

Standing Committee on the Law of Patents

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EXCEPTIONS AND LIMITATIONS TO PATENT RIGHTS: FARMERS' AND/OR BREEDERS' USE OF PATENTED INVENTIONS

Document prepared by the Secretariat

INTRODUCTION

1. At its twentieth session, held from January 27 to 31, 2014, the Standing Committee on the Law of Patents (SCP) agreed that, in relation to the topic "exceptions and limitations to patent rights", the Secretariat would prepare, *inter alia*, a document, based on input received from Member States, on how the following four exceptions and limitations were implemented in their countries or regional systems, without evaluating the effectiveness of those exceptions and limitations: (i) acts for obtaining regulatory approval from authorities; (ii) exhaustion of patent rights; (iii) compulsory licensing and/or government use; and (iv) exceptions and limitations relating to farmers' and/or breeders' use of patented inventions. The document should also cover practical challenges encountered by Member States in implementing them.
2. Pursuant to the above decision, the Secretariat invited Member States and Regional Patent Offices, through Note C. 8343, dated March 10, 2014, to submit information to the International Bureau in addition to, or updating, the information contained in their responses to the Questionnaire on Exceptions and Limitations to Patent Rights on the above four exceptions and limitations. In addition, Member States and Regional Patent Offices which had not yet submitted their responses to the questionnaire were invited to do so.
3. Accordingly, this document provides information on how exceptions and limitations regarding farmers' and/or breeders' use of patented inventions have been implemented in Member States. The document aims at providing a comprehensive and comparative overview of the implementation of this exception under the applicable laws of Member States. Reference is made to the original responses submitted by the Member States and a regional patent office to clarify the scope of the exception in a particular jurisdiction. The Questionnaire and

responses are available in full on the website of the SCP electronic forum at: <http://www.wipo.int/scp/en/exceptions>. With a view to facilitating access to the information contained in the responses, the website presents all responses in a matrix format with hyperlinks to each section in each response.

4. This document consists of four sections: (i) Background; (ii) Public Policy Objectives for Providing the Exception; (iii) The Applicable Law and the Scope of the Exception; and (iv) Implementation Challenges.

BACKGROUND

5. The following Member States indicated that their applicable laws provided for exceptions and/or limitations related to farmers' and/or breeders' use of patented inventions: Albania, Austria, Bosnia and Herzegovina, Brazil, Bulgaria, Croatia, Czech Republic, Denmark, Finland, France, Germany, Greece, Latvia, Lithuania, Mexico, Netherlands, Norway, Poland, Portugal, Republic of Moldova, Saudi Arabia, Serbia, Slovakia, Spain, Sweden, Switzerland, United Kingdom, Viet Nam (28 in total).

6. Compared with other kinds of exceptions and limitations, the number of countries that have introduced exceptions and limitations relating to farmers' and breeders' use of patented invention is smaller. This may be due to the fact that, first, if plants and animals are excluded from patentable subject matter, there is no need to provide an exception for farmers and breeders to use plant or animal inventions.¹ Second, national laws may vary with respect to the scope of the right conferred by a patent on self-reproducible material, i.e., to what extent the scope of a patent on biological material extends to propagated or multiplied biological material that possesses the same characteristics as the patented material. Consequently, the necessity of providing specific exceptions and limitations as well as the applicability of the general exhaustion rule on such further propagation or multiplication may also vary among Member States.

7. The responses from the above Member States revealed that, in general, there are mainly four types of exceptions and limitations in this area:

(i) where plant propagating material is sold or commercialized by the patent holder or with his consent to a farmer for agricultural use, the farmer is authorized to use the product of his harvest for further propagation/multiplication on his own farm; similarly, the sale etc. of animal reproductive material by the patent holder or with his consent implies authorization for the farmer to use the protected livestock for an agricultural purpose (hereinafter referred to as "farmers' use");

(ii) the patent right does not extend to propagated/multiplied biological material obtained from the biological material placed on the market by the patent holder or with his consent, if the propagation/multiplication necessarily results from the application for which the biological material was marketed, provided that the material obtained is not subsequently used for other propagation/multiplication (hereinafter referred to as "use of propagated material for its marketed purpose");

(iii) the patent right does not extend to acts for creating or developing a new plant variety (hereinafter referred to as "development of a new plant variety"); and

¹ See the response from India.

