

## **Summary Report**

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### **2025 – Study Question**

#### **Compulsory licensing**

##### **Introduction**

This Study Question concerns compulsory licensing. This Study Question focuses on examining: (i) whether additional harmonization (whether through minimum standards or otherwise) of compulsory licensing is needed; (ii) what kind of interests can justify the grant of a compulsory license (overriding interests); and (iii) the conditions for, and characteristics of, a compulsory license. This Study Question also examines the supportive mechanisms for a functioning compulsory licensing system.

The issue of compulsory licensing has frequently resurfaced in recent times. While certain minimum standards for compulsory licensing have been laid out for long 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. This has resulted in differences in the grounds for the granting of compulsory licenses as well as in procedural aspects. Thus, as the question of compulsory licensing has re-emerged more prominently in recent years (e.g., due to the COVID-19 pandemic), also the question of further harmonization in this field has resurfaced. While compulsory licensing has traditionally been mostly linked to public health, there has also been call for compulsory licensing in relation to various other technology areas in which



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inventions may have a high public interest potential (e.g., green tech, technologies to combat climate change, environmental hazards, e-waste, natural disasters, clean energy/infra).

Further, while compulsory licensing regimes have been traditionally predominantly considered to cater to the domestic markets, 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; political agreement on the framework was reached in May 2025.

For the above reasons AIPPI has considered studying questions around compulsory licensing timely.

The Reporter General has received Reports from the following Groups and Independent Members in alphabetical order: Argentina, Australia, Austria, Belgium, Brazil, Bulgaria, Canada, Chile, China, Chinese Taipei (Independent Member), Denmark, Ecuador, Egypt, Finland, France, Germany, Hungary, India, Indonesia, Italy, Japan, Malaysia, Mexico, the Netherlands, Paraguay, the Philippines, Poland, the Republic of Korea, the Russian Federation, Singapore, Spain, Sweden, Switzerland, Turkey, the United Kingdom (UK), the United States of America (USA), and Vietnam.

38 Reports were received in total.<sup>[1]</sup> The Reporter General Team thanks the Groups and Independent Members for their helpful and informative Reports. All Reports may be in AIPPI's library at [www.aippi.org](http://www.aippi.org).

The Reports provide a comprehensive overview of national and regional laws, practices, and policies relating to compulsory licensing set out in three parts:

- Part I – Current law and practice
- Part II – Policy considerations and proposals for improvements of your Group's current law
- Part III – Proposals for harmonisation.

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This Summary Report does not summarise Part I of the Reports received. Part I of any Report is the definitive source for an accurate description of the current state of the law in the jurisdiction in question.

This Summary Report has been prepared on the basis of a detailed review of the Reports<sup>[2]</sup> (including Part I) but focuses on Parts II and III, given AIPPI's objective of proposing improvements to, and promoting the harmonisation of, existing laws. As it is a summary, if any question arises as to the exact position of a particular Group in relation to Parts II or III, please refer to the relevant Report directly.

In this Summary Report:

- references to Reports of or responses by one or more "Groups" may include references to Independent Members;
- where percentages of responses are given, they are rounded to the nearest 5%; and
- in Part IV below, some conclusions have been drawn in order to provide guidance to the Study Committee for this Study Question.

**I. Current law and practice**

For the replies to Questions 1) to 13) set out in the Study Guidelines for this Study Question, reference is made to the full Reports. The Study Guidelines may be accessed in AIPPI's library at [www.aippi.org](http://www.aippi.org).

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

**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.**

24 of the Groups (70%) stated YES, while 10 (30%) of the responding Groups stated NO. Four (4) Groups refrained from answering.

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Thus, a vast majority of the Groups considered that the current law regarding compulsory licensing is adequate and/or sufficient in their jurisdiction. However, a significant minority also found development needs.

With respect to the Groups who found their current system to be sufficient, some Groups (such as the Indian Group) indicated that the current legal framework is "well-structured" and provides an adequate basis for compulsory licensing. Some others noted that, while their respective laws may not include specific provisions, the framework may still be considered sufficient.

It is worth noting that while many Groups answered "YES" to the sufficiency of the current framework, many still acknowledged that there may be room for incremental improvements or harmonization. Some Groups highlighted specific needs in particular around procedural aspects. For example, the Finnish Group noted that clarification would be needed as to whether it is possible to obtain a compulsory license without first negotiating with the patentee, i.e. whether the requirement to negotiate may be waived in a national emergency and in other extremely urgent cases involving public, non-commercial use.

As to the Groups who answered "NO", many suggested detailed amendments to their current systems. Again, with these Groups, emphasis on the identified development needs was on procedural aspects. E.g., the Belgian Group called for more procedural structure and co-operation in relation to the compulsory licensing framework.

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

The Groups presented various different policy rationales for compulsory licensing. Some Groups (such as the Dutch and the French Groups) also considered there to be different policy rationales for different categories of compulsory licenses.<sup>[3]</sup>

One of the main themes arising as a rationale for compulsory licenses was striking a balance between patent rights and public interests: A number of Groups (among others the Australian, Austrian, Chinese, Egyptian, Hungarian, Japanese, Italian, Korean, Paraguayan, Philippine, Russian, Singaporean, Swedish, Taiwanese, and Vietnamese Groups) emphasized that the rationale for compulsory licensing is to balance the legitimate interests of patent holders against broader societal needs

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(public interest). In this connection, a number of Groups also noted the importance of respecting innovation incentives while ensuring public access to important technologies.

Another main rationale highlighted by the Groups is accessibility of technology.

Some Groups, such as the UK Group, noted that the rationale for compulsory licensing is that it works as a mechanism to ensure that the societal need for a given technology is met. According to some Groups, reasons for such a situation may include, e.g., refusal to license, non-working of patents, or unfair pricing strategies and/or linkage of dependent patents. The Austrian Group also stresses the role of compulsory licensing as an enabler of dependent innovations to remedy from innovation blockage by earlier patents.

On the other hand, e.g., the Finnish Group notes, that "*the policy rationale for compulsory licensing should be based on the following factors: Prior use, non-working of the patented invention by the patentee, significant public interest, and for dependent patents*".

Similar reasoning is provided by a number of the Groups (e.g., the Austrian, Bulgarian, Indian, Korean, and Philippine Group) which describe as a main rationale for compulsory licensing the need to ensure accessibility and affordability of essential technologies (including access for dependent patents) as well as addressing market failures. A number of Groups emphasized the importance of this in contexts such as healthcare and public health emergencies. The German Group noted that "the policy rationale is to limit deficient market behaviors that hinder substantial technical development, economic growth, or imperil considerable social needs".

Furthermore, a number of Groups (e.g., the Argentinian, Brazilian, French, Peruvian, Swedish, and the UK Group) emphasized the exceptional nature of compulsory licensing and that compulsory licensing should be limited to very specific situations rather than applied broadly. E.g., the Swedish Group emphasizes that compulsory licensing should be available in the intellectual property system as one of the means to achieve an adequate balance between the interests of the rights holder and the interests of society. Joining the Argentinian Group's notion of the need of compulsory licensing to be limited to very concrete and specific cases, the Swedish

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Group however emphasizes that compulsory licensing must be seen as an exceptional measure [applicable] under strictly defined circumstances.

Emphasizing also the exceptional nature of compulsory licensing, the Australian Group notes that compulsory licensing should be available in exceptional circumstances to protect specific public interests, e.g., (1) meeting public demand for patented inventions on reasonable terms; (2) promoting competition and avoiding anticompetitive practices; and (3) ensuring that pharmaceutical products are available to eligible importing countries under certain circumstances.

The US Group considers there to be no 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.**

The overwhelming majority of the Groups noted that there was little to no evidence of effectiveness. This is due to limited or no case law contributing to no empirical data, analysis, or specific evidence available to demonstrate improved access, price impact, or product availability.

One of the exceptions to this is the Indian Group who reported evidence of reduced pricing in a case where a 97% price reduction was effected for Nexavar (Natco-Bayer case). The Turkish Group also reported a compulsory license for COVID-19 antiviral treatment from 2021, in which case a generic version of the drug was produced and distributed free of charge by the Ministry of Health at no cost.

**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?**

As to other policy considerations, the UK Group pointed out the importance of considering also other laws, for example human rights law and competition law, when deciding whether or not to grant a licence through a legislative framework.

