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# The European Research and Bolar Exemptions – Background, Status Quo and a Look at the Agreement on a Unified Patent Court (UPCA) and the EU Commission’s New Draft Directive for the Reform of Pharmaceutical Legislation

A patent is a form of state monopoly granted to the owner of an invention. A patent rewards its owner with exclusive rights in exchange for innovation (*‘quid pro quo’*) for a limited period of time. These exclusive rights allow the patent holder to prohibit others from using the patented invention, helping to recover their research and development (R&D) costs and thereby create an incentive for further innovation. However, patents can hinder technical progress if no restrictions are imposed. Therefore, exceptions and restrictions exist to balance patent protection with the right to freedom of research under Art. 13 of the EU Charter. The most important exceptions are the so-called Bolar and research exemptions. The Bolar exemption allows generics manufacturers to seek authorization or approval under pharmaceutical law before a patent expires, enabling market entry immediately after patent expiration. The research exemption permits the use of patented inventions for research purposes. These two exceptions are increasingly important due to a shift in patent law favoring patent holders through simplified procedures and expanded rights. This article briefly outlines the history and application requirements of these two exemptions and the limits and restrictions to be observed. It also discusses the national differences in application of the Bolar and research exemptions within Europe and the new Art. 27 UPCA introduced in June 2023. Finally, the proposed amendments published in April 2023 as part of the new European pharmaceutical package will be discussed.

## I. Research exemption

### 1. What is the research exemption?

Patent law in its modern form developed in Europe from the late 19th century onwards. Its purpose was to encourage innovation. Patents and other technical property rights grant the respective right holders a time-limited and temporary monopoly to exploit the protected inventions commercially, the intention being to create incentives for investment in research and development. However, it soon became apparent that unrestricted patent rights put a brake on scientific research and technological progress. A balance was struck with the so-called research exemption,<sup>1</sup> which restricts the patent holder’s basic exploitation monopoly by allowing third parties to study, analyze and test the patented technologies under certain conditions in order to gain new knowledge or to drive innovation. The aim of this exemption was and is to aid progress in science and technology without unduly restricting the rights of the patent holder.

Today, corresponding exemptions from patent protection can be found in almost all national patent laws.

However, the exact criteria and the scope of the exemption granted vary from country to country, even within the European Union.

### 2. Origin of the research exemption: USA

The research exemption has its origins in the USA. As is the case in Europe, it is still not defined by law there. However, the scope and application of the research exemption have been developed and refined by court rulings over time. Over 200 years ago, in 1813, Mr. Justice Joseph Story declared in *Whittemore v Cutter*<sup>2</sup> that it was not the intention of the legislator to hinder or penalize research activities through the grant of patent protection.

In the following years, more and more courts in the USA emphasized in their decisions<sup>3</sup> that scientific research and experimental activities that are non-commercial, i.e. not for profit and not for the purpose of producing or selling products, are generally not regarded as patent infringement. Until 1861, it was considered ‘established that an experiment with a patented object for the sole purpose of satisfying a philosophical taste or curiosity or for mere amusement does not constitute an infringement of the rights of the patent

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<sup>1</sup> Also known as ‘experimental privilege’ or the ‘experimental use exemption’.

<sup>2</sup> cf *Whittemore v Cutter* 29 Fed. Cas. 1120 (C.C.D. Mass. 1813) (No 17, 600).

<sup>3</sup> See, eg, *Sawin v Guild* 21 Fed. Cas. 554, No. 12,391 (C.C.D. Mass. 1813).

proprietor'.<sup>4</sup> Rather, in the context of research and development activities, patent infringement should only be deemed to occur if the user uses the patented subject matter for the precise purpose for which it was invented, not if the experiments are carried out merely to satisfy scientific curiosity. In 2002, however, the Court of Appeals for the Federal Circuit also clarified in *Madey v Herzog*<sup>5</sup> that the research privilege should not be interpreted 'so broadly as to permit infringement of the patent laws under the guise of "scientific investigation" when that investigation has a clear, recognizable and not insubstantial commercial purpose'.<sup>6</sup>

### 3. European basis of the research exemption and national implementation

#### a) European basis

There is no uniform basis for the research exemption in European law. However, Art. 27 of the Community Patent Convention of 1975 provides a basis for many European countries, although the Convention has never actually entered into force. Article 27 states that acts directed to the subject matter of the patented invention that are, however, carried out for experimental purposes are exempt from patent infringement. This exemption ties in with Art. 30 of the TRIPS Agreement,<sup>7</sup> which permits limited exemption to patent protection to be introduced into national law. Article 27 of the Community Patent Convention of 1975 has been adopted verbatim or almost verbatim in the jurisdictions of many countries.

#### b) German case law

In Germany, the experimental use privilege was introduced with the new Patent Act passed in 1981.<sup>8</sup> According to Sec. 11 No. 2 of the new German Patent Act, 'acts for experimental purposes which relate to the subject matter of the patented invention' do not constitute infringing use of a patent. This includes experiments that serve to further develop an invention protected by a patent, as well as experiments that are solely for the purpose of determining whether the protected product or the protected process is realizable, useful or technically feasible. In other words, all such experiments are permitted which study the invention yet do not use it as a means of gathering knowledge in another field. In other words, research *on* the invention is permitted, but not research *using* the invention.

The scope of this privilege was more precisely defined in the 1990s, in particular by two decisions of the Federal Court of Justice (Bundesgerichtshof, BGH) (*Clinical Trials I*<sup>9</sup>

and *Clinical Trials II*<sup>10</sup>). In the *Clinical Trials I* decision<sup>11</sup> handed down in 1995, the Federal Court of Justice initially clarified that 'any (planned) procedure for gaining knowledge, irrespective of the purpose for which the knowledge gained is ultimately intended',<sup>12</sup> is to be regarded as an exempted act within the scope of Sec. 11(2) Patent Act.

