THE CZECH REPUBLIC

26th March 2024

(i) INPUTS FOR THE PREPARATION OF A DRAFT REFERENCE DOCUMENT ON THE EXCEPTION REGARDING EXTEMPORANEOUS PREPARATION OF MEDICINES

According to Section 18 paragraph c) of Act No. 527/1990 Coll. on Inventions and Rationalisation Proposals, as amended, the rights of the patent holder are not infringed by use of the protected invention in the individual preparation of a medicine in a pharmacy based on a medical prescription including acts concerning the medication so prepared.

This provision was adopted as part of the international harmonization of patent law for the purpose of public interest in health protection.

In order to apply this exception, several conditions must be fulfilled simultaneously[1].

First, the medicine must be prepared in a pharmacy. A pharmacy is an operator authorized to dispense medicinal products according to Act No. 378/2007 Coll., on Pharmaceuticals, as amended. 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 (Act No. 258/2000 Coll., on the Protection of Public Health, as amended) in the case of human autogenous vaccines.

Second, 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.

Third, the medicine is created on a prescription. Only 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. ‘Acts concerning the medication so prepared’ means that the drug 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.

The application of this exception does not represent a practical problem in patent law as applicable in the Czech Republic. The Industrial Property Office of the Czech Republic is not aware of any court judgements regarding the interpretation of this exception.

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[1] Chloupek V., Hartvichová K. et al. (2017) *Patent Act – Commentary*. (1st edition). C.H.Beck

(ii) INPUTS FOR THE PREPARATION OF A STUDY ON VARIOUS ASPECTS OF THE UNITY OF INVENTION, INCLUDING DIVISIONAL APPLICATIONS

According to Section 26 paragraph 1) of Act No. 527/1990 Coll. on Inventions and Rationalisation Proposals, as amended (the Patent Act), an application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept. Where a group of inventions is claimed in one and the same patent application, the requirement of unity of invention shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression 'special technical features' shall mean those features which define each of the claimed inventions considered as a whole which make a contribution to the prior art.

Divisional applications are regulated by Section 13 of Degree No. 550/2000 Coll., on proceedings in matters of inventions and industrial designs.

> Pursuant to Paragraph 1 of this Section, if the Industrial Property Office ascertains that the application for an invention does not comply with the requirements of Section 26 (1) of the Patent Act, it invites the applicant to remedy this defect within a set time limit. Divisional patent applications enjoy the priority right of the original application if the applicant files them within 3 months after remedying the defect from the original application. The applicant may also divide the application for an invention up to the date of grant of patent, on his/her own initiative.
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> Paragraph 2 of Section 13 stipulates, that, if the application is divided after the launch of the full examination in accordance with Section 33 of the Patent Act, the divisional application is deemed to be an application for which a request for full examination was filed.
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> Finally, according to paragraph 3 in the case of a divisional application, the applicant is obliged to pay administrative fees corresponding to the state of the procedure in terms of the original application at the time of division.

Under the EPO cooperation programme focused on the convergence of practice, the Czech Republic participated in the Working Group on the unity of invention. The patent practice of the Industrial Property Office as regards the examination of unity of invention is in line with the recommendations provided by the Working Group. For additional information, please follow these two links:

https://www.epo.org/en/law-practice/convergence-of-practice

https://link.epo.org/web/common_practice_examination_of_unity_of_invention_en.pdf