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MEMBER STATES' EXPERIENCES AND CASE STUDIES ON THE EFFECTIVENESS OF EXCEPTIONS AND LIMITATIONS

Document prepared by the Secretariat

1. At its twenty-second session, held from July 27 to 31, 2015, the Standing Committee on the Law of Patents (SCP) agreed that a compilation of Member States' experiences and case studies on the effectiveness of exceptions and limitations, in particular, in addressing development issues, would be prepared by the Secretariat. Pursuant to the above decision, Member States and regional patent offices were invited, through Note C. 8481, dated September 4, 2015, to submit information to the International Bureau on the above elements under the applicable law. This document contains a compilation of the information submitted by the following Member States: Australia, Colombia, El Salvador, Iraq, Japan, Mexico, Portugal, Switzerland and Tanzania (United Republic of). Taking into account the limitation of the volume of meeting documents under the WIPO language policy, this document summarizes the information received. The information in its entirety is available on the SCP electronic forum.[1]

Australia

2. IP Australia has not conducted research on the use and effect of the exemptions and limitations to patent rights, and in particular, in addressing development issues. However, while litigation concerning those provisions is rare, they can be relevant to the resolution of disputes between parties and the terms of licence agreements. Since such agreements tend to be confidential, the extent and effect of the exemptions and limitations remains difficult to determine.

[1] http://www.wipo.int/scp/en/meetings/session_23/comments_received.html.

3. In relation to specific development issues, Australia has implemented the TRIPS Protocol interim waiver (and the TRIPS Protocol, when it comes into effect) into our domestic legislation. Under the new scheme, Australian laboratories will be able to apply to the Federal Court for a compulsory license to manufacture generic versions of patented medicines and export these medicines to developing countries that are experiencing serious public health issues. IP Australia will monitor the effect of this implementation over the coming years.

Colombia

4. The Agreement on Trade-Related Aspects of International Property Rights (TRIPS) establishes exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties. In particular, Article 31 of TRIPS specifies the conditions for use of the subject matter of a patent without the authorization of the rights holder, for example, in matters of national emergency or other circumstances of extreme emergency. Similarly, Chapter VII of Decision 486 of the Andean Community considers the regime of compulsory licenses on the condition that the applicant for such licenses attempts to obtain prior approval of a contractual license from the patent holder.

5. In Colombia, the most relevant case involving exceptions and limitations in patent law concerns the combination of active ingredients known as lopinavir/ritonavir (Kaletra®). The following is a summary of the main reasons for granting the patent and the circumstances that resulted in the rejection of an application for a declaration of public interest as a pre-requisite for the compulsory licensing process.

6. The original patent application that was submitted to the Directorate of New Creations by the pharmaceutical company Abbott Laboratories included a combination of drugs known as lopinavir/ritonavir. It was registered under reference number 96-65280 on December 12, 1996, and benefitted from the priority rights based on the US applications US 08/572,226 dated December 13, 1995, and US08/753, 201 dated November 21, 1996. The first substantive examination gave rise to three divisional applications which were presented in compliance with Article 36 of Decision 486 relating to the division of the subject matter as contained in the initial application. The first application identified under number 96-65280 claimed a method for the chemical synthesis of lopinavir, the product obtained according to said method, i.e. the active compound lopinavir, pharmaceutical compositions containing said compound and formulations containing the pharmacological combination of HIV protease inhibitors lopinavir and ritonavir known under the trademark Kaletra®. The second application filed under reference number 96-65280A contained the chemical and functional structure of HIV viral protease inhibitor compounds defined in generic form by Markush formula (I) and a method for the chemical synthesis of antiretroviral compounds. The third application 96-65280B, which was derived from the original subject matter that was claimed in the parent application, claimed the chemical compounds 2S-(1-tetrahydro-pyrimid-2-onyl)-3-methylbutanoyl and (2S,3S,5S)-2-N,N-dibenzylamino-3-hydroxy-5-(2S-(1-tetrahydro-pyrimid-2-onyl)-3-methyl-butanoyl)amino-1,6-diphenylhexane, synthesis intermediaries used in the method for producing the viral protease inhibitor lopinavir. The application also claimed protection for the lopinavir (S) piroglutamate salt and for an alternate method of synthesis in order to obtain the active compound lopinavir.

