

Research Exception in Germany

Section 11 [Permitted acts] The effect of a patent shall not extend to [...]

2. acts done for experimental purposes relating to the subject matter of the patented invention;

I. Introduction

German patent law contains an exception for experimental or research purposes (*research exception*) in Section 11 no. 2 of the Patent Act (*Patentgesetz*). The provision is essentially based on Art. 31(b) of the *Convention for the European Patent for the Common Market (Community Patent Convention)* of 15 December 1975.¹ Although this Convention has not entered into force, Germany and other contracting states have brought their national laws into line with the Convention.² Section 11 no. 2 of the Patent Act entered into force on 1 January 1981 and stipulates that acts done for experimental purposes which relate to the subject matter of a patented invention are exempt from patent protection.³

The Federal Court of Justice (*Bundesgerichtshof - BGH*) dealt with Section 11 no. 2 of the Patent Act in particular in the decisions *Klinische Versuche I*⁴ and *Klinische Versuche II*⁵ (clinical trials) and shaped the interpretation of the provision. The interpretation of the *Klinische Versuche I* proceedings was indirectly confirmed by the Federal Constitutional Court (*Bundesverfassungsgericht - BVerfG*).⁶

II. Objective of the provision

The purpose of patent law is to promote technical progress. To this end, an exclusive right is granted as an incentive. This may impede research into inventions already patented. Against this background, the exemption provision of Section 11 no. 2 of the Patent Act limits patent protection and thus facilitates the development of new technologies on the basis of patented inventions.⁷

III. Conditions of the provision

Section 11 no. 2 of the Patent Act is applicable if (1) an act is performed for experimental purposes which (2) relates to the subject matter of the patented invention.

1. Act done for experimental purposes

An experiment is any planned action for gaining knowledge.⁸ According to the case law of the Federal Court of Justice, the term must be interpreted broadly and, as a rule, covers all experimental acts, irrespective of the motivation and the purpose for which the knowledge gained is ultimately intended.⁹ Therefore, experiments, tests or trials, etc. aimed at removing

¹ BIPMZ 1979, p. 305 (309); Mes, PatG, 4th ed. 2015, Sec.11 marginal no. 5.

² BGH, judgement of 11 July 1995 – X ZR 99/92 – *Klinische Versuche I*.

³ BGBl. I of 3 August 1979, p. 1284, Art. 17(3).

⁴ BGH, *Klinische Versuche I*.

⁵ BGH, judgement of 17 April 1997 – X ZR 68/94 – *Klinische Versuche II*.

⁶ BVerfG, ruling of 10 May 2000 – 1 BvR 1864/95.

⁷ Scharen in: Benkard, PatG, 11th ed. 2015, Sec.11 marginal no. 2; BGH, *Klinische Versuche I and II*.

⁸ BGH, *Klinische Versuche I*; Rinken in: Schulte, PatG, 10th ed. 2017, Sec.11 marginal no. 10.

⁹ BGH, *Klinische Versuche I and II*.

an existing uncertainty (e.g. by finding something unknown or testing a hypothesis) may be considered.¹⁰

In its decision *Klinische Versuche I*, the Federal Court of Justice affirmed the applicability of Section 11 no. 2 of the Patent Act also for experiments on humans which are conducted with the intention to find out whether a patented drug is suitable for curing or alleviating other diseases (second indication). The exemption provision is even applicable if the nature of experiments goes beyond pure research and economic interests are also pursued.¹¹

This broad interpretation was confirmed by the Federal Court of Justice in 1997 in a second ruling on clinical trials: According to the court, Section 11 No. 2 of the Patent Act was also applicable if the trials served the purpose of obtaining data for gaining authorisation to put medicinal products on the market in respect of a pharmaceutical composition. In this context, the Federal Court of Justice adhered to its view that economic interests, as a rule, did not conflict with the application of Section 11 no. 2 of the Patent Act. However, the court specified that the exemption provision did not apply to experiments which only served to clarify commercial factors, such as market needs, price acceptability and distribution options.¹²

2. Relation to the subject matter of the patented invention

Furthermore, the experimental act must relate to the subject matter of the patented invention. This is the case if the technical teaching of the patent claim is the object of the experimental act.¹³

This criterion is used by the Federal Court of Justice to limit the broad scope of application of the term “experiment”.¹⁴ In its *Klinische Versuche II* decision, the court made it clear that the experimental act and the subject matter of the patented invention are not related if the experiment is performed on such a large scale that it is no longer justifiable by the experimental purpose.¹⁵ Even if the sole purpose of the experiment is to lastingly disrupt the sale of another person’s patented product, there is no relation to the subject matter of the patented invention. In keeping with the spirit and the purpose of the provision, it is also necessary to promote technical progress.¹⁶ If a patented subject matter is only used as a tool within the scope of the experiment, there is no relation either.¹⁷ The same applies to bioequivalence studies, which merely aim to establish that medicinal products with the same active substance that are manufactured in different ways can be substituted for each other without putting the patient at risk.¹⁸ However, bioequivalence studies may be covered by the exemption provision of Section 11 No. 2b of the Patent Act (referred to as *Bolar exception*).¹⁹

¹⁰ Scharen, loc.cit., Sec.11 marginal no. 6.

¹¹ BGH, *Klinische Versuche I*.

¹² BGH, *Klinische Versuche II*.

¹³ BGH, *Klinische Versuche I and II*; Rincken, loc. cit., Sec.11 marginal no. 10.

¹⁴ BGH, *Klinische Versuche I and II*; OLG Düsseldorf, GRUR-RR 2014, 100 (103).

¹⁵ BGH, *Klinische Versuche II*.

¹⁶ BGH, *Klinische Versuche II*; Ensthaler in: Fitzner/Lutz/Bodewig, PatG, 4th ed. 2012, Sec.11 marginal no. 10.

¹⁷ Keukenschrijver in: Busse/Keukenschrijver, PatG, 8th ed. 2016, Sec.11 marginal no. 18; Holzapfel in: GRUR, 2006, 10 (13); Hufnagel in: PharmaR 2006, 209 (214).

¹⁸ Scharen, loc. cit., Sec.11 marginal no. 8; Keukenschrijver, loc. cit., Sec.11 marginal no. 16.

¹⁹ Mes, loc. cit., Sec.11 marginal no. 10; Rincken, loc. cit.; Sec.11 marginal no. 19.