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Editors: Karin Hoffmann, postal address c/o Verlag C.H.BECK oHG, Wilhelmstr. 9, 80801 Munich, and Attorney Rolf-Georg Müller, LL.M., Wilhelmstraße 9, 80801 Munich

Essays

Dr. Marco Stief*

Pharmaceutical patents: Exceptions to patent protection — trial privilege, Bolar exemption, SPC waiver, and compulsory license

The first part of this series of articles, published in PharmR 2024, 577, analyzed in detail the forms and acts of infringement within the meaning of Section 9 of the German Patent Act (PatG) in relation to pharmaceutical patents. This second part now provides an overview of existing restrictions and exceptions to patent protection in the pharmaceutical sector, focusing on current developments in German and European law.

I. Introduction

Patent law serves to protect innovations and guarantees inventors the exclusive right to exploit their inventions. The patent holder receives compensation for enriching technology and innovation with their invention and making it available to the general public. The temporary monopoly in the form of an exclusive right, which does not allow third parties to use the invention without the patent holder's permission, is intended to promote technical progress and create an incentive for investment in research and development. However, in the conflict between protecting innovation and the public interest, situations arise in which the strict enforcement of property rights can be inappropriate or obstructive to technical and innovative progress. In order to strike a fair balance between protecting the rights of patent holders and the public interest in new developments and the availability of affordable medicines, legislators and courts recognized early on that exceptions to patent protection are necessary to promote research and development, which is precisely

should be incentivized by patents, should not be subject to excessive fees.¹ The most important exceptions are probably the so-called experimental privilege², which allows the use of patented inventions for research purposes, and the so-called Bolar privilege³, which allows preparatory acts for the market launch of generics⁴ before the patent expires. In any case, compulsory licensing, which allows government authorities to permit third parties to use a patent without the consent of the patent holder in order to ensure access to essential medicines, has been of relatively little significance in practice to date. While the above exceptions are now considered to be largely established, a special further exception for the manufacture, storage, and export of medicines in the EU was introduced about five years ago with the so-called "SPC waiver." This makes it possible to manufacture, store, and export medicines in the EU before the expiry of the supplementary protection certificate.

* Dr. Marco Stief, LL. M., is a lawyer and partner at Maiwald's Munich office, where he heads the legal department, www.maiwald.eu. The author would like to thank research assistant Arzu Genc for her assistance in preparing this article.

1 See *Hufnagel*, PharmR 2006, 209 (209).

2 Also known as "research privilege," "research exemption," and "experimental use exemption."

3 Also known as market authorization privilege or "Bolar exemption."

4 According to Art. 10(2)(b) of the amended Directive 2001/83/EC, a generic drug is a medicinal product that has the same qualitative and quantitative composition of active ingredients and the same dosage form as the reference medicinal product and whose bioequivalence with the reference medicinal product has been demonstrated by appropriate bioavailability studies.

Protective certificate (SPC) for export to third countries or only six months before its expiry for future sale in the EU. Another restriction on patent protection is the so-called exhaustion.

II. Exceptions to patent protection

1. The experimental privilege

As already mentioned at the outset, unrestricted exclusive rights can not only promote scientific progress, but also hinder it. In order for research and the general public to be able to build on patented inventions, it was recognized early on that, at least in principle, it must be possible to use patented inventions for experiments and testing purposes. Following this idea, the experimental privilege was introduced, which allows third parties, under certain conditions, to research patented technologies in order to create new knowledge. Among other things, this also guarantees the freedom of research and teaching enshrined in Article 5(3) of the German Basic Law.

a) Origin of the experimental privilege

The privilege of experimentation originated in the United States. Unlike in all European countries, where the privilege of experimentation is enshrined in law, its scope in the US has been defined by case law. As early as 1813, Justice Joseph Story ruled in the landmark decision *Whitmore v. Cutter*⁵ that pure research activities should not be considered an infringement of patent rights. This view was further consolidated in the case law that followed over the next few decades. The relevant decisions emphasize⁶ that scientific research and experimental activities that do not pursue a commercial purpose, i.e., are not aimed at making a profit or at the production or sale of products, do not constitute patent infringement.

b) European development

In any case, with the harmonization of the European Patent Law

, the granting of an experimental privilege. For example, Article 20(3) of the "Preliminary Draft of an Agreement on European Patent Law" of 1962 already provided for a provision that excluded acts for experimental purposes from patent protection.⁷ This provision was later incorporated in revised form into Article 31 of the Community Patent Convention⁸ (CPC) of 1975 and was transferred to Article 27 CPC in 1989 and retained unchanged.

Although the GPÜ itself never came into force, it nevertheless had a significant influence on the shaping of European and German patent law. All member states have now incorporated identical or at least similar provisions into their national jurisdictions, even if the scope and limits vary from member state to member state.⁹ The German Community Patent Act () adopted in

1981¹⁰ adopted essential parts of the system developed in the EPC, including, among other things, the provisions on the privilege of disclosure. After the relevant provision was initially included in Section 6b of the then Patent Act¹¹, it was transferred to Section 11 PatG¹² in the course of a comprehensive reform of patent law, where it can still be found today.

c) German legal situation

Sections 11(1) to (6) of the PatG regulate a number of exceptions to the effects of a patent as regulated in Section 9 PatG. According to Section 11 No. 2 PatG, which codifies the experimental privilege, "actions for experimental purposes relating to the subject matter of the patented invention" are privileged and do not constitute an infringement of the exclusive rights granted to the patent holder. All experiments that serve the purpose of researching the invention are permitted, although the invention itself may not be used to gain knowledge in another field. Accordingly, research *on* the invention is permitted, but not research *with* the invention.

The decisions *Klinische Versuche I* (Clinical Trials I)¹³ and *Klinische Versuche II* (Clinical Trials II)¹⁴ handed down by the Federal Court of Justice (BGH) in 1995 and 1997 had a significant influence on the interpretation and legal framework of the experimental privilege in the field of pharmaceutical research in Germany. In *Clinical Trials I*, the generic drug company sued for alleged patent infringement conducted clinical studies to research new applications for the patented active ingredient. The BGH ruled that, in order to qualify as an experiment within the meaning of Section 11 No. 2 PatG, it was sufficient that the experiments were carried out to gain new knowledge, regardless of the purpose for which the knowledge gained was intended to be used.¹⁵ The Federal Court of Justice affirmed the application of the experimental privilege to the clinical trials, since at least one of the purposes of the trials was to investigate a patented active ingredient for a previously unknown effect. The court found that the exemption

"[...] exempts all experimental activities, insofar as they serve to gain knowledge and thus advance scientific progress

5 *Whittemore v. Cutter*, 29 Fed. Cas. 1120 (C.C.D. Mass. 1813) (No. 17, 600).