7. The Department of Trade and Industry (SIC) conducted an examination of the patentability of each of the divisional applications under Articles 45 and 48 of Decision 486 and decided to grant a patent for the parent application 96-65280 and divisional application 96-65280B on the grounds that they met patentability requirements. Both patents were granted for a duration of 20 years from the filing date, i.e. December 12, 1996 until December 12, 2016 in accordance with Article 50 of Decision 486. In the case of divisional application 96-65280A, the

applicant was informed of the decision to reject the patent on the grounds that the prior art contained publications which anticipated the technical characteristics of the claimed compounds and method. For this reason the claimed subject matter was deemed to lack novelty and inventive step and therefore failed to meet the requirements for granting the right of exclusivity, as indicated in Articles 16 and 18 of Decision 486.

8. In the present case, the IFARMA Foundation and the Social Mission Foundation presented an application for a declaration of public interest and the Public Health Department of the Ministry of Social Protection provided the Department of Trade and Industry (SIC) with the necessary documentation. However, the Department of Trade and Industry stated that it lacked the legal competence to establish a procedure for declaring the existence of reasons of public interest, as indicated in Decree No. 4302 of 2008.

9. The Technical Committee tasked with the declaration of reasons of public interest in the Ministry of Social Protection issued an administrative act which initiated the administrative procedure for establishing if there were sufficient reasons to declare that, on the grounds of competition, access to Kaletra and its links with Abott as an interested third party, were of public interest. It concluded that access to the Kaletra product could not be declared to be of public interest and in Resolution 1444 of May 8, 2009 it stated the following *inter alia*:

(i) It had not been proven that there were problems in gaining access to the medicament known as Kaletra, since it was public knowledge that the medicament had been included in the Compulsory Health Plan.

(ii) The Price Regulator had included Kaletra in a list of medicaments with regulated price freedom.

(iii)According to the information that had been provided, there were no reasons to declare public interest on the grounds of competition.

10. In its ruling of February 29, 2012, Administrative Court No. 37 of the Judicial Circuit of Bogotá decided to order the Ministry of Health to initiate penalty proceedings for threats to and infringement of collective interests and the right to public health by maintaining internal prices for said medicament that were above and beyond international reference prices. It also ordered that the medicament should be included in a list of “parallel imports” so that the international reference price could be ensured in the domestic market and that FOSYGA could recover the losses that it had suffered. Subsequently, in its judgement of September 27, the Administrative Tribunal of Cundinamarca ordered the Ministry of Social Protection to bring the prices of the medicament into line and the Department of Trade and Industry began an investigation to determine whether Abbot had respected fixed reference prices. Once the investigation had been concluded, the Department of Trade and Industry decided to sanction ABBOTT LABORATORIES OF COLOMBIA S.A. for selling the medicament Kaletra ® to treat HIV/AIDS above the maximum allowed price (see Resolution No. 11990 of February 26, 2014). The penalty imposed by the Department of Trade and Industry gave effect to the ruling of the Administrative Tribunal of Cundinamarca on public interest litigation initiated on behalf of the REOLVIH Association. It is noteworthy that Circular No. 06 of 2013 included the product Kaletra® and its commercial forms in the direct price control regime and set a maximum retail price for its distribution and institutional networks.

11. The decision not to declare the use of the lopinavir/ritonavir medicament (Kaletra) as being of public interest was due to the fact that the Ministry of Social Protection had published a guide for managing infection caused by the HIV virus. The document contains a set of recommendations which have been systematically developed to assist health professionals in taking the appropriate decisions on how to treat patients in specific clinical conditions such as

those characterizing infection by the HIV virus. The guide is based on evidence from Colombia and contains a series of guidelines aimed at standardizing clinical practice, according to stricter quality parameters, for the treatment of patients that follow the pharmacotherapeutic recommendations based on scientific evidence.

12. In the specific case of antiretroviral therapy, the Ministry has indicated that there is sufficient evidence to initiate antiretroviral therapy in symptomatic patients and the patient's risk of advanced progression to AIDS or death, depending upon the characteristics of his or her infection in addition to the number of therapeutic regimens available, is the key factor to be considered when taking a decision on when to initiate therapy. According to the guide, there are no preferred pharmacotherapeutic regimens. However, this does not mean that any form of combined treatment should be initiated since some regimens are more efficient than others and the tolerance, toxicity, convenience and possibility of affecting previous regimens can vary.