(iv) where a breeder cannot exploit a plant variety right without infringing a prior patent, a compulsory license may be issued. In such a case, the holder of the patent is entitled to a cross-license on reasonable terms to use the protected plant variety (hereinafter referred to as “compulsory cross-licenses”).

8. Since Directive 98/44/EC of the European Parliament and of the Council of July 6, 1998, on the legal protection of biotechnological inventions regulates the exceptions and limitations to the patent rights regarding (i), (ii) and (iv) above², it is not surprising that countries that answered this particular section of the Questionnaire are predominantly from Europe.

9. Some countries responded to this section of the Questionnaire with respect to farmers’ and breeders’ exceptions to plant variety rights, instead of patent rights.³ While such information, available on the SCP Electronic Forum website, is also informative, this document does not cover that type of information, since the SCP has been examining exceptions and limitations to patent rights.

PUBLIC POLICY OBJECTIVES FOR PROVIDING THE EXCEPTION

10. In general, the responses from the Member States stated that the purpose of the farmers’ and breeders’ exception was to balance the interests of a patent owner and farmers and breeders, pursuant to the sale of the patented product. For example, the response from France explained that the exception links patent rights and plant/animal reproduction laws. The response from Portugal stated that the policy objective is to “avoid abuse of the monopoly that is granted with a patent, and to protect the farmers’ rights”. Looking more closely, each type of exception listed in (i) to (iv) above involves a different policy consideration.

Agricultural use of propagated plants and reproduced animals by farmers

11. In general, the policy objective of the exception was that farmers should be able to use propagated or reproduced biological material under patent protection, if it is used for the purposes for which it was sold, i.e., agricultural use. The responses from Austria and Germany stated that the “objective is to allow the farmer to use a part of his harvest product again for planting even if the propagating material is patented, since the seeds are intended for agricultural use and were sold for this purpose” and that this “applies *mutatis mutandis* to the reproduction of animals”.

12. Some Member States noted the similarity of farmers’ exception to private and non-commercial use or the implementation of the exhaustion rule.⁴ For example, the response from Spain explained that farmers’ use of propagated plants and reproduced animals “resembles the use of protected inventions in a private capacity and not for commercial purposes, since its use remains restricted specifically to the needs of agricultural or livestock breeding activities”. Similarly, the response from Serbia emphasized that the exception “[m]ay not be used for commercial purposes”.

² Many countries referred to Article 11(1) of the Directive 98/44/EC of the European Parliament and of the Council of July 6, 1998 on the legal protection of biotechnological inventions and Article 14 of the Council Regulations (EC) No. 2100/94 of the Council of the European Union of July 27, 1997 on Community Plant Varieties Rights (Official Journal L 227) (Denmark, Finland, France, Germany, Slovakia, Spain and Sweden) or EU Law in general (Latvia, Lithuania and the Netherlands).

³ See the responses from Argentina, Bhutan, Burkina Faso, France, India, Israel, the Philippines, the Republic of Korea, South Africa, Sudan, Uganda and the United States of America.

⁴ See the response from Norway.

13. Some Member States put emphasis on the importance of the development of new varieties for agricultural production. For example, the response provided by Mexico stated that “the conventional activity of farmers to use live material as a source of variation (to obtain new varieties) shall not be considered a sanction”. The response from Spain noted that free use of seeds or animal reproduction material by farmers should be permitted for “developing and protecting agricultural and livestock production”.

Acts for creating or developing new varieties

14. Some Member States considered that the development of new plant varieties was a policy objective underpinning the exception allowing third parties to use patented biological material. For example, the response from Mexico stated that the aim of the exception was “not to hamper technological development, allowing activities that promote and foster inventive industrially applicable activity, technical improvements and the dissemination of technological knowledge within the field of patents relating to living material”. The response from Switzerland explained that “[t]he breeders’ privilege accorded by the Law on the Protection of Plant Varieties and the related issue of patent protection should be mentioned in connection with the experimental use privilege. The breeders’ privilege is a significant restriction on the Law on the Protection of Plant Varieties which makes possible not only the breeding and development of new plant varieties but also, at the present time, their commercialization without the permission of the legitimate owner of the original plant variety”.

