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PRACTICAL EXPERIENCES ON THE EFFECTIVENESS OF, AND CHALLENGES ASSOCIATED TO, EXCEPTIONS AND LIMITATIONS

Document prepared by the Secretariat

1. At its twenty-fourth session, held from June 27 to 30, 2016, the Standing Committee on the Law of Patents (SCP) agreed that a compilation of information regarding practical experiences of members and observers of the SCP on the effectiveness of, and challenges associated to, exceptions and limitations, in particular, in addressing development issues, would be prepared by the Secretariat. Pursuant to the above decision, members and observers of the SCP were invited, through Notes C. 8585, C.8587 and C. 8588 dated August 16, 2016, to submit information to the International Bureau on the above subject.

2. In their submissions, some members noted that they do not have such experiences, and some other members stated that they had already submitted the information on their experiences, as contained in document SCP/23/3. This document contains a compilation of the new information submitted by the following members and observers of the SCP: Guatemala, United Nations Conference on Trade and Development (UNCTAD), World Trade Organization (WTO), Innovation Insights, Intellectual Property Owners Association (IPO) and Third World Network (TWN). Taking into account the limitation of the volume of meeting documents under the WIPO language policy, this document summarizes the information received. The submissions in their entirety are available on the SCP electronic forum.[1]

Guatemala

3. In Guatemala, practical experience on the effectiveness of, and challenges associated to, exceptions and limitations, in particular, in addressing development issues, is closely linked with the quality of patents, since the protection conferred by patents shall be determined by their claims. On exceptions and limitations, Guatemala is aware that the issue should be further

[1] http://www.wipo.int/scp/en/meetings/session_25/comments_received.html.

addressed in the SCP, which should analyze each applicable national legislation and see the differences between the laws of developing countries and developed countries.

4. Guatemala, within its national law, regulates compulsory licenses. It develops the procedures that must be taken to obtain such licenses as well as the conditions for their use, modification and revocation, and most importantly, the conditions under which compulsory licenses can be sought and the time of their validity.

UNCTAD

5. In the context of its technical cooperation activities, the UNCTAD Secretariat through its Intellectual Property Unit, Division on Investment and Enterprise, has gathered some experience on the effectiveness of the use of certain exceptions and limitations to patent rights in various developing countries. This experience mainly relates to: (i) regulatory review ("Bolar") exception; (ii) experimental use exception; and (iii) concept of exhaustion of patent rights.

6. The regulatory review ("Bolar") exception has not been implemented in all developing countries' patent regimes. Especially countries still relying on pre-TRIPS patent laws provide no legal possibility for generic producers to use patented substance without the patentee's authorization for marketing approval purposes. This is particularly true for those countries that have limited their domestic experimental use exception to acts solely carried out for non-commercial research (see below). UNCTAD experience shows that even in some of the countries that have enacted the regulatory review ("Bolar") exception, it is not necessarily used much by generic producers, due to their lack of awareness of patent issues or limited production capacities. It may also be observed that this exception may vary in scope, depending on national implementing legislation. Some countries limit covered activities to those that are directly related to the act of seeking regulatory approval, while other countries include certain preparatory activities even if the latter never actually result in the submission of a request for regulatory approval. Another difference in scope is territorial: while some countries limit the exception to activities undertaken for regulatory approval in their own territory, other legal systems allow preparatory acts to request regulatory approval abroad.

7. The experimental use exception, while being implemented in the overwhelming majority of developing countries, including those that still rely on pre-TRIPS legislation, widely varies in scope. A considerable number of developing countries limit the scope of this exception to research done solely for non-commercial purposes. This is not in line with economic realities, where research undertaken for scientific purposes may at the same time be used for commercial purposes. Developing countries that recently amended their patent laws often reflect this reality by allowing research on the patented substance to enable the generation of new knowledge, even where there may be a distant commercial purpose. This follows the 2008 Resolution Q 202 by the International Association for the Protection of Intellectual Property (AIPPI), stating that: "1.1) Patent law should provide for an exception to the rights of a patentee, allowing a party to undertake, without the authorization of the patentee, experiments relating to the subject-matter of the invention, irrespective of whether the ultimate aim of the experiments may be commercial. […]"

8. With regards to patent exhaustion, there appears to be a great degree of unawareness of the issue in many developing countries. Some countries' laws include an express exception of the rights conferred under a patent, where the patented article has been commercialized in any country of the world with the consent of the patent holder. At the same time, these laws expressly include the right to prevent the importation of the patented good among the rights conferred by a patent. Another challenge is specific to the area of pharmaceuticals. Some countries that allow for parallel importation of patented medicine lack guidelines for their

medicine regulatory agencies on how to authorize parallel imported pharmaceutical products. There is a need for coherence and complementarity between the areas of patent law and drug regulatory law in respect of parallel imports.