El Salvador

13. With respect to acts for experimental purposes or scientific, academic or educational research (Intellectual Property Act, Art. 116(c)), some Salvadorian inventors have in their patent applications referred to patents that are in force as part of the state of the art of their inventions. Further, during the workshops on patent search and drafting, databases such as Espacenet, Patentscope, LATIPAT and INVENES are used to locate granted or pending patents. As regards compulsory licenses, to date, none have been granted.

Iraq

14. The intellectual property is an important element in the institutional infrastructure to encourage private investment in research and development, particularly in the industrial, scientific and commercial fields. The TRIPS Agreement, which led to increased awareness among policy makers with respect to patents and its role in economic development.

15. The role of the patent system in the economic development depends on different industries and contrast between countries. Patents can adopt a leading role in turning innovative ideas and inventions into competitive products and market them successfully. The Industrial Property Division/Iraqi Patent Office plays a major role in promoting patents through the publication of patents on internet sites, by publishing in scientific journals as well as by connecting all the relevant ministries and providing them with summaries of patents in diverse disciplines that are compatible with the work of those ministries and government institutions.

Japan

16. A court case on an herbicide in 1987 was the first case in which the scope of "experimental or research purposes" under Article 69(1) was defined.[2] The point in dispute was whether experiments, which were conducted on the effects of the herbicide for registering and selling it as an agricultural chemical, fell under the exceptions stipulated under Article 69(1). The court determined that such experiments did not fall under those exceptions because they were conducted exclusively for the purpose of selling the herbicide, not for the purpose of advancing technologies on it. However, few judicial precedents regarding the general interpretation of "experiments and research" under Article 69(1) have been set. One generally accepted academic theory is that the scope of "experiments or research" to which the effects of patent rights are not extended should be limited to those conducted for the purpose of

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[2] Tokyo District Court, July 10, 1987 (Case No. 7463(wa) of 1985).

"technological advancement," i.e. patentability searches, function searches, and experiments for the purpose of technological improvements and development.

17. Opinions are divided on whether clinical investigations needed for filing applications seeking approval for manufacturing generic drugs fall under "experiments or research," to which the effects of patent rights are not extended. Both academic theories and court decisions are divided on this issue. In the Supreme Court decision on a case concerning generic drugs,[3] the Court recognized the following: (i) if any clinical investigations needed for getting approval of manufacturing generic drugs were not able to be conducted during the time when the patent rights are effective, this would substantially result in third parties not being freely able to use the patented inventions for a considerable length of time, even after the patent rights have expired; and (ii) patent right holders can ensure their economic benefits based on the exclusive licensing of their patented inventions. Consequently, the Court ruled that any working of patented inventions for the purpose of clinical investigations that are needed for getting approval for manufacturing drugs would be regarded to be "experiments and research" under Article 69(1). Since the Supreme Court based its decision on the regulations under the Pharmaceutical Affairs Act, the scope of the decision may be extended to patented inventions for cosmetics, medical equipment, and agricultural chemicals.

18. Until now, 23 requests for compulsory licenses were filed with respect to patents, utility models, and designs. Among them, nine were based on the claim that the inventions had not been worked, and 14 involved the interests of use. All of them, however, were withdrawn before grant of any award.

Mexico

19. The Mexican Government has adopted the so-called regulatory exception, also known as the Bolar clause or exception. While Article 25 of the Industrial Property Act establishes the exclusive rights conferred by a patent, the Health Commodities Regulations were adopted by a Decree published in Mexico's Official Gazette on September 19, 2003. Article 167*bis*, paragraph 3 of the Regulations establishes that registration of the generic form of a drug whose active substance or ingredient is patent-protected may be requested during the three years prior to the patent's expiration for the purpose of conducting research, tests and experimental production, on the understanding that, in such cases, sanitary registration shall not be granted until the patent has expired; this makes it possible to import a primary or active substance that is patent-protected. The application of this exception has been successful, since generic drugs have been granted sanitary registration in a timely and adequate manner, and respecting patent rights.

20. Concerning the flexibility granted to developing countries on the implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and public health, Mexico has stipulated that it will only use the system as an importer in the event of a national emergency or under other circumstances of extreme urgency. No such eventuality has occurred and to date, no public utility license has been granted despite the provisions of Article 77 of the Industrial Property Act.

21. Except for the granting of the public utility licenses mentioned in the second and third paragraphs of this Article, other licenses shall be granted in accordance with the second paragraph of Article 72. None of the licenses mentioned in this Article shall be exclusive or transferable.

