

Standing Committee on the Law of Patents

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EXCEPTIONS AND LIMITATIONS TO PATENT RIGHTS: EXTEMPORANEOUS PREPARATION OF MEDICINES

Document prepared by the Secretariat

INTRODUCTION

1. At its nineteenth session, held from February 25 to 28, 2013, 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 five exceptions and limitations are implemented in Member States, without evaluating the effectiveness of those exceptions and limitations: private and/or non-commercial use; experimental use and/or scientific research; preparation of medicines; prior use; use of articles on foreign vessels, aircrafts and land vehicles. The document should also cover practical challenges encountered by Member States in implementing them.
2. Pursuant to the above decision, the Secretariat invited, through Note C.8261, Member States and Regional Patent Offices to submit information to the International Bureau additional to, or updating, the information contained in their responses to the questionnaire on exceptions and limitations to patent rights (hereafter “the questionnaire”) on the above five exceptions and limitations. In addition, Member States and Regional Patent Offices that had not yet submitted their responses to the questionnaire were invited to do so.
3. Accordingly, this document provides information on how exceptions and/or limitations related to extemporaneous preparation of medicines have been implemented in Member States. The document aims at providing a comprehensive and comparative overview of the implementation of an exception and/or limitation related to this subject 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 as well as the responses received from Member States are available in full on the website of the SCP electronic forum at: <http://www.wipo.int/scp/en/exceptions/>. With a view to assisting easier 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. The document consists of three Sections: (i) Public Policy Objectives for Providing the Exception; (ii) The Applicable Law and the Scope of the Exception; and (iii) Implementation Challenges.

5. The following Member States and Patent Offices indicated that their applicable laws provided for exceptions and/or limitations related to the preparation of medicines: Albania, Armenia, Azerbaijan, Bosnia and Herzegovina, Brazil, Bulgaria, Croatia, Cyprus, Czech Republic, Democratic People's Republic of Korea, Denmark, Finland, France, Germany, Greece, Hong Kong (China), Hungary, Italy, Japan, Latvia, Lithuania, Morocco, Norway, Philippines, Poland, Portugal, Republic of Korea, Republic of Moldova, Russian Federation, Serbia, Slovakia, Spain, Sweden, Tajikistan, Thailand, Turkey, United Kingdom, Viet Nam and the Eurasian Patent Office (EAPO) (39 in total).

PUBLIC POLICY OBJECTIVES FOR PROVIDING THE EXCEPTION

6. The question on public policy objectives of the exception was answered by Member States as follows: The response from Brazil highlighted the importance of establishing a right balance between the interest of the right holders and the users of those rights and protection of public interests "by setting limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with its normal exploitation and do not unreasonably harm the legitimate interests of the patent owner, taking into account the legitimate interests of third parties. Therefore, the exception is considered to contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations."

7. The response from some Member States highlighted public health, in particular, access to medicines and treatment of patients. Thus, the response from Cyprus stated that the exception was "based on principles of the public benefit and the well being of mankind [...]".¹ Similarly, the response from France stated that the "exception is in the interest of public health". The answer from Poland was "not making impossible individual treatment". The Republic of Moldova responded that the policy objective for providing the exception was "not to restrict the use of medicine in individual cases in order to improve access to medicines". Portugal's answer was "not to limit access to treatment and not to interfere with the relationship doctor/patient". Similarly, Spain responded that the objective of the provision was "to provide patients with access to medicines prescribed by medical professionals and capable of being prepared in a pharmacy. That is, on the one hand, healthcare reasons are protected and on the other, such acts are considered as not impairing the usual working of the patent subject matter".

8. The responses from Germany and Italy also stated that the provision "is intended to facilitate the exercise of medical activities, since patents should not restrict the freedom of the doctor (physician) to prescribe medicines in the interest of health promotion. This is to allow doctors to prescribe medicines to their patients in the individual case, which are prepared in pharmacies, irrespective of possible patent rights". Similarly, Sweden's response stated that the

¹ The response also stated that such an exception was soundly convincing in remote areas or in developing countries.

policy objective of the exception was to enable personnel at pharmacies, “in an individual case, to prepare medicine in accordance with a prescription by a physician without being exposed to the risk of infringing a patent”. In the same manner, the response from the United Kingdom stated that “pharmacists should be free to make individual medical preparations as prescribed by a doctor without threat of patent infringement”. The response from Germany added that “the provision is to supplement the prohibition of patent protection of methods for treatment of the human or animal body by surgery or therapy”.

9. The response from Hungary stated that the policy objective for providing the exception “is to provide patients with low cost quality medicines and to decrease the spending of the state health scheme”. The response however noted that the “use of the exception concerns minimal quantities”, so it is “not prejudicial to the normal exploitation of the patent”. The response from Norway stated that the “preparation of medicines in pharmacies should be possible regardless of patent rights, as long as the preparation happens in connection with a prescription”.