Moreover, in *Klinische Versuche I (Clinical Trials I)*,<sup>13</sup> the Federal Court of Justice held for the first time that, in principle, actions by a generics company for experimental purposes may also be exempt from unlawful infringement of the patent pursuant to Sec. 11(2) Patent Act.<sup>14</sup> In that particular case, the generics company had conducted trials for the purpose of researching new applications for a patented active ingredient (*interferon-gamma*) with drug authorization in mind. With regard to the interpretation of Sec. 11(2) Patent Act, the Federal Court of Justice first of all stated that the court of appeal had wrongly relied on the law prior to the introduction of the German Patent Act of 1981. Rather, the Community Patent Convention (CPC)<sup>15</sup> should be used when interpreting national patent provisions, as the national patent laws were adapted to the CPC. The court then pointed out that the exemption in Sec. 11(2) Patent Act permits all experimental acts 'insofar as they serve to gain knowledge and thus promote scientific research on the subject matter of the invention, including its use'.<sup>16</sup> The Federal Court of Justice ruled that clinical trials also fall under this exemption if the aim of the trials is to investigate a patented active ingredient for a previously unknown effect. This is the case even if the results of the trials are also to be used for the purpose of obtaining regulatory approval. The Federal Court of Justice stressed that the application of Sec. 11(2) Patent Act to clinical trials cannot be ruled out on the grounds that the results of these trials are also used to pursue commercial interests in connection with the marketing authorization of medicinal products.<sup>17</sup> For the application of Sec. 11(2) Patent Act, it is not necessary that the knowledge gained from the trials be exclusively of a scientific nature.

In the later decision *Clinical Trials II*,<sup>18</sup> the Federal Court of Justice expanded on its explanations regarding the application of Sec. 11(2) Patent Act to clinical trials. The court first stated that clinical trials can also be covered by the privilege:

'Clinical trials in which the efficacy and tolerability of a medicinal product containing the protected active ingredient are tested on humans are also

<sup>4</sup> *Poppenhusen v Falke* 19 F. Cas. 1048, 1049 (C.C.S.D.N.Y. 1861) (No 11, 279).

<sup>5</sup> See 307 F.3d 1351 (Fed. Cir. 2002).

<sup>6</sup> Judge Story, memorandum of decision in *Whittemore v Cutter* (n 2).

<sup>7</sup> 'Agreement on Trade-Related Aspects of Intellectual Property Rights'.

<sup>8</sup> Previously, the starting point for the exemption from patent infringement in Germany was often that the exclusive right of the patent proprietor did not extend to every type of use, but only to the 'commercial' use of the invention, whereby 'commercial' was generally interpreted broadly by case law and literature. Accordingly, not only activities aimed at profit and acquisition were considered commercial, but in principle any act of use that was not purely private (see Henrik Holzapfel, *Das Versuchsprivileg im Patentrecht und der Schutz biotechnologischer Forschungswerkzeuge* (Nomos 2004) 33 ff).

<sup>9</sup> Federal Court of Justice, [1996] GRUR 109 – *Clinical Trials I*.

<sup>10</sup> Federal Court of Justice, [1997] NJW 3092 – *Clinical Trials II*.

<sup>11</sup> *Clinical Trials I* (n 9).

<sup>12</sup> *Clinical Trials I* (n 9) 109 (112).

<sup>13</sup> *ibid* 109.

<sup>14</sup> In the first instance, the Düsseldorf Higher Regional Court ruled to the contrary and classified experimental acts carried out for the purpose of obtaining marketing authorization for a medicinal product as infringing acts, see OLG Düsseldorf, 9 July 1992 – 2 U 47/91.

<sup>15</sup> The CPC ('Community Patent Convention') was first concluded by the members of the European Economic Community in Luxembourg in 1975. It is an independent treaty under international law and was revised in 1989 before it came into force. This agreement enables the granting and administration of patents in several European countries through a centralized patent application. It was developed to simplify the granting of patents in Europe and make it more efficient.

<sup>16</sup> *Clinical Trials I* (n 9) 109 (113).

<sup>17</sup> *Clinical Trials I* (n 9) 109 (115).

<sup>18</sup> *Clinical Trials II* (n 10).

permissible if the trials are carried out with the aim of obtaining data for the marketing authorization of a pharmaceutical composition.’<sup>19</sup>

The Federal Court of Justice reaffirmed the statement it had made in the *Clinical Trials I* decision that the intention to (also) utilize the results obtained for commercial purposes does not in itself mean that the experimental activities fall outside the experimental privilege granted by Sec. 11(2) Patent Act.<sup>20</sup> However, here the Court delimited cases in which the experiments are (solely) aimed at clarifying commercial aspects such as market demand, price acceptance and distribution possibilities, but also the properties, effects, possible applications and/or manufacturability of the patented subject matter.<sup>21</sup> Such activities aimed solely at the commercial utilization and exploitation possibilities are not subject to the protection exemption pursuant to Sec. 11(2) Patent Act.

Even though the Federal Court of Justice in principle opted for a rather generous interpretation of the experimental privilege in its two decisions *Clinical Trials I* and *II*, it denied the application of the experimental privilege for so-called mere bioequivalence studies with the argument that the aim of these studies is not to gain new knowledge but only to confirm or verify data. Instead of the more complex clinical trials, bioequivalence studies aim to prove that two medicinal products with the same active ingredient, namely the already authorized originator product on the one hand and the generic product still awaiting authorization on the other, can be substituted for each other without risk and with essentially identical efficacy for the patient. The aim is therefore to prove that the new medicinal product applied for has the required ‘essential similarity’ to the already authorized medicinal product and therefore the same pharmacological properties as the already authorized product.