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A number of Groups (e.g., the Canadian, Chilean, Chinese, Chinese Taipei, Egyptian, French, German, and Indian Groups) call for more structure to the procedural framework:

For example, the Turkish Group – supported among others by the Egyptian and Indian Groups – highlights the importance of clearly defining how reasonable remuneration should be determined for compulsory licenses to ensure fair and transparent compensation mechanism. The Turkish Group also calls for, e.g., more detailed procedure for applying for a compulsory license as well as more specificity and systemacy as to the timelines, the appeal mechanisms, and monitoring mechanisms (e.g., further inspection and/or audit authority to assess whether the overriding interest still exists or the terms of the compulsory license are respected, regular reporting obligations obligations for the licensee on the utilization of the licensed patent and periodic controls to verify the utilization of the patent). In the same vein, the Chinese Taipei Group proposes streamlining the compulsory licensing application process to reflect the urgency of such situations, for example, by shortening review times or reducing required documentation and enhancing international cooperation.

The Chinese Group, supported by the Indian Group, also notes that as the existing framework does not adequately define the rights and responsibilities of parties involved in compulsory licensing (e.g., obligation to assist, reporting obligations, effects of breach of compulsory license terms), the system would benefit from clear guidelines on rights and obligations for parties involved.

The French Group, also supporting streamlining the processes, proposes the establishment of a single specialized tribunal or administrative authority in order to simplify and streamline the process.

The Egyptian Group also proposes increasing the awareness of compulsory licensing and creating more transparency and consistency through publication of decisions concerning compulsory licensing.

The German Group also noted that more clarity would be needed as to the treatment of compulsory licenses concerning patent applications.

### **III. Proposals for harmonisation**

**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.**

30 of the responding Groups stated YES (80%), while 8 Groups stated NO (20%).

Thus, a vast majority of the Groups support continued harmonization of compulsory licensing.

Many of the responding Groups reflected on the need for a consistent application of Article 31 and 31bis of the TRIPS Agreement, which would enhance the legal certainty, predictability, and harmonization of the patent systems, given the cross-border jurisdictional nature of IP matters. As an example, Chinese Taipei (Independent Member) highlighted that the continued need to have global harmonization regarding compulsory licensing regime to ensure fair treatment across jurisdictions and to reduce uncertainties in cross-border IP matters. Also, the Indian Group's notion summarized well views shared by many Groups: *"[c]ompulsory licensing regimes differ significantly across jurisdictions, leading to inconsistencies in enforcement, remuneration, and procedural requirements. A standardized global framework would enhance predictability and fairness."* As the Polish Group further pointed out, such *"differences add unnecessary complexity and risk"* with the Australian Group adding that *"[a] harmonious regime will continue to encourage innovation and facilitate better access to medicine and technologies in response to future global emergencies and/or other areas concerning public health, bioterrorism, natural disasters, and environmental crises etc."* The Swiss Group, among others, emphasized harmonization as a means to tackle global emergencies like pandemics in an efficient and timely manner: *"In light of the recent COVID-19 pandemic and the extensive discussion and negotiation about the TRIPS waiver for COVID-19 vaccines, harmonization of different IP regimes would be desirable in order to be able to react in a timely manner to situations of worldwide urgency."*

On the other hand, some Groups noted that there may be jurisdictional differences. For example, the Finnish Group remarked that different countries are likely to have different priorities. In the same vein, the Peruvian Group added that granting a compulsory license will also depend on the political, social, and health situation and the industrial capability of each country while the Chinese Group for its part

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considered that due its exceptional nature, compulsory licensing should be considered based on the needs of specific jurisdictions and policies.

Some Groups (Austrian, Chinese, Hungarian, Indonesian, Paraguayan, Peruvian, Russian, and the US Groups) considered that there is already sufficient harmonization under Article 31 and 31bis of the TRIPS Agreement. The Peruvian Group, e.g., considered that the conditions for granting a compulsory license depend on the political, social, and health situation and the industrial capability of each country and, therefore, the current level of harmonization as sufficient. However, even among these Groups, e.g., the Hungarian Group called for a coordinated approach on certain types of compulsory licenses on regional level (e.g., in the EU).

**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.**

22 of the responding Groups stated YES (60%), while 16 Groups stated NO (40%).

A majority of the responding Groups considered Art. 31 and 31bis of the TRIPS Agreement sufficient as these provisions set a minimum standard while enabling flexibility. For example, the Austrian Group noted that these provisions provide a comprehensive and detailed framework that establishes essential minimum standards and principles for the use of patents under compulsory licenses.

However, a significant minority considered that further clarity would be needed through additional harmonization. These views arose from the notion that – although existing provisions provide a general framework for compulsory licensing – effective harmonization across jurisdictions has not been achieved due to varying interpretations and implementations of the relevant TRIPS provisions given by different jurisdictions and diverse practices adopted by different member states. To mention an example, the Polish Group considered that there are certain detailed aspects or requirements that could benefit from additional harmonization. This need for further guidelines was shared also by a number of Groups having answered YES.

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

The responding Groups that answered NO considered that there is a need for additional harmonization on a variety of issues. Such issues include, e.g., defining the overriding interests, remuneration, expedited procedures for emergencies (pandemics, environmental crises, etc.), handling of know-how (when essential for implementation), provisioning and handling of cross border compulsory licenses, scope of a compulsory license, procedure of compulsory licensing (e.g., triggers, requirements, time limits), prevention of abuse of compulsory licenses, monitoring, and enforcement. In particular, the Bulgarian Group highlighted that the current law on compulsory licensing does not specify how to deal with trade secrets.

**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.**

16 of the responding Groups stated YES (70%), while 6 stated NO (30%).

A vast majority on the responding Groups considered that the grant of compulsory licenses should be limited to specific overriding interests in order to balance the underlying patent rights. For example, the Indian Group found that compulsory licenses should be granted only when overriding public interests outweigh the patent rights.

Some responding Groups considered that the grants of compulsory licenses should not be limited to any specific overriding interests. For example, the Swedish Group noted that compulsory licenses should be available when there is a clear and substantial overriding public interest, case-by-case, while, e.g., the French Group considered that there should be no distinction between different technical fields.

One responding Group (the US Group) found compulsory licensing undesirable because it increases uncertainty regarding the value of IP rights, whereas such uncertainty will discourage investment.

**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 as HIV/AIDS, tuberculosis, other public health crises)? Please answer YES or NO, you may add a brief explanation.**

17 of the responding Groups stated YES (85%), while 3 Groups (15%) stated NO thereto (10%). 16 Groups refrained from a YES/NO answer.

The vast majority of the responding Groups considered that public health such be considered overriding interest given rise to compulsory licensing.

On the other hand, some responding Groups emphasized case-by-case assessments as a basis for determination rather than specifying any particular overriding interests. For example, the Belgian Groups noted that each compulsory licence should be judged on its merits without prejudging whether a particular overriding interest should apply.

As noted above, a number of Groups generally view that compulsory licenses should not be limited to specific overriding interests. Out of these Groups, for example, the French Group highlights that there should be no distinction between different technical fields and that the process of compulsory licensing should always be driven by state interests.

- 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.**

28 of the responding Groups stated YES (80%), while 6 stated NO (20%). 4 Groups refrained from answering.

The vast majority of the responding Groups found that environmental circumstances and events should constitute overriding interests giving rise to a compulsory license. E.g., the Mexican Group, however, highlights that compulsory licensing in such scenarios should be subject to strict scrutiny with priority being given to the patentee exploit the patented technology: "[compulsory licensing should be available in the event of environmental circumstances and events] but if and only if it is

determined based on evidence that the grant of a compulsory license will indubitably help to solve the circumstance, clearly identifying why a determined patent is critical and instrumental for the solution to the emergency or crisis and why is it that the patent holder cannot be trusted to solve the situation".

However, the importance of balancing incentives for innovation are highlighted also with respect to environmental technologies. As pointed out by the Chinese Group: "any environmental technologies, such as carbon capture, renewable energy advancements, and pollution control systems, are developed through years of research and substantial financial risk. Weakening intellectual property protections through compulsory licensing could slow the pace of innovation, ultimately delaying the development of more effective environmental solutions that are crucial for combating climate change."

As noted above, a number of Groups generally view that compulsory licenses should not be limited to specific overriding interests. Out of these Groups, for example, the French Group highlights that there should be no distinction between different technical fields and that the process of compulsory licensing should always be driven by state interests.

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

28 of the responding Groups stated YES (80%), while 7 stated NO (20%). 3 Groups refrained from answering.

The vast majority of the responding Groups considered that cybersecurity should constitute an overriding interest giving rise to compulsory licensing. A number of Groups (e.g., the Argentinian, Indian, Korean, Russian, Swedish, Turkish, and Vietnamese Groups) noted in particular the protection of national infrastructure/security and national emergencies as one of the key justifications for such compulsory licenses.

On the other hand, some responding Groups found that cybersecurity should not justify a compulsory license. However, many of these Groups

are among those that generally view that compulsory licenses should not be limited to specific overriding interests. Out of these Groups, for example, the French Group highlights that there should be no distinction between different technical fields and that the process of compulsory licensing should always be driven by state interests.

