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DRAFT REFERENCE DOCUMENT ON THE EXCEPTION REGARDING EXTEMPORANEOUS PREPARATION OF MEDICINES

Document prepared by the Secretariat

INTRODUCTION

1. At its thirty-fifth session, held in Geneva from October 16 to 20, 2023, the Standing Committee on the Law of Patents (SCP) agreed that the Secretariat would continue working on a draft reference document on the exceptions and limitations to patent rights in conjunction with patent protection. In particular, it was agreed that the Secretariat would, *inter alia*, prepare and submit a draft reference document on the exception regarding extemporaneous preparation of medicines to the thirty sixth session of the SCP (see document SCP/35/10, paragraph 30, under "Exceptions and Limitations to Patent Rights").

2. In accordance with the above decision of the SCP, the Annex to this document contains the said draft reference document for the Committee's discussion at its thirty-sixth session to be held in Geneva from October 14 to 18, 2024. In the preparation of the draft reference document, the Secretariat made use of information provided by the Member States[1], including national/regional legislative provisions and court cases, as well as other information made available through various SCP activities. In addition, the Secretariat consulted other sources of information to obtain supplementary material on the topic.

3. This document contains the following sections: (i) Overview of the exception regarding extemporaneous preparation of medicines; (ii) Objectives and goals of the exception;

[1] Member States and Regional Patent Offices were invited, through its Note C. 9199, dated December 7, 2023, to submit to the International Bureau any inputs for the preparation of the draft reference document on the exception regarding extemporaneous preparation of medicines. The inputs received are published on the website of the SCP electronic forum at: https://www.wipo.int/scp/en/meetings/session_36/comments_received.html.

(iii) International legal framework regarding the exception; (iv) Regional instruments relating to the exception; (v) National implementation of the exception; (vi) Challenges faced by Member States in implementing the exception; and (vii) Results of national/regional implementation of the exception. In addition, the document contains an Appendix, in which legal provisions on the exception regarding extemporaneous preparation of medicines from various national/regional laws are compiled.

[Annex follows]

DRAFT REFERENCE DOCUMENT ON THE EXCEPTION REGARDING EXTEMPORANEOUS PREPARATION OF MEDICINES

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1. Overview of the Exception Regarding Extemporaneous Preparation of Medicines

1. A number of countries provide within their applicable laws an exception regarding the extemporaneous preparation of medicines. In the context of preparation of medicines in pharmacies, extemporaneous preparation refers to the process of preparing medications on the spot, often customized for an individual patient, based on a doctor's prescription.[2] This can involve compounding drugs, mixing ingredients, or creating dosages and forms of medication tailored to the unique needs of a patient which are not commercially available.

2. In countries that provide this exception, in general, the effect is that the extemporaneous preparation of a medicine in a pharmacy, on an individual basis, in accordance with a medical prescription, does not constitute an infringement of the patentee's exclusive rights. In many countries, patentee's rights also do not extend to any acts concerning the medicine so prepared.

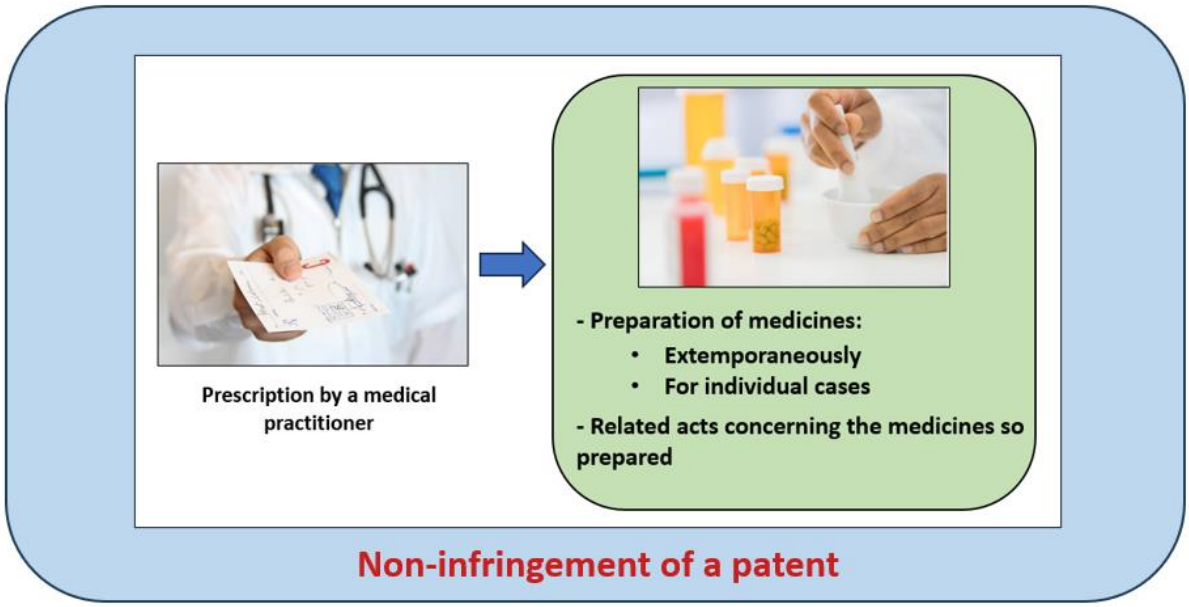
3. At the international level, Article 30 of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) provides general principles regarding the exceptions to the patent rights, which may be implemented by the Members of the World Trade Organization (WTO). However, no international instrument expressly regulates this specific exception regarding the extemporaneous preparation of medicines.

4. The main policy objectives for providing this exception are to achieve an appropriate balance of rights, support public interest in health protection, recognize the special social mission of healthcare providers in restoring the health of patients, and facilitate the exercise of medical-pharmaceutical activities allowing the doctors to issue prescriptions and pharmacists to prepare the prescribed medicines.

5. While national and regional law provisions on this exception share common aspects, textual differences may result in a varying scope of the exception across different countries. The following sections of this paper provide information on various aspects of the exception, detailing its scope in different jurisdictions based on provisions of laws and court decisions.

[2] According to the Merriam-Webster dictionary "extemporaneous" means "composed, performed, or uttered on the spur of the moment" or "carefully prepared but delivered without notes or text".