9. In sum, it may be stated that patent exceptions and limitations, while available in domestic law, are often unclear in scope and therefore difficult to make operational.

WTO

10. The Secretariat of the WTO sent two documents. The first document is an extract from the WHO-WIPO-WTO Trilateral Study "Promoting Access to Medical Technologies and Innovation: Intersections between public health, intellectual property and trade", namely, Chapter IV, Section C.3(a)(iii)[2] and Annex II[3] of that Study regarding the Paragraph 6 System that provides an additional flexibility aimed at enhancing access to medicines.

11. The key points are:

- In 2003, WTO members agreed to introduce a new flexibility into the TRIPS Agreement. The flexibility, known as the Paragraph 6 System, is designed to enhance access to medicines by removing a potential barrier for countries that need to import medicines;

- While the reasons for the limited use of the Paragraph 6 System are still under consideration, it could be more widely used in the future, for example, following the introduction of the product patent regime in key potential exporting countries, or in the case of a pandemic or some other health security event where effective treatments may be patented in all major supplier countries.

12. The above Section of the Study first describes the legislative history of the establishment of the Paragraph 6 System. It then explains that the System applies in a particular procurement scenario where an importing country needs medicines to deal with a public health problem, but a potential exporting country faces a legal impediment because Article 31(f) of the TRIPS Agreement limits supply under a compulsory license predominantly to the domestic market. The special export license under the System is free of such constraint, enabling and requiring the full production under a compulsory license to be exported.

13. Furthermore, the Study indicates a case study on supply of a triple combination ARV (zidovudine, lamivudine and nevirapine) to Rwanda, where a Canadian company used a special export license to ship the medicine to Rwanda. It also refers to two other cases where use of the Paragraph 6 system was reportedly considered. It then reports the discussions held in the TRIPS Council regarding the implementation of the System, including the diverse observations made by the WTO Members on whether the System is fulfilling its intended function. While full operational context of the Paragraph 6 System is still being mapped, the above Section concludes with the descriptions of the potential enabling environment and opportunities for future use of the System.

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2 See WHO-WIPO-WTO Trilateral Study "Promoting Access to Medical Technologies and Innovation: Intersections between public health, intellectual property and trade", page 117-180. The full text of the Trilateral Study is available at: www.wto.org/trilateralstudy.

3 See WHO-WIPO-WTO Trilateral Study "Promoting Access to Medical Technologies and Innovation: Intersections between public health, intellectual property and trade", page 224-230.

14. Annex II of the Study contains detailed explanations about the context and scope of the operation of the Paragraph 6 System as well as use and domestic implementation of the System.

15. The second document submitted by the WTO Secretariat is a summary of the WTO dispute settlement case DS114, "Canada – Pharmaceutical Patents" between the European Communities (complainant) and Canada (respondent). It summarizes the key panel findings with respect to the stockpiling provision[4], regulatory review provision[5] and burden of proof[6].

Innovation Insights

16. A well-functioning patent system encourages investments in research and enables valuable ideas to be expeditiously transformed into solutions that improve people's lives. The exchange of information between partners and "handoff" of promising research between institutions, firms, and other innovators – facilitated by patents and other forms of IPRs – is crucial to the development of solutions and their delivery, adaptation, and improvement.

17. In contrast, non-commercial technology transfer approaches based on broadening exceptions and limitations to patent protection are likely to be ineffective in, and even counterproductive to, accelerating technology innovation and diffusion. Government actions that reduce the availability or enforceability of patents can generate uncertainty in the marketplace, slowing the development and deployment of new technologies over the long term.