Compulsory cross-licensing of patents and plant variety rights

15. The response from France stated that the policy objective of a compulsory cross-license procedure as a limitation to patent rights as well as plant variety rights was to “encourage patent owners to grant a license voluntarily”.

THE APPLICABLE LAW AND THE SCOPE OF THE EXCEPTION

Agricultural use of propagated material or livestock by farmers

Scope of patent rights on biological materials

16. A number of Member States which provide farmer’s use exception clarified that, as a general rule, the protection conferred by a patent on biological material possessing specific characteristics as a result of the invention extended to any biological material derived from that biological material through multiplication or propagation in an identical or divergent form and possessing those same characteristics.⁵ The response from Austria specified that biological materials were only protected if they were “directly derived” from the patented biological material. Similarly, the protection conferred by a patent on a process to produce biological material extends to biological material directly obtained through that process.

General scope of an exception for agricultural use of propagated material or livestock by farmers

17. As derogation from the above patent rights, certain Member States provide for an exception for agricultural use of propagated material or livestock by farmers. As regards plant propagating material, in general, their laws state that the sale or any other form of commercialization of plant propagating material to a farmer by the patent holder or with his

⁵ For example, Section 22b(1) of the Austrian Patent Act 1990.

consent for agricultural use implies authorization to the farmer to use the product of his harvest for propagation or multiplication by him on his own farm.⁶

18. With respect to animal reproductive material, in general, the sale or any other form of commercialization of breeding stock or other animal reproductive material to a farmer by the patentee or with his consent implies authorization to the farmer to use the protected livestock for an agricultural purpose.⁷ This includes “making the livestock or other animal reproductive material available for the purposes of pursuing his agricultural activity”, but not the “sale”⁸ or “commercial exploitation” within the framework, or for the purpose of, a commercial reproduction activity.

Implied authorization by commercialization

19. The exception is provided under the concept of implied authorization included in the sale of the materials. The law of the Czech Republic provides that the materials “being subject of patent” have to be received “from its holder or with his consent” in order for use for agricultural activities to be authorized.⁹ The response from Bulgaria specified that the “selling or any other form of trading comprises an authorization for the agricultural producer to use the product for his harvest for propagation or multiplication purposes in his farm”.¹⁰

Use for farming, agricultural or non-commercial purposes

20. In general, the farmers’ use exception does not cover the “commercial exploitation”, “commercial reproductive activity” or the “sale within the framework of a commercial reproduction activity”. As specified in the responses from Denmark and France, many national laws apply the exception to the use of the product of farmer’s harvest for reproduction or propagation by himself on his own farm.¹¹ In Greece the exception regarding use of harvested product and livestock by a farmer allows him/her to pursue his/her own agricultural activity.¹²

21. With respect to farmers’ use of an animal or animal reproductive material for an agricultural purpose, many Member States clarified that while such use included a farmer’s use of animal reproductive material for his agricultural activities, it did not cover a farmer’s use of animal reproductive material in relation with business, such as a commercial reproduction activity. For example, the response from the United Kingdom stated that a farmer was not allowed to sell any animals or animal reproductive material derived from “his agricultural use of the original animal or material as part of a commercial reproduction activity”. In Latvia, the permission shall include the offering of an animal or the reproductive material of animals for the

⁶ For example, Article 75(3) of the Patent Law (Official Gazette of Bosnia and Herzegovina No. 53/10); Section 22 of the Austrian Patent Act; Article 23(3) of the Law 50/2008 on the Protection of Invention of the Republic of Moldova; Article 65(3) of the Croatian Patent Act (Official Journal Number 173/2003, 87/2005, 76/2007, 30/2009, 128/2010 and 49/2011); Section 3b(2) of the Consolidate Patents Act of Denmark (Act No. 91 of January 28, 2009); Section 19(4) of the Latvian Patent Law; Section 3b(1) of the Finnish Patents Act; Section 3b(1) and (3) of the Norwegian Patents Act; and Section 16(3) of the Slovakian Patent Act (Act No. 435/2001 Coll. on Patents, Supplementary Protection Certificates).

