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Information to the International Bureau on experiences and case studies on the effectiveness of exceptions and limitations, in particular, in addressing development issues (note C. 8481)

The information is provided on behalf of:

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1. Exceptions and limitations under the Swiss Patent Law - General

The Swiss Federal Act on Patents for Inventions (hereinafter: the Patents Act) of 25 June 1954, as amended in 2007, contains a number of provisions setting out exceptions and limitations to patent rights. In particular, Article 9 (1) of the Patents Act provides for general exceptions to effects of the patent, whereas Article 29 and Articles 37-40 contain rules on compulsory licenses. Situations of dependent inventions and dependent plant variety rights are governed by Article 36 of the Patent Act, and the farmers' privilege exception is contained in Article 35 a. Furthermore, Article 35 (1) lays down the prior use exception and Article 35 (3) governs the use of articles on vehicles which are only temporarily in Switzerland. Finally, Article 9 a addresses the issue of exhaustion of patent rights. Further information on the exceptions and limitations to patent rights and the relevant articles is SCP Forum available Electronic website at on http://www.wipo.int/scp/en/exceptions/replies/suisse.html.

2. Particular exception and limitation provisions under the Patents Act

a) Instruments of Research - Article 40 b of the Patents Act

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. Thus, biotechnological inventions are patentable as long as they meet the conditions of novelty, inventive step and industrial applicability.

However, certain patentable biotechnological inventions can be commercial end products for patent holders, while important research tools for others. An important example is the polymerase chain reaction. These research tools may serve as indispensable auxiliaries for research and development of medicinal products. 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. According to **Article 40 b of the Patents Act**, "any person who intends to use a patented biotechnological invention as an instrument or means for research is entitled to a non-exclusive licence." 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,



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the interested person may apply to the court for the grant of a licence to use the invention in question, Article 40 e Patents Act.

Article 40 b is one of the provisions introduced at the last revision of the Patents Act in 2007, which entered into force on 1 July 2008. Proceeding revision, the Swiss Federal Institute of Intellectual Property undertook a survey asking research institutes and private companies in the field of biotechnology about their positions on problematic issues in biotechnology research and patenting¹. Its main objectives were to find out shortcomings within the then Swiss legislation and to obtain a reliable empirical basis for the revision of the patent law in Switzerland.

The study did not find a systematic abuse of the existing patent system for biotechnological inventions in Switzerland². 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"3. 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 licence under Article 40 b, are to be distinguish 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 this field of the biotech sector⁴. Instead the Swiss legislator guaranteed access to research tools through legal non-exclusive licenses.

Article 40 b 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 40 b Patents Act are known.

b) Farmers' Use of Patented Invention - Article 35 a of the Patents Act

Pursuant to Article 35 a (1) of the Patents Act, "farmers who have acquired plant reproduction material placed on the market by the proprietor of the patent or with his consent may reproduce, on their own farm, the product from this material cultivated on their own farm." Likewise, paragraph 2 states that "farmers who have acquired animal reproductive material or animals places on the market by the

¹ Thumm, N., "Research and Patenting in Biotechnology. A Survey in Switzerland," <u>Swiss Federal Institute of Intellectual Property</u>, Publication No. 1 (12.03) [hereinafter Thumm N., 2003] available at https://www.ige.ch/fileadmin/user_upload/Juristische_Infos/e/j10005e.pdf

² Thumm N. / Technovation 25 (2005) 1410–1417, at 1416.

³ Thumm N., 2003, p. 62.

⁴ Message concernant la modification de la loi sur les brevets et l'arrêté fédéral portant approbation du Traité sur le droit des brevets et du Règlement d'exécution, Swiss Federal Council, 23 novembre 2005, p.73 [hereinafter: Message LB].

⁵ Message LBI, p.141.



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proprietor of the patent or which his consent may reproduce, on their own farm, the animals obtained through reproduction of this material or these animals on their own farm."

The farmers' exception 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 35 b 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 35 a Patents Act are known.

c) Compulsory Licences for the Export of Pharmaceutical Products to Developing Countries – Article 40 d of the Patents Act

Article 40 d (1) states that: "Any person may bring an action before the court to be granted a non-exclusive licence for the manufacture of patent-protected pharmaceutical products and for their export to a country that has insufficient or no production capacity of its own in the pharmaceutical sector and which requires these products to combat public health problems, in particular those related to HIV/AIDS, tuberculosis, malaria and other epidemics."

The inclusion on this new type of compulsory licences 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" of 30 August 2003, ratified by Switzerland in 2006, which establishes a mechanism allowing WTO Members to manufacture and export patented pharmaceutical products under a compulsory licence to countries that cannot make medicines themselves.

Countries that have declared in the World Trade Organization that they wholly or partly renounce their claim to a licence are excluded from being beneficiary countries. What is more, pursuant to Article 40 d (3), the licence 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 licence 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 40 d Patents Act are known.

3. Cases related to exceptions and limitations

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.

Article 36 Dependent inventions:

1 If a patented invention cannot be used without infringing a prior patent, the proprietor of the later patent has the right to a non-exclusive license to the extent required to use his invention, provided that the invention represents an important technical advance of considerable economic significance in relation to the invention that is the subject-matter of the prior patent.



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2 A license to use the invention that is the subject-matter of the prior patent may only be transferred jointly with the later patent.

3 The proprietor of the prior patent may make the grant of a license conditional on the proprietor of the later patent granting him a license to use his invention in return.

Related case law:

- a) Two cases were decided under the former Article 36 Patents Act:
- BGE 29 II 564 c. 8 (f.) Schülerpult (from the year 1903):
 The court analysed in detail the conditions for granting sub- licenses for dependent inventions.
- BGE 42 II 269 c. 2 (f.) Transformer (from the year 1916): The court fixes the modalities for remuneration for granting a sub-license.

Another case discussed the conditions of the former Article 36 Swiss Patent Act in the course of an infringement proceeding:

- BGer 18.1.1990, SIM 1991, 198 E. 4b Doxycyclin III
 The court discussed the difference between imitation and reproduction and dependency of a later patent in relation to a prior right.
- b) Under the revised provision one decision has been issued:

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

The case concerns two patents in the field of concrete formwork. According to the cantonal court the requirements for obtaining a sub-license are:

- A valid later patent
- The use of the later patent would constitute an infringement of the prior patent
- 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" Article 36 (1) Patents Act:

- The later invention creates a procedural simplification or procedural acceleration, or
- it is less susceptible to operational faults, or
- it solves the same problem in a different way. Here 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" 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.