### c) UK case law

The BGH thus followed the UK *Touchdown* decision<sup>22</sup> from the mid-1980s. The UK Court of Appeal had held that trials lacked the overall quality of experimental activities if they were carried out (on products with known properties) solely for the purpose of proving to a third party that the product is feasible, or to gather information to satisfy a third party, as is probably the case with bioequivalence trials carried out as part of a marketing authorization process on the back of a previous marketing authorization. In other words, only tests that generate new knowledge are exempted, not tests that verify existing knowledge, for example for the purpose of obtaining official authorization. This case concerned field trials involving a plant protection product, yet because of its general wording, the judgment also applied to trials involving pharmaceutical products.

### d) Other European countries

Almost all other European countries have similar regulations on the research exemption. Countries such as

Belgium, France, Italy, Spain, the Netherlands and the UK allow research to be carried out *on* the invention. However, with the exception of Belgium and Italy, these countries do not permit research *using* the invention.

For example, Art. L.613-5 of the French Intellectual Property Code stipulates that no patent infringement occurs if the invention is used for experiments ‘on the subject matter of the patented invention’. Consequently, the use of the invention in experiments for the purpose of gaining knowledge about something else is not exempt.

Article 53(3) of the Dutch Patent Act stipulates that activities carried out for the exclusive purpose of research on the patented subject matter, including on the product obtained as a direct consequence of the use of the patented process, do not constitute patent infringement. However, Dutch courts apply the research exemption restrictively. This means that only purely scientific activities that serve exclusively to study the patented invention are privileged.

According to Art. 68(1)(a) of the Italian Intellectual Property Code (IP Code), the exclusive right conferred by the patent ‘does not protect against: a) activities carried out [...] for experimental purposes, regardless of the scope of the invention’. According to Italian case law, all experimental activities (both in the academic field and in commercial enterprises) on the subject matter of a patented invention are lawful provided they serve to gain knowledge and thus contribute to the advancement of scientific research on the subject matter of the invention.

### e) ‘Research tools’

A particular problem is whether and to what extent the experimental privilege can also be applied in the context of so-called research tools. This question is dealt with/discussed in detail in Chapter II.5.c).

## II. Bolar exemption

### 1. What is the Bolar exemption?

While the research and experimental exemption was accepted and debated as early as the 19th century, at least in the USA, as a necessary corrective to patent protection that was otherwise too far-reaching, the so-called Roche-Bolar exemption was not developed until the end of the 20th century. The main idea behind this regulation is to allow generics manufacturers to carry out those activities that are necessary to obtain marketing authorization for their preparation as a generic drug even before the expiry of patent protection. As a rule, the studies required for a generic drug authorization are considerably less costly and time-consuming than the clinical studies required for the first marketing authorization of a drug. But even these so-called equivalence studies can also take many months or even years. If the performance of these studies were to be regarded as patent infringement, companies would only be able to perform the studies required for authorization after the expiry of the respective patent(s). Ultimately, the requirement of a marketing authorization under pharmaceutical law would effectively extend patent protection by many months or even years.

<sup>19</sup> *Clinical Trials II* (n 10) 3092 (3092).

<sup>20</sup> *Clinical Trials II* (n 10) 3092 (3092).

<sup>21</sup> *Clinical Trials II* (n 10) 3092 (3094).

<sup>22</sup> Decision of the Court of Appeal, 11 June 1985, [1987] GRUR Int 108 – *Monsanto v Stauffer Chemical*.



## 2. Origin of the Bolar exemption: USA

As early as 1984, the US Court of Appeals for the Federal Circuit ruled in *Roche v Bolar*<sup>23</sup> that the use of a patented substance for clinical tests was to be regarded as commercial use and therefore did not fall under the general experimental privilege under US law. Accordingly, the use of a patented substance in the context of clinical trials was to be classified as patent infringement.

An immediate reaction to this decision was the enactment of the so-called Hatch-Waxman Act in 1984<sup>24</sup> by the US Congress. As part of the Hatch-Waxman Act, the Bolar exemption or so-called ‘safe harbor’ provision was codified in 35 U.S.C. § 271 (e)(1) as follows:

‘It shall not be an act of infringement to make, use, offer to sell or sell [...] a patented invention [...] solely for uses reasonably related to development and submission of information under a Federal Law which regulates the manufacture, use, or sale of drugs or veterinary biological products’.

This regulation was intended to enable generics manufacturers to launch generics on the market directly after expiry of patent protection and in this way strengthen the generics market in the USA. US case law generally interprets the Bolar exemption more broadly.<sup>25</sup> The US Supreme Court in its landmark decision *Eli Lilly & Co. v Medtronic, Inc.* of 1990 clarified that the term ‘patented invention’ in § 271(e)(1) includes all inventions and not solely drug-related inventions. Thus, a patented invention can also include a medical device, which is also subject to premarket approval.<sup>26</sup> The Hatch-Waxman Act does not contain a blanket trial privilege, but only regulates the exemption of trials as far as marketing authorization for generic drugs is concerned.

## 3. Implementation of the Bolar exemption outside the US

### a) WTO panel: Dispute settlement procedure Canada 1998

In Canada, a similar but even more far-reaching regulation was introduced by Sec. 55(2)(1) of the Canadian Patent Act, containing a so-called *regulatory review exception*, which exempted experimental activities used for the purpose of obtaining data required for a marketing authorization. In addition, Sec. 55(2)(2) contained a so-called *stockpiling exception*, which regulated the permitted manufacture and storage of patented medicinal products during a period determined by special regulations. The European Union (EU) and its Member States – contractual partner of TRIPS – initially had concerns regarding the admissibility of these provisions. After Canada was unsuccessfully asked for consultation in 1997, the EU appealed to the Dispute Settlement Body of the World Trade Organization (WTO). The aim was to reconcile the Canadian Patent Act with the provisions of TRIPS.