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

31 of the responding Groups stated YES (85%), while 5 stated NO (15%). 2 Groups refrained from answering.

The vast majority of the responding Groups considered that security of national infrastructure (incl. biological threats) should constitute an overriding interest giving rise to compulsory licensing. As with respect to cybersecurity, a number of groups noted national security and national emergencies as one of the key justifications for such compulsory licenses.

As noted above, a number of Groups generally view that compulsory licenses should not be limited to specific overriding interests. Out of these Groups, for example, the French Group highlights that there should be no distinction between different technical fields and that the process of compulsory licensing should always be driven by state interests.

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

30 of the responding Groups stated YES (80%), while 7 stated NO (20%). 1 Group refrained from answering.

The vast majority of the responding Groups considered that national defence should constitute an overriding interest giving rise to compulsory licensing. The Brazilian Group, however, expands on various intricacies involving compulsory licensing for national defence by noting that "*[i]n imminent war or existential national security crises, it may be justified for rapid access to vital technologies, especially when no alternatives exist, and the patent holder is uncooperative. However, a broad definition of*

*'national defense' risks abuse, stifling innovation. Targeting foreign companies can also strain diplomacy and create market uncertainty. Governments often have alternative means, such as funding R&D or negotiating exclusive contracts. Therefore, compulsory licensing for national defense should be an extreme last resort, used only in dire circumstances with strict legal safeguards and after exhausting all other options."*

As noted above, a number of Groups generally view that compulsory licenses should not be limited to specific overriding interests. Out of these Groups, for example, the French Group highlights that there should be no distinction between different technical fields and that the process of compulsory licensing should always be driven by state interests.

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

19 of the responding Groups stated YES (55%), while 17 stated NO (45%). 2 Groups refrained from answering.

The responding Groups were divided on economic security as an overriding interest. On the one hand, the Indian Group noted that monopolistic pricing of essential technologies could harm a country's economic security. On the other hand, the Brazilian Group found that economic security is a broad and subjective term: what one country might consider essential for its economic security, another might view as a way to gain an unfair economic advantage. The Swedish Group also noted that *"protection of economic continuity...could qualify under broad economic security...however, this ground must be carefully applied to avoid protectionism"*. On a similar vein, the Philippine Group noted that *"[e]conomic security should primarily be upheld through a competitive market. Compulsory licensing should be reserved for addressing abuses of market dominance and monopolistic practices..."*

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

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16 of the responding Groups stated YES (50%), while 16 stated NO (40%). 6 Groups refrained from answering.

Some responding Groups found that there could be additional overriding interests. For example, the Dutch Group noted that other overriding interest may exist that affect public health or safety, provided there is a direct, demonstrable and objectively verifiable relation between matter falling within the scope of the patent and any solution for the relief of such suffering for which a compulsory licence may be provided. The Canadian Group also identified nuclear and energy as further examples, while the Vietnamese Group suggested energy, security & education as relevant factors and the Swedish Group access to digital public infrastructure, access to AI tools for public good, and cultural preservation technologies as sufficient overriding interests. Also, the Indian Group also that factors such as food security (agricultural biotech patents) or AI governance, may justify compulsory licensing.

In contrast, other responding Groups maintained that the overriding interests need not be specified. Thus, according to the French Group, it is crucial to emphasize that there is no need to distinguish between different technical fields, but rather it is essential to ensure that the process is always driven by state interests rather than private interests.

**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.**

The Groups were split on the need for cross-jurisdictional compulsory licensing: 16 of the responding Groups stated YES (45%), while 21 stated NO (55%). 1 Group refrained from answering.

**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.**

13 of the responding Groups stated YES (70%), while 6 stated NO (30%).

Some of the responding Groups noted the potentially global nature of public health emergencies, which would justify cross-jurisdictional compulsory licensing. For example, the Mexican Group stated that a patent must not hinder resolving a global emergency, whereas international cooperation may be necessary for reaching such a solution. However, the Mexican Group also noted that the conditions for such compulsory licensing must be proven based on facts that clearly identify why a given patent will be necessary to resolve the emergency.

In this regard, some of the responding Groups also observed the territoriality of patent rights. For example, the Danish Group took the view that national courts should only have jurisdiction to grant compulsory licenses for national rights, e.g., a Danish patent (or a European patent validated in Denmark or with unitary effect) and/or a Danish utility model.

It is also notable that, e.g., Brazilian Group considered that cross-jurisdictional compulsory licensing poses significant risks to the national sovereignty. On the same line, the US Group emphasized that "*cross-jurisdictional compulsory licensing is undesirable, and should not be available*".

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

14 of the responding Groups stated YES (75%), while 5 stated NO (25%).

Some of the responding Groups noted the cross-border nature of environmental circumstances and events as a justification for cross-jurisdictional compulsory licensing. The Egyptian Group specifically noted that environmental challenges may be

international and may thus need cross-border solutions. On the other hand, the UK Group found that no particular category should be subject to a cross-jurisdictional compulsory license above any other categories.

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

9 of the responding Groups stated YES (45%), while 10 stated NO (55%).

The responding Groups were divided on cross-jurisdictional compulsory licensing for cybersecurity. For example, the Swedish Group noted that cross-jurisdictional compulsory licensing may be justified where cyber tools are necessary to protect critical civilian infrastructure, patents are held in only a few jurisdictions and licenses are being denied for political or anticompetitive reasons. However, the Swedish Group also noted that national security concerns and dual-use risks would require strict safeguards and oversight.

On the other hand, the Philippine Group noted that such compulsory licensing might not be justified a cybersecurity technologies deal with information with national security implications and an application for a compulsory license covering cybersecurity could expose system vulnerabilities and weak points which could be susceptible to abuse.

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

11 of the responding Groups stated YES (60%), while 8 stated NO (40%).

The responding Groups were divided on cross-jurisdictional compulsory licensing for security of national infrastructure. The German Group emphasized infrastructure that is systemically

important, e.g., for traffic, communication and other systems on which the economy and society rely. On the other hand, the Belgian Group found that matters of national infrastructure are not cross-jurisdictional as such.

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

5 of the responding Groups stated YES (25%), while 14 stated NO (75%).

While the Groups were divided on cross-jurisdictional compulsory licensing for national defense, some of the Groups found that cross-jurisdictional compulsory licensing should be available. Thus, the Mexican Group noted that a patent should not be a barrier to protecting national infrastructure and the safety of people, whereas the Belgian Group found that matters of national defense are not cross-jurisdictional as such.

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

5 of the responding Groups stated YES (25%), while 14 stated NO (75%).

The majority of the responding Groups found that cross-jurisdictional compulsory licensing should not be available for economic security given that there are many differences between the global economies. For example, the Egyptian Group noted that economic policies and priorities vary significantly between countries, and what constitutes an economic necessity in one jurisdiction may not apply in another. The Philippine Group also remarked that economic security should be supported primarily by a competitive economy and thus compulsory licensing should be used only to dismantle abuse of market dominance and monopolies.

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

4 of the responding Groups stated YES (25%), while 14 stated NO (75%).

A minority of the responding Groups that found that there might be additional overriding interests for granting cross-jurisdictional compulsory licenses. For example, the German Group noted that all situations of higher urgency that cause difficulties beyond mere unmet demand, unreasonable pricing or market failure should be able to justify compulsory licensing, especially if interests protected by fundamental rights are at stake.

**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.**

13 of the responding Groups stated YES (65%), while 7 stated NO (35%).

A large majority of the Groups considered that there should be a special organization or committee for operating cross-jurisdictional compulsory licensing. As an example, the Egyptian Group highlighted that "*a specialized international organization or committee could help manage cross-jurisdictional compulsory licensing by developing unified guidelines, facilitating coordination among national authorities, ensuring consistency and fairness, and supporting dispute resolution*". In a similar vein, the Swedish Group expressed the view that an organisation or a committee can "*coordinate requests, match licensees with technical capability, and monitor compliance and fair compensation*". Some Groups also suggested specific organizations for this task: For example, the Turkish Group considered the World Health Organization (WHO), whereas Chinese Taipei (Independent Member) further considered the World Intellectual Property Organization (WIPO).

On the other hand, some of the Groups did not agree that there should be such an organization or committee in charge and instead advocated

national authorities. For example, the Chilean Group noted that, as national property rights are impacted, it is essential that the authorities of that country are responsible for assessing compulsory licensing.

- 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.**

13 of the responding Groups stated YES (80%), while 3 stated NO (20%).

A large majority of the responding Groups considered that the modalities under Article 31bis of the TRIPS Agreement could serve as a useful framework for cases involving cross-border compulsory licensing. For example, the Swiss Group found that it would ensure a consistent and comprehensive process. On the other hand, the Mexican Group noted that the modalities of Article 31bis are very specific to the situation of the pharmaceutical industry whereby these consider asymmetries and practices that are not applicable or convenient for other types of emergencies.