10. The responses from Japan and the Republic of Korea indicated that taking into account that an act of preparing medicine by a physician or a dentist has a social mission with a particular purpose of helping patients in recovering their health, it is considered inappropriate for the effect of a patent right to extend to an act of preparing medicine”.²

11. While the Russian Federation responding to this question stated that the use of such inventions is “in the interests of the health of people and animals”, it also noted that “these cases can take place in extreme situations when it is necessary to administer urgent medical help” and that “one-off preparation of medicine may be considered only in the amount specified in the prescription”. The response from Serbia stated that the general ethical and health interest required that the patent for the drug would not be an obstacle that the drug in individual cases was produced and put on the market. The policy objectives for providing the exception in the Eurasian Patent Convention were “protection of the human health, assurance of the access to medicines”.

12. The policy objective for providing the exception for Denmark was to align the national law with Agreement relating to the Community patents.³ In the same manner, the response from Latvia indicated that the exception was adopted in order to harmonize the national patent law with the laws of Member States of the European Union.

13. Many Member States did not respond to the question on public policy objectives of the exception.

THE APPLICABLE LAW AND THE SCOPE OF THE EXCEPTION

14. 39 Member States reported their laws that provide for exceptions and/or limitations related to extemporaneous preparation of medicines. Many Member States whose laws provided for such exception⁴ specified that the “extemporaneous” preparation of a medicine in a pharmacy

² The responses also noted that “it is interpreted that medicine itself is generally deemed to be prepared by a medicine manufacturer with a patent license granted, and legally sold by a physician or a dentist”.

³ Agreement 89/695/EEC of 15 December 1989 relating to Community patents.

⁴ 38 Member States and one regional patent office provide a specific statutory provision on this matter. However, in Viet Nam, while there was no specific provision regulating the act of preparation of medicines in pharmacy, such act was considered to fall under the exception on non-commercial use. Similarly, while the response from Indonesia indicated that the applicable law did not provide for such an exception, it referred to a government use exception for public health reasons. In China, medical prescriptions and preparation of medicines based on those prescriptions were not considered as being industrially applicable, and therefore not patentable. In addition, the response from the United Republic of Tanzania referred to the methods for treatment which were excluded from the patentable subject matters.

according to a medical prescription is excluded from the scope of the rights conferred by a patent.⁵ The applicable laws of many of those Member States state that such preparation should also be for “individual cases”. In addition, the “acts”, “actions”, “treatment” or “procedures” relating to the medicine so prepared are also considered to be within the scope of the exception in many Member States.⁶

Permissible activities

15. The following details on the scope of the exception were provided in the responses of some Member States. In France, the rights conferred by a patent shall not extend to the extemporaneous preparation of medicines and preparation of a medicine “done by unit” in pharmacies in accordance with a medical prescription.⁷ In Armenia and Latvia, the use of a patented invention does not constitute an infringement of the exclusive rights of the patent owner if used for “single” preparation of medicaments in pharmacies based on physicians’ or doctors’ prescriptions.⁸ Similarly, Article 1359(5) of the Civil Code of the Russian Federation uses the phrase “one-off” preparation of medicines. Article 23 of the Law on Patent of the Republic of Azerbaijan provides that preparation of medicines should be “occasional” not to infringe the patent holder’s exclusive rights. Different from that approach, the Patent Act of Thailand generally states that patent holder’s rights do not extend to the “compounding of a drug specifically to fill a doctor’s prescription [...]”⁹

16. In Turkey, the preparation of medicines in pharmacies “involving no mass production” and carried out “solely in making up a prescription” shall remain outside the scope of rights conferred by a patent.¹⁰ In Italy, the exception does not apply to the “use of active ingredients made in industrial mode”.¹¹ In the Russian Federation, the preparation of a medicine “for subsequent storage and sale” may not be considered a single use, and therefore, may be regarded as an infringement of the patent holder’s exclusive rights.¹² While the applicable law of Serbia specifies that the rights of the patentee *inter alia* shall not apply “to the placement of such drug on the market”, the explanation clarifies that the exception “does not apply for preparation of drugs for stockpiling, but only applies to the case when the drug is aimed at making the execution of specific medical orders for treatment of a particular person in accordance with a prescription”.¹³

Entitlement

17. In relation to the categories of users entitled to claim the exception, the following tendency can be noted. In most of the Member States, such standing was not expressly indicated in the

⁵ See Article 38 of Law No. 9947 on Industrial Property of Albania; Section 27(3)(iv) of the Patent Law of Cyprus; Article L613-5 of the French Intellectual Property Code; Section 11 no. 3 of the Patent Act of Germany; Section 75(c) of 514 Patents Ordinance of Hong Kong, China; Article 55 of Law No. 17-97 on the Protection of Industrial Property of Morocco; Article 69 (1) (v) Industrial Property Law of Poland; Article 22 of the Law 50/2008 on the Protection of Inventions of the Republic of Moldova; Article 52.1(c) of the Law on Patents of Spain; Section 60(5)(c) of the Patents Act of the United Kingdom; Rule 19 of Patent Regulations under the Eurasian Patent Convention.