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[3] Second Petty Bench of the Supreme Court, April 16, 1999 (Case No.153(ju) of 1998) (Minshu 53 (4) 627).

Portugal

22. Concerning the exception with respect to acts performed exclusively for trial or experimental purposes (Industrial Property Code, Article 102(c)), Portugal enacted Law 62/2011 of December 12, 2011, which created a composition scheme for disputes concerning industrial property rights relating to reference medicines and generic drugs, including injunctive procedures. Following the legislation, companies have to solve their disputes by mandatory arbitration in arbitration courts. After the submission of a marketing authorization by a generic company, the patent proprietor has 30 days to present an opposition before the arbitration court; after the communication of the opposition, the generic company has 30 days to reply. The arbitration decision may be appealed to the competent court of law. The law clarifies that acts concerning the granting of marketing authorization, selling price to the public and reimbursement of medicines are not contrary to the rights relating to patents or supplementary protection certificates, and the law makes clear that marketing authorizations applications, selling price to the public and reimbursement of medicines cannot be rejected due to the existence of industrial property rights.

Switzerland

Instruments of Research

23. In Switzerland, patents are available for inventions in any area of technology, as prescribed by the constitutional principle of equal treatment and Article 27 of the TRIPS Agreement. However, certain patentable biotechnological inventions can be commercial end products for patent holders, while important research tools for others. To facilitate access to these important tools without inhibiting the future development of such instruments, the Swiss legislator has introduced a right to a non-exclusive license with regard to the use of research tools under Article 40b of the Patents Act. Thus, in cases where the patented biotechnological invention is used as a research tool, in particular, for the purposes of carrying out tests or developing a new pharmaceutical product, the interested person shall first seek a voluntary licence from the patent holder, and if the latter refuses, the interested person may apply to the court for the grant of a licence to use the invention in question (Article 40e Patents Act).

24. Article 40b was introduced at the last revision of the Patents Act in 2007, which entered into force on July 1, 2008. Proceeding revision, the Swiss Federal Institute of Intellectual Property undertook a survey to find out shortcomings within the then Swiss legislation and to obtain a reliable empirical basis for the revision of the patent law. The study did not find a systematic abuse of the existing patent system, and the results confirmed that the patent system is “an important incentive for investment in research and development in the field of biotechnology”, and that “patens and licenses for biotechnological inventions are considered an important incentive to stimulate research, knowledge flows and the entry of new technologies into markets”. The findings make clear that patents are important for small- and medium-sized companies, in particular for the acquisition of venture capital. The survey participants expressed difficulties with DNA patents and their impact on research and further development. Consequently, the Swiss legislator introduced a statutory research exemption in Article 9 Patents Act. Situations where an invention is used as a research tool, which require a license under Article 40b, are to be distinguishing from those where a patented invention is used with the aim to obtain knowledge about the subject-matter of the invention. The latter research exception is addressed by Article 9(1)(b) of the Patents Act and does not require a licence. In the Swiss Federal Council’s view, it was not advisable to extend the application of Article 9(1)(b) to the use of inventions as a research tool, as this would jeopardise a number of companies specialising in the discovery and development of research tools and would eliminate any

interest in research and development in the biotech sector. Instead, the Swiss legislator guaranteed access to research tools through legal non-exclusive licenses.

25. Article 40b Patents Act is applicable exclusively in the biotechnological field. The regulation comprises any "application integrated in biochemistry, molecular biology, microbiology and engineering processes with the aim of technical use of all or parts of the potential of microorganisms, cell and tissue cultures." The scope and duration of such a licence are to be determined by the judge based on the needs of the research project. So far no actual cases under Article 40b Patents Act are known.

Farmers' Use of Patented Invention

26. The farmers' exception prescribed in Article 35a(1) and (2) of the Patents Act is subject to a number of restrictions. Firstly, it applies only to farmers and does not extend to breeders or those practicing horticulture and arboriculture. Secondly, under Article 35b of the Patents Act, it is limited to plant species which are of "importance as raw materials for food and feed." Thirdly, the reproduction must take place on farmer's own farm. So far no actual cases under Article 35a Patents Act are known.