In 1998 the Dispute Settlement Body decided that a panel should deal with this.<sup>27</sup> The EU took the view that Sec. 55(2)(2) of the Canadian Patent Act was not compatible with Art. 28(1) TRIPS, which states the rights conferred on a patent owner, and with Art. 33 TRIPS, which stipulates the protection period to be 20 years. If the manufacture, storage and use of patented active pharmaceutical ingredients were generally permitted in the last six months of the patent term, patented pharmaceuticals would no longer be protected from commercial use by third parties for 20 years, but only for 19.5 years. For the EU Member States, this constituted unequal treatment regarding the term of patent protection as stipulated in Art. 33 TRIPS and also a violation of the prohibition of discrimination specified in Art. 27(1) TRIPS.<sup>28</sup> Section 55(2)(1) of the Canadian Patent Act was also criticized for discriminating against pharmaceutical patents. According to the EU and its Member States, this provision was also in violation of Art. 27(1) and Art. 28(1) TRIPS. The exclusivity rights granted by a patent would be unduly affected if acts for licensing purposes were to be exempted without limitation.<sup>29</sup> The EU also argued that the new legal regulations introduced in Canada could hinder international trade in pharmaceuticals and adversely affect the protection of intellectual property. The WTO panel found the *regulatory review exception* to be TRIPS-compliant. The *stockpiling exception* in Sec. 55(2)(2) of the Canadian Patent Act, on the other hand, was found to be incompatible with the TRIPS Agreement, in particular with Art. 30 TRIPS. Article 30 TRIPS requires that ‘Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties’. However, the panel emphasized that the balance between the rights and obligations of patent holders under the TRIPS Agreement should not be significantly altered. The WTO has applied the so called ‘three-step test’ to interpret Art. 30 TRIPS. Accordingly, only those exceptions are permissible which (1) are limited, (2) do not unreasonably conflict with the normal exploitation of the patent, and (3) do not unreasonably prejudice the legitimate interests of the patent owners. The interests of third parties must also be considered.<sup>30</sup> According to the WTO panel, however, Canada had interpreted the term ‘limited’ (1) too broadly, which

<sup>27</sup> World Trade Organization, ‘Canada – Patent Protection of Pharmaceutical Products’ WT/DS114/R (WTO, 17 March 2000) <[http://www.wto.org/english/tratop\\_e/dispu\\_e/7428d.pdf](http://www.wto.org/english/tratop_e/dispu_e/7428d.pdf)> accessed 23 May 2024.

<sup>28</sup> cf. Holzapfel (n 8) 95.

<sup>29</sup> *ibid* 96.

<sup>30</sup> In Research Paper No 14-19 of the Max Planck Institute for Innovation and Competition, the panel’s decision was criticized for failing to recognize that the three conditions of the three-step test are not cumulative. Rather, the three-step test can be understood as requiring a comprehensive overall assessment and not a separate and independent assessment of each individual criterion. Therefore, the absence of one condition does not preclude the recognition of an exception (Matthias Lamping and others, ‘Declaration on Patent Protection – Regulatory Sovereignty under TRIPS’ (2014) Max Planck Institute for Innovation and Competition Research Paper No 14-19, (2014) 45 IIC 679-98 <<https://ssrn.com/abstract=2500784>> or <<http://dx.doi.org/10.2139/ssrn.2500784>> accessed 23 May 2024).

<sup>23</sup> See *Roche Products, Inc. v Bolar Pharmaceutical Co., Inc.* 733 F.2d 858 (Fed. Cir. 1984).

<sup>24</sup> The Hatch-Waxman Act is formally known as the ‘Drug Price Competition and Patent Term Restoration Act’.

<sup>25</sup> See, eg, *Eli Lilly & Co. v Medtronic Inc* 496 U.S. 661 (1990).

<sup>26</sup> *ibid*.

is why it confirmed that the *stockpiling exception* violates Art. 30 TRIPS.<sup>31</sup>

#### b) European Directive 2004/27/EC amending Directive 2001/83/EC

Despite the initial criticism leveled by the EU at both the US and Canadian Bolar exemptions, a similar regulation was introduced a few years later which was also intended to allow clinical trials to be carried out within the EU during the patent term in order to strengthen the European generics industry and at the same time bring down the cost of pharmaceuticals. This effectively brought European patent law into line with the privileged status of Sec. 271(e) of the US Patent Code.<sup>32</sup> With the implementation of this regulation, it should now also be possible for manufacturers of generics within the EU to obtain authorization or approval under pharmaceutical law before the expiry of a patent and to carry out the necessary trials or studies.<sup>33</sup> The main aim was to promote European generics companies on the international market in the hope of boosting the European generics market along the lines of the USA.<sup>34</sup> The declared aim of this authorization privilege was also to secure patient care in a cost-efficient manner by giving generics and biosimilar manufacturers the opportunity to obtain approval or authorization (particularly in third countries) before expiry of the patent.<sup>35</sup>

European Directive 2004/27/EC amending Directive 2001/83/EC on the Community code relating to medicinal products for human use also included the following provision in Art. 10(6):

‘The performance of the studies and trials necessary for the application of paragraphs 1, 2, 3 and 4 and the practical requirements arising therefrom shall not be regarded as conflicting with the rights conferred by patents or supplementary protection certificates for medicinal products.’

Accordingly, tests and studies that are performed to obtain data for an authorization procedure in an EU or EEA country do not constitute patent infringement if they are necessary for the authorization application. Paragraphs 1-4, to which reference is made, contain explanations and definitions of generics and biosimilars.

The aim of this regulation was to remove the existing uncertainties regarding the scope of application of the research exemption. In accordance with Art. 13(6) of Directive 2004/28/EC and 2001/82/EC on the Community code relating to veterinary medicinal products, the new regulation also applies to veterinary medicinal products in addition to medicinal products for human use.

## 4. Bolar privilege in European countries

Within just a few years, a Bolar exemption was introduced in almost all EU Member States in order to enable

clinical trials to be carried out before the respective patents expired. However, as the Bolar exemption was introduced in the EU as a Directive and the specific wording was thus left to the Member States, interpretation and implementation in the various EU countries vary considerably.