⁷ For example, Article 38 of the Law No. 9947 on Industrial Property of Albania.

⁸ For example, Section 22c(3) of the Austrian Patent Act; Article 75(2) of the Patent Law (Official Gazette of Bosnia and Herzegovina No. 53/10); similarly, Section 22 of the Austrian Patent Act.

⁹ Article 65(2) of the Czech Patent Act (Act No. 527/1990 Coll. on Inventions and Rationalization Proposals.

¹⁰ Similarly, Article 65(3) of the Patent Act (Official Journal Number 173/3003, 87/2005, 76/2207, 30/2009, 128/2010 and 49/2011) Patent Act; Section 3b(2) of the Consolidate Patents Act of Denmark (Act No. 91 of January 28, 2009); Section 3b(1) of the Finish Patents Act (No. 550/67 of December 15, 1967, as last amended by Act No. 954/2010 of November 12, 2010).

¹¹ Section 3b of the Consolidate Patents Act of Denmark (Act No. 91 of January 28, 2009); L613-5-1 French Intellectual Property Code (CPI).

¹² Article 9(1) of the Presidential Decree 321/2001 of Greece; similarly Article 38 of the Law No. 9947 on Industrial Property of Albania “for the purposes of his agricultural activity”.

performance of agricultural activities.¹³ In Spain, a farmer may continue “his activity for farming or breeding activity, but not the sale in the context of a commercial reproductive activity or for such purposes” and that the “scope and arrangements should correspond to those established by Law”. The response from Spain, however, noted that such legal development was still to occur.

Conditions for and restrictions on the farming activities allowed

22. Some Member States provide for specific restrictions of the farmers’ use or set certain conditions, such as the payment of remuneration. The response of the Netherlands specified that the conditions were set by Article 14 of the Regulation (EC) No. 2100/94 and the Implementing Regulation No. 874/2009. For example, (i) the exception on plant propagating material applied only to certain agricultural plant species; (ii) there shall be no quantitative restriction of the level of the farmer’s holding to the extent necessary for the requirements of the holding; (iii) the product of the harvest may be processed for planting, either by the farmer himself or through services supplied to him, subject to national restrictions; (iv) small farmers shall not be required to pay any remuneration to the holder; (v) other farmers shall be required to pay equitable remuneration to the holder, which shall be sensibly lower than the amount charged for the licensed production of propagating material of the same variety in the same area; and (vi) the actual level of such equitable remuneration may be subject to variation over time, taking into account the varieties under the exception. Similarly, the United Kingdom reported that the conditions in its law include “(i) the requirement that a farmer (other than a ‘small farmer’) must pay equitable remuneration to the proprietor (which must, however, be less than the farmer would have paid for buying more plant propagating material from the proprietor); and (ii) certain specified information must be supplied by the farmer and by the proprietor, on request from the other”.¹⁴

23. The response from Poland stated that the extent of and conditions for farmers’ use of patented biological material shall be the same as the farmers’ exception under the national plant variety protection law.¹⁵ The response from Norway stated that “the King may, by regulation, determine the conditions and the extent of the farmers’ rights”, but the “farmer should not have to pay a remuneration”.

24. In Denmark, the conditions of farmers’ exploitation of animal reproductive material are laid down by the Minister of Economic and Business Affairs¹⁶, while in the United Kingdom, the farmers’ use exception with regard to animal materials applies without restrictions “to all varieties of animals”.

25. In Switzerland, farmers must obtain the consent of the patentee in order to transfer to a third party, for the purposes of reproduction, the product of crops, animals or the reproductive animal material. “All agreements restricting or invalidating the farmers’ privilege with regard to food and animal feed shall be void” in Switzerland. The response from Sweden stated that the right of a farmer “must not be exercised to an extent wider than what is reasonable, taking into account the needs of the farmer and the interest of the patent holder”.