Compulsory Licenses for the Export of Pharmaceutical Products to Developing Countries

27. The inclusion of a new type of compulsory licenses under Article 40d in the 2007 revision of the Patents Act gives effect to the Decision of the WTO General Counsel "Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and public health", ratified by Switzerland in 2006. Countries that have declared in the WTO that they wholly or partly renounce their claim to a licence are excluded from being beneficiary countries. What is more, pursuant to Article 40d(3), the license is "limited to the production of the pharmaceutical product in the quantity that meets the requirements of the beneficiary country; the total quantity must be exported to the beneficiary country." The compulsory license may not be requested by an importing country, but only by an enterprise that has the capacity to produce the patented pharmaceutical product in question. Such a licence is a non-exclusive licence and is subject to payment of adequate remuneration, taking into account the economic situation of the beneficiary country. So far no actual cases of compulsory licenses under Article 40d Patents Act are known.

Cases related to exceptions and limitations

28. Switzerland's cases related to exceptions and limitations to patents concern basically licenses for dependent rights (Article 36 Patents Act). A few decisions have been issued since the introduction of the regulation more than 100 years ago. The provision was revised and the actual text entered into force July 1, 1995.

29. Under the revised provision, one decision[4] has been issued. The case concerns two patents in the field of concrete formwork. According to the cantonal court, the requirements for obtaining a sub-license are: (i) a valid later patent; (ii) the use of the later patent would constitute an infringement of the prior patent; and (iii) the later patent represents an important technical advance of considerable economic significance in relation to the invention that is the subject-matter of the prior patent. Criteria to determine the term "important technical advance" under Article 36(1) Patents Act are: (i) the later invention creates a procedural simplification or procedural acceleration; (ii) it is less susceptible to operational faults; or (iii) it solves the same

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[4] HG BE, sic! 2006, p. 348, c. 4, Anschlaghalter III (in German).

problem in a different way. The important technical advance in relation to the prior patent is only given in case that there was need for a substitute or additional solution. A criterion to determine the “considerable economic significance” under Article 36(1) Patents Act is the value of the invention for the holder of the later patent. In the case of low demand for the patented product, the importance of the invention for the patent holder is also considered as minor. Because of lack of need for an improvement and low demand for the product based on the later patent, the Court considered that neither an important technical advance nor a significant commercial relevance is given. In consequence the conditions for granting the license were not met.

Tanzania (United Republic of)

30. The United Republic of Tanzania administers the Patents Registration Act Cap 217 R.E.2002 and the Industrial Property Act of 2008 of Tanzania- Zanzibar that enjoys an independent jurisdiction including intellectual property matters. Section 37 of the Patents Registration Act provides that the scope of protection under the patent shall be determined by the terms of the claims; nevertheless, the description and the drawings included in the patent may be used to interpret the claims. In essence, the elasticity of the extent to which the scope of protection is capable of being stretched under the law, is subject to determination by the Registrar of Patents, which is appealable to the court as preferred at the instance and by any person affected or likely to be affected by such determination pertaining to the scope of protection.

31. According to Section 38 of the cited law, the rights under the patent shall extend only to acts done for industrial or commercial purposes and in particular not acts done for scientific research. Therefore, scientific research activities are capable of being carried out and or conducted free from and of any obligation that falls in the exercise of patent rights except for industrial or commercial purposes. Despite the fact that the strict interpretation of the foregoing provisions exonerate scientific researchers from any liability arising from an exercise of entitlement or enforcement of patent rights, there is no show case that demonstrates any set of parameters used for measuring the demarcation line between the scientific research for industrial or commercial purposes within the meaning of the foregoing provisions. In essence, any such scientific research conducted, for example, to meet educational interests, unless disputed, shall constitute a scientific research conducted for non-industrial or commercial purpose.

32. Section 62 of the cited law provides that where a vital public interest (in particular, national security, health or the development of vital sectors of the public economy) so demand interference with patent rights otherwise granted to the patentee, such patent shall be exploited by or through the Government subject to payment of remuneration as fixed and or determined by the Registrar of patents.

33. The submission by Tanzania also contains information concerning exclusions from patentable subject matter, in particular, Sections 12 (against public order and morality) and 13 (certain kinds of products and processes temporarily excluded from patentability). Further, it refers to Section 16(1) which regulates the right to a patent for an invention made in execution of a commission or of an employment contract. In addition, the submission includes the description of the Harare Protocol on Patents and Industrial Designs within the Framework of the African Regional Industrial Property Organization (ARIPO), particularly on the point that the protection of a patent granted by ARIPO is not automatically accorded in its Member States.

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