18. Innovation Insights submits the following points for consideration by WIPO members:

- Innovation critically depends on collaboration between all relevant organizations – public research institutes, universities, established firms, individual inventors, startups, and others – when conducting research and also when adapting and deploying solutions in the market. Collaboration permits the sharing of knowledge and capabilities, ensuring that technology advancement and deployment can benefit from a broader pool of ideas and resources;

- Quality, enforceable IP rights can help to direct resources towards innovation, while also supporting technical collaborations;

- The approach most likely to advance technological innovation as well as the deployment of new solutions on the ground is one based on voluntary technology partnering and technology transfer on mutually agreed terms;

- In contrast, policies that encourage non-commercial technology transfer can inhibit innovation investments, FDI, and knowledge sharing. In particular, policy tools like compulsory licensing can undermine the role that IP rights can play in facilitating the critical exchanges of knowledge that are most likely to boost absorptive capacity and economic development, especially in developing countries. While such instruments may be applied in specific, narrow contexts, encouraging their broader use is unlikely to stimulate technology and knowledge flows. Rather, they discourage innovators, whether domestic or foreign, from sharing technology and know-how;

- Incremental and adaptive innovations, i.e., novel refinements and improvements to existing solutions, deserve patent protection;

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4 In relation to Articles 28.1 and 30 of the TRIPS Agreement.

5 in relation to Articles 28.1 and 30 as well as Article 27.1 of the TRIPS Agreement.

6 in relation to Article 30 of the TRIPS Agreement.

- IP systems should be business model-neutral, supporting innovation in all its forms and across all fields of technology. IP policies should not be designed based on a static snapshot of an economy at a given moment in time;

- Finally, it is important to note that IP systems are only one component of a functioning enabling policy environment for innovation, the transformation of ideas to deployable solutions, and ultimately their utilization.

IPO

19. IPO members expend significant resources and take on considerable risk when developing a new technology, whether we are innovating anew or tailoring solutions to meet local needs. Intellectual property and patents, in particular, facilitate investments in such developments by providing the potential to recoup investment costs on successful technologies. This benefit of IP rights in fostering the development of new technologies has been well documented.

20. What might be less appreciated is that IP rights enable the exchange of practical details necessary to deploy and refine innovations. These vital interactions between technology developers, their suppliers, and other partners can accelerate the introduction of technology to more people and places. Essentially such collaborations help innovators move faster by allowing them to leverage expertise in many forms, including by gaining local insights, which help identify the most fruitful approaches to solve a given challenge.

21. Without a supportive policy framework in place, however, revealing or implementing the knowledge gained from innovative efforts can erode their investment value. There are compelling reasons to share information with those who can contribute to an innovator's success. If the result of information exchange, however, puts others in a position to use those developments without co-investing or otherwise participating, that would deter rather than encourage innovation. This is the main reason why the existence of robust local patent systems are essential; they underpin necessary and mutually beneficial collaborations by providing tangible reassurance that cooperation will not end up jeopardizing innovators' investments. For example, strong patent systems allow innovators to better leverage global supply chains.

22. Yet patent protection can only provide this support if patents are reliably obtainable and enforceable in local jurisdictions. The transfer of knowledge only works if innovators feel secure that patent rights will function as intended. Policies that encourage the weakening of patent rights create increased uncertainty. The use of exceptions and limitations to patent rights, for example exempting certain areas of technology from patent protection or imposing compulsory licensing, can impair innovators' desire and ability to collaborate with partners. These policies hinder the exchange of information and discourage investment and development, even if they are seldom implemented, and can leave countries without their much needed innovations.

23. Exceptions and limitations to patent rights can also negatively impact the Small and Medium-sized Enterprises (SMEs) otherwise poised to become an engine of economic growth for many countries. Many of these entities need partners to scale their solutions. When faced with uncertain patent protection in their country, however, SMEs can struggle to attract investors or partners.

24. Discussions within the SCP appear to indicate that at least some Member States view exceptions and limitations as a preferred policy to gain access to technology. IPO is concerned that this policy actually makes it more difficult for innovators to share what knowledge with

potential partners globally and to scale solutions for widespread deployment. Therefore, IPO suggests that policymakers consider that exceptions and limitations are a tool of last resort.

TWN

25. In its submission, TWN states that even though there is no systematic assessment of contribution of the TRIPS flexibilities to access to patented medicine among all WTO Member States, the experiences of various developing countries show that the use of TRIPS flexibilities facilitates access to patented medicine. For example, the use of compulsory licenses for HIV/AIDS and other medicines dropped the costs of treatment in various countries, e.g. Brazil, India, Malaysia and Thailand. In addition, Egypt and China rejected patents on sofosbuvir, using the flexibility on the threshold level of patentability.