Figure 1: Conceptual image of the exception regarding extemporaneous preparation of medicines



2. Objectives and Goals of the Exception Regarding Extemporaneous Preparation of Medicines

6. As stated in the submissions of Member States, in general, the policy objectives for the exception regarding the extemporaneous preparation of medicines in pharmacies address the following several interconnected key areas:

Balancing rights: The exception achieves an appropriate balance between the rights of patent holders and the needs of patients and healthcare providers.[3] This balance is essential not to hinder individual patients' right to health and their access to necessary medications, while pharmaceutical innovation is protected by patents.[4]

Supporting public interest in healthcare: Allowing pharmacists to prepare prescribed medicines based on prescriptions without fear of patent infringement supports the

[3] See, e.g., a response of Brazil to the Questionnaire on Exceptions and Limitations to Patent Rights (hereafter "the Questionnaire") found at: https://www.wipo.int/scp/en/exceptions/.

[4] E.g., the judgments of the Supreme Court of Italy (e.g., No. 2241/2008, and No. 5573/2012) clarified that the limitation of the statutory rights of patent owners, established by the 'galenical exception', is justified by the necessity of protecting the right to health. In a judgement of the Supreme Court No. 39187/2013, it was further clarified that the "purpose of the galenical exception is, precisely, that of allowing the pharmacist to prepare and sell the patient a medicine with a different dosage or with a different excipient compared to that of the medicine offered for sale by the patent holder and this only in cases where the patient requires this different dosage or is allergic to the excipient used for the medicinal product marketed by the patent holder" (non-official translation).

public interest in healthcare, thus safeguarding patient care and addressing specific medical needs.[5,6]

Facilitating medical-pharmaceutical activities: The exception facilitates the exercise of medical and pharmaceutical activities, particularly the freedom of doctors to issue prescriptions that are tailored to the specific needs of their patients. This ensures that doctors can prescribe the most appropriate treatment without being constrained by the exclusive rights.[7] In addition, with a view to safeguarding the freedom of doctors to conduct medical treatment, the exception is considered to complement the exclusion from patentability of diagnostic, therapeutic and surgical methods for the treatment of humans or animals.[8]

Social mission of healthcare providers: Recognizing the special social mission of pharmacists and healthcare providers in restoring the health of patients, it would be considered inappropriate if the effect of a patent right extended to an act of preparing medicines in pharmacies. This includes allowing the preparation of personalized medications that cater to individual patient needs, which is important for effective healthcare delivery.[9]

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5 See, e.g., submissions from the Republic of Korea and the Czech Republic to SCP/36, available at: https://www.wipo.int/scp/en/meetings/session_36/comments_received.html. The Republic of Korea: "[…] the legislation is intended, for the public welfare, to prevent any person from having an exclusive right when it comes to a medical personnel's preparation, and thereby not to harm the freedom of a pharmacist's preparation in accordance with a doctor's or a dentist's prescription or of a doctor's treatment in accordance with a patient's condition". The Czech Republic: "This provision was adopted as part of the international harmonization of patent law for the purpose of public interest in health protection.".

6 Similarly, the responses of some Member States to the Questionnaire with respect to policy objectives of the exception highlighted public health, in particular, access to medicines and treatment of patients. For example, the response from Cyprus stated that the exception was "based on principles of the public benefit and the well-being of mankind". 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". Sweden's response stated that the 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 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".

7 E.g., a submission from Germany to SCP/36 explains: "[i]ts purpose is to facilitate medical-pharmaceutical activities, in particular the freedom of doctors in issuing recipes." (BeckOK PatR/Ensthaler, 30th edn. 15th July 2023, PatG § 11 para 17; Mes, 5th edn. 2020, PatG § 11 para 12; Schulte, Patentgesetz mit EPÜ, 11th edn. 2022, § 11 PatG, para 21; Ann, Patentrecht, 11th edn. 2022, § 33 para 265). In addition, a submission from Japan to SCP/36 with respect to the policy objectives of the exception noted, *inter alia*, that "(A) Persons who engage in the extemporaneous preparation of medicines cannot avoid obeying the prescriptions. (B) It is difficult for doctors and others to judge whether or not the method of mixing conflicts with patent rights.". The submission from Spain to SCP/36 also explains that at times, physicians prescribe a medicine tailored to the particular treatment needs of the patient, with dosage and excipients that differ from those applied to industrial preparation.

8 See the submission from Germany to SCP/36.

9 See, e.g., a submission from Japan to SCP/36 with respect to the policy objectives of the exception noted, *inter alia*, that "[t]he extemporaneous preparation of medicines by doctors and others is related to their special social mission of restoring the health of patients.". A response from Portugal to the Questionnaire notes that the policy objective of the exception is "not to limit access to treatment and not to interfere with the relationship doctor/patient". A submission from Spain to SCP/36, in this respect, states: "1. The reason for this exception is to allow pharmacists, on an exceptional basis, to prepare medicines for a particular patient. 2. The objective, therefore, is to allow the prescription of a master formula with dosage and

[Footnote continued on next page]

7. These objectives collectively aim to ensure that while the patent system continues to incentivize pharmaceutical innovation, it does not hinder the ability of healthcare providers to meet an individual patient's specific needs through tailored medication preparation based on a doctor's prescription.

3. International Legal Framework of the Exception Regarding the Extemporaneous Preparation of Medicines

8. No international treaty expressly addresses the exception regarding the extemporaneous preparation of medicines in pharmacies. However, Article 30 of the TRIPS Agreement outlines general principles regarding the exceptions to the rights which may be provided by the WTO Members. Since Article 30 is a permissive ("may") provision, Members are permitted, but not obliged, to provide such limited exceptions to the rights. It states:

> "*Exceptions to Rights Conferred*
>
> *Members may provide limited 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*."

9. While the wording of Article 30 does not expressly make any reference to the exception regarding the extemporaneous preparation of medicines in pharmacies, the negotiation history of this provision shows that early drafts of this provision contemplated the inclusion of an illustrative list of exceptions that contained this exception, among others.[10] Specifically, Draft of July 23,1990 (W/76) stated:

> *"[Provided that legitimate interests of the proprietor of the patent and of third parties are taken into account,] limited exceptions to the exclusive rights conferred by a patent may be made for certain acts, such as:*
>
> *[…]*
>
> *2.2.4 Preparation in a pharmacy in individual cases of a medicine in accordance with a prescription, or acts carried out with a medicine so prepared*."

10. Ultimately, the illustrative list approach was abandoned in favor of a more general wording as provided in current Article 30 of the TRIPS Agreement. The negotiation records of the TRIPS Agreement, however, provide no explanation of the reason for this decision.[11]

11. The WTO Dispute Settlement Panel in *Canada - Patent Protection of Pharmaceutical Product* case[12] provided some guidance with respect to the interpretation of Article 30 of the TRIPS Agreement, the summary of which has been provided elsewhere.[13] However, as the exception regarding the extemporaneous preparation of medicines in pharmacies was not

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excipients that differ from those applying to industrial preparations in order to make the treatment for a given patient more effective." See also a response of the Republic of Korea to the Questionnaire.

