

WIPO Circular C.9199

Contribution of Germany to a draft reference document on the exception regarding extemporaneous preparation of medicines

A. General Remarks

In German Patent law, an exception regarding extemporaneous preparation of medicines is laid down in **Section 11 para 3** of the German Patent Act. It has been introduced in 1981.¹ According to this provision, the effect of a patent shall not extend to the extemporaneous preparation in a pharmacy, in individual cases, of a medicine in accordance with a medical prescription or acts concerning the medicine so prepared.² Its purpose is to **facilitate medical-pharmaceutical activities**,³ in particular the freedom of doctors in issuing recipes.⁴ With a view to safeguarding the freedom of doctors to conduct medical treatment, the provision is widely considered a “complement” to the exclusion from patentability in Section 2a para 1 number 2 sentence 1 German Patent Act of methods for the treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body.⁵

The exception relates to both product patents and process patents.⁶ The reference to “*acts concerning the medicine so prepared*” (Section 11 para 3, final half-sentence) expressly constitutes a limitation on the protection of products directly obtained by a patented process (“*unmittelbare Verfahrenserzeugnisse*” according to Section 9 sentence 2 number 3 German Patent Act).⁷ The German Utility Models Act, although also offering protection for medicines, does not contain a provision such as section 11 para 3 German Patent Act.⁸

B. Legal literature and case law on selected criteria of the provision

I. Medicine

¹ Ann, Patentrecht, 11th edn. 2022, § 33 para 264.

² Translation according to https://www.gesetze-im-internet.de/englisch_patg/englisch_patg.html#p0092, an online service by the German Federal Ministry of Justice. Please note that the translations of German statutes into languages other than German available there are intended solely as a convenience to the non-German-reading public and that any discrepancies or differences that may arise in translations of the official German versions of these materials are not binding and have no legal effect for compliance or enforcement purposes (https://www.gesetze-im-internet.de/Teilliste_translations.html). The original German wording of the provision is: „Die Wirkung des Patents erstreckt sich nicht auf die unmittelbare Einzelzubereitung von Arzneimitteln in Apotheken auf Grund ärztlicher Verordnung sowie auf Handlungen, welche die auf diese Weise zubereiteten Arzneimittel betreffen.“

³ BeckOK PatR/Ensthaler, 30th edn. 15th July 2023, PatG § 11 para 17; Mes, 5th edn. 2020, PatG § 11 para 12; Schulte, Patentgesetz mit EPÜ, 11. Edn. 2022, § 11 PatG, para 21.

⁴ Ann, Patentrecht, 11th edn. 2022, § 33 para 265.

⁵ Ann, Patentrecht, 11th edn. 2022, § 33 para 265; Mes, 5th edn. 2020, PatG § 11 para 12; Schulte, Patentgesetz mit EPÜ, 11th edn. 2022, § 11 PatG, para 21.

⁶ Benkard PatG/Scharen, 12th edn. 2023, PatG § 11 para 11.

⁷ BeckOK PatR/Ensthaler, 30th edn. 15th July 2023, PatG § 11 para 18; Busse/Keukenschrijver, PatG, § 11 para 23.

⁸ Ann, Patentrecht, 11th edn. 2022, § 33 para 264.

The exception relates to “medicines” without explicitly defining this term. The legal commentary literature suggests to take recourse to the definition of “medicinal product” in Section 2 of the German Medicinal Products Act (Arzneimittelgesetz).⁹ Cosmetics¹⁰ and food¹¹ have been found by courts to not be “medicines”.

II. Pharmacy

The preparation must take place in a pharmacy.¹² It can be done by the pharmacist herself/himself and/or the pharmacist’s assisting staff.¹³ Also pharmacies of hospitals can be pharmacies in the sense of the provision, as long as the other criteria of the provision are fulfilled.¹⁴ The provision does, in contrast, not apply where the medicine is prepared by the doctor herself/ himself,¹⁵ in a drugstore, in the laboratory of a hospital,¹⁶ or in any other place of manufacturing.¹⁷

III. Medical prescription

The medical prescription must have been issued by a doctor. This encompasses medical doctors, dentists and veterinarians, but not alternative/ homeopathic practitioners.¹⁸

IV. Extemporaneous preparation in individual cases

The preparation of the medicine must relate to individual cases. The provision does thus not apply in case of production on stock / “stockpiling” of medicines by the pharmacy.¹⁹ Rather, the preparation must be aimed at a specific prescription and a specific person.²⁰ Repeated application to the same specific patient is permissible.²¹ The delineation between preparation upon individual recipe (“Rezepturazneimittel”) and non-individual preparation can be done

⁹ 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.

¹⁰ Cf. BGH GRUR 2001, 450 - *Franzbranntwein-Gel*.

¹¹ Cf. BGHZ 151, 286 (295 f.) – *Muskelaufbaupräparate*; BGH GRUR 2000, 528 - *L-Carntin*; BGH GRUR 2004, 79 - *Sportlernahrung II*.

¹² According to Schulte, Patentgesetz mit EPÜ, 11th edn. 2022, § 11 PatG, para 22, the pharmacy must have a license according to the Law on Pharmacies (“Gesetz über das Apothekenwesen”) of 20th August 1960 (BGBl I 697).

¹³ LG Hamburg Mitt. 1996, 315 (319); Mes, 5th edn. 2020, PatG § 11 para 14.

¹⁴ 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.

¹⁵ Mes, 5th edn. 2020, PatG § 11 para 14.

¹⁶ Benkard PatG/Scharen, 12th edn. 2023, PatG § 11 para 11.

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

¹⁸ BeckOK PatR/Ensthaler, 30th edn. 15th July 2023, PatG § 11 para 17; Benkard PatG/Scharen, 12th edn. 2023, PatG § 11 para 11.

¹⁹ 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.

²⁰ BeckOK PatR/Ensthaler, 30th edn. 15th July 2023, PatG § 11 para 17.

²¹ Benkard PatG/Scharen, 12th edn. 2023, PatG § 11 para 11.

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).²²

V. “Acts concerning the medicine so prepared”

“Acts concerning the medicine so prepared” (Section 11 para 3, final half-sentence) are encompassed by the provision only insofar as they are destined for the implementation of the medical prescription.²³

²² Benkard PatG/Scharen, 12th edn. 2023, PatG § 11 para 11. Section 4 para 1 of the German Medicinal Products Act reads, according to https://www.gesetze-im-internet.de/englisch_amg/englisch_amg.html#p0108 (please note the information on the legal validity of translations in footnote 1): “*Finished medicinal products are medicinal products that are manufactured beforehand and placed on the market in packaging intended for distribution to the consumer, or other medicinal products intended for distribution to the consumer in the preparation of which any form of industrial process is used, or medicinal products that are produced commercially, except in pharmacies. Finished medicinal products are not intermediate products intended for further processing by a manufacturer.*”

²³ BeckOK PatR/Ensthaller, 30th edn. 15th July 2023, PatG § 11 para 18; Ann, Patentrecht, 11th edn. 2022, § 33 para 266.