The countries can basically be divided into two categories: on the one hand, there are countries in which the exemption is limited to activities in connection with the marketing authorization of generics, bioequivalents and biosimilars;<sup>36</sup> and then there are countries that, in a broader sense, exempt all activities required for marketing authorization as well as legal activities in connection with innovative medicinal products.<sup>37</sup> There are also differences between the Member States as to whether the Bolar exemption only applies to products that are to be authorized not only in the European economic area (EEA) but also outside the EEA.<sup>38</sup>

#### a) Germany

In Germany,<sup>39</sup> the Bolar privilege (also known as the ‘market authorization privilege’)<sup>40</sup> was introduced in September 2005 in the form of the new Sec. 11(2b) Patent Act.<sup>41</sup> According to this provision, the effect of the patent does not extend to

‘Studies and trials and the resulting practical requirements necessary to obtain a marketing authorization for medicinal products in the European Union or a marketing authorization for medicinal products in the Member States of the European Union or in third countries’.

In German legal practice, Sec. 11(2b) Patent Act was interpreted broadly from the outset. The general opinion is that it covers all activities that are objectively necessary to obtain a desired approval or marketing authorization for an innovative medicinal product as well as a generic or biosimilar product and are directly related to such approval or authorization.<sup>42</sup> The German Bolar exemption in Sec. 11(2b) Patent Act therefore does not extend solely to the exemption of studies for generic marketing authorizations, but also includes studies and activities

<sup>36</sup> Biosimilars are imitation preparations of biotechnologically manufactured medicinal products (biopharmaceuticals) which are *not identical* to the original preparation. Generics are also imitation preparations, but their active ingredient *is identical* to that of the original preparation, cf. <<https://www.vfa.de/de/wirtschaft-politik/abgesundheitspolitik/biosimilars-schnell-erklaert.html>> accessed 20 June 2024.

<sup>37</sup> cf. Paul A Calvo, ‘Bolar Exemption in Europe and Asia’ (Sterne, Kessler, Goldstein & Fox, 18 December 2017) <<https://www.sterneksler.com/news-insights/publications/bolar-exemption-europe-and-asia>> accessed 23 May 2024.

<sup>38</sup> cf. Raphaël De Coninck and others, ‘Assessing the economic impacts of changing exemption provisions during patent and SPC protection in Europe’ (European Commission, Charles River Associates) 46 <<https://op.europa.eu/en/publication-detail/-/publication/6e4ce9f8-aa41-11e7-837e-01aa75ed71a1/language-en>> accessed 20 June 2024.

<sup>39</sup> In addition to the Bolar privilege in s 11 No 2b Patent Act, the plant research privilege was also introduced in s 11 No 2a Patent Act, according to which the effect of a patent does not extend to the use of biological material for the purpose of breeding, discovering and developing a new plant variety.

<sup>40</sup> See also Maximilian Haedicke, *Patentrecht* (6th edn, Kluwer 2022) ch 7, para 25.

<sup>41</sup> BT-Drs. 15/5316, pp 1, 29.

<sup>42</sup> Scharen in Benkard (n 35); Alfred Keukenschrijver in Rudolf Busse and Alfred Keukenschrijver (eds), *Patentgesetz* (9th edn, De Gruyter 2020) s 11, para 20 (with further references).

<sup>31</sup> cf. Holzapfel (n 9) 97, 98.

<sup>32</sup> Henrik Holzapfel, ‘Keine Entschädigung für mittelbare Erfindungsbenutzungen?’ [2006] GRUR 10 (16).

<sup>33</sup> BT-Drs. 15/5316, pp 1, 31.

<sup>34</sup> Ulrich M Gassner, ‘Unterlagenschutz im Europäischen Arzneimittelrecht’ [2004] GRUR Int 983 (990).

<sup>35</sup> Uwe Scharen in Georg Benkard, *Patentgesetz* (12th edn, CH Beck 2023) s 11, para 10 (with further references).

that are related to and necessary for the marketing authorization application for an originator product (see II.5.a)). Hence, it also includes experimental activities involving innovative medicinal products with the goal of obtaining regulatory authorization. The explanatory statement to the draft bill on Sec. 11(2b) Patent Act also makes it clear that the Bolar privilege – at least in principle – also covers preparatory activities that establish the basic conditions for a trial or study authorization in the first place.

According to this provision, not only experiments *on*, but also experiments *using* the invention are privileged. In contrast to Sec. 11(2) Patent Act, there is no requirement that studies and experiments must relate to the subject matter of the invention.<sup>43</sup> Rather, the Bolar exemption in Sec. 11(2b) Patent Act is *lex specialis* to the experimental privilege under Sec. 11(2) Patent Act. The feature of ‘*practical requirements*’ has also created a catch-all provision for all patent uses necessary prior to studies and trials.<sup>44</sup> Furthermore, the exemption applies in Germany regardless of whether the research leads to new findings or not. However, purely preliminary research (which is not directly required for the approval of an application for marketing authorization, as is usually the case when using research tools) is not privileged.<sup>45</sup>

Section 11(2b) Patent Act also does not make a distinction between official authorizations or approvals from Germany, the EU or non-EU countries (see II.5.b)). According to its express wording, trials whose aim is to obtain authorization in another EU Member State as well as in non-EU countries are therefore covered by the authorization privilege. It is therefore irrelevant whether the product is placed on the market inside or outside the EU or the EEA and in which country the marketing authorization is to be applied for. The question of necessity, which according to the wording of Sec. 11(2b) Patent Act is a prerequisite for the exemption, is determined by the law of the country of authorization.