10 Chairman's Text of 23 July 1990 (Document MTN.GNG/NG11/W/76 of 23 July 1990). See also Daniel Gervais, The TRIPS Agreement, Drafting History and Analysis, Third Edition, Sweet and Maxwell, 2008, p. 380.

11 See WTO document WT/DS114/R, paragraph 7.70, p.165.

12 WTO document WT/DS114/R.

13 For the summary of the case, see document SCP/13/3, pp. 21 and 22, and document SCP/28/3, pp. 6-8.

the specific focus of the dispute, the compliance of this exception with Article 30 of the TRIPS Agreement was not discussed.[14,15] The only instance where the exception in question is mentioned in the Panel's report is when the European Communities and their member states described this exception as "mostly historic".[16]

12. In parallel with the 1990 negotiations in the Uruguay Round Negotiating Group on TRIPS, the negotiation on a global treaty aimed at harmonizing a number of formality and substantive issues in the area of patents was taking place at the World Intellectual Property Organization (WIPO). A draft "Treaty Supplementing the Paris Convention for the Protection of Industrial Property as far as Patents are Concerned" (draft 1991 Patent Harmonization Treaty) was discussed at the first part of the Diplomatic Conference, held in The Hague in 1991.[17] The draft text dealing with rights conferred by the patents and exceptions to those rights was contained in Article 19 of the draft Treaty. The list of exceptions contained in that provision included the exception regarding the extemporaneous preparation of medicines in pharmacies. The texts in question read as follows:

> "*Article 19(3)(a). Notwithstanding paragraphs (1) and (2), any Contracting Party shall be free to provide that the owner of a patent has no right to prevent third parties from performing, without his authorization, the acts referred to in paragraphs (1) and (2) in the following circumstances:*
>
> *[…]*
>
> *(iv) where the act consists of the preparation for individual cases, in a pharmacy or by a medical doctor, of a medicine in accordance with a medical prescription or acts concerning the medicine so prepared."*

13. While the negotiation of the Patent Harmonization Treaty reached an impasse in 1993 due to developments beyond the scope of this paper,[18] the pre-Diplomatic Conference records on Article 19 of the draft Treaty indicate that the majority of countries were in favor of retaining draft Article 19(3)(a)(iv).[19] During the discussions, however, some delegations expressed various views on this exception, which reflected their concerns at that time on the scope of the draft provision:

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14 See WTO document WT/DS114/R and document SCP/28/3.

15 Some commentators have expressed their views on the consistency of this exception with Article 30 of the TRIPS Agreement. E.g., Nuno Pires de Carvalho stated that "Following the reasoning of the Panel in *Canada – Patent Protection of Pharmaceutical Products*, it is difficult to accept that such exception could be a "limited" one, because it gives third parties the unqualified and unlimited right "to make" and "sell" the patented medicine […]". Nuno Pires de Carvalho, "The TRIPS Regime of Patent Rights", 2002, pp. 227, Kluwer Law International.

16 In particular, in response to a question from the Panel, the EC stated: "the "practicing pharmacist" exception, which existed in a number of countries, concerned a unique, in the meantime mostly historic situation, in which a pharmacist could produce on the prescription of a doctor a small quantity of a pharmaceutical product for an individual patient without the consent of the patent holder […]". See footnote 139 in WTO document WT/DS114/R.

17 Records of the Diplomatic Conference for the Conclusion of a Treaty Supplementing the Paris Convention as Far as Patents are Concerned can be found in WIPO Knowledge Repository at: https://tind.wipo.int/record/28773?ln=en&v=pdf.

18 For the discussions, see Records of the Consultative Meeting for the Further Preparation of the Diplomatic Conference for the conclusion of the Patent Law Treaty, Geneva May 8 to 12, 1995 (PLT/CM/2).

19 See "Committee of Experts on the Harmonization of Certain Provisions in Laws for the Protection of Inventions", Fifth Session (Geneva, June 13 to 17, 1988) (HL/CE/V/4). In paragraph 77, the Chair stated: "in conclusion, in spite of certain objections which had been voiced in respect of the provision, the majority of national delegations wished to retain the provision, subject perhaps to some drafting alterations and to the inclusion of preparations by physicians."

- The Delegations of Germany stated that “the provision should be applied only to exempt the preparation of medicines for concrete individual cases”;[20]

- The Delegation of Australia considered that “the wording of the provision was too broad, and drew attention to the situation of a hospital where hundreds of prescriptions might be prepared for individual cases on a daily basis”;[21] and

- The Delegation of Japan suggested that the words “or by a doctor” be added to the provision, as doctors were permitted to prepare medicines in Japan (not just pharmacists).[22]

4. Exception Regarding Extemporaneous Preparation of Medicines under Regional Instruments

14. Two regional instruments provide for an exception regarding extemporaneous preparation of medicines. These are the Agreement on a Unified Patent Court (UPCA)[23] and the Patent Regulations under the Eurasian Patent Convention.[24, 25]

UPCA

15. Article 27(e) of the UPCA states:

“27. Limitations of the effects of a patent

The rights conferred by a patent shall not extend to any of the following:

[…]

(e) the extemporaneous preparation by a pharmacy, for individual cases, of a medicine in accordance with a medical prescription or acts concerning the medicine so prepared;”

16. As of June 2024, there have been no specific cases or decisions directly related to Article 27(e) of the UPCA. Although it does not provide an official interpretation of the UPCA, a book edited by Winfried Tilmann and Clemens Plassmann[26] contains the following commentary on this provision:

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20 The Delegations of Germany (Federal Republic of). See HL/CE/V/4, *Ibid*, paragraph 76.

21 See HL/CE/V/4, *Ibid*, paragraph 74.

22 In addition, the Representatives of the AIPLA, IFPMA and NYPTC supported the deletion of Article 19 of the draft Treaty, since in their views, it unfairly discriminated against the pharmaceutical industry. See HL/CE/V/4, *Ibid*, paragraph 75.

23 The Agreement on a Unified Patent Court of June 1, 2023. The Agreement applies to European patent applications, European patents with unitary effects as well as those European patents and supplementary protection certificates that take effect in Contracting Member States of the Agreement (See Art. 3 of the UPCA).

24 Patent Regulations under the Eurasian Patent Convention (as adopted on December 1, 1995, with the amendments and addenda adopted as up to January 1, 2024).

25 In addition, Article 27(c) of the Agreement relating to Community patents (89/695/EEC) (done at Luxembourg on December 15, 1989) provides the exception in question. As of June 15, 2024, the Agreement has not entered into force.

26 Chapter V, Sources of Law and Substantive Law in *Unified Patent Protection in Europe. A Commentary* (edited by Winfried Tilmann and Clemens Plassmann), Oxford University Press (2018), pp. 534 and 535, available at: https://academic.oup.com/book/41092/chapter/350018499.

"Through Art 27(e) UPCA, extemporaneous preparation of medicines by a pharmacy and the processing of such medicines is exempted, subject to certain conditions, from the effects of patent protection. Contrary to what would appear to be the case initially, the provision is not primarily intended to protect the commercial activity of pharmacists. Rather, it is intended to facilitate medical curative treatments. This is clear from the fact that acts are privileged only if there is a corresponding medical prescription. A medical prescription requires that it is issued by a person authorized to practise the medical profession in accordance with the national regulations of the MSs. According to the spirit and purpose of Art 27(e) UPCA, not only prescriptions by doctors of human medicine but also prescriptions by veterinarians are covered. Alternative practitioners are not medical doctors. The prescription itself must refer to a particular person. No further requirements for prescription are stipulated by Art 27(e) UPCA.

First of all, extemporaneous preparation of medicines, to the extent done in accordance with a medical prescription, is privileged. Extemporaneous preparation means that it has to be an individual preparation in accordance with a prescription. If drugs are manufactured to stock, this does not fall under the exemption. Art 27 UPCA itself does not define what a medicine is. In this regard, recourse may be [made] to the legal definition found in Art 1(2) Directive 2001/83/EC[…] and Art 1(2) Directive 2001/82/EC.[…] Preparation must take place in pharmacies. These include not only pharmacies open to the general public but, for example, also hospital pharmacies. Since the provision refers to 'pharmacies' in general, acts by pharmacists in addition to those of supporting staff are privileged.[…] Preparation by the prescribing doctor is not exempted. As follows from the second half-sentence of Art 27(e) UPCA, the privilege covers, in addition to extemporaneous preparation as such, also acts relating to medicines prepared in this way. […]."

Patent Regulations under the Eurasian Patent Convention

17. Rule 19 of the Patent Regulations under the Eurasian Patent Convention states:

"19. Actions not Infringing the Eurasian Patent

The following cases of the use of the patented invention shall not constitute an infringement of the Eurasian patent:

[…]

- *use for the occasional preparation, in a pharmacy, of a medicine on a medical prescription;*

[…]."

18. No judicial decisions have been documented with respect to the above provision in any of the Contacting States of the Eurasian Patent Convention.

5. National Implementation of the Exception Regarding Extemporaneous Preparation of Medicines

5.1 Legal Frameworks Regulating the Exception Regarding Extemporaneous Preparation of Medicines

19. In total, 85 countries and territories have been identified to provide for the exception regarding extemporaneous preparation of medicines through a specific statutory provision within the respective IP or patent legislation. The Appendix to this document contains provisions of laws of those countries and territories on this exception.

Table 1: List of countries and territories which provide for the exception regarding extemporaneous preparation of medicines

Countries and territories	Total number
Albania, Andorra, Antigua and Barbuda, Argentina, Armenia, Azerbaijan, Belarus, Belgium, Belize, Bosnia and Herzegovina, Botswana, Brazil, Brunei Darussalam, Bulgaria, Cabo Verde, Chile, Croatia, Cuba, Cyprus, Czech Republic, Democratic People's Republic of Korea, Denmark, Dominica, Estonia, Finland, France, Germany, Greece, Grenada, Hong Kong China, Hungary, Iceland, Ireland, Italy, Jamaica, Japan, Kazakhstan, Latvia, Liberia, Lithuania, Luxembourg, Macao China, Malta, Mauritius, Montenegro, Morocco, Mozambique, Myanmar, Namibia, Netherlands (Kingdom of the), North Macedonia, Norway, Philippines, Poland, Portugal, Republic of Korea, Republic of Moldova, Russian Federation, Saint Kitts and Nevis, Saint Lucia, Saint Vincent and the Grenadines, San Marino, Sao Tome and Principe, Serbia, Seychelles, Singapore, Slovakia, Slovenia, Spain, Sweden, Switzerland, Syrian Arab Republic, Tajikistan, Thailand, Trinidad and Tobago, Tunisia, Turkmenistan, Türkiye, Uganda, United Arab Emirates, United Kingdom, Uruguay, Uzbekistan, Vanuatu, and Zambia.	85

20. In general, the national law provisions are formulated to state that the “extemporaneous” preparation of a medicine in a pharmacy according to a medical prescription does not constitute an infringement of the patentee’s exclusive rights. Many countries’ laws also 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 countries.

21. With respect to the scope of respective provisions in the national laws, in most of the countries, no judicial interpretation has been established. In other countries, few court cases have dealt with the exception in question. The following subsections provide information on various aspects of the exception in different countries based on the available information.

The formulation of the provisions on the exception regarding the extemporaneous preparation of medicines

22. In most of the countries that provide this exception, it is impossible to enforce a patent in case where extemporaneous preparation of medicines is carried out in pharmacies. Thus,

the relevant provisions would typically state: "the rights conferred by the patent shall not extend to" or "the right conferred by a patent shall have no effect against" the extemporaneous preparation of a medicine in a pharmacy for individual cases, or such preparation is "not deemed to be patent right infringement", in the jurisdiction concerned.

23. For example, Section 32(4)(d) of the Patent Act № 22 of 2018 of Antigua and Barbuda states:

> *"(4) The rights under the patent shall not extend to –*
>
> *[…]*
>
> *(d) the extemporaneous preparation for individual cases, in a pharmacy, of a medicine in accordance with a medical prescription or acts concerning the medicine so prepared;"*

24. Similarly, Article 36(b) of the Law № 24.481 of March 30, 1995, on Patents and Utility Models of Argentina states:

> *"36. The right conferred by a patent shall have no effect against:*
>
> *[…]*
>
> *b) the routine dispensation of drugs by authorized professionals, individually on medical prescription, or against acts relating to drugs so dispensed;"*

25. In Uzbekistan, according to Article 12 of the Law № 1062-XII of May 6, 1994, on Inventions, Utility Models and Industrial Designs, it is

> *"Not recognized as an infringement of the exclusive right of the patentee:*
>
> *[...]*
>
> *One-time manufacture of medicines in pharmacies according to doctor's prescriptions."*

26. In Zambia, the patentee's rights are *a priori* limited to "commercial activities". Specifically, Section 75(1)(j) of the Patents Act 2016 states:

> *"(1) Despite any other provision of this Act, rights under a patent shall be limited to industrial or commercial activities and shall not extend to the following:*
>
> *[…]*
>
> *(j) the preparation for individual cases, in a pharmacy or by a medical doctor, of a medicine in accordance with a medical prescription;"*

27. Yet, in Türkiye, Article 85(3)(ç) of the Industrial Property Law refers to the scope of the patent rights, stating that:

> *"(3) The practices mentioned below shall be out of the scope of the rights provided by a patent:*
>
> *[…]*

(ç) using the drugs prepared in pharmacies without a mass production in order to prepare only one prescription and practices regarding drugs prepared this way;"

5.2 Scope of the Exception Regarding Extemporaneous Preparation of Medicines

28. The analysis of national law provisions regarding the exception for the extemporaneous preparation of medicines reveals similarities and differences in their formulation. In general, in many countries, the following conditions shall be fulfilled simultaneously for the exception to apply[27], i.e., the preparation of a medicine shall:

- take place in a pharmacy;
- be in accordance with a doctor's prescription; and
- be extemporaneous preparation in individual cases.

29. The scope of the exception regarding the preparation of medicines based on medical prescriptions is formulated differently in the applicable laws of Japan and the Republic of Korea.[28] They state that a patent right for an invention of a medicine (X) that is manufactured by two or more medicines mixed together, or a process invention for manufacturing a medicine (X) by mixing two or more medicines, has no effect against the act of preparation of the medicine (X) as per a medical prescription. Similarly, in the United Arab Emirates, the right conferred does not extend to an act of "combining more than one medication for the purpose of medical treatment by a licensed pharmacist".[29]

30. In addition, in many national statutes, "acts concerning the medicine so prepared", or those expressed with similar words, are also covered within the scope of the exception.

31. The following paragraphs provide information on the scope of the exception in different countries based on the analysis of national law provisions and court decisions, where identified or reported.

The preparation of a medicine in a pharmacy

Definitions: "medicine" and "pharmacy"

32. Patent laws of most countries do not provide a legal definition of the term "medicine" in relation to the provision concerning the exception under consideration,[30] while courts may interpret that term through judicial interpretation of statutory law. One of the few countries that include an explanation of that term in the statute is Japan, where Article 69(3) of the Patent Act states that a "patent right for a medical invention (whereby medicine refers to a product used in the diagnosis, therapy, treatment or prevention of human diseases; hereinafter the same applies in this paragraph) […], or for the invention of a process by which a medicine is manufactured […]."[31]

33. In some countries, the definition provided in national or regional legislation governing pharmaceutical products is taken into account for the interpretation of this particular exception in their patent laws. For example, in Germany, the legal commentary literature

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27 In this respect, the submission of the Czech Republic to SCP/36 refers to Chloupek V., Hartvichová K. *et al.* (2017) *Patent Act – Commentary*. (1st edition). C.H.Beck.

28 Article 69(3) of the of the Patent Act of Japan and Article 96(2) of the Patent Act of the Republic of Korea.

29 Article 22.3 of the Federal Law No. 11 of 2021 on the Regulation and Protection of Industrial Property Rights of the United Arab Emirate.

30 See Appendix to this document for provisions of laws.

31 Article 96(2) of the Patent Act of the Republic of Korea also contains a similar provision.

suggests that the definition of the term “medicinal product” in Section 2 of the German Medicinal Products Act (*Arzneimittelgesetz*) be taken into consideration.[32] Furthermore, German courts have determined that “cosmetics”[33] and “food”[34] do not qualify as “medicines”.[35]

34. Similarly, according to the submission of Spain, Article 61.1(d) of the Patent Act concerning the exception to extemporaneously prepared medicines in pharmacies should be read together with Article 8 of Act No. 29/2006, of July 26, 2006, on Guarantees and the Rational Use of Medicines and Health Products.[36] The latter provision includes a definition of the term “master formula” as a “medicine for an individual patient, prepared by or under the direction of a pharmacist with a view to filling a medical prescription detailing its main active ingredients, in accordance with the regulations governing correct preparation and quality control, and dispensed in a pharmacy or pharmaceutical service, whereby the user is provided with the pertinent information set forth in Article 42.5.” Following those provisions, it is understood that the exception relates to the professional judgment of the pharmacist and the need to allow him/her to prepare a specific medicine tailored to the particular needs of the patient.[37]

35. Most national laws state that the preparation of a medicine must take place in a “pharmacy” for the exception to apply. While pharmacies may differ considerably in terms of size, staffing as well as the services they provide, a general dictionary defines “pharmacy” as “the art, practice, or profession of preparing, preserving, compounding, and dispensing medical drugs”.[38] Operating as a pharmacy requires a compliance with all legal and regulatory requirements for pharmacies in a relevant jurisdiction.

36. In this respect, the submissions from the Czech Republic clarified that a pharmacy is an operator authorized to dispense medicinal products according to Act No. 378/2007 Coll., on Pharmaceuticals. This Act further specifies that medicinal products can only be prepared in a pharmacy, at the nuclear medicine workplace of the health service provider in the case of radiopharmaceuticals, or at the immunological or microbiological workplace of the health service provider or at a health service provider operating in accordance with special legal regulation[39] in the case of human autogenous vaccines.[40]

Persons entitled to invoke the exception

37. Many legislations do not specify the exact categories of individuals entitled to this exception, but rather identify the locations where such activities can occur, such as pharmacies. Nevertheless, some countries’ statutes and submissions provide further relevant information in this regard.

38. For example, in the submission of Germany, it was clarified that the medicine in a pharmacy can be prepared by the pharmacist herself/himself and/or the pharmacist’s

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32 Cf. Benkard PatG/Scharen, 12th edn. 2023, PatG § 11 para 11; Mes, 5th edn. 2020, PatG § 11 para 13; Busse/Keukenschrijver, PatG, § 11 para 23.
33 Cf. BGH GRUR 2001, 450 – Franzbranntwein-Gel.
34 Cf. BGHZ 151, 286 (295 f.) – Muskelaufbauprärarate; BGH GRUR 2000, 528 - L-Carntin; BGH GRUR 2004, 79 - Sportlernahrung II.
35 See the submission of Germany to SCP/36.
36 See the submission of Spain to SCP/36.
37 *Idem*.
38 See the Merriam-Webster dictionary.
39 Act No. 258/2000 Coll., on the Protection of Public Health, as amended.
40 See the submission of the Czech Republic to SCP/36.

assisting staff.[41] In addition, pharmacies of hospitals can be pharmacies in the sense of the provision, as long as the other criteria of Section 11(3) of the German Patent Act are fulfilled.[42] In contrast, the provision does not apply where the medicine is prepared by the doctor herself/ himself,[43] in a drugstore, in the laboratory of a hospital,[44] or in any other place of manufacturing.[45]

39. In comparison, in Zambia, the scope of the exception covers the preparation of a medicine for individual cases in a pharmacy "or by a medical doctor",[46] while in the Philippines, such a preparation shall be made in a pharmacy "or by a medical professional".[47]

40. Similarly, in Thailand, the relevant provision of law refers to a "professional pharmacist or a medical practitioner".[48] In Cabo Verde, Macao China and Tunisia, the individual preparation of medically prescribed drugs shall be carried out by "dispensing chemists".[49] In the United Arab Emirates, the applicable law refers to "licensed pharmacists".[50] In Uruguay, the preparation of a medicine shall be made under the "supervision of an authorized professional".[51] In Argentina and Cuba, the relevant provisions of laws in this context refer generally to "authorized professionals",[52] while in Brazil to a "qualified professional".[53,54]

The preparation in accordance with a doctor's prescription

41. While some statutes state generally that the effect of the patent does not extend to the act of preparation of a medicine based on, or according to, a "medical prescription", some countries' patent laws provide further details on who can issue such a prescription.

42. For example, a prescription by a "physician" is referred to in the relevant provisions of laws of Armenia, Iceland, Lithuania, Poland, and Sweden. The provisions of laws of Ireland and Mozambique specify that the preparation of a medicine must be in accordance with a medical prescription issued by a "registered medical practitioner".[55]

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41 LG Hamburg Mitt. 1996, 315 (319); Mes, 5th edn. 2020, PatG § 11 para 14. See the submission of Germany to SCP/36.

42 Benkard PatG/Scharen, 12th edn. 2023, PatG § 11 para 11; Mes, 5th edn. 2020, PatG § 11 para 13; Schulte, Patentgesetz mit EPÜ, 11th edn. 2022, § 11 PatG, para 22.

43 Mes, 5th edn. 2020, PatG § 11 para 14.

44 Benkard PatG/Scharen, 12th edn. 2023, PatG § 11 para 11.

45 BeckOK PatR/Ensthaler, 30th edn. 15th July 2023, PatG § 11 para 17.

46 Section 75(1) (j) of the Patents Act 2016 (Act № 40 of 2016).

47 Section 72.5. of the Intellectual Property Code of the Philippines (Republic Act № 8293) (2015 Edition).

48 Section 36(3) of the Patent Act of Thailand.

49 See Article 47(b) of the Industrial Property Code; Article 47(c) of the Patents Act № 2000-84 of August 24, 2000; and Article 105 (a) of the Decree-Law No. 97/99/M of Macao China.

50 Article 22(3) of the Federal Law № 11 of 2021 on the Regulation and Protection of Industrial Property Rights of the United Arab Emirates.

51 Article 39(b) of the Law № 17.164 of September 2, 1999, on Patents.

52 Article 36(b) of the Law № 24.481 of March 30, 1995 on Patents and Utility Models of Argentina, and Article 47(d) of the Decree-Law № 290 of November 20, 2011 on Inventions and Industrial Designs of Cuba.

53 Article 43(III) of the Law on Industrial Property of Brazil.

54 In response to the Questionnaire some countries also provided information on entitlement. E.g., in the response from Latvia, three categories of professionals were mentioned: pharmacists, doctors, and physicians. In the response of Portugal "anyone entitled to prepare this kind of medicinal products" was covered.

55 Section 42(c) of the Patents Act, 1992 of Ireland, and Article 75(e) of the Industrial Property Code of Mozambique.

43. In many other countries, the applicable laws state that, in addition to a registered medical practitioner, a "registered dentist"[56], "registered dental practitioner",[57] or "dental specialist or a dental surgeon"[58] can produce such a prescription. Similarly, in Japan, a patent right for a medical invention shall not be effective against the act of preparation of a medicine as per a "physician" or a "dentist".[59] In Germany, a doctor encompasses "medical doctors, dentists and veterinarians, but not alternative/homeopathic practitioners".[60]

44. With respect to the "medical prescription", the submission from the Czech Republic explains that "[o]nly a doctor can evaluate which medication is most suitable for the patient at a given moment. If it is a medicinal product that has yet to be prepared, as a very specific composition is needed to meet the needs of the patient, the doctor will prescribe the preparation of such a medicine."[61]

Supreme Court decision No. 39187 of September 23, 2013 (Italy)

In Italy, the Supreme Court (Corte di Cassazione) in a decision of September 23, 2013, noted that the exception in question should apply in "exceptional situations in which existing drugs on the market are not able to cure a certain patient, when it is necessary to set up a different dosage than that contained in the specialties medicines offered by the market."

Assessing the facts of the case, the Court found that the preparation of the medicine was not strictly based on the medical prescription,[62] and that the prescription did not require any personalized dosage of the active ingredient in light of specific medical needs of the patient. The fundamental requisite of the 'galenical exception' was, therefore, missing.[63]

The Supreme Court also clarified that the prohibition of the use of industrially-produced active ingredients highlighted the artisanal character of the exception. It clarified that the "sale of the active ingredient carried out following purchase from an industrial manufacturer in violation of the patent rights […], not for therapeutic needs of the patient but for economic reasons, could not fall within the scope of the exception. It must therefore be assumed that the galenic exception, as it was configured by the legislator, cannot absolutely legitimize a sort of parallel market for patented substances." [non-official translation]

56 Article 75(c) of the Patents Ordinance 2017 of Hong Kong, China.

57 See provisions of laws of Brunei Darussalam, Jamaica, Myanmar, Saint Lucia, Seychelles, Singapore, the United Kingdom, and Vanuatu.

58 Section 21(2) (d) of the Industrial Property Act 2019 of Mauritius.

59 Article 69(3) of the Patent Act of Japan, Act № 121 of April 13, 1959.

60 See submission of Germany to SCP36 citing: BeckOK PatR/Ensthaler, 30th edn. 15th July 2023, PatG § 11 para 17; Benkard PatG/Scharen, 12th edn. 2023, PatG § 11 para 11.

61 See the submission of the Czech Republic to SCP/36.

62 A medical prescription required the active ingredient Finasteride 1 mg, while the accused pharmacist employed Finastid 5mg and Proscar 1 mg, and their related excipients, bought from a third party.

63 Previous judgments of the Supreme Court (e.g., n. 2241/2008, and n. 5573/2012) clarified that the 'galenic exception' is subject to four requisites: (i) the extemporary character, which means that the medicine should be prepared only when needed, (ii) the quantitative restriction, as the production should be carried out on an individual scale, (iii) the presence of a medical prescription catering to specific needs of the patient, and (iv) the use of active ingredients not produced on an industrial scale.

Extemporaneous preparation in individual cases

45. In many countries, relevant laws state that the exception covers "extemporaneous" preparation of medicines in pharmacies. According to the explanation provided by some countries, the "extemporaneous preparation" refers to the process of preparing a customized medication according to a specific prescription, rather than producing it in bulk or in advance. Additionally, quantitative restrictions to the preparation apply: it must relate to individual cases, meaning that a prescription must be written for one particular individual, and production should be carried out on an individual scale.

46. For example, the submission from Czech Republic notes in this respect that "it must be an individual preparation, i.e. made *ad hoc* for the specific case of a particular patient. Therefore, it is not possible to create stocks or mass-produce a given medicine and store it for the future for other patients. Such use would already mean commercial use of the invention and would not fall under the exemption under Section 18". While the applicable law of Serbia states 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".[64]

47. Similarly, the submission of Germany explains that Section 11(3) of the Patent Act "does not apply in case of production on stock/"stockpiling" of medicines by the pharmacy".[65] Rather, it notes, "the preparation must be aimed at a specific prescription and a specific person".[66] It further states that repeated application to the same specific patient is permissible in Germany.[67] In addition, it clarifies that the delineation between preparation upon individual recipe (*Rezepturarzneimittel*) and non-individual preparation (which is deemed to be outside the scope of the exception) can be done, taking into account the definition of "finished medicinal products (*Fertigarzneimittel*)" in the sense of section 4 para 1 of the German Medicinal Products Act (*Arzneimittelgesetz*).[68]

48. In Belgium, France, Italy and San Marino, patentee's rights do not extend, *inter alia,* to the "extemporaneous preparation", and "by unit", of medicines in pharmacies on medical prescription.[69] In Italy, such exception applies "provided that industrially produced active ingredients are not used".

49. The relevant statutory provisions of some other countries do not use the word "extemporaneous", but employ other terms, such as "only one time prescription", "one-time manufacturing" (e.g., Belarus and Tajikistan), "single preparation" (e.g., Armenia, Latvia and Estonia), or preparation "made up on the spot and for individual cases" (e.g., Macao, China), "in exceptional cases" (e.g., Azerbaijan), "for immediate use in individual cases" (e.g., Netherlands (Kingdom of the)) or "for a single patient" (e.g., Uruguay).

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64 See the response of Serbia to the Questionnaire.

65 Regional Court Munich I 11th November 1998 – file number 21O214395 21 O 2143/95; Higher Regional Court of Munich 22nd February 2001; BeckOK PatR/Ensthaler, 30th edn. 15th July 2023, PatG § 11 para 17; Benkard PatG/Scharen, 12th edn. 2023, PatG § 11 para 11; Mes, 5th edn. 2020, PatG § 11 para 13; Ann, Patentrecht, 11th edn. 2022, § 33 para 266, *cited in* the submission of Germany to SCP/36.

66 BeckOK PatR/Ensthaler, 30th edn. 15th July 2023, PatG § 11 para 17.

67 Benkard PatG/Scharen, 12th edn. 2023, PatG § 11 para 11.

68 See the submission of Germany to SCP/36.

69 For provisions of laws, see Appendix to this document.

50. Some other national law provisions express the similar notions by other words, such as "immediate" and "individual" preparation of medicines (e.g., Syrian Arab Republic) or "direct and individual" preparation of medicines based on a "single" prescription (e.g., Serbia, Montenegro and North Macedonia).

51. As the further examples of variations in wording, in Türkiye, the preparation of medicines in pharmacies involving "no mass production" and carried out to prepare "only one prescription" shall remain outside the scope of the rights conferred by a patent. In Argentina, "the routine dispensation" of drugs by authorized professionals, individually on medical prescription is authorized under the exception in question. In addition, the Patent Act of Thailand states that patent holder's rights do not extend to the "compounding of a drug specifically to fill a doctor's prescription".[70]

Sanofi-Aventis Farmaceutica Ltda and others v. Sp Farma Ltda, Court of Justice of the State of São Paulo, April 18, 2013[71] (Brazil)

This case concerns a dispute between Sanofi-Aventis Farmaceutica Ltda and Farma Ltda over the patented active ingredient 'rimonabant', used for treating obesity and cardiovascular diseases. Sanofi-Aventis Farmaceutica Ltda claimed, inter alia, that the defendant infringed its patents by importing and marketing rimonabant in Brazil. It also alleged that the activity carried out by the defendant did not fall within the exception provided for Article 43.III. of Law No. 9.279 of May 14, 1996. Specifically, Sanofi-Aventis asserted that Farma Ltda was not preparing medicines for individual cases as per medical prescriptions but was instead supplying the active ingredient to compounding pharmacies without authorization, thereby violating its patents.

The Court of Justice of the State of São Paulo, on April 18, 2013, decided, inter alia, that the supply of the active ingredient to compounding pharmacies is within the scope of Article 43 (III) of the Law on Industrial Property of Brazil.[72]

Specifically, the Court found that the defendant demonstrated, through the documents that accompanied the contestation, that it acted in the interests of compounding pharmacies, importing, in their favor, the active ingredient to be used by them for the preparation of individual medicines in accordance with medical prescriptions made for specific cases. Thus, it concluded that there had been no violation of the patent rights.

The Court also noted that the advertisement by the defendant to increase its clientele was irrelevant to the characterization of infringement or non-infringement of the patent rights, being just the way it used to stand out in the market in which it operated to attract new customers.

The Court also found that, in this case, it was demonstrated that the defendant's actions were linked to the activities developed by its clients, i.e., the compounding

70 *Ibid*.

71 Process No. 0158190-77.2008.8.26.0100.

72 Article 43 (III) of Law No. 9.279 of May 14, 1996 (Law on Industrial Property, as amended up to Law No. 14.200 of September 2, 2021) states: "43. The provisions of the previous Article do not apply: […] III. to the preparation of a medicine in accordance with a medical prescription for individual cases, carried out by a qualified professional, as well as to the medicine so prepared".

pharmacies, and the import orders assumed the existence of medical prescriptions for the active ingredient rimonabant for individual cases.[73] [non-official translation]

52. Some academic literature emphasize that the use of the exception must be medically, rather than economically, motivated. For example, in one study it is stated that "[…] the exception probably only matters in situations where there is medical justification for the pharmacy making up the medicament on the premises. In other situations, pharmacy staff doubtless prefer to sell an existing, ready packaged medicament. Economic considerations are usually of minor importance in these situations. Should it ever happen that hospital pharmacies systematically, but still for individual patients, and for economic – that is not medical – reasons choose to manufacture patented medicinal products under their own auspices, a teleological interpretation of the provision suggests that such action must be regarded as patent infringement, because the provision implies only sporadic, improvised and medically prompted use of patented medicinal products […]".[74]

"Acts concerning the medicine so prepared"

53. As noted above, most of the countries' laws which provide this exception state that "acts concerning the medicine so prepared", "activity related to a medicine prepared in this way", or "dealing with a medicine so prepared" are also within the scope of the exception.

54. In this respect, the submission of the Czech Republic explains that since the exception covers the preparation of medicines based on a prescription of a doctor who prescribes medication that is most suitable for the patient at a given moment, the phrase "acts concerning the medication so prepared' in its applicable law means that the medicine so prepared is "really usable only *ad hoc* for the needs of a specific patient, and the acts are limited to the possibility of delivering the prepared drug to the patient, sending it to another workplace or storing it until the collection time".[75]

55. According to the submission by Germany, while the exception relates to both product patents and process patents, the reference to "acts concerning the medicine so prepared" in Section 11 para 3, final half-sentence of the Patent Act of Germany expressly constitutes a limitation on the protection of products directly obtained by a patented process.[76] These acts "are encompassed by the provision only insofar as they are destined for the implementation of the medical prescription". [77]

6. Challenges Faced by the Member States in Implementing the Exception

56. Based on the responses to the Questionnaire from the Member States as well as their submissions to SCP/36, it may be concluded that the exception regarding extemporaneous

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73 The Court of Justice of the State of São Paulo, April 18, 2013, *Sanofi-aventis Farmaceutica Ltda and others v. Sp Farma Ltda*, No. 0158190-77.2008.8.26.0100.

74 Bengt Domeij, "Pharmaceutical Patents in Europe", Kluwer Law International, 2000, p. 310.

75 See the submission of the Czech Republic to SCP/36.

76 "*Unmittelbare Verfahrenserzeugnisse*" according to Section 9 sentence 2 number 3 German Patent Act. BeckOK PatR/Ensthaler, 30th edn. 15th July 2023, PatG § 11 para 18; Busse/Keukenschrijver, PatG, § 11, para 23 *cited in* the submission of Germany to SCP/36.

77 See the submission of Germany to SCP/36.

preparation of medicines has not posed any notable implementation issues at the national level across various countries.[78]

57. Although the ambiguity and uncertainty of national law provisions haven't been explicitly identified as implementation challenges for governments, as discussed elsewhere,[79] these matters may affect the utilization of the exception by relevant stakeholders, such as pharmacists and doctors.

7. Results of National/Regional Implementation of the Exception

58. As illustrated in Section 5 of this document, the exception regarding the extemporaneous preparation of medicines is found in the national laws of many countries. While widely adopted, no information has been identified or provided by countries with respect to the socio-economic effects resulting from the implementation of this exception at the national level.

59. As stated above, pharmacies differ in terms of the services they provide. The submissions from some European countries indicate that the preparation of medicines no longer takes place in pharmacies in their jurisdictions. Therefore, the practical use of the exception has been questioned.[80,81] The little number of court cases on this exception may also support this line of reasoning.[82,83]

60. Nevertheless, when viewed in terms of its primary role in balancing the interests of medical technology producers and users of patented products, submissions from some Member States indicate that the exception has been implemented at both national and

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78 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. See the responses to the Questionnaire at: https://www.wipo.int/scp/en/exceptions/. In the submission of the Czech Republic to SCT/36 also noted that: "[t]he application of this exception does not represent a practical problem in patent law as applicable in the Czech Republic.".

79 See document SCP/26/5.

80 See the responses to the Questionnaire from Denmark, Norway and Sweden. One specialized literature also confirms that: "[i]n the past, pharmacies revolved around the manufacture and provision of medicines, rather than on those who consumed them. However, in the latter half of the twentieth century extemporaneous preparations largely disappeared in many European countries, such as Denmark, Greece, Portugal and Sweden. In the Netherlands they currently constitute 5.3% of all dispensed medicines" ("Pharmacy Practice" edited by Kevin M.G.Taylor, Taylor & Francis e-Library, 2005, p.53).

81 Referring to the capacity of pharmacies, the response from the Russian Federation to the SCP/36 notes that: "[…] a one-off pharmacy manufacturing according to an individual prescription cannot be regarded as a patent infringement, since it covers such inventions that relate to methods of obtaining medicines and these technical solutions utilize either industrial technological methods of obtaining compounds or compositions comprising medicines which are not used in pharmacies […]".

82 Several countries reported responding to the Questionnaire that no single judicial decision exist with respect to the exception in respective countries. See also the responses of Lithuania and the Czech Republic to SCP/36.

83 Such conclusions can also be found in some literature. E.g., a study by UNCTAD-ICTSD raised questions about the continued appropriateness and impact of the exception concerned. It notes that the exception "is unlikely to provide much, if any, assistance at the present day". This is because most pharmacies, even in developed countries, lack the resources and capabilities of pharmaceutical companies and therefore cannot produce generic versions of patented medicines on demand. Consequently, the study argues, this exception is mostly applicable to simpler tasks, such as making variations of topical creams, and poses little commercial threat to pharmaceutical companies. Historically, the exception might have been more useful when the preparation of patented medicines was less complex. In the future, the study notes, if pharmacies gain access to advanced technologies, the utility and implications of this exception might change. UNCTAD-ICTSD "Exceptions to patent rights in developing countries", by Christopher Garrison, p.7 and 8, August 2006.

regional levels without disturbing this balance.[84] Additionally, in responding to the Questionnaire, all Member States that addressed the adequacy of the legal framework for this exception confirmed its effectiveness in achieving the intended objectives.

[Appendix follows]

84 See *supra* note 78.