- 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.**

30 of the responding Groups stated YES (80%), while 7 stated NO (20%). 1 Group refrained from answering.

The vast majority of the responding Groups considered national emergency should be categorically considered a justified ground for granting a compulsory license in the presence of an overriding interest. For example, the Japanese Group noted that a compulsory license should not be available unless it is "*necessary for the public interest*".

Accordingly, negotiations with the patentee (that were unsuccessful or could not be held) should also be required for an application for a compulsory license.

On the other hand, some of the responding Groups did not consider that there are sufficient grounds for granting a compulsory license. For example, the Chilean Group noted that the mere fact that there is a preponderant interest should never be considered as a sufficient reason for granting a compulsory license as it could lead to a disincentive to the development of useful solutions to such problems. Instead, the possibility of the patentee to supply the product or alternatives to the patented technology should be considered.

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

26 of the responding Groups stated YES (70%), while 11 stated NO (30%). 1 Group refrained from answering.

Majority of the Groups consider that there are also other circumstances of extreme urgency that should be categorically considered as justified grounds for granting a compulsory license in the presence of an overriding interest. For example, the Finnish Group noted licensing for public non-commercial purposes or the scenario in which the urgency otherwise has a tangible link to public interest.

On the other hand, some of the responding Groups did not find other such circumstances. For example, the Brazilian Group noted that "*extreme urgency*" is subjective and open to interpretation, which could lead to the abuse of and undermine the certainty of patent rights. Accordingly, such urgency should not bypass the need for a fair and transparent process for granting compulsory licenses.

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

17 of the responding Groups stated YES (45%), while 19 stated NO (55%). 2 Groups refrained from answering.

The responding Groups were divided on whether a general public interest should be categorically considered a justified ground for granting a compulsory license in the presence of an overriding interest. For example, the Korean Group noted that a general public interest should be considered a justifiable ground if there is clear public necessity, whereas for example the Malaysian Group found that it should not be considered a justifiable ground unless there are clear criteria. Notably, the Mexican Group noted that *"the protection to inventors is in itself of general public interest, and the exploitation of a patented invention without the consent of the patent holder must be justified by an extraordinary situation"*.

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

16 of the responding Groups stated YES (40%), while 21 stated NO (60%). 1 Group refrained from answering.

Majority of the responding Groups considered that public non-commercial use should not be categorically considered a justified ground for granting a compulsory license in the presence of an overriding interest. For example, the Swedish Group found that this is one of the most clearly permitted grounds under TRIPS Article 31(b), whereas for example the Dutch Group found that public non-commercial use relates to patent infringement and not compulsory licensing.

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

17 of the responding Groups stated YES (45%), while 19 stated NO (55%). 2 Groups refrained from answering.

The Groups were divided on whether unmet needs should be categorically considered a justified ground for granting a compulsory license in the presence of an overriding interest.

A number of the Groups noted that unmet needs should not be considered a sufficient ground for categorically granting a compulsory license as it is not clear what would be encompassed by such unmet needs. This was noted, e.g., by the Italian, Swiss, and Mexican Groups. On the other hand, the Spanish Group considered that essential public needs, such as the supply of gas or semiconductors are grounds for granting a compulsory license.

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

14 of the responding Groups stated YES (60%), while 22 stated NO (40%). 2 Groups refrained from answering.

Majority of the Groups found that unreasonable pricing should not categorically be considered a justified ground for granting a compulsory license in the presence of an overriding interest. A number of Groups considered, e.g., that pricing belongs to the exclusive rights of the patentee and there would be other mechanism for addressing pricing. For example, the Finnish Group found that unreasonable pricing is a question of competition law.

In contrast, the Spanish Group considered that unreasonable pricing would be a sufficient ground for categorically granting a compulsory license if the high price results from anti-competitive practice, such as the abuse of dominant position, provided that there is a final decision by an administrative or judicial body declaring the infringement of competition law.

Further, it is noteworthy that, while the Brazilian Group found unreasonable pricing as a valid ground, they did note that such ground should come along with strong caveats: "*Clear criteria are needed to determine what constitutes unreasonable pricing, considering factors like R&D costs, comparable products, and affordability. Price negotiations, voluntary agreements, or price controls might be more appropriate solutions in some cases*".

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

23 of the responding Groups stated YES (60%), while 14 stated NO (40%). 1 Group refrained from answering.

The majority of the responding Groups considered that non-working or insufficient working of the patented invention should be categorically considered a justified ground for granting a compulsory license in the presence of an overriding interest. For example, the Swedish Group explained that is a traditional and codified ground in Swedish law, whereas for example the Polish Group noted that this should be applied as an isolated criterion.

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

26 of the responding Groups stated YES (70%), while 11 stated NO (30%). 1 Group refrained from answering.

A large majority of the responding Groups considered that a related or dependant patent should be categorically considered a justified ground for granting a compulsory license in the presence of an overriding interest. For example, Chinese Taipei (Independent Member) remarked that a compulsory license may be allowed if a second patent cannot be used without infringing an earlier patent. In this vein, the Finnish group found that a compulsory license may be allowed in such circumstances, if considered reasonable.

On the other hand, some responding Groups did not agree that that a related or dependant patent would be a sufficient ground for categorically granting a compulsory license. For example, the Chilean Group found that the mere fact that a compulsory license is necessary for exploiting a related or dependent patent should not be a sufficient ground for granting a compulsory license.

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

19 of the responding Groups stated YES (50%), while 18 stated NO (50%). 1 Group refrained from answering.

The responding Groups were divided on whether remedying anti-competitive practices should be categorically considered a justified ground for granting a compulsory license in the presence of an overriding interest. For example, the Hungarian Group considered that the rules on non-working/insufficient working should already cover these scenarios. The Swiss Group concurred that there are other mechanisms for addressing competition issues, with the German Group agreeing by noting that: *"the grant of compulsory licenses for anti-competitive behaviour should remain reserved to the authorities / courts competent for assessing such behaviour under antitrust law"*. However, for example the Korean Group noted that a compulsory license should be available to remedy anti-competitive practices.

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

7 of the responding Groups stated YES (20%), while 24 stated NO (80%). 7 Groups refrained from answering.

The majority of the responding Groups considered that there would not be other grounds that should be categorically considered a justified ground for granting a compulsory license in the presence of an overriding interest. Some of these Groups, such as Poland, highlighted the fact compulsory licenses should only be allowed in exceptional circumstances. On the contrary, the Indian Groups identified technology transfer mandates and food security (agricultural biotech patents) as potential justifications in specific contexts.

**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.**

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14 of the responding Groups stated YES (40%), while 22 stated NO (60%). 2 Groups refrained from answering.

While the Groups were divided on the question, a majority of the responding Groups considered that compulsory licenses should not be available for pending patent applications as these are yet unenforceable and may ultimately be refused or revoked during the prosecution procedure.

In contrast, for example the Spanish Group adopted a more contractual approach by noting that the patent application may be subject to contractual licenses and thus it would be equally susceptible to compulsory licenses.

Further, as to the Groups in support of patent applications being also subject to compulsory licensing, the Vietnamese Group noted that *"in case of emergency (e.g., global pandemic), pending patent applications should also be also considered for compulsory licensing"*, while the Swiss Group in the same vein noted that *"that restricting the compulsory license access only to granted patents would unduly restrict and go against the aims of the compulsory licenses"*.

**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.**

26 of the responding Groups stated YES (75%), while 8 stated NO (25%). 4 Groups refrained from answering.

A large majority of the responding Groups noted that compulsory licensing should apply to patent term extensions on the same basis as it applies to the underlying patent. As the Italian group put it, *"patent term extensions grant to the patent owner a protection whose scope is analogous to that previously conferred by the patent, [so] we do not see any reason why compulsory licensing should not be available also with regard to said extensions."*

On the other hand, among the Groups expressing reservations, some of the concerns centered around the legal distinction between patents and SPCs, with some arguing that SPCs are separate rights, often subject to different legal regimes, and that compulsory licensing should be limited to the original patent

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term. The US group, for example, maintained that compulsory licenses should not be available at all, and thus not for patent term extensions either. However, it stands out that in a number of the responding Groups that stated NO as their response, patent term extensions are unavailable (e.g., Ecuador, Egypt and Peru).

- 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.**

23 of the responding Groups stated *a. Yes, to any (local or foreign) party* (60%), while 9 Groups (20%) stated *b. Yes, but to local parties only*. 1 Group (5%) stated *c. No, only to certain categories of local compulsory licensees*, 3 Groups (10%) stated *d. No, only to certain categories of local or foreign compulsory licensees*, and 2 Groups (5%) stated *e. No, to only to another specific group of compulsory licensees*.