## b) The Netherlands

In the Netherlands, on the other hand, the privilege is interpreted more narrowly and closer to the wording of Art. 10(6) of Directive 2004/27/EC or 2001/83/EC. Here, too, the performance of the necessary studies and trials required in order to obtain a marketing authorization for a generic and biosimilar product is privileged under Art. 53(4) of the Dutch Patent Act:<sup>46</sup>

‘The performance of the necessary studies, tests and trials for the purposes of Article 10(1) to (4) of Directive 2001/83/EC on the Community code relating to medicinal products for human use (OJ 2001 L 311) or Article 13(1) to (5) of Directive 2001/82/EC on the Community code relating to

veterinary medicinal products (OJ 2001 L 311) and the practical requirements arising therefrom shall not be regarded as infringements of patents relating to medicinal products for human or veterinary use.’

However, only those activities in connection with the marketing of generics, bioequivalents and biosimilars that are solely carried out for the purpose of an abridged application for marketing authorization are exempted from patent infringement.<sup>47</sup> Moreover, the activities are limited to marketing authorizations within the EU (see II.5.b)).<sup>48</sup>

## c) United Kingdom

In the UK, due to a change in the law in 2014, there are currently three exemptions in force: Firstly, there is the ‘original’ experimental use exemption provided under Sec. 60(5)(b) of the UK Patents Act (UKPA) 1977, which is still in force today and applies to *inter alia* medicinal products, medical devices and agrochemicals. Essential for understanding the legal situation in the UK is the *Monsanto Co. v Stauffer Chemical Co.* decision from 1985.<sup>49</sup> This case concerned the validity of a patent granted to Monsanto Co. on a specific herbicide. Stauffer Chemical Co. disputed the validity of the patent, arguing that it was not novel and did not involve an inventive step. The court’s ruling stipulates that the ‘experimental use’ exemption covers activities focused on creating new information, such as exploring the unknown, testing hypotheses or examining varied conditions, but it doesn’t encompass efforts aimed at confirming existing knowledge or proving a product’s effectiveness to regulators or customers. The crucial factor is whether the studies advance scientific understanding and reveal something new regarding the patented invention. The exemption includes experiments directly linked to the patented invention, including tests on its production, functionality or potential enhancements, but it doesn’t permit using the patented invention to assess other products or processes.<sup>50</sup>

There is also the ‘Bolar exemption’ in Sec. 60(5)(h)(i) of the UK Patents Act 1977 (as amended), which is an implementation of Directive 2001/83/EC and stipulates:

‘An act which, apart from this subsection, would constitute an infringement of a patent for an invention shall not do so if it consists of [...] (i) an act done in conducting a study, test or trial which is necessary for and is conducted with a view to the application of paragraphs 1 to 5 of article 13 of Directive 2001/82/EC or paragraphs 1 to 4 of Article 10 of Directive 2001/83/EC.’

This provision exempts activities that are carried out solely for the purpose of obtaining an abridged marketing authorization for a generic medicinal product. Moreover,

<sup>43</sup> cf Johannes W Bukow in Maximilian Haedicke und Henrik Timmann, *Handbuch des Patentrechts* (2nd edn, CH Beck 2020) s 13, para 37 (with further references).

<sup>44</sup> Haedicke (n 40).

<sup>45</sup> Thomas Kühnen, *Handbuch der Patentverletzung* (15th edn, Carl Heymanns 2023) pt E, para 1087 (with further references).

<sup>46</sup> Hans-Rainer Jaenichen and Johann Pitz, ‘Research Exemption/ Experimental Use in the European Union: Patents Do Not Block the Progress of Science’ (2014) 5(2) Cold Spring Harbor Perspectives in Medicine <<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4315916/>> accessed 23 May 2024.

<sup>47</sup> See Paul England, ‘Upgrading the single market: updating the Bolar exemption’ (TaylorWessing, 6 December 2015) <<https://www.taylor-wessing.com/en/insights-and-events/insights/2015/12/upgrading-the-single-market>> accessed 23 May 2024.

<sup>48</sup> cf England ‘Upgrading the single market: updating the Bolar exemption’ (n 47).

<sup>49</sup> *Monsanto Co v Stauffer Chemical Co* [1985] RPC 515.

<sup>50</sup> Paul England, ‘Bolar and the experimental use exemptions in the UK’ (27 April 2018) <<https://www.lexology.com/library/detail.aspx?g=ee3cac2f-2f4e-414d-87be-e8d9c47d2bb9>> accessed 23 May 2024; Jaenichen and Pitz (n 46).



the exempted tests must be for marketing authorizations that cover the European Union market (see II.5.b)).<sup>51</sup>

As mentioned, with effect from October 2014, a third exemption was introduced into the Patents Act, namely in Sec. 60(6D) and (6E) Patents Act 1977: the ‘new’ experimental use exemption, which expands the comparatively narrow privilege in Sec. 60(5) lit. i). However, this has not changed the above-mentioned Bolar provision. Rather, this amendment is an extension of the research exemption within the meaning of Sec. 60(5)(b) of the UK Patents Act. Section 60(6D) of the 2014 Act states:

‘For the purposes of subsection (5)(b), anything done in or for the purposes of a medicinal product assessment which would otherwise constitute an infringement of a patent for an invention is to be regarded as done for experimental purposes relating to the subject-matter of the invention.’