¹³ Section 19(5) of the Latvian Patent Law.

¹⁴ Section 60(6A) of the Patents Act 1977 of the United Kingdom and its Schedule A1.

¹⁵ Article 93 of the Industrial Property Law of Poland and the Act of June 26, 2003 on the Legal Protection of Plant Varieties (JL No. 137, text 1300 of 2006 No. 126, text 877 and of 2007 No. 99, text 662).

¹⁶ Section 3b of the Consolidate Patents Act of Denmark (Act No. 91 of January 28, 2009).

Accidental or not avoidable use

26. A few Member States expressly specified that patent protection for plant and animal materials did not extend to accidental or technically unavoidable use of products. According to the response provided by Austria, patent protection does not apply for biological material, which was obtained “accidentally or technically not avoidable in the agricultural sector”.¹⁷ Similarly, the law of Germany provides that the rights of the patentee should not apply to biological material whose production in agriculture was “adventitious or technically unavoidable”.¹⁸

Use of propagated material for its marketed purpose

27. Some Member States’ laws provide that the protection conferred by a patent shall not extend to biological material obtained from the propagation or multiplication of biological material placed on the market, “where the propagation or multiplication necessarily results from the application of the biological material for which it was marketed”.¹⁹ The biological material may be marketed, for example, for agricultural use by farmers, for use at a private garden or for development of a biological product. The exception applies if the material obtained is not subsequently used for other propagation or multiplication. For example, the response from Poland noted that such act shall be “a single act of propagation or multiplication”. The response from Austria stated that patent protection “shall not extend to biological material obtained from the generative or vegetative multiplication of biological material, put on the market in the territory within the European Economic Area by the patentee or with his consent, if the generative or vegetative multiplication necessarily results from the application for which the biological material was marketed, provided that the material obtained is not subsequently used for other generative or vegetative multiplication”.²⁰ In the Republic of Moldova, a similar exception applies only to materials put on the market in the territory of the Republic of Moldova.²¹

28. The law of Portugal provides, in conjunction with the exhaustion of rights, a similar provision for patented biological material sold in the European Economic Area by the patentee or with his consent.²²

Development of a new plant variety

29. The laws of some Member States provide derogation from the rights of the patentee when the patented plant material was used to develop another plant variety. For example, the law of France provides that “the rights conferred [...] shall not extend to the acts performed with a view to creating or discovering and developing other plant varieties”.²³ Similarly, in Brazil, the “non-commercial use of the subject matter of a patent related to living material by third parties was allowed as an initial source of variation or propagation to obtain other products”.²⁴ The response from Mexico noted that patent rights did not extend to “a third party who, in the case of patents relating to living material, uses the patented product as an initial source of variation or propagation in order to obtain other products, apart from where said use is repeated”.²⁵

¹⁷ Article 22c(4) of the Austrian Patent Act 1990.

¹⁸ Section 9c(3) of the German Patent Act.

¹⁹ Article 93.1 of the Industrial Property Law of Poland.

²⁰ Section 22c(1) of the Austrian Patent Act.

²¹ Article 23(2) of the Law 50/2008 on the Protection of Invention of the Republic of Moldova.

²² Article 103 of the Industrial property Code of Portugal.

²³ L613-5-3 of the French Intellectual Property Code (CPI). See also Article 28(5) of the Law 50/2008 on the Protection of Inventions of Saudi Arabia.

²⁴ Article 43, paragraph V of the Brazilian Law N. 9,279 of May 14, 1996.

²⁵ Article 22, paragraph V of the Law on Industrial Property (LPI) of Mexico.