The majority of the responding Groups considered that no restrictions to access should apply and that compulsory licenses should be available to anybody who meets the relevant criteria for the granting of a compulsory license.

A minority of the Groups supported more restrictive approaches, limiting eligibility to specific groups such as government bodies, non-profit organizations, or commercial entities with demonstrated capacity.

- 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.**

9 of the responding Groups stated YES (75%), while 3 stated NO (25%).<sup>[4]</sup>

The majority of the responding Groups considered that in general compulsory licenses should be available for governmental bodies. For instance, the Philippine Group noted that government bodies have adequate specialization to ensure that the invention subject to the compulsory license is effectively used. In the same vein, the Brazilian Group, reminding in parallel of the importance of preventing abuse, noted that making governmental bodies eligible for compulsory licenses is crucial for their ability to address critical public needs.

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

10 of the responding Groups stated YES (85%), while 2 stated NO (15%). A majority of the responding Groups thus considered that compulsory licenses should be available for non-commercial research organizations.

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

9 of the responding Groups stated YES (75%), while 3 stated NO (25%). A majority of the responding Groups thus considered that compulsory licenses should be available also for other non-profit organizations.

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

10 of the responding Groups stated YES (85%), while 2 stated NO (15%). A majority of the responding Groups thus considered that compulsory licenses should be available for commercial entities.

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

3 of the responding Groups stated YES (25%), while 9 stated NO (75%). The Swiss Group pointed out that in general, compulsory licenses should only be given to corporations, organizations, and other entities that have the means to make use of the compulsory license so as to benefit society as a whole or those in most need.

**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.**

31 of the responding Groups stated YES (85%), while 6 stated NO (15%). 1 Group refrained from answering.

A vast majority of the responding Groups considered that there should continue to be a requirement of an effort to obtain a license on commercial terms. For example, the Korean Group referred to respecting the will and the rights of the patentee as an underlying rationale. In addition, as an example, the Chinese Group referred to the principle of autonomy of will, which allows both parties to negotiate based on their interests, potentially leading to mutually beneficial agreements that balance the interests of both the patentee and the licensee and reduce the need for compulsory licensing. However, some of the Groups also noted that there should be room for exceptions to this requirement, e.g., in relation to circumstances of national emergency or other extreme urgency.

In contrast, the Swedish Group noted that it would not be reasonable to require such continued efforts once a party has been deemed to fulfil the requirements for obtaining a compulsory license. Similarly, the Brazilian Group stressed that compulsory licenses are intended to address exceptional circumstances, market needs, and emergencies, which cannot await lengthy procedures.

**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?**

Many of the responding Groups referred to reasonable commercial and good faith efforts. On the other hand, the UK Group also considered that the efforts should not be perfunctory but rather realistic with regard to reasonable terms and a timeframe.

**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?**

Some of the responding Groups noted that voluntary licensing negotiations should last from between three months to one year.

On the other hand, other responding Groups found that there should not be any fixed timelines. For example, the Finnish Group noted that no fixed timelines should be applied as it depends on the urgency of the situation. For a national emergency, it may be acceptable to apply for a compulsory license if an agreement is not reached immediately, but for dependent patents with primarily financial interests involved, even long negotiations can be considered reasonable.

**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.**

11 of the responding Groups stated YES (35%), while 20 stated NO (65%). 7 Groups refrained from answering.

A majority of the Groups considered that disagreement on the cost of a voluntary license should not in itself constitute a sufficient criterion for initiation of procedure of compulsory licensing.

However, some of the responding Groups also considered that disagreement on the cost of a voluntary license should in itself constitute a sufficient criterion for the initiation of procedure of compulsory licensing. These Groups noted, e.g., that there should be reasonable disagreement (Denmark) and that the applicant should have made genuine efforts to negotiate reasonable terms in good faith (Egypt).

On the other hand, some of the responding Groups found that a party that does not agree to the proposed terms should not automatically be considered guilty of disagreement (Poland).

**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.**

17 of the responding Groups stated YES (50%), while 17 stated NO (50%). 4 Groups refrained from answering.

The responding Groups were divided on whether compulsory licenses should be available irrespective of how the patent has been, or has not been, worked within the jurisdiction involved.

On the one hand, some of the responding Groups held that a compulsory license should be available based on public interest (e.g., the Republic of Korea), but then on the other hand some of the responding Groups held that a compulsory license should not be automatically available as each application for a compulsory license should be considered on its individual merits (e.g., Australia).

- i. 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.**

17 of the responding Groups stated YES (55%), while 14 stated NO (45%). 7 Groups refrained from answering.

For this scenario, the responding Groups were also divided. In general, the Groups considered that the patentee's working of the patent should not in of itself preclude compulsory licensing (e.g., Denmark and Italy). However, for example the Indonesian Group took account of the exclusive rights conferred by a patent and thus noted that if the patent is being worked, compulsory licensing should not be necessary.

**ii. 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.**

2 of the responding Groups stated YES (5%), while 27 stated NO (95%). 9 Groups refrained from answering.

The vast majority of the responding Groups considered that compulsory license should be available, even if the patent is currently not being worked within the jurisdiction involved but has in the past been worked within the jurisdiction involved. The overarching considerations included the notion that the focus is on the current availability and accessibility of patented technology to meet public needs rather than on past use (e.g., China). According to the Vietnamese Group, a compulsory license should be allowed if the current status shows lack of working or results in lack of access. On the other hand, the UK Group noted that this is a fact-sensitive question that should be determined case-by-case rather than under any rigid rule setting a minimum standard.

**28) Procedural considerations:**

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

The predominant response was that the applicant for the compulsory license should bear the burden of proof of establishing that conditions for the grant of a compulsory license are met. However, the Ecuadorian Group reminded that all parties involved should be heard.

**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).**

31 of the responding Groups stated YES (85%), while 5 stated NO (15%). 2 Groups refrained from answering.

The majority of the responding Groups thus considered that the patentee should always have a right to receive prior notification of a potential compulsory license before such is granted. For example, the Polish Group justified this stance by noting that a compulsory license is an exception to the general rule and standards established under both international and national law based on which limitations on exclusive rights should be applied only in exceptional circumstances. The Dutch Group further noted that such notification is also required under administrative law where a license on the grounds of public interest is concerned.

On the other hand, for example the Korean Group considered that prior notification should be waived in the case of urgent situations, in addition to which the Russian Group held that a prior notification would be necessary only if a compulsory license is issued for commercial use.

**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).**

33 of the responding Groups stated YES (90%), while 4 stated NO (10%). 1 Group refrained from answering.

The vast majority of the responding Groups stated that the patentee should always have a right to be heard in cases of compulsory licensing given the protection of fundamental rights. However, some Groups noted that cases of extreme urgency could amount to exceptions (e.g., Hungary). The Finnish Group also found that an interim or short-term license could potentially be granted without hearing the patentee if the matter is very urgent. Even the minority responses stating NO mentioned the need for a circumstantial assessment (e.g., Bulgaria) and emphasized the precedence of circumstances, such as public health emergencies and national security over the right to be heard (e.g., Vietnam).

### **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]**

35 of the responding Groups (92%) considered that compulsory licenses should be categorically non-exclusive, while 1 (3%) considered that compulsory licenses should be categorically exclusive, and 2 (5%) considered that the nature of exclusivity should depend on the case.

As per the responses, there is near-unanimous agreement that compulsory licenses should be non-exclusive.

The main justification arising from the responses is that compulsory licenses should be non-exclusive to allow the patent holder itself to exploit the invention and to grant licenses to third parties as well as to allow compulsory licenses to be granted to multiple entities as required. On principle level a number of Groups also highlighted in this context that the compulsory licenses are exceptional limitations to the patent holder's rights and, therefore, also the interference to patent holder's rights should be kept to a minimum.

##### **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]**

35 of the responding Groups (90%) considered that compulsory licenses should be non-transferrable, while no Groups (0%) considered that they should be transferable. 3 Groups (10%) considered that the transferability of the compulsory license should be case dependent.

Out of Groups who considered that compulsory licenses should be non-transferrable, 21 Groups (60% of all responding Groups), however, considered that compulsory licenses should be transferable in the context of the transfer of the relevant business/assets.

The overwhelming majority of the Groups thus consider that compulsory licenses should not be transferable, while a majority consider that an exception could be made in connection with the transfer of the relevant business/assets.

Based on the responses, the main reasoning against transferability is that license is granted on the ability of the licensee to work the invention adequately and any abuse of the license should be prohibited. E.g., the Chinese Group notes that permitting transfers of compulsory licenses may create uncertainty, as the transferee's qualifications to exploit the patent may be unclear, thereby potentially undermining both the patentee's and the public interest. Furthermore, the Chilean and Brazilian Groups emphasize that compulsory licenses, being exceptions to the patentee's rights, must remain non-transferable in order to safeguard the patentee's interests and to prevent unauthorized third parties from deriving benefits beyond what is strictly permitted by law.