6 See, e.g., *Sawin v. Guild*, 21 Fed. Cas. 554, No. 12,391 (C.C.D. Mass. 1813); *Poppenhusen v. Falke*, 19 F. Cas. 1048, 1049 (C.C.S.D.N.Y. 1861) (No. 11, 279); *Madey v. Herzog*, 307 F. 3d 1351 (Fed. Cir. 2002).

7 See *Holzappel*, The Experimentation Privilege in Patent Law and the Protection of Biotechnological Research Tools, p. 53.

8 The CPTA is an independent treaty under international law.

9 See overview: *Epping/Gerstberger*, PharmR 2003, 257.

10 Act of July 26, 1979, Federal Law Gazette I, p. 1269.

11 For a detailed history of the experimental privilege, see: *Holzappel*, Das Versuchsprivileg im Patentrecht und der Schutz biotechnologischer Forschungswerkzeuge, p. 53 ff.

12 Act of December 16, 1980, Federal Law Gazette 1981 I p. 1.

13 BGH, GRUR 1996, 109 — Clinical Trials I.

14 BGH, NJW 1997, 3092 — Clinical Trials II.

15 BGH, GRUR 1996, 109 (112) — Clinical Trials I.

scientific research on the subject matter of the invention, including its use" ¹⁶.

This applies regardless of the fact that the defendant subsequently (also) used the study results in the context of a drug approval procedure. The court further clarified that the mere fact that the trials also serve a commercial purpose does not automatically render the exemption inapplicable.¹⁷ However, if the experiments or studies serve solely to research commercial interests, the experimental privilege does not apply.

In its subsequent ruling on *Clinical Trials II*, the Federal Court of Justice then ruled that clinical trials may fall under the exemption even if the main or even sole motivation for the trials was to obtain data for the purpose of obtaining regulatory approval for a pharmaceutical composition and to use the results obtained for commercial purposes.¹⁸ The Federal Court of Justice took a different view with regard to so-called bioequivalence studies and held that the trial privilege does not apply to such studies. Bioequivalence studies aim to confirm that two drugs with the same active ingredient, namely an approved original preparation and a generic drug, are interchangeable without risk to the patient, despite differences in the manufacturing process and/or excipients.¹⁹ Their objective is to prove that the new drug is substantially similar to the already approved product and has the same pharmacological properties.²⁰ Bioequivalence studies are therefore not intended to generate new knowledge, but to confirm that a generic drug and an original drug are interchangeable. In this respect, the Federal Court of Justice followed, at least in its conclusion, the British " " (Touchdown decision) issued by the " " (Medicines Commission) in 1985 ¹⁹⁸⁵ "Touchdown" decision.²¹ The *Clinical Trials II* decision is particularly significant in view of the Bolar exception introduced in the EU seven years later (see B.II.).

d) Limits of the experimental privilege: research tools

While case law and legal doctrine have further elaborated and clarified the scope of the privilege of experimentation over the past decades, the highest court has not yet ruled on whether patented

"Research tools" fall under the exemption of Section 11(2) PatG. Such research tools are understood to be processes and products that are (primarily) used to investigate other objects, e.g., microscopes, reagents, or chemical processes, but also monoclonal antibodies, animal models, or sequence databases.²² The purpose of using these tools is therefore not to explore their own patented functionality, but to research other objects. The prevailing view is therefore that including research tools in the scope of the experimental privilege would undermine patent protection.²³

A key argument against the application of the experimental privilege is the risk that patent protection for such tools would effectively be rendered meaningless if the experimental privilege also permitted the use of such tools. This, in turn, would not only reduce the economic incentive to develop new research tools, but also lead to a situation where the experimental privilege would be used to circumvent the protection of such tools.

protection for such tools would become de facto meaningless if the testing privilege also allowed the use of such tools. This, in turn, would not only reduce the economic incentive to develop new research tools, but also make it more difficult to disclose innovative technologies.

2. The Bolar exception²⁴

The experimental privilege is supplemented by the so-called Roche-Bolar rule²⁵ (hereinafter referred to as the Bolar exemption). This exemption from patent protection allows drug manufacturers to conduct clinical trials that are necessary for obtaining marketing authorization under pharmaceutical law, even while the patent or SPC is still in force.²⁶ The aim of the Bolar Exemption is to enable generic drug manufacturers to conduct the studies and trials required for the granting of marketing authorization before the patent expires, so that they can enter the market quickly after the expiry of the property right (known as Day 1 Entry). Without this exception, the tests and clinical trials required to prove equivalence for the approval of a generic or biosimilar could only be started after the expiry of the property right. This would mean that the patent protection of the original product would be extended de facto by several months or even years beyond the statutory term of protection until the drug approvals required for the marketing of the generic drug had been granted.²⁷ This would lead to considerable additional financial burdens for the public health system and unduly prolong the monopoly position of the holder of pharmaceutical patents.

a) Origin and legal basis

aa) Origin of the Bolar exception

The Bolar exception²⁸ has its origin in the United States, more specifically in a court case before the *United States Court of Appeals for the Federal Circuit*

¹⁶ BGH, GRUR 1996, 109 (113) — Clinical Trials I.

¹⁷ BGH, GRUR 1996, 109 (115) — Clinical Trials I.

¹⁸ BGH, NJW 1997, 3092 (3092) — Clinical Trials II.

¹⁹ Higher Regional Court of Düsseldorf, GRUR-RR 2014, 100 (102).

²⁰ Higher Regional Court of Düsseldorf, GRUR-RR 2014, 100 (102).

²¹ Monsanto v. Stauffer Chemical, Decision of the Court of Appeal of June 11, 1985, GRUR Int. 1987, 108.

²² See Holzappel, GRUR 2006, 10 (11).

²³ See, for example, Haedicke, Patentrecht (Patent Law), 6th ed. 2022, Chapter 7, margin note 21 and Holzappel, GRUR 2006, 10 (16 f.).

²⁴ For details on the Bolar exception in the EU, see: Stief, GRUR Int. 2024, 824.

