - Fines?

☐ iii. **YES** - Other remedies?

☐ iii. **NO** - Other remedies?

197. **36) d)** Please add a brief explanation.

As the compulsory licence acts as a quasi agreement where the parties shall be able to use all the possible remedies which can be used in case of a license agreement. Therefore, in the Hungarian group's view unjust enrichment gained by licensee as well as compensation of damages suffered by the patent holder because of the breach of the licence should be available. However, in our view the compulsory licence is a civil law matter therefore no fine should be available.

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

N/A

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

In-house counsel and in-house patent attorney from the pharmaceutical sector.