With respect to the exception to transfer a compulsory license in connection with the transfer of the relevant business/asset, the German Group highlights the reasoning through functional analysis by noting that: "*Transfer should only be permitted where functionally justified, such as in the case of business succession, to maintain continuity in achieving the public interest purpose of the compulsory license.*"

- 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]**

34 of the responding Groups (90%) considered that compulsory licenses should be non-sublicensable, while 1 Group (2%) considered that compulsory licenses should be sublicensable, and 3 Groups (8%) considered that the sublicensability should depend on the case.

Out of the Groups who considered that compulsory licenses should not in general be sublicensable, however, 19 Groups (50% of all responding Groups) considered that sublicensing could be permitted to the extent needed to effect the exploitation of the permitted license (e.g., sublicensing required within supply chain).

The overwhelming majority of the Groups thus consider that sublicensing of a compulsory license should not in general be sublicensable, while half of the Groups consider that an exception to this main rule could be made to the extent required to effect the exploitation of the permitted license.

Based on the responses, the main rationale against sublicensability among the Groups revolves around the notion that the compulsory license is in the first place granted to a specific person/entity and, as noted by the Mexican Group, a third party wanting a license may request another compulsory license. The Chinese Group, e.g., also noted that: *"Allowing sublicenses could undermine the integrity of the compulsory licensing system, as it is difficult to ensure that a sublicensee possesses the same qualifications and capabilities as the original licensee to effectively exploit the patent. Moreover, sublicensing could lead to a lack of control over the distribution and use of the patented technology, potentially resulting in misuse or over-exploitation."*

**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.**

22 of the responding Groups (70%) stated YES, while 11 (30%) stated NO. 5 Groups refrained from taking a YES/NO stand.

Irrespective of the YES/NO answers, a vast majority of the Groups consider that there should not be any categorical limitation of the type of

activities for which a compulsory license may be granted but that the licensed activities should be determined based on the need addressed by the compulsory license. Again here a number of Groups emphasize the exceptional nature of compulsory license by noting that the scope of a compulsory limited should be limited and the compulsory license should intervene with a patent right only to such an extent as necessary for achieving the purpose of the license.

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

A large number of the responding Groups consider that the territorial scope of a compulsory licence should be confined to the jurisdiction or country in which the patent is granted and the licence is issued. Conversely, while Groups such as the Indian, French, and German Groups consider that the territorial scope of a compulsory licence should generally be limited to the jurisdiction in which it is granted, they also envisage the possibility of exports under justifiable circumstances. For instance, the Indian group notes that "*[a compulsory license] should generally be limited to the jurisdiction where it is granted unless cross-border use is justified under international agreements such as TRIPS Article 31bis (e.g., for export to least-developed countries facing health crises).*" In this regard, the German group further clarifies that "*...export-oriented compulsory licenses cannot serve as a substitute for a domestic compulsory license in the destination country; rather, a separate compulsory license would be required in the jurisdiction of the destination country, if patent protection exists there.*" However, a number of Groups (e.g., the Chilean, Polish, and Spanish Groups) also emphasize the relevance of the reason for the grant of the compulsory license in the first place, namely, that the territory of the compulsory liense should be defined by the territory of the emergency.

**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.**

30 of the responding Groups (80%) consider that the compulsory license should be limited for the duration of the existence of the overriding interest, while 3 Groups (7%) consider that compulsory licenses should be available for a fixed term. 5 Groups (13%) consider that the determination should be more or less case specific.

The vast majority of the Groups consider that the term of the compulsory license should be aligned with the existence of the overriding interest. This is primarily reasoned by the Groups based on the exceptional nature of compulsory licenses.

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

**a. Specified products/processes? Please answer YES or NO and add a brief explanation.**

27 of the responding Groups (80%) answered YES, while 6 Groups (20%) answered NO. 5 Groups refrained from answering YES or NO.

Thus, a vast majority of the responding Groups considered that compulsory licenses should be limited to specified products/processes.

In general, the reporting groups noted that the use of a compulsory licence should be limited to the extent necessary to fulfil the purpose for which it is granted. Notably, the group representing the Philippines points out that *"such limitations are necessary to avoid stockpiling, price manipulation, and unregulated sale of the invention."* Furthermore, the Chinese group observes that such limitations *"ensure that the license is granted only for particular purposes that address public interest concerns, while still respecting the patent holder's rights"*.

Again here a number of Groups emphasized the exceptional nature of compulsory licenses and in particular, as noted by the Swiss Group, that *"a compulsory license should intervene with a patent right only to such an extent as necessary for achieving the purpose of the license"*.

**b. Specified quantities or volumes? Please answer YES or NO and add a brief explanation.**

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22 of the responding Groups (65%) stated YES, while 11 Groups (35%) stated NO. 5 Groups refrained from answering YES or NO.

Thus a strong majority of the Groups considered that compulsory licenses should be limited to specified quantities or volumes. The rationale behind the majority view is again the exceptional nature of compulsory licenses calling for a limited scope. In particular, some of the Groups noted that such limitation would be required so as to ensure that the use of the patented invention is controlled and does not exceed what is necessary to address the public interest or specific needs for which the license was granted.

Some other Groups, however, also contemplate on practical difficulties in determining volumes. For instance, the German Group notes that *"the extent of the need may not be foreseeable at the outset"* and further notes that *"a rigid limitation could therefore impair the practical effectiveness of the compulsory license."* In a similar vein, the Hungarian group notes that *"quantities or volumes should be specified in said type of compulsory licenses,"* but goes on to observe that *"...should the case be that there is additional unmet need, an opportunity could be provided to amend the compulsory license"*.

**c. Specified uses of the patented invention? Please answer YES or NO and add a brief explanation.**

26 of the responding Groups (80%) stated YES, while 6 of the Groups (20%) stated NO. 6 Groups refrained from a YES/NO answer.

Thus, the overwhelming majority of the Groups considered that compulsory licenses should be limited to specified uses of the patented invention. This view is supported by the same reasoning as with the other limitations, namely by the exceptional nature of compulsory licenses calling for a limited scope.

**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.**

12 of the responding Groups (35%) answered YES, while 22 of the Groups (65%) stated NO. 4 Groups refrained from a YES/NO answer.

Thus, a strong majority of the Groups considered that the patent holder should not be required to provide further information on the implementation of the patent to the compulsory licensee given the overall forced nature of the compulsory license.

As to the minority view, for instance, the Turkish Group considered that "*obligations may be necessary to enable the licensee to implement the patent effectively, particularly in complex technologies.*" In this regard, the Vietnamese Group noted that the information required for implementation should be determined on a case-by-case basis and should be limited to what is necessary for the effective use of the licensed invention.

**b. Should the patent holder be required to provide to the compulsory licensee trade secrets or other knowhow for the purposes of the compulsory licensee to work the invention effectively? Please answer YES or NO and add a brief explanation.**

5 of the responding Groups (15%) answered YES, while 29 Groups (85%) answered NO. 4 Groups refrained from a YES/NO answer.

Consequently, an overwhelming majority of the Group considered that the patent holder should not be required to provide to the compulsory licensee trade secrets or other knowhow for the purposes of the compulsory licensee to work the invention effectively.

As to the small minority view, the Turkish Group noted that the patent holder should provide the licensee with all technical information—including trade secrets, if necessary—to enable the effective use of the invention, while the licensee must safeguard any confidential information received.

**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.**

37 of the responding Groups (100%) stated YES, while no Groups (0%) stated NO. One Group refrained from answering.

The Groups share a unanimous view that the patentee should always be entitled to a remuneration for a compulsory license. This consensus is predominantly rooted in the understanding that a patent is an exclusive right, and that this right is being interfered with through the grant of a compulsory licence; thus, in order to balance public interest with the rights of the patentee and to foster incentives for continued innovation, remuneration is viewed as mandatory.

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

As per the responses, it appears that there is no uniform approach to determining the adequacy of remuneration. However, a large number of Groups – including those from Australia, the Philippines, Singapore, Turkey, Egypt, France, and others – considered it appropriate to decide remuneration at the time of negotiation or prior to the grant of the compulsory licence. However, differing views also were presented, e.g., by the Korean Group who noted that remuneration should be determined after the grant of the licence.

**c. Should remuneration be based on reasonable compensation comparable to a license fee. Please answer YES or NO and add a brief explanation.**

34 of the responding Groups (90%) answered YES, while 3 Groups (10%) answered NO. One Group refrained from a YES/NO answer.