⁶ See, for example, Article 73 of the Patent Law of Bosnia and Herzegovina; Article 63(3) of the Patent Act of Croatia; Section 18(c) of the Patent Act of the Czech Republic; Section 3(3)5 of the Patents Act of Finland; Article L613-5 of the French Intellectual Property Code; Section 11(3) of the Patent Act of Germany; and Article 19 of Act XXXIII of 1995 on the Protection of Inventions by Patents of Hungary.

⁷ Article L613-5 of the French Intellectual Property Code.

⁸ Article 17 (3) of Law on Inventions, Utility models and Industrial Designs of Armenia and Section 20.4 of the Patent Law of Latvia, respectively.

⁹ Section 36 of Patent Act of Thailand.

¹⁰ Article 75(c) of the Turkish Patent Decree Law.

¹¹ Article 68.1(c) of the Industrial Property Code of Italy.

¹² Article 1359(5) of the Civil Code of the Russian Federation.

¹³ Article 21 item 3 of the Law on Patents of Serbia.

relevant statutes.¹⁴ However, some countries provided helpful interpretation. Most of the responses noted that the exception covered the activities of the “pharmacist” preparing such medicines.¹⁵ In the responses of some other Member States, the reference was made to “pharmacist and doctors”.¹⁶ In Italy, it is a “chemist” who is entitled to use the exception. Yet, in the response from Latvia, all three categories of professionals were mentioned: pharmacists, doctors, physicians. In the Russian Federation, in addition to the physician and chemist, the exception covers any “person for whom the medicine is prepared”. In the response of Portugal “anyone entitled to prepare this kind of medicinal products” was covered.¹⁷

18. Article 43 of the Industrial Property Law of Brazil establishes that the preparation should be carried out by a “qualified professional” to be considered within the scope of the exception.¹⁸ Likewise, in the Philippines, it is indicated in the statute that the patentee cannot prevent a “medical professional” from the use of the exception. In Thailand, the medicine should be prepared by a “professional pharmacist” or “medical practitioner” to be considered within the scope of the exception.

19. Further, while some statutes state generally that the effect of the patent does not extend to the act of preparation of a medicine on the basis of, or according to, a “medical prescription”, some Member States’ laws provide further details on who can make such a prescription. For example, the patent law of Hong Kong specifies that the preparation of a medicine must be in accordance with a medical prescription issued by a “registered medical practitioner” or “registered dentist”.¹⁹ Similarly, in Japan, a patent right for the invention of a medicine shall not be effective against the act of preparation of a medicine as is written in a prescription from a “physician” or a “dentist”.²⁰ The Patent Act of the United Kingdom also states that a prescription must be given by a “registered medical or dental practitioner”.²¹

Quantitative limitations

20. In many countries, the applicable law does not expressly limit the amount of medicine that can be prepared under the exception. However, some responses emphasized that the exception covers only “one-off”,²² “extemporaneous”,²³ or “by unit”²⁴ preparation in pharmacies in “individual cases”.²⁵ The response from Germany stressed that under the national law, the preparation of larger quantities of medicines for several patients was not covered by the provision. In the response of the Russian Federation, it was noted that one-off preparation of medicine may be considered only in the amount specified in the prescription. However, the physician was not restricted by the number of prescriptions that he may write for the same medicine to many patients.

¹⁴ In many countries, the entitlement was not indicated in the relevant statutes but a place where such permissible action could take place (e.g. pharmacy, pharmaceutical laboratories).

¹⁵ In Norway, it is understood that it is an “authorized” personnel in a pharmacy who is covered by the exception. Yet, the response from Sweden mentions generally “personnel at pharmacy”.

¹⁶ For example, in France, Germany and Cyprus. In Thailand, the reference was made to a “professional pharmacist or a medical practitioner” (Section 36(3) of Patent Act of Thailand).

¹⁷ Article 102 of the Industrial Property Code of Portugal.

¹⁸ Law n. 9.279 of May 14, 2006 (Industrial Property Law) of Brazil.

¹⁹ Section 75(c) of Patents Ordinance of Hong Kong, China.

²⁰ Article 69 (3) of the Japanese Patent Act.

²¹ Section 60(5)(c) of the Patents Act of the United Kingdom.

²² In the responses from the Russian Federation and the Republic of Moldova.

²³ In the responses from France, Sweden and EAPO.

²⁴ In the response from France.

²⁵ In the response from Finland, Hungary, Italy and Serbia.

IMPLEMENTATION CHALLENGES

21. All the Member States that responded to the question as to whether the legal framework of the exception was adequate to meet the objectives sought replied positively. In this regard, Denmark, Norway and Sweden noted that the exception was not in use, since preparation of medicines in pharmacies was no longer common in their countries.

22. All the Member States that replied to the question on whether any challenges had been encountered in relation to the practical implementation of the exception responded negatively.

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