²⁵ The Roche-Bolar rule owes its name to the US case *Roche v. Bolar*, which was decided in 1984 before the US Court of Appeals for the Federal Circuit, see Roche Products, Inc. Appellant, v. Bolar Pharmaceutical Co., Inc., Appellee, 733 F. 2d 858, Fed. Cir. 1984.

²⁶ See Kühnen, Handbuch der Patentverletzung (Handbook of Patent Infringement), 16th ed. 2024, Chapter E, para. 1120.

²⁷ European Commission, Commission Staff Working Document Impact Assessment, May 28, 2018, SWD(2018) 240 final, p. 15, available at <https://ec.europa.eu/docsroom/docu-ments/29463>.

²⁸ Often referred to as "safe harbor" in the US.

Circuit in 1984. *Roche* had sued *Bolar Pharmaceutical Co.* for alleged patent infringement after the latter had conducted clinical trials for the approval of a generic drug using technology patented by *Roche*, which was undisputed. In response, the US Congress passed the Drug Price Competition and Patent Term Restoration Act, also known as the Hatch-Waxman Act, in the same year. This law introduced Section 271(e) 35 USC, according to which the use of patented inventions for the purpose of developing and submitting information under a federal law regulating drugs or veterinary products does not constitute patent infringement. The US Bolar exception allows generic manufacturers to conduct studies and trials necessary for (referential) regulatory approval²⁹ before a patent expires. This was intended to facilitate the market entry of generics and biosimilars. The US legislature thus eliminated the conflict between patent law and drug approval requirements by introducing a separate privilege within the framework of drug legislation specifically for the pharmaceutical sector, independent of the narrower testing privilege.⁽³⁰⁾ However, the Hatch-Waxman Act does not contain a general testing privilege (see B.I. 1.), but is limited to the exemption of tests and studies related to the approval of generic drugs.

bb) European developments

Around 20 years later, in 2004, a similar privilege was included in the EU with European Directive 2004/27/EC in Article 10(6) of Directive 2001/83/EC:

"The performance of the studies and tests necessary for the application of paragraphs 1, 2, 3, and 4 and the resulting practical requirements shall be considered not to conflict with the rights arising from patents or supplementary protection certificates for medicinal products."

Unlike the experimental privilege and compulsory license (see B.VI.), the Bolar privilege is based on European law. Its aim was to enable generic manufacturers in the EU to carry out the tests and studies required for marketing authorization under pharmaceutical law.

before the patent expires,³² in order to strengthen their competitiveness

competitiveness on the global market, as had already been successfully practiced in the US.³³ It was hoped that this would also promote competition in the EU and, in particular, ensure the rapid availability of low-cost generic drugs immediately after patent expiry.

Since the regulation was only a directive and not a directly applicable regulation, it first had to be transposed into national law by the Member States. Not least due to the rather general wording of Article 10(6) of Directive 2001/83/EC regarding the scope and limits of the Bolar exception, this led to considerable national divergences in some cases with regard to the scope of application of the Bolar exception in the individual Member States. A

Most EU countries have enacted Bolar regulations that go beyond the privileges provided for in Article 10(6) of Directive 2001/83/EC. For example, in some countries, unlike the provisions of the Directive, the privileges are not limited to generics and biosimilars, but have also been extended to innovative medicinal products.³⁴ In contrast, however, there are also countries, such as the Netherlands and Belgium, which have closely followed the wording of Article 10(6) of Directive 2001/83/EC and opted for a restrictive implementation of the Directive in national patent law.

cc) German legal situation

In Germany, Article 10(6) of Directive 2001/83/EC was implemented by the introduction of the new Section 11(2b) of the German Patent Act (PatG), which came into force on September 6, 2005.³⁶ Accordingly, the effect of the patent does not extend to

"studies and trials and the resulting practical requirements necessary for obtaining a marketing authorization under pharmaceutical law in the European Union or a pharmaceutical license in the Member States of the European Union or in third countries."

Section 11(2b) of the German Patent Act (PatG) thus permits actions that are objectively necessary to obtain marketing authorization or approval under pharmaceutical law for a generic drug, biosimilar, or innovative drug.³⁷ This means that, in contrast to the wording of Article 10(6) of Directive 2001/83/EC, the German Bolar provision is not limited to generic drugs. In particular, clinical trials required for marketing authorization under Section 24b AMG are exempted.³⁹ Compared to the general testing privilege of Section 11 No. 2 PatG, which protects only acts relating to the patented invention itself, the Bolar exception in No. 2b is broader in scope. While the testing privilege requires that the tests relate to the subject matter of the patented invention, this is not necessary in the case of the Bolar exception in Section 11 No. 2b PatG. This means that not only studies *about* the invention, but also those *involving* the invention are privileged. In addition, the provision in Section 11 No. 2b PatG covers all *practical applications*

²⁹ Approval in the USA is granted by the Food and Drug Administration (FDA).

³⁰ *Hess-Blumer*, sic! 2005, 506 (509), available at https://www.sic-online.ch/fileadmin/user_upload/Sic-Online/2005/documents/506.pdf.

³¹ *Stief*, GRUR Int. 2024, 824 (827).

³² BT-Drs. 15/5316, 1, 31.

³³ *Gassner*, GRUR Int. 2004, 983 (990); *Epping/Gerstberger*, PharmR 257 (262).

³⁴ For example, in Germany, France, and Spain.

³⁵ See overview of the Bolar exception in EU member states (selection): *Stief*, GRUR Int 2024, 824.

³⁶ BT-Drucks. 15/5316, p. 1, 29.

³⁷ See *Benkard/Scharen*, PatG, 12th ed. 2023, Section 11, margin note 10.

³⁸ Pharmaceutical companies must submit an application to the Federal Institute for Drugs and Medical Devices (BfArM) for this purpose.

³⁹ *Kühnen*, Handbook of Patent Infringement, 16th ed. 2024, Chapter E, para. 1121.

requirements that are necessary in the run-up to studies or trials in order to obtain market approval. This created a catch-all provision for patent uses that are directly related to the preparation of approval.

Furthermore, Section 11 No. 2b PatG is not limited to approvals within the EU, but also extends to approval procedures in non-EU countries. This means that pharmaceutical companies seeking marketing authorization in non-EU countries can also benefit from this provision, and clinical trials can be conducted in the EU even if the data obtained from them is intended for a marketing authorization procedure outside the EU. The decisive factor here is always that the actions in question are objectively necessary to obtain the respective approval. The decisive factor here is the approval law of the respective country in which market approval is sought.

b) Limits of the Bolar privilege: Suppliers (Section 10 No. 3 PatG)

It has not yet been clarified by the highest court whether mere suppliers of active ingredients or excipients, i.e., companies that do not themselves operate a drug approval procedure but rather, in a sense, provide support to the respective company, are also subject to

Section 11 No. 2b PatG, or whether they are liable for indirect patent infringements within the meaning of Section 10 (3) PatG, regardless of the privileged status of their customers.⁴¹In its decision in²⁰¹², the Regional Court of Düsseldorf clarified that acts of provision by third parties only fall under the privilege of the Bolar exception under certain restrictive conditions. According to this, the purpose of the act, namely the performance of trials or approval procedures, must be pursued by the supplier in its own person. The supplier must therefore be regarded as a "co-organizer" of the trials and studies. This was not the case in the present case, which is why the Regional Court assumed that the defendant had infringed the patent. The Court of Appeal, which was subsequently called upon to rule on the matter, assessed the legal situation differently in 2013⁴³ and took the view that third-party suppliers of active ingredients (so-called "APIs")⁴⁴ are protected as long as the supply serves a purpose that falls under the Bolar exception and the third-party supplier implements sufficient measures to ensure that the API is actually only used to the extent privileged. The Düsseldorf Senate referred corresponding questions to the ECJ for a preliminary ruling. Before the ECJ could rule on the questions, the legal dispute was settled by an out-of-court settlement between the parties.

The prevailing opinion supports the admissibility of acts of provision by third parties,⁴⁵ but attaches varying degrees of strictness to the personal extension of the Bolar Exemption.⁴⁶

This summer, for the first time, a supreme European court, the Italian Supreme Court (OGH), had to rule on the applicability of the Bolar exemption to the manufacture of APIs by contract manufacturers who are not themselves involved in the approval process. In its decision⁴⁷

The Supreme Court ruled that third-party companies can also be included in the privileges of the Italian Bolar exception, but attached strict conditions to this. They must act on the specific instructions of the company that is conducting the drug approval process. The court emphasized that the Bolar exception does not apply to the contract manufacturer's or supplier's own marketing activities and must be used exclusively to obtain marketing authorization under pharmaceutical law. In the present case, the contract manufacturers had violated this rule by starting production and advertising of the active ingredient for manufacture and delivery even before receiving a specific order from a generic drug manufacturer. In the opinion of the Supreme Court, it is not sufficient that the manufacture of the respective drug or active ingredient is intended solely for the purpose of conducting clinical trials and is declared as such, as was the case with some of the defendant contract manufacturers. Rather, clear evidence of a specific order from a generic drug company that is conducting the trials required for marketing authorization under pharmaceutical law is necessary.⁴⁸

c) Recent developments: European harmonization of patent law

With the new EU pharmaceutical package and the introduction of the Unified Patent Court (UPC), significant changes are imminent that could redefine the application and scope of the European Bolar exception.

aa) EU pharmaceutical package

As part of the discussion on new, harmonized pharmaceutical legislation within the EU, on April 26, 2023, the EU Commission presented a far-reaching reform proposal⁴⁹ for the revision of EU pharmaceutical legislation.⁵⁰ Article 85 of the draft directive aims to significantly amend the rules governing the Bolar exception, which is currently codified in Article 10(6) of Directive 2001/83/EC.

⁴⁰ Kühnen, Handbook of Patent Infringement, 16th ed. 2024, E. para. 1122.

⁴¹ Stief/Matschke, GRUR 2021, 1241 (1241).

⁴² LG Düsseldorf, BeckRS 2013, 1711.

⁴³ Higher Regional Court of Düsseldorf, GRUR-RR 2014, 100 — Market authorization privilege.

⁴⁴ "Active Pharmaceutical Ingredients."

⁴⁵ See Haedicke/Timmann/Bukow, Section 13, margin note 26 et seq.; Fährdrich/Tilmann, GRUR 2001, 901 (902 f.); Worms/Guski, Mitttdt-PatA 2011, 265 (270); Kraßer, Patentrecht, 5th ed., § 33 p. 836; LG Düsseldorf judgment of July 3, 2012 — 4 a O 282/10, BeckRS 2013, 1711; OLG Düsseldorf GRUR-RR 2014, 100 — Market Access Privilege.

⁴⁶ For details, see: Stief/Matschke, GRUR 2021, 1241.

⁴⁷ Corte Suprema Di Cassazione, decision of July 5, 2024 — No. 18372.

⁴⁸ For details on the decision, see: Stief, GRUR-Prax 2024, 595.

⁴⁹ See European Commission, Proposal for a Directive of the European Parliament and of the Council on the Union code relating to medicinal products for human use, and repealing Directive 2001/83/EC and Directive 2009/35/EC, April 26, 2023, COM(2023) 192 final 2023/0132(COD).

⁵⁰ For an overview of the new draft directive, see Stief/Grabow, PharmR 2023, 317.

and extend it. In this way, the Commission aims to counteract the fragmented application of the Bolar privilege in the Member States. The aim of the reform is to define the scope of the Bolar exception more clearly and to create harmonized rules at European level. This should overcome the previous differences in national regulations and ensure a uniform legal basis for the use of the exception throughout the EU. It is hoped that this will enable faster market access for generics and biosimilars immediately after the expiry of patent or SPC protection.

According to Article 85(a), the Bolar exemption will in future cover not only studies and trials related to applications for marketing authorization for generics and biosimilars, but also hybrid and biohybrid medicinal products. In addition, acts of use necessary for the assessment of health technologies within the meaning of Regulation (EU) 2021/2282, as well as price setting and reimbursement issues, shall also be covered by the exception. The new regulation thus goes beyond the previous scope of Article 10(6) of Directive 2001/83/EC.

Article 85(b) of the draft directive also exempts from patent protection activities that are exclusively related to the objectives defined in Article 85(a). These include, among other things, the application for market authorization, as well as the offering, production, sale, delivery, storage, import, use, and acquisition of patented medicinal products or processes, now explicitly also by third parties and service providers.⁵² However, it remains unclear under what conditions the supply to third parties is covered by the exemption and whether actions taken in the context of an application for market authorization outside the EU are also privileged.

On April 10, 2024, the European Parliament responded positively to the Commission's proposals.⁵³ The planned reform also received widespread support in general, but was not without criticism. For example, the European Parliament's Committee on the Environment, Public Health, and Food Safety (ENVI) proposed removing refunds and price negotiations from the exempted activities.⁵⁴

The timing and exact implementation of this reform are currently still open. The next step will be negotiations in the EU Council.

bb) Changes brought about by the EPGÜ

On June 1, 2023, the Unified Patent Court (UPC), which has been supported by 18 EU member states since September 1, 2024, began operating for the first time. Together with the Agreement on a Unified Patent Court (UPC Agreement)⁵⁶, which came into force at the same time, and the introduction of the unitary patent, it creates a uniform system for patent protection and enforcement across the national borders of the participating EU countries.⁵⁷ The EPGÜ contains a testing privilege in Art. 27 lit. b) and a

Bolar privilege. According to Article 27(b) EPGÜ, acts for experimental purposes relating to the patented invention are not covered by the rights conferred by a unitary patent. Article 27 EPGÜ lists permitted acts

i. Pursuant to Art. 10(6) of Directive 2001/83/EC. The reference to the Directive limits the scope of the Bolar exception to generics and biosimilars, which means that studies involving innovative medicinal products or new indications would not be exempt, at least according to the wording. Furthermore, Article 27 EPGÜ is geographically limited to the conduct of studies for marketing authorization procedures within the EU. In view of the increasing internationalization of clinical studies, this does not appear to be in line with current trends. Compared to the new proposal by the EU Commission, the previously adopted EPGÜ thus significantly restricts the Bolar exception and makes it more difficult to conduct clinical studies in Europe. It therefore remains to be seen how the EPO will interpret Article 27 EPC.

3. Further exceptions to patent protection

Patents should only have an effect in an economic context and should not interfere with privacy. Therefore, actions carried out in a personal or domestic environment and without a commercial background are not considered patent infringements pursuant to Section 11 No. 1 PatG. The private sphere refers only to natural persons and includes all activities that serve one's own needs, such as in the family or in the household.⁵⁸ The decisive factor is that these actions do not pursue an economic purpose. Commercial activities, even if they are only indirectly aimed at making a profit, as well as hand-

⁵¹ Communication from the Commission — Reform of the pharmaceutical legislation and measures to combat antimicrobial resistance, COM(2023) 190 final, p. 3 f.; see also Kühnen, Handbook of Patent Infringement, 16th ed. 2024, E. para. 1120.

⁵² Stief/Grabow, PharmR 2023, 317 (320).

⁵³ See Opinion of the European Parliament, Committee on Legal Affairs, Opinion on the Proposal for a Directive of the European Parliament and of the Council on the Union code relating to medicinal products for human use, and repealing Directive 2001/83/EC and Directive 2009/35/EC — (COM(2023)0192 — C9-0143/2023 — 2023/0132(COD)), 13 April 2024, available at https://www.europarl.europa.eu/doceo/document/JURI-AL-758884_EN.pdf.

⁵⁴ See European Parliament, Committee on the Environment, Public Health and Food Safety, I Draft report on the "Proposal for a Directive of the European Parliament and of the Council on the establishment of a Union code relating to medicinal products for human use and repealing Directive 2001/83/EC and Directive 2009/35/EC," (COM(2023)0192 — C9-0143/2023 — 2023/0132(COD)), Amendments 22 and 23 for recitals 63 and 64, available at https://www.europarl.europa.eu/doceo/document/ENVI-PR-753470_EN.pdf.

⁵⁵ J. Evans, in: *pharmazeutische-zeitung.de*. "EU pharmaceutical package clears next hurdle," April 10, 2024, <https://www.pharmazeutische-zeitung.de/eu-pharmapaket-hat-naechste-huerde-genommen-146677/> (accessed on September 16, 2024).

⁵⁶ Agreement on a Unified Patent Court, 2013/C 175/01, published in the Official Journal of the European Union on June 20, 2013.

⁵⁷ See overview of the EPG: Stief, A&R 2024, 197.

⁵⁸ Mes, PatG GebrMG, 5th ed. 2020, PatG, § 11 Rn. 3; Benkard/Scharen, PatG, 12th ed. 2023, § 11 margin note 3 f.

Public institutions or freelancers are not covered by this exception.

In addition to the Bolar privilege in § 11 No. 2b PatG, § 11 No. 2a PatG also introduced the so-called plant research privilege. This excludes the patent effect for the use of biological material for the breeding, discovery, and development of new plant varieties, thus extending the experimental privilege to this area. However, the commercial exploitation of the newly obtained material remains subject to patent protection.⁶⁰

According to Section 11 No. 3 of the German Patent Act (PatG), the effect of the patent does not extend to medicinal products that are prepared directly and individually in pharmacies on the basis of a doctor's prescription, nor to actions relating to medicinal products prepared in this way. This includes substances for the treatment, prevention, or diagnosis of diseases in humans or animals, for the detection of bodily functions, and for the control of pathogens. Cosmetics and foodstuffs, on the other hand are not covered. The preparation must be carried out in a pharmacy, but not in drugstores, hospital laboratories, or by doctors themselves. It must be an individual preparation based on a specific medical prescription for a specific patient, so that, for example, production for stock is not privileged. Manufacturing processes and application patents are also restricted.

4. SPC waiver

In view of the de facto reduction in the term of patents due to the mandatory approval procedure required before a drug can be marketed, the EU introduced supplementary protection certificates (SPCs) in 2009 with Regulation (EC) No. 469/2009. This effectively extends patent protection by up to five or five and a half years.