The overwhelming majority of the Groups consider that remuneration should be based on reasonable compensation comparable to a license fee. As stated by the Vietnamese Group: "*Remuneration should be based on reasonable compensation comparable to a license fee, in order to*

*ensure the balance of both public interest and the legitimate rights of the patentee".* In the same vein the Singaporean Group noted that remuneration for a compulsory licence should be comparable to a reasonable license fee in a voluntary market transaction, thereby ensuring fairness to the patent holder while promoting.

**i. If you answered YES to c, how should the reasonable compensation be determined?**

Varied factors were presented by the Groups in response to how should the reasonable compensation be determined:

Many Groups considered that the reasonable compensation should be determined based on reasonable compensation comparable to a license fee to reflect the market value of the patented invention (i.e., what the compensation would have been in free market conditions).

Some Groups further noted various cost elements as factors to be taken into consideration when determining the compensation. Such included, e.g., cost of development. Furthermore, some Groups noted that the costs of producing and marketing the product under the compulsory license should also be considered.

Many Groups also noted economic value of the license as the baseline for determining the compensation. Various Groups noted different factors as potentially influencing the determination of such economic value. Such factors, included, e.g., usage, scope, significance of the invention, non-exclusive nature of the compulsory license, whether the right holder has received public funds to develop the invention, the degree of amortization of the development costs by the right holder, the economic importance of the invention, the usual royalty rates for comparable licenses in each sector, usefulness and similar circumstances of the case together with market price.

Some Groups noted that the determination should always be purely case by case.

As to the formulation of the compensation, many Groups considered that the compensation could be formulated as a royalty rate as a percentage of net sales, while others suggested lump sums.

**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.**

4 of the responding Groups (10%) answered YES, while 33 of the responding Groups (90%) answered NO. One Group refrained from answering.

An overwhelming majority of the Groups considered that there should be no fixed cap on remuneration. As to the reasoning, e.g., the Philippine Group noted that: "*A fixed cap may not adequately account for the varying economic impact of different patents, industries, and circumstances surrounding the grant of a compulsory license. Instead, factors such as market value, investment costs, and the public interest should guide the determination of fair compensation.*" In a similar vein, the Korean Group pointed out that: "*Imposing a fixed cap on remuneration could be unreasonable, as the scope of a compulsory license, the economic value of the patent, and other factors may vary from case to case.*"

**e. Who should determine the remuneration?**

The Groups expressed various views as to the body determining the remuneration. Some Groups suggested that the body should be the same body who decides on the compulsory license, while others suggested the patent authority, other Courts, experts, and other specialized bodies.

**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.**

20 of the responding Groups (55%) answered YES, while 16 Groups (45%) answered NO. Two Groups refrained from answering.

The responding Groups were relatively divided on the question of whether the remuneration should be the same for compulsory licenses granted in

situations of extreme urgency and of other nature. Some Groups considered that the method of calculation should be the same as the value of the patented invention does not change. Some other Groups for their part considered, that the method should not be the same as in situations of extreme urgency a lower compensation could be warranted.

## **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.**

34 of the responding Groups (90%) answered YES, while 3 Groups (10%) answered NO. One Group refrained from answering.

An overwhelming majority of the Groups consider that compulsory licensee should be required to provide periodic reporting of the exploitation of the license. The main reasoning arising from the responding groups revolve around the checks and balances of the compulsory licensing system and on ensuring accountability (incl. effective utilization of the license and prevention of misuse), transparency, as well as compliance.

As to the small minority, e.g., the Japanese Group notes that "*an obligation to provide periodic reporting would place a burden on the licensee and should not be imposed. Rather, it would be desirable to have a system designed so that the granting authority can ask the licensee to provide a report on the exploitation upon request from an interested party such as the patentee or at the discretion of the granting authority*".

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

30 of the responding Groups (80%) answered YES, while 7 Groups (20%) answered NO. One Group refrained from answering.

An overwhelming majority of the Groups consider that the patentee should have the right to audit the compulsory licensee. In addition to the reasoning laid out above in relation to periodic reporting, many Groups also note that regular audits are common practice in licensing and are needed to verify that the licensee respects the agreed-upon boundaries. As noted by the Turkish Group: *"It is appropriate to check to determine whether the terms of the compulsory license contract have been implemented. Thus, if the patentee detects an inappropriate implementation, the patentee can use his/her right granted by law by submitting a request to the court for the cancellation of the compulsory license."*

Some of the Groups in the minority consider that the audit right should be reserved for the granting authority.

**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.**

Some Groups suggest, e.g., voluntary disclosures by the licensee, periodic checks of the continued existence of the public interest having given rise to the compulsory license, penal provisions for licensee if the compulsory license is not used, price monitoring, as well as periodic reassessment of the remuneration based on market performance, sales volumes, and/or profit margins.

**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.**

All 38 of the responding Groups (100%) consider that compulsory license should be revocable or otherwise capable of being terminated during its term.

**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.**

36 of the responding Groups (100%) stated YES, while no Groups stated NO. Two Groups refrained from giving a YES/NO answer.

The responding Groups were thus unanimous in that a compulsory license should be capable of being revoked or terminated if circumstances having led to the compulsory license cease to exist or are unlikely to recur.

In this regard, e.g., the German Group noted that :*"...if the aforementioned circumstances end or become unlikely to reoccur, the purpose of the compulsory license expires and thus the justification for its continued use"*. In the same vein, the Swiss Group noted that *"[i]f the circumstances that justified the issuance of the compulsory license no longer exist or are unlikely to recur, it would be reasonable to terminate the license"* further explaining that *"[t]his ensures that the license is only in effect as long as it is necessary to address the specific needs or issues that warranted its grant."*

**ii. Breach of the compulsory license? Please answer YES or NO and add a brief explanation.**

34 of the responding Groups (95%) stated YES, while two Groups (5%) stated NO. Two Groups refrained from giving a YES/NO answer.

The Groups were nearly unanimous in that a breach of a compulsory license should give rise to termination or revocation of the license. As the Swiss Group noted: *"Compliance with the agreed-upon terms is essential for maintaining the integrity of the license, and failure to adhere to these terms undermines the purpose of the agreement"*.

**iii. Failure to pay remuneration for the compulsory license? Please answer YES or NO and add a brief explanation.**

33 of the responding Groups (95%) answered YES, while 2 Groups (5%) answered NO. Three Groups refrained from answering YES/NO.

The Groups were nearly unanimous in that failure to pay remuneration for the compulsory license should give rise to revocation or termination of the license. As the Swiss Group noted: *"...payment is a fundamental aspect of the licensing agreement, compensating the patent holder for the use of their intellectual property. Non-payment violates the terms and justifies termination."*

**iv. Other? Please add a brief explanation.**

Limited comments were received from the Groups as to other grounds. However, the Swiss Group noted that *"the licensee's inability to effectively utilize the technology, resulting in market inefficiencies or unmet public needs. Additionally, termination could be triggered if the licensee engages in unethical practices or uses the licensed technology in a way that harms public interest or the invention itself."*

**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?**

Many of the Groups would place primary responsibility for monitoring compulsory licence conditions on the granting authority, with an additional burden placed on the patentee.

**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.**

33 of the responding Groups (97%) stated YES, while one Group (3%) stated NO. Four Groups refrained from answering YES/NO.

The responding Groups were practically unanimous in finding that damages should be available for the patentee against breach of the compulsory license.

**ii. Fines? Please answer YES or NO and add a brief explanation.**

25 of the responding Groups (75%) stated YES, while 8 Groups (25%) stated NO. Five Groups refrained from answering YES/NO.

A vast majority of the responding Groups thus consider that fines should be available as a remedy for the patentee against breach of the compulsory license.

**iii. Other remedies? Please answer YES or NO and add a brief explanation.**

Some Groups suggest also other remedies to be available for the patentee against breaches of compulsory licenses. Such potential other remedies include, e.g., injunctions, specific performance, criminal sanctions, as well as seizure and forfeiture of products.

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

Limited number of additional issues were brought up by the Groups. However, for instance, the Swiss Group highlighted that policymakers must recognise that "*granting compulsory licences could impact incentives for future innovation.*" Along similar lines, the groups representing India and Chinese Taipei called for greater clarity in defining public interest grounds and procedural aspects, in order to ensure fairness. Furthermore, the Egyptian group pointed out that the compulsory licensing regime "*faces challenges such as economic and political pressures, difficulties in determining fair compensation for patent holders, and its impact on parallel trade.*" It also noted that "*its implementation varies across countries under TRIPS, and its scope is expanding beyond pharmaceuticals to areas like the environment*"

The US Groups highlights the lack of evidence of compulsory licensing improving access to medicine "*there is limited evidence that compulsory licensing leads to*

*greater access to medicine or otherwise leads to better outcomes for the health and welfare of populations" and further notes that "voluntary licensing of innovative technologies, including medicines, has proven effective in increasing access".*

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

The responses indicate that in-house counsels from various industry sectors have provided input. Such industries include, e.g. agro, automotive, chemical, communications, electronics, environmental, household appliances, information technology, Internet, learning, life sciences, materials, medical informatics, mining, pharmaceuticals, semi-conductor technology, and telecommunications.

**IV. Conclusions**

From the Reports, the conclusion can be drawn that a vast majority of the Groups agree that harmonisation regarding compulsory licensing regime continues to be desirable. There is also strong support for further harmonization.

It can be drawn that a majority of the responding Groups find that the grant of a compulsory license should be limited to specific overriding interests or circumstances. As to such specific overriding interests, the majority of the Groups (although not each of the points below is necessarily supported by the "same" majority) finds that:

- Public health (e.g., pandemics such as COVID-19, epidemics such as HIV/AIDS, tuberculosis, other public health crises) should constitute an overriding interest giving rise to compulsory licensing
- Environmental circumstances and events (e.g., natural disasters, environmental protection, climate change) should constitute an overriding interest giving rise to compulsory licensing
- Cybersecurity should constitute an overriding interest giving rise to compulsory licensing

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- Security of national infrastructure (incl. biological threats) should constitute an overriding interest giving rise to compulsory licensing
- National defense should constitute an overriding interest giving rise to compulsory licensing
- Economic security may also constitute an overriding interest giving rise to compulsory licensing

**Cross-jurisdictional compulsory licensing:**

- As to cross-jurisdictional compulsory licensing, the Groups were divided on whether cross-jurisdictional compulsory licensing should be available. Should cross-jurisdictional compulsory licensing be available, the majority of the Groups (while not necessarily the same majority in each case) consider that it should be categorically available for overriding interests such as:
  - o Public health (e.g., pandemics such as COVID-19, epidemics such as HIV/AIDS, tuberculosis, other public health crises);
  - o Environmental circumstances and events (e.g., natural disasters, environmental protection, climate change); and
  - o Security of national infrastructure (incl. biological threats).
- However, with respect to cross-jurisdictional compulsory licensing, the Groups were divided on whether or not cybersecurity should qualify as such overriding interest. At the same time, majority of the Groups consider that cross-jurisdictional compulsory licensing should not be available based on reasons concerning national defense or economic security.
- With respect to the implementation of cross-jurisdictional compulsory licensing, majority of the Groups consider that there should be a special

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organization or committee for operating cross-jurisdictional compulsory licensing.

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- Majority of the responding Groups consider also that the modalities enshrined in Article 31bis TRIPS should be extended to apply to cross-jurisdictional compulsory licensing.

**Grounds meriting the grant of compulsory license:**

- Majority of the Groups consider that when an overriding interest is present:
  - o National emergency should categorically be considered a justified ground for granting a compulsory license
  - o Other circumstances of extreme urgency should categorically be considered a justified ground for granting compulsory license
  - o Unreasonable pricing should categorically be considered a justified ground for granting compulsory license
  - o Non-working/insufficient working should categorically be considered a justified ground for granting compulsory license
  - o Related or dependant patent should categorically be considered a justified ground for granting compulsory license
- Continuing on justified grounds for granting a compulsory license, the majority of the Groups also considered that:
  - o General public interest should not be considered a justified ground for granting compulsory license
  - o Public non-commercial use should not be considered a justified ground for granting compulsory license

- o Unmet needs should not be considered a justified ground for granting compulsory license
- o The Groups were, however, split on whether compulsory licensing to remedy anti-competitive practice(s) should be a justified ground for granting a compulsory license
  
- Majority of the Groups also considered that:
  - o Compulsory licenses should be available for granted patents only
  - o Compulsory licenses should be extended to patent term extensions (e.g. supplementary protection certificates)
  - o Compulsory licenses should be available to any (local or foreign) party including, e.g.,
    - § Governmental bodies
    - § Non-commercial research organizations
    - § Other non-profit organizations
    - § Commercial entities
  
- With respect to the requirements for a compulsory license, majority of the Groups considered that:
  - o There should continue to be a requirement of an effort to obtain a license on commercial terms (a voluntary license).
  - o Disagreement on the cost of a voluntary license should not in itself constitute a sufficient criterion for initiation of procedure of compulsory licensing.
  
- The Groups are split on significance of working, or non-working, of the patent in determining of the grant of a compulsory license. However, a

strong majority of the Groups considered that there should not be categorical prohibition against compulsory licenses being available if the patent is currently not being worked within the jurisdiction involved but has in the past been worked within the jurisdiction involved.

**Procedural considerations:**

- As to procedural considerations, majority of the Groups consider that:
  - o Potential licensee should bear the burden of proof of establishing that conditions for the grant of a compulsory license are met.
  - o The patentee should always have a right to receive prior notification of a potential compulsory license before such is granted.
  - o The patentee should always have a right to be heard in cases of compulsory licensing.

**Scope and characteristics of a compulsory license:**

- As to the scope and characteristics of a compulsory license, majority of the Groups considered that:
  - o Compulsory licenses should be categorically non-exclusive
  - o Compulsory licenses should be categorically non-transferable except in the context of transfer of the relevant business/assets
  - o Compulsory licenses should categorically be non-sublicensable (provided, however, that the Groups were split on whether sublicensing needed to effect the exploitation of the permitted license would merit an exception)
  - o Compulsory licenses should categorically be available for all activities within the scope of the patent

- o With respect to the territorial scope, some Groups considered that the territory should be limited to the jurisdiction or country in which the patent is granted and license issued while other considered that the territory should be defined by the emergency in question
- o Compulsory licenses should be limited for the duration of the existence of the overriding interest
- o Compulsory licenses should be limited to specified products/processes
- o Compulsory licenses should be limited to specified quantities or volumes
- o Compulsory licenses should be limited to specified uses of the patented invention
- A strong majority of the Groups also considered that the patent holder should not be required to provide further information on the implementation of the patent to the compulsory licensee
- An overwhelming majority of the Group considered that the patent holder should not be required to provide to the compulsory licensee trade secrets or other knowhow for the purposes of the compulsory licensee to work the invention effectively.

**Remuneration:**

- As to remuneration the Groups share a unanimous view that the patentee should always be entitled to a remuneration for a compulsory license. However, as per the responses, it appears that there is no uniform approach to determining the adequacy of remuneration or as to who should determine the remuneration.
- The overwhelming majority of the Groups consider that:

- o Remuneration should be based on reasonable compensation comparable to a license fee
  - o There should be no fixed cap on remuneration
- The responding Groups were relatively divided on the question of whether the remuneration should be the same for compulsory licenses granted in situations of extreme urgency and of other nature

### **Measures for monitoring compliance with a compulsory license**

- An overwhelming majority of the Groups consider that:
  - o Compulsory licensee should be required to provide periodic reporting of the exploitation of the license
  - o The patentee should have the right to audit the compulsory licensee
- Many Groups also suggest various additional measures to ensure that the use of the license remains within its permitted sphere, e.g., voluntary disclosures by the licensee, periodic checks of the continued existence of the public interest having given rise to the compulsory license, penal provisions for licensee if the compulsory license is not used, price monitoring, as well as periodic reassessment of the remuneration based on market performance, sales volumes, and/or profit margins.

### **Revocation of a compulsory license**

- All the responding Groups consider that compulsory license should be revocable or otherwise capable of being terminated during its term.
- All the responding Groups consider that a compulsory license should be capable of being revoked or terminated if circumstances having led to the compulsory license cease to exist or are unlikely to recur.

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- The Groups were also nearly unanimous in that a breach of a compulsory license should give rise to termination or revocation of the license
- The Groups were also nearly unanimous in that failure to pay remuneration for the compulsory license should give rise to revocation or termination of the license
- Many of the Groups would place primary responsibility for monitoring compulsory licence conditions on the granting authority, with an additional burden placed on the patentee.
- The rGroups were practically unanimous in finding that damages should be available for the patentee against breach of the compulsory license.
- A vast majority of the responding Groups also consider that fines should be available as a remedy for the patentee against breach of the compulsory license.
- Some Groups suggest also other remedies to be available for the patentee against breaches of compulsory licenses. Such potential other remedies include, e.g., injunctions, specific performance, criminal sanctions, as well as seizure and forfeiture of products.

<sup>[1]</sup> 38 Reports were received within the time limit set for the responses and are included in the analysis part of this Summary Report.

<sup>[2]</sup> 38 Reports were received within the time limit set for the responses and such Reports are included in the analysis part of this Summary Report.

<sup>[3]</sup> For examples, please see, e.g., the Report by the Dutch Group.

<sup>[4]</sup> Please note that some Groups having answered YES to question 25 opted to continue to answer to question 27.