30. In Switzerland, the scope of patent protection does not extend to the use of patented biological material for the purposes of the production or the discovery and development of a plant variety.²⁶

Compulsory license for conflicting plant variety protection

31. Some Member States reported that their compulsory license and compulsory cross-license procedures applied to plant breeders' use of a patented invention, and patent holder's use of a plant protected by a plant variety right.²⁷ For example, the relevant provision of the law of France reads: "Where a breeder may not obtain or work a plant breeders' right without infringing an earlier patent, he may request the grant of a license for this patent to the extent that this license is required for working the plant variety to be protected and insofar as the variety constitutes, in relation to the invention claimed in this patent, significant technical progress and is of considerable economic interest".²⁸ Such a license is non-exclusive, non-assignable except with that part of the enterprise, and subject to payment of an appropriate royalty to the patentee. A request for a compulsory license shall be accompanied with a justification that the breeder was not able to obtain a voluntary license from the patentee and that the breeder is in the position to exploit the invention seriously and effectively. Further, where such a compulsory license is granted, the patent owner will be entitled to obtain the grant of a reciprocal license for using the protected variety.

32. Similarly, in Poland, a compulsory license is granted if a refusal by a patentee of concluding a licensing agreement prevents a plant breeder from meeting "home market demands through the exploitation of the patented invention".²⁹

Other types of exceptions and limitations

33. In addition to the above, some countries provided information regarding other general types of exceptions and limitations that might be also relevant to farmers' and breeders' activities. The response from Viet Nam stated that the exception regarding personal and non-commercial use³⁰ applied to farmers' and breeders' use of patented inventions.

34. Further, a provision in the law of Mexico clarifies its rule concerning the exhaustion of patent rights on living material. It states that once a patented product consisting of living material has been lawfully marketed by the patentee or with his consent, a third party may use, place in circulation or markets the patented product for purposes that are not multiplication or propagation.³¹ The response from Mexico explained that the main aim of the provision was "to guarantee the free circulation of goods that have been lawfully marketed, which will produce better competition within the domestic market, and benefit consumers with lower prices".

²⁶ Article 9.1 of the Federal Law on Patents for Inventions of Switzerland.

²⁷ Article 23a of the Law on Inventions, Utility Model Registration (LPUMR) of Bulgaria; Article 38 of the Patent Law of the Republic of Lithuania (January 18, 1994 No. I.372, as last amended on May 10, 2007 – No. X-1119); Article L613-15-1 of the French Intellectual Property Code (CPI); Article 28(5) of the Law 50/2008 on the Protection of Invention of the Republic of Moldova; Article 82(6) of the Industrial Property Law of Poland; Article 29 of the Law on Patents (Official Gazette of the Republic of Serbia, No. 99/1, dated December 27, 2011).

²⁸ L613-15-1 of the French Intellectual Property Code (CPI).

²⁹ Article 82(6) of the Industrial Property Law of Poland.

³⁰ Article 125.2 of the Law on Intellectual Property 2005 (Amending and Supplemented in 2009) of Viet Nam.

³¹ Article 22.VI of the Law on Industrial Property (LPI) of Mexico.

IMPLEMENTATION CHALLENGES

35. Most of the Member States stated that the applicable legal framework of the exception was considered adequate to meet the objectives sought, or provided no answer on this question.³² The response by the Netherlands stated that the Dutch Association of Plant Breeders had started a public debate on the desirability of the introduction of a breeders' exemption. According to the Association, "the pool of plant varieties available for further breeding activities has declined rapidly over the last decade, due to increasing existing patent rights". The Netherlands, thus, prepared "the introduction of a limited breeders exception [...] which will apply to the use of patented biological material for breeding purposes, i.e., to discover and develop new plant varieties". The limited exception, however, will not apply to the commercial exploitation of new plant varieties developed through the use of patented biological material, at least as long as the biological material of that new variety possesses the specific traits that were produced by the patented invention. Latvia, the Netherlands, Poland, Portugal and the United Kingdom stated that no or no further amendments were foreseen.

36. Most of the Member States stated that no challenges had been encountered in relation to the practical implementation of the exception.³³ However, the response from Mexico stated that as the exception that allowed third parties to use the patented product as an initial source of variation or propagation to obtain other products related to "the traditional practice of its farmers", "due to the imminent approval of commercial transgenic crops", there has been a great concern about the interpretation of the exception as regards "transgenic plants and possible contamination by pollen of traditional crops".

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³² Bosnia and Herzegovina, Croatia, Denmark.

³³ Bosnia and Herzegovina, Croatia, Denmark, Poland, Portugal, United Kingdom.