The unrestricted extension of the patent's effect led to significant competitive disadvantages for generic and biosimilar manufacturers based in the EU. Unlike manufacturers from non-EU countries, they are only allowed to start manufacturing SPC-protected drugs after the SPC has expired. Manufacturers outside the EU, on the other hand, can manufacture their products for the European market during the term of the SPC and import them in large quantities immediately after expiry. This situation prompted the EU to introduce the so-called "SPC Manufacturing Waiver" with Regulation 2019/933⁶⁴, which came into force on July 1, 2019. This exemption allows manufacturers of generics and biosimilars to manufacture products for export to non-EU countries during the term of the SPC (Art. 5(2)(a)(i) SPC Regulation) and, within the last six months of the SPC term, to store the products for release in the EU immediately after the expiry of the SPC (Art. 5(2)(a)(iii) SPC Regulation). Related activities such as import, storage, advertising, and possession are also permitted under certain conditions, as long as they are necessary for the authorized manufacture, export, or storage. However, manufacturers must meet strict requirements in order to benefit from these privileges, such as notification obligations to

the competent authority and the certificate holder, as well as due diligence obligations along the supply chain and labeling obligations in the case of exports to third countries.⁶⁶ In accordance with Article 288 TFEU, Regulation 2019/933 is directly applicable in the EU and, with some modifications, also in the EEA.

a) Material scope

Article 5(2)(a) of Regulation (EU) 2019/933 provides for two exceptions: The "manufacturing waiver" under Article 5(2)(a)(i) allows the manufacture of a product or a medicinal product containing that product throughout the term of protection of the SPC for the purpose of export to third countries where no protection exists. The "stockpiling waiver," on the other hand, under Article 5(2)(a)(iii), privileges the manufacture of a product or a medicinal product containing that product six months before the expiry of the certificate for the purpose of storage in the Member State of manufacture for Day 1 EU market entry after the expiry of the corresponding SPC.

Both waivers also privilege "related acts" under Art. 5(2)(a)(ii) and (iv). These are acts that are not the main acts *per se*, but are absolutely necessary for the latter, namely either the manufacture and actual export under Article 5(2)(a)(i) or the manufacture and actual storage under Article 5(2)(a)(iii). Typical examples would be the possession, import, use, or synthesis of an active ingredient.⁶⁸ This exception should also apply to related acts carried out by third parties who are in a contractual relationship with the manufacturer.⁶⁹

While the manufacturing waiver grants privileges for manufacturing activities for export to third countries during the entire term of the SPC, the stockpiling waiver allows the manufacture and stockpiling of a medicinal product still protected by an SPC for a maximum of six months prior to the expiry of the respective SPC, thereby enabling market entry immediately after its expiry in the EU.

⁵⁹ Haedicke, Patent Law, 6th ed. 2022, Chapter 7, margin note 26.

⁶⁰ Benkard/Scharen, PatG, 12th ed. 2023, § 11 margin note 9; Ann, PatR, 8th ed., § 33 margin note 253.

⁶¹ Benkard/Scharen, PatG, 12th ed. 2023, § 11 margin note 11 with further references.

⁶² See Benkard/Scharen, PatG, 12th ed. 2023, § 11 margin note 11 with further references.

⁶³ Regulation (EC) No. 469/2009 of the European Parliament and of the Council of May 6, 2009, concerning the supplementary protection certificate for medicinal products, OJ L152/1.

⁶⁴ Regulation (EU) 2019/933 of the European Parliament and of the Council of May 20, 2019, amending Regulation (EC) No. 469/2009 concerning the supplementary protection certificate for medicinal products, OJ L135/1.

⁶⁵ Kühnen, Handbook of Patent Law, Chapter E, para. 1128.

⁶⁶ For details on the SPC manufacturing and stockpiling waiver, see: Stief, JIPLAP 2024, Vol. 19, No. 9, 695 ff. and Stief, JIPLAP 2024, Vol. 19, No. 10, 754 ff.

⁶⁷ See Section 62a of the Norwegian Patent Act and Article 65a of the Icelandic Patent Act. Specifically, this means that where Regulation 2019/933 refers to the EU or the Member States, this now also includes the EEA Member States Norway and Iceland, with the exception of Liechtenstein, which does not grant SPC protection.

⁶⁸ Recital 9.

⁶⁹ Recital 9.

b) Obligations of the manufacturer

In order to invoke the manufacturing privilege, the manufacturer must fulfill notification, due diligence, and labeling obligations. A breach of these obligations will result in the privilege being denied and thus in an infringement of the SPC in the respective Member State of manufacture.

aa) Notification obligations

Pursuant to Article 5(2)(b), the manufacturer must inform the competent authority of the Member State in which the manufacture is to take place and the certificate holder, in an appropriate and documented manner, of the information listed exhaustively in Article 5(5) no later than three months before the date of commencement of manufacture or the first related operation in that Member State.⁷¹ The competent authority pursuant to Article 9(1) of the amended Regulation (EC) No. 469/2009 is the competent authority for industrial property rights of the Member State that issued the applicable protection certificate,⁷² in Germany, therefore, the German Patent and Trademark Office (DPMA) in Munich.

bb) Duties of care

Pursuant to Art. 5(2)(e), the manufacturer must further ensure, by appropriate and documented means, that any person in a contractual relationship with the manufacturer who performs acts falling under Art. 5(2)(a), is fully informed and aware: (a) that these actions are subject to Art. 5(2) and (b) that the placing on the market, import, or re-import of the product or the medicinal product containing this product is subject to Art. 5(2)(a) (i) or the placing on the market of the product or medicinal product containing this product in accordance with Art. 5(2)(a)(iii) may violate the certificate referred to in Art. 5(2), insofar as and for as long as this certificate is valid. The manufacturer can ensure compliance with the so-called duty of care by including this information verbatim in contracts with third parties along the supply chain in the EEA who perform acts privileged by the manufacturing privilege that would otherwise require the consent of the certificate holder, for example, the exporter and the person performing the storage.⁷³ As clarified in recital 9, the manufacturing privilege should "also apply to related acts of third parties who are in a contractual relationship with the manufacturer."

cc) Labeling requirements

Pursuant to Art. 5(2)(d), the manufacturer must ensure that, in the case of products or medicinal products containing these products that are manufactured for export to third countries, a logo in the form specified in Annex I is affixed to the outer packaging of the product or the medicinal product containing this product and, where practicable, on its primary packaging. The logo must be black and of a size that makes it sufficiently visible. With regard to EEA countries that are not EU Member States, the

Logo that must be affixed as part of the manufacturer's labeling requirements, "EEA export" instead of "EU export."⁷⁴ In addition, pursuant to Article 5(8), the manufacturer must ensure that medicinal products manufactured for export to third countries do not bear an active individual identifier within the meaning of Commission Delegated Regulation (EU) 2016/161. Recital 21 of Regulation (EU) 2019/933 confirms that compliance with the labeling requirements is a prerequisite for the application of the SPC exemption. This refers to labeling requirements under both Article 5(2)(d) and Article 5(8) with regard to the active individual identifier, as recital 21 requires that the product be "labeled in the manner provided for in this Regulation." The exact interpretation of the term "affix" remains unclear, in particular with regard to whether it requires permanent affixing or whether, for example, the use of a removable sticker would suffice.