The aim of this ‘new’ experimental use exemption is – in addition to the activities covered by the Bolar exemption – to allow a broader application than the ‘original’ experimental use exemption. Like the Bolar exemption in Sec. 60(5)(i), the ‘new’ exemption also applies only to medicinal products under the Directive. But it covers not only abridged marketing authorizations but also trials involving innovative products with the goal of obtaining marketing authorizations in countries worldwide, or to carry out Health Technology Assessments (see II.5.a)).<sup>52</sup> Regarding medicinal products, the distinction made in the case of *Monsanto v Stauffer* between experiments aimed at testing novel properties versus verifying known properties for regulatory purposes is nullified by this new exemption.<sup>53</sup>

#### d) Spain

In 2006, the amendment to Directive 2004/27/EC was implemented in Spain by the Second Final Provision of Law 29/2006. This resulted in a rewording of Art. 52(1) lit. b) of the Patent Act of 1986 in force at that time. The effect of this provision is that studies and trials carried out to obtain marketing authorization for generic medicinal products should also be included among the exempt experimental activities. Following the entry into force of the new Spanish Patent Act of 2015 in April 2017, the Bolar provision is now enshrined in Art. 61(1) lit. b) and c). According to this, patent rights do not extend to

‘b) acts carried out for experimental purposes and that relate to the subject matter of the patented invention;

c) carrying out the studies and trials necessary to obtain the authorization to place medicinal products on the market in Spain or outside Spain and the practical requirements arising therefrom, including the manufacture, procurement and use of the active substance for these purposes.’

Like Germany, Spain interprets the Bolar exemption broadly. In particular, the Spanish legislator deleted the term ‘generic medicinal product’ from the new Patent

Act, which was intended to clarify that the Bolar exemption also covers biosimilars and other medicinal products such as veterinary medicinal products (see II.5.a)). With regard to the territorial scope of the exemption, the wording of Art. 61(1) lit. c) refers to ‘Spain or outside Spain’. The activities listed in Art. 61 para. 1 lit. c) are therefore exempt, regardless of where the authorization is applied for (see II.5.b)).<sup>54</sup>

#### e) France

In France, the Bolar exemption was implemented in Art. L. 613-5 lit. b) and d) of the French Intellectual Property Code (FIPC). According to this provision, the rights conferred by the patent do not extend to

‘b) acts that are carried out on an experimental basis and that relate to the subject matter of the patented invention;

d) the studies and tests required to obtain an authorization to place a medicinal product on the market as well as the acts necessary to carry them out and obtain the marketing authorization.’

Hence, the French Bolar exemption is not limited to generics (see II.5.a)), but also applies to trials involving innovative medicinal products, as is also the case in Germany. Moreover, all activities required to secure a marketing authorization for a medicinal product are covered, including also so-called biosimilars. The exemption also applies to all types of marketing authorizations, so it is not limited to generic products. The exemption is more expansive and encompasses any act required to obtain a marketing approval for any medicinal product, including biosimilars. Whether conducting studies for authorization procedures outside Europe should also be privileged has not yet been clarified by the highest courts (as far as can be seen). However, there is a clear tendency on the part of the French courts not to restrict research and generics (see II.5.b)).<sup>55</sup> In its decision of 7 October 2014, the High Court of Paris confirmed<sup>56</sup> that the Bolar exemption also applies when trials have as their aim the securing of marketing authorizations outside the EU.

#### f) Belgium

Article 10(6) of Directive 2004/27/EC or 2001/83/EC was implemented in Belgium through the introduction of Art. 6<sup>bis</sup> Sec. 1 in the Belgian Medicinal Products Act of 25 March 1964:

‘The performance of the necessary studies, tests and trials with a view to fulfilling the conditions and modalities referred to in paragraphs 1 to 7 and any practical requirements arising therefrom shall not be deemed to infringe patent rights or supplementary certificates for medicinal products for human use.’

Accordingly, the Bolar exemption is limited to generics and biosimilars and does not apply to innovative medicinal

<sup>51</sup> England, ‘Bolar and the experimental use exemptions in the UK’ (n 50).

<sup>52</sup> *ibid.*

<sup>53</sup> *ibid.*

<sup>54</sup> cf András Kupecz and others, ‘Safe Harbours in Europe: An Update on the Research and Bolar Exemptions to Patent Infringement’ (2015) 33 *Nature Biotechnology* 710 (714).

<sup>55</sup> cf Kupecz and others (n 54) 710 (713).

<sup>56</sup> High Court of Paris, 15 December 2014 and 7 October 2014 – *Sanofi-Aventis Germany v Lilly France*.

products (see II.5.a)). The territorial scope of application is limited to activities carried out for the registration of a medicinal product in the EU (see II.5.b)).<sup>57</sup> Consequently, activities carried out exclusively for the registration of a medicinal product outside the EU are not covered.<sup>58</sup>

On 28 December 2017, the 'Act amending various provisions concerning patents in relation to the implementation of the unitary patent and the unified patent court' (Amending Act) was published in the Belgian Official Gazette. Following this amending law, Book XI of the BCEL was adapted to the provisions of the UPCA (see IV.), although this is not in principle required by the UPCA. The Belgian legislator wanted, however, to create legal certainty by harmonizing the Belgian legal framework as far as possible with the situation in the other EU Member States.<sup>59</sup> Article XI.34(d) of the BCEL now contains a literal transposition of Art. 27(d) of the UPCA:

'The rights of the patent proprietor do not extend to [...] the acts permitted under Article 6bis, Sec. 1, paragraph 12, and Sec. 6, paragraph 13, of the Belgian Medicines Act of 1 May 2006 in respect of a patent on the product within the meaning of one of these provisions.'<sup>60</sup>

While Belgium decided to maintain the EU's narrow Bolar exemption for generics and biosimilars, the Amending Act simultaneously extends the scope of application of the research privilege.<sup>61</sup> The corresponding provisions of the Amending Act have been in force since 1 June 2023, i.e. since the UPCA came into force.

### g) Switzerland

As Switzerland is not an EU Member State, Directives 2004/27/EC and 2001/83/EC do not apply. Nevertheless, it has a statutory Bolar exemption which, like the German regulation, is interpreted broadly. According to Art. 9(1) lit. b) and c) of the Swiss law on invention patents, the effect of the patent does not extend to

'Article 9(1) lit. b): acts carried out for research and experimental purposes whose aim is to obtain knowledge of the subject matter of the invention, including its uses; in particular, all scientific research on the subject matter of the invention is exempt;

Article 9(1) lit. c): acts required for the authorization of a medicinal product in Switzerland or in countries with comparable medicinal product control.'

Clinical trials conducted for research purposes and/or for marketing authorization are therefore exempt from patent infringement. Furthermore, the Bolar privilege not only applies to generics but also, as in Germany, to new medicinal products (see II.5. a)). This means that any form of research or experimental use (see Art. 9(1) lit.

b)) as well as all activities necessary to obtain marketing authorizations (see Art. 9(1) lit. c)) are exempt.<sup>62</sup>

## 5. Special cases under Bolar

In the past, the CJEU generally advocated a restrictive interpretation of exceptions.<sup>63</sup> In its case law on copyright, the CJEU now assumes that exceptions and limitations create rights for users and serve to create an appropriate balance between the interests of right holders and those of users. When interpreting limitations and exceptions, their practical effectiveness must be ensured and their purpose taken into account.<sup>64</sup> It is not apparent that anything different should apply to intellectual property law. With this in mind, certain special cases need to be considered with regard to the research and Bolar exemptions concerning their respective areas of application, as already mentioned in the context of the individual national jurisdictions.

### a) Generics vs. originators

The first question that arises is whether the Bolar exemption only applies to studies for generic marketing authorizations or whether it also covers studies and activities directed to the development of a new medicinal product, i.e. an originator product.

Originator products are medicines that are introduced into the market for the first time by research-based pharmaceutical companies. Originator medicines contain a new active ingredient or an existing active ingredient in a particular administration form. They carry brand names and must undergo a complex and cost-intensive first authorization procedure. Generics are copycat products that correspond to the original in terms of active ingredient, potency and form of delivery. However, they may differ with regard to the excipients they contain. Some originator companies also produce generics that correspond to their originator product. In many cases, the only difference between originator products and generics is the packaging. Generics generally only display the name of the active ingredient and the manufacturer's name.

While in Germany, Spain, France, the UK<sup>65</sup> and Switzerland the Bolar exemption is *not* limited to activities in connection with studies for the marketing authorization of a generic medicinal product (see II.4.a), c), d), e), g)), the Bolar exemptions in the Netherlands and Belgium cover *only* activities in connection with obtaining a marketing authorization for generics and biosimilars (see II.4.b), f)).

### b) Regulatory approval within the EU/EEA vs. outside the EU/EEA?

There are also national differences regarding whether or not the relevant studies must be directed towards a

<sup>57</sup> Olivier Mignolet and others, 'Research and Bolar Exemptions from UPC, Belgian and French Perspectives' in Luc Desautnettes-Barbero and others (eds), *The Unitary Patent Package & Unified Patent Court: Problems, Possible Improvements and Alternatives* (1st edn, Ledizioni 2023) ch 22, 499.

<sup>58</sup> Kupecz and others (n 54) 710 (712).

<sup>59</sup> Chamber of Representatives, Doc 54-2755/001, pp 6-22; Mignolet and others in Desautnettes-Barbero and others (n 57) 502.

<sup>60</sup> Mignolet and others in Desautnettes-Barbero and others (n 57) 502.

<sup>61</sup> cf in detail: ibid 502 ff.

<sup>62</sup> See also CMS law tax future, 'CMS Expert Guide on Bolar Provisions' (CMS, 26 July 2022) <<https://cms.law/en/int/expert-guides/cms-expert-guide-on-bolar-provisions/Switzerland>> accessed 2 May 2023.

<sup>63</sup> Case C-83/99 *Commission v Spain* ECLI:EU:C:2001:31, para 19 with further references.

<sup>64</sup> Case C-516/17 *Spiegel Online GmbH v Volker Beck* ECLI:EU:C:2019:625, paras 54-55.

<sup>65</sup> In the broader 'Exemption for new experimental uses' of October 2014 (see II.4.c)).



European medicinal product authorization in order for the Bolar exemption to apply, or whether a marketing authorization for a medicinal product in a non-European country is sufficient. Again, Germany, Spain, France, the UK<sup>66</sup> and Switzerland interpret their Bolar provisions more broadly in this respect by also privileging activities directed towards marketing authorizations outside the EU or the EEA (see II.4.a), c) d), e), g)). In the Netherlands and Belgium, on the other hand, the exempted activities are limited to authorizations within the EU (see II.4.b), f)).

### c) Research tool

Another question is whether the research and Bolar exemptions also permit the use of patented research tools<sup>67</sup> if these are used in an experimental context and to obtain new information or are used in the context of bioequivalence studies. This question has not yet been clarified by the respective national case law. However, as research tools are regularly only used in the context of research, extending the Bolar as well as research exemption to research would lead to a de facto abolition of patent protection for research tools. This is because researchers are the customary and major users of patented research tools, meaning that their use would effectively be rendered unpatentable. Accordingly, an overly broad interpretation of the research exemption could inhibit the incentives to invent new research tools, which would ultimately hinder rather than support research activities. A careful balance is required.

In Germany as well as in the UK, France, Spain, Belgium and the Netherlands, the research exemption is limited to experiments relating to the subject matter of the patented invention. However, experimental activities with research tools are not carried out to obtain new information about the patented technology, but about different subject matter.<sup>68</sup>

Similarly, the US courts have also repeatedly found that research tools not subject to FDA approval are not immunized from infringement by the safe harbor provision of 35 U.S.C. § 271(e)(1).<sup>69</sup>

Accordingly, it is generally assumed that neither the research exemption nor the Bolar exemption applies to research tools. This would also apply if the use would only be in the context of non-commercial, academic or basic research.

### d) Third-party suppliers as beneficiaries of the Bolar exemption

It is also a matter of dispute whether only the persons conducting the relevant trials or studies themselves are

privileged, or whether third parties – such as suppliers – can also invoke the exemptions to patent protection. In 2013, the Polish Supreme Court ruