

Draft Reference Document on the Exception Regarding Extemporaneous Preparation Of Medicines (SCP/36/3)

Presentation by the Secretariat

Standing Committee on the Law of Patents
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SCP/36/3: Background

At SCP 35 (October 16 to 20, 2024), the Committee agreed that:

The Secretariat would

- Continue working on a draft reference document on exceptions and limitations to patent rights
- Submit a draft reference document on [exception regarding extemporaneous preparation of medicines](#) to SCP/36

Annex to document SCP/36/3 contains the draft reference document

The Secretariat made use of information provided by the Member States, as well as other information made available through various SCP activities

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APPENDIX

Section 1: Overview of the exception regarding extemporaneous preparation of medicines

- ❑ Extemporaneous preparation - the process of preparing medications on the spot, often customized for an individual patient, based on a doctor's prescription
 - Ex. process of compounding drugs, mixing ingredients, or creating dosages and forms of medication tailored to the unique needs of a patient.
- ❑ In general, the effect of the exception - **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.**

Section 2: Objectives and goals of the exception regarding extemporaneous preparation of medicines

Balancing rights

The exception achieves an appropriate balance between the rights of patent holders and the needs of patients and healthcare providers

Supporting public interest in healthcare

Allowing pharmacists to prepare prescribed medicines based on prescriptions without fear of patent infringement supports the public interest in healthcare, thus safeguarding patient care and addressing specific medical needs

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

Recognizing the social mission of healthcare providers

Recognizes the special social mission of pharmacists and healthcare providers in restoring the health of patients

Section 3: International legal framework of the exception regarding the extemporaneous preparation of medicines

- ❑ No international treaty expressly addresses the exception regarding the extemporaneous preparation of medicines in pharmacies.
- ❑ Article 30 of the TRIPS Agreement outlines general principles regarding the exceptions to the rights which may be provided by the WTO Members.
- ❑ In WTO Dispute Settlement Panel in *Canada - Patent Protection of Pharmaceutical Product* case, the exception described as “mostly historic”.

Section 4: Exception regarding extemporaneous preparation of medicines under regional instruments

Regional instruments

Agreement on a Unified Patent Court (UPCA)

Article 27(e) of the UPCA:

“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;”

Patent Regulations under the Eurasian Patent Convention

Rule 19 of the Patent Regulations:

“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;”

Section 5: National implementation of the exception regarding extemporaneous preparation of medicines

Countries and territories	Total number
<p>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.</p>	85

Section 5: National implementation of the exception regarding extemporaneous preparation of medicines

Scope of the exception

□ Conditions to be fulfilled simultaneously:

- 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.

Section 5: National Implementation of the Exception Regarding Extemporaneous Preparation of Medicines

Scope of the exception

□ Definitions:

“Medicine” –

- No definition provided in patent laws of most countries (except Japan)
- In some countries, a definition provided in national/regional laws governing pharmaceutical products are relevant (e.g. Germany and Spain)
 - In Germany, “cosmetics” and “food” do not qualify as “medicines”

“Pharmacy” –

- “the art, practice, or profession of preparing, preserving, compounding, and dispensing medical drugs” (Merriam-Webster dictionary)
- Operating as a pharmacy requires a compliance with all legal and regulatory requirements for pharmacies in a relevant jurisdiction

Scope of the exception

❑ Persons entitled to invoke the exception

- ❑ Many legislations do not specify the entitlement, but locations, such as ‘pharmacies’
- ❑ In Germany - pharmacist, pharmacist’s assisting staff are entitled
 - ❑ The exception does not apply where the medicine is prepared by the doctor, in a drugstore, in the laboratory of a hospital, or in any other place of manufacturing
- ❑ In Zambia, the preparation of a medicine for individual cases shall be made in a pharmacy “or by a medical doctor”
- ❑ The Philippines, a preparation shall be made in a pharmacy “or by a medical professional”
- ❑ In Thailand, the provision refers to a “professional pharmacist or a medical practitioner”
- ❑ In Cabo Verde, Macao China and Tunisia, the individual preparation of medically prescribed drugs shall be carried out by “dispensing chemists”
- ❑ In Argentina, Cuba, and Uruguay, the relevant provisions refer to “authorized professional”

Scope of the exception

The preparation in accordance with a doctor's prescription

- ❑ Some statutes provide details on who can issue a prescription
- ❑ In Armenia, Iceland, Japan, Lithuania, Poland, and Sweden - a prescription by a “physician”
- ❑ In Ireland and Mozambique - a prescription by a “registered medical practitioner”
- ❑ In many other countries - in addition to a registered medical practitioner, a “registered dentist”, “registered dental practitioner”, or “dental specialist or a dental surgeon” can produce such a prescription
- ❑ In Germany, a doctor encompasses “medical doctors, dentists and veterinarians, but not alternative/homeopathic practitioners”

Scope of the exception

Extemporaneous preparation in individual cases

- ❑ The “extemporaneous preparation” - the process of preparing a customized medication according to a specific prescription.
- ❑ Quantitative restrictions - it must relate to individual cases:
 - ❑ a prescription must be written for one particular individual, and production should be carried out on an individual scale, not a large-scale manufacturing, in advance production and stockpiling.
- ❑ Other terms used: “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).

Scope of the exception

“Acts concerning the medicine so prepared”

- ❑ In many countries, “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.
- ❑ The Czech Republic, the phrase “acts concerning the medication so prepared” 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”.
- ❑ In Germany, the reference to “acts concerning the medicine so prepared” in Section 11 para 3 of the Patent Act constitutes a limitation on the protection of products directly obtained by a patented process. These acts “are encompassed by the provision only insofar as they are destined for the implementation of the medical prescription”.

Section 6: Challenges faced by the member states in implementing the exception

- ❑ The exception regarding extemporaneous preparation of medicines **has not posed any notable implementation issues** at the national level

(based on the responses to the Questionnaire from the Member States as well as their submissions to SCP/36)

- ❑ However, **the ambiguity and uncertainty of national law provisions may affect the utilization of the exception** by relevant stakeholders, such as pharmacists and doctors

Section 7: Results of national/regional implementation of the exception

- ❑ 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.
- ❑ Some submissions indicate that the preparation of medicines no longer takes place in pharmacies in their jurisdictions.
- ❑ Nevertheless, some submissions indicate that the exception has been implemented at national level without disturbing a balance between the interests of medical technology producers and users of patented products.

Thank you for your attention.