5. Exhaustion

Another barrier to patent protection is the so-called principle of exhaustion. This refers to the exhaustion of patent rights by the patent holder.⁷⁵ Exhaustion is not expressly regulated in patent law,⁷⁶ but Section 17(2) of the German Copyright Act (UrhG) (see also Section 24 of the German Trademark Act (MarkenG)) reflects a general legal principle that also applies to other industrial property rights, in particular patent law.⁷⁷

According to the principle of exhaustion, the patent holder loses his right to prohibit the use of a product as soon as it has been placed on the market either by himself or, with his consent, by a third party.⁷⁸ The patent holder's legal authority over the specific product is thus "exhausted," whereby the original right of prohibition expires and the product can be freely traded. This means that third parties are free to use the product

⁷⁰ According to recital 13, the European legislator considers these measures to be a series of

"effective and proportionate safeguard measures [...] to improve transparency, assist the holder of a certificate in enforcing its protection in the Union, verify compliance with the conditions laid down in this Regulation, and reduce the risk of illegal diversion to the Union market during the period of validity of the certificate."

⁷¹ See recital 19 for notification during the transition period.

⁷² See recital 14.

⁷³ See recital 20.

⁷⁴ Decision of the EEA Joint Committee No. 197/2022 of June 10, 2022, amending Annex XVII (Intellectual Property) to the EEA Agreement [2022/1897], Article 1(4).

⁷⁵ Benkard/Scharen, PatG, 12th ed. 2023, § 9 margin note 16 with further references.

⁷⁶ However, since February 28, 2005, patent law has included a special case of exhaustion for the reproduction of biological material in § 9b PatG.

February 28, 2005, there has been a special exhaustion provision for the reproduction of biological material.

⁷⁷ Mes, PatG GebrMG, 5th ed. 2020, PatG, § 9 margin note 82, 83 with further references.

⁷⁸ See only BGHZ 143, 268 (270 f.) = GRUR 2000, 299 — Ka-rate; BGHZ 171, 167 marginal no. 27 = GRUR 2007, 769 — Pipette system.

to sell, offer for sale or otherwise use, regardless of the consent of the patent holder. This principle applies equally to products that were manufactured directly using a patent-protected process and fall within the scope of protection of the process patent.⁷⁹ However, exhaustion does not apply to process claims.⁸⁰ The burden of proof and demonstration of exhaustion always lies with the party invoking it.⁸¹

The principle of exhaustion aims to shift patent exploitation to the early stages of the value chain.⁸² This ensures that subsequent players in the distribution chain, in particular dealers and end users, are not burdened by additional patent restrictions. This contributes to the creation of an undisturbed and free movement of goods, which is essential for a functioning market economy.⁸³

In the pharmaceutical sector, the principle of exhaustion under trademark law pursuant to Section 24 (1) of the German Trademark Act (MarkenG) plays a central role in parallel imports of pharmaceuticals within the EU and the EEA. Due to different pricing for pharmaceuticals in the individual member states, there are incentives for importers to purchase pharmaceuticals cheaply in one country and sell them at a profit in another country. In principle, importers can invoke the free movement of goods within the EU (Articles 34 and 36 TFEU) and the principle of Community-wide patent exhaustion. Once the patent-protected medicinal product has been placed on the market—by the patent holders themselves or with their consent—i.e., once the parallel importer has legally purchased the medicinal product in another Member State, the patent holders can no longer invoke their intellectual property rights, and others can sell the medicinal product freely within the EU. However, Section 24(2) of the German Trademark Act (MarkenG) provides for an exception that allows the trademark owner to oppose distribution if the product has been repackaged. In numerous decisions, the ECJ has developed the so-called "BMS criteria," which specify the circumstances under which repackaging is permissible. These include, among other things, that repackaging must not impair the original condition of the product and that repackaging or relabeling must not impair the reputation of the trademark. In its ruling of November 17, 2022⁸⁴, the ECJ also had to decide whether and under what conditions a parallel importer may import and distribute a generic drug under the brand name of the original product. The central question here was whether a parallel importer may purchase an identical generic drug that is offered at a lower price than the reference drug and, after repackaging, sell it as the more expensive original. The ECJ ruled that trademark owners generally have the right to oppose the renaming of the generic drug to the name of the reference drug. However, repackaging in the sense of relabeling or reboxing is only possible under strict conditions. These include, in particular, that (1) the two drugs must be identical in every respect, whereby mere bioequivalence is not sufficient, and (2) the repackaging must meet the so-called BMS criteria, in particular the criterion of

objective necessity. The ECJ thus clarified that trademark law should only be restricted where it is absolutely necessary for the functioning of the internal market and the free movement of goods. The fact that identical products can be sold under different trademarks at different prices is certainly a cause for concern, but solutions to this problem must be found outside of trademark law.

6. Compulsory license

Another restriction on the patent holder's exclusive right is the compulsory license, which is regulated in Section 24 of the German Patent Act (PatG). While the compulsory license was of little practical significance for many years,⁸⁶ it has received increased attention in the recent past, particularly in the wake of the coronavirus pandemic.

A compulsory license allows third parties to use a patented invention even if the patent holder refuses to do so. A compulsory license is granted by the Federal Patent Court if the conditions laid down by law are met. In doing so, the Third Senate of the Federal Patent Court, which is responsible for compulsory licenses, must weigh up the overriding public interest in the use of the invention against the exclusive rights of the patent holder.⁸⁷ In particular, if the strict enforcement of the patent holder's exclusive right leads to technical progress or economic development being unreasonably impeded or essential social needs remaining unmet, a compulsory license may be granted by court decision.⁸⁸ This is intended to prevent abuse of the patent holder's rights and at the same time ensure access to important innovations if and to the extent that this is in the public interest.⁸⁹ At the same time, however, the patent holder does not have to tolerate interference with his rights without compensation. Rather, Section 24 (6) PatG provides for the payment of reasonable compensation by the compulsory licensee.⁹⁰ The amount is based on the terms that would have been agreed in a regular license agreement between the parties.

Section 24 of the German Patent Act (PatG) also applies to supplementary protection certificates, utility models, European patents with effect in Germany, and other similar rights.

⁷⁹ *Ann*, PatR, 8th ed., Section 33 marginal no. 274.

⁸⁰ See also *Haedicke/Timmann/Bukow*, PatR-HdB, Section 13 marginal number 100; *Mes*, PatG GebrMG, 5th edition, PatG, Section 9 marginal number 80; *Benkard/Scharen*, PatG, 12th edition, Section 9 marginal number 25.

⁸¹ *BGH*, GRUR 2012, 626 — *Converse I*.

⁸² *BeckOK/Ensthaler/Gollrad*, 33rd edition, PatG, Section 9 marginal number 74.

⁸³ *BeckOK/Ensthaler/Gollrad*, 33rd edition, PatG, Section 9 marginal number 74.

⁸⁴ *ECJ*, judgment of November 17, 2022 — Ref. C-253/20 and C-254/20.

⁸⁵ For details on the ECJ decision, see: *Stief*, PharmR 2023, 24.

⁸⁶ The compulsory license is not based on EU law. The EPC also does not contain any provisions on compulsory licenses. For detailed information on compulsory licenses, see *Haedicke/Stief/Wünsche*, Legal Handbook on Chemical, Pharmaceutical, and Life Sciences Patents 1st edition 2024, § 9.

⁸⁷ *BeckOK/Wilhelmi*, 33rd edition, PatG, § 24 margin note 3, 4.

⁸⁸ See *Stierle*, GRUR 2024, 419 (420).

⁸⁹ See *Ann*, PatR, 8th edition, Section 34 marginal number 99; *BeckOK/Wilhelmi*,

33rd edition, PatG, Section 24 marginal number 5.

⁹⁰ *Ann*, PatR, 8th edition, § 34 margin note 100.

in Germany and for unitary patents within the meaning of the EPGÜ.⁹¹ In contrast to the state order to use in Section 13 PatG, which completely suspends patent protection for the duration of the order and thus has the character of a last resort, the compulsory license is based on a civil law claim and therefore only applies *inter partes*.⁹²

The application of Section 24 PatG is very restrictive due to the particularly high importance of patent protection in German patent law. To date, only in the case of *Raltegravir*⁹³ has a compulsory license for an HIV drug been confirmed by the highest court in Germany. In 2019, however, the Federal Court of Justice rejected a compulsory license for a cholesterol-lowering drug in the *Alirocumab* case⁹⁴ a compulsory license for a cholesterol-lowering drug due to insufficient efforts to obtain a legal license and the lack of credible evidence of an overriding public interest.⁹⁵ In particular, the public interest does not prevail if it can be satisfied by equivalent alternatives.⁹⁶

On April 27, 2023, the EU Commission published a proposal for a regulation on EU-wide compulsory licenses for crisis management as part of the pharmaceutical package. This regulation is intended to enable crisis-relevant products to be made available more quickly throughout the EU as soon as crisis mode is activated, similar to what happened during the coronavirus pandemic. The proposal stipulates that compulsory licenses shall only apply for the duration of the crisis and shall cover all patent categories, including European patents. Interest groups criticize the proposal in particular for limiting the amount of compensation to a maximum of 4% of the licensee's gross revenue, which they say is inappropriate given the high investments made by patent holders, especially in the pharmaceutical sector. Furthermore, it is unclear what exactly is meant by a "crisis," and there is no independent review body for the licenses granted, as the EU Commission will only carry out a review upon request, according to the proposal.

III. Conclusion

The patent system, particularly in the pharmaceutical sector, is characterized by a tension between promoting innovation and ensuring adequate access to essential medicines. The various exceptions, such as the experimental privilege, the Bolar exception, the SPC waiver, the principle of exhaustion, and compulsory licensing, are levers for maintaining the balance between the interests of patent holders and the needs of the general public, because both insufficient and excessive protection can hinder innovative processes and impair the supply of medicines. The aforementioned exceptions are not only important for ensuring scientific progress, but also for ensuring that essential medicines are available at reasonable prices and that market access barriers for generics and biosimilars are lowered. However, the legitimate interests of patent holders in adequate patent protection, which allows them to recoup their research and development investments, which are particularly significant in the pharmaceutical sector, must not be lost sight of.

⁹¹ *BeckOK/Wilhelmi*, 33rd edition, PatG, Section 24 margin note 2, 3.

⁹² See *BeckOK/Wilhelmi*, 33rd edition, PatG, Section 24 marginal number 5.

⁹³ *BGH*, GRUR 2017, 1017 — *Raltegravir*.

⁹⁴ *BGH*, GRUR 2019, 1038 — *Alirocumab*.

⁹⁵ See *BeckOK/Wilhelmi*, 33rd edition, PatG, Section 24 marginal number 7.

⁹⁶ *BGH*, GRUR 2019, 1038 margin note 31 — *Alirocumab*; GRUR 2017, 1017 marginal no. 39 — *Raltegravir*; for details on the *Raltegravir* decision, see: *Holtorf/Traumann* GRUR-Prax 2018, 295.

Author's address:

Dr. Marco Stief, LL.M. (University of Chicago) Attorney at Law

Representative before the EPG (UPC)

Maiwald GmbH

Elisenhof, Elisenstraße 3

80335 Munich

Tel.: 089/747266-0

Email Stief@maiwald.eu

www.maiwald.eu

Ulf Zumdick, Christine Lietz, and Prof. Dr. Jens Peters

Medical Research Act — good news for the pharmaceutical industry?

The German Bundestag passed the federal government's draft bill "Draft Medical Research Act"¹ at its meeting on July 4, 2024, in accordance with the recommendation and report of its leading health committee, with amendments and additions². In its plenary session on September 27, 2024, the Bundesrat passed the German Bundestag's legislative decision³. The provisions of the new law came into force in large parts on ...⁴.

I. Introduction

The Medical Research Act aims to improve the framework conditions for the development, approval, and manufacture of drugs and medical devices.⁵ The Medical Research Act is

Part of a strategy paper entitled "Improvements to the framework conditions for the pharmaceutical sector in Germany" ⁶ adopted by the federal government on December 13, 2023, which aims to strengthen Germany's attractiveness as a location for research and production. The legislature has recognized that the pharmaceutical industry is also a leading industry in the German economy. Above all, it is important to

¹ BT-Drs. 20/11561.

² BT-Drs. 20/12149.

³ BR-Drs. 416/24.

⁴ Federal Law Gazette I ...

⁵ BT-Drs. 20/11561 (p. 1).

⁶ Available at: www.bundesgesundheitsministerium.de/presse/pressemitteilungen/nationale-pharmastrategie-beschlossen-pm-13-12-23.