26. However, there are structural constraints, which prevent many WIPO Members from using exceptions and limitations.

27. First, a lack of technological capacities, especially manufacturing capability, prevents many WIPO Member States from using exceptions and limitations to patent rights. For instance, the vast majority of the developing countries and all LDCs, except Bangladesh, lack the manufacturing capacity in the pharmaceutical sector. In the absence of local manufacturing capabilities, many developing countries cannot use the TRIPS flexibilities effectively without depending on another country. The amendment of Article 31(f) of the TRIPS Agreement failed to offer an effective solution to ease the restriction to issue compulsory licenses only for export purposes. The Agreement on Trade-Related Investment Measures (TRIMs) and other investment rules, which are part of the Free Trade Agreements (FTAs), also compromise the efforts of many developing countries to achieve self-sufficiency in manufacturing medical products by making the application of many local production stimulation tools like local content rule, export obligation, etc. illegal. Therefore, for countries not having manufacturing capability in the pharmaceutical sector, the incorporation and use of exceptions and limitations will not ensure access to patented medicine without the availability of a generic version of patented medicine in another country.

28. Second, due to the lack of institutional and administrative mechanisms, many developing countries do not incorporate the TRIPS flexibilities to the optimum level. Without the incorporation of flexibilities in the domestic law, it is impossible to use the TRIPS flexibilities. Furthermore, many countries do not have an examination system for patents, and therefore are not in a position to apply flexibilities on the scope of patentability. Even those countries having a patent examination system need resources and infrastructure to use the flexibilities related to patentability. Often, the technical assistance programs of developed countries and international organizations like WIPO are not directed to optimize the use the TRIPS flexibilities but to reduce the scope of flexibilities.

29. Third, the effective use of exceptions and limitations also depends on the existence of robust public health institutions. It is important to build up a public health objective while invoking compulsory licenses or government use such as prevalence of a disease condition and number of people requiring access to the medicine in question etc. The absence of such information alone prevents the use of the TRIPS flexibilities. In the absence of public health institutions to monitor diseases burden, medicine sales, availability of medicines etc., it would be extremely difficult to use these flexibilities, because such decisions would be challenged by the patent holder at the domestic courts. Further, there is no institutional mechanism in many developing countries to monitor the impact of patented drugs on access to medicine and to invoke timely measures like compulsory licenses or government use provisions to facilitate the introduction of affordable generic version of the patented medicine.

30. Four, often developed countries oppose the use of the TRIPS flexibilities and attempt to restrict the scope of flexibilities to only essential medicines. Developed countries exert political pressure on developing countries against the use of the TRIPS flexibilities. Apart from the political pressure, industry also exerts pressure on many developing countries against the use of exceptions and limitations to patent rights, such as compulsory license.

31. Fifth, there are attempts to influence the developing country judges in order to delay or reduce the use of exceptions and limitations to patent rights in developing countries.

32. Apart from the above-mentioned constraints, there are certain specific threats related to the use of exceptions and limitations. First, TRIPS plus obligations limit the scope of flexibilities by imposing such obligations on developing countries through FTAs. A working paper prepared by the WTO states that some 54 Regional Trade Agreements (RTAs) were found to contain at least one of the pharma-related provisions. It also found that the provision most frequently included in RTAs relates to patentability criteria and exclusions.

33. In addition, IP enforcement initiatives contain TRIPS plus enforcement provisions limiting the use of exceptions and limitations. For example, border measures are expanded to imports and exports and are applied to all forms of IP, although countries are obliged to apply border measures only to counterfeited trademarks and pirated copyrights. Most IP enforcement initiatives, except for patents, impose criminal sanctions on the infringer of IP rights. Furthermore, IP enforcement initiatives impose intermediary liabilities for the infringement of IP, and target the raw material suppliers to prevent them from cooperating with generic manufacturers.

34. Originator companies use voluntary licenses (VL) to prevent the use of the TRIPS flexibilities. VL with restrictive conditions would prevent the use of compulsory licenses and forestall competition in the market. Often VL would prevent the local production and allow the licensee to market the originator’s product with a different brand name. Furthermore, it imposes geographical restrictions on the licensee and often leaves out middle-income countries from the scope of the license.

35. Another important instrument used by pharmaceutical industry to deter developing countries from using TRIPS flexibilities are the investment protection clauses contained in the Bilateral Investment Treaties (BITs) and other international investment protection agreements like FTAs. International investment protection agreements contain provisions to protect the investment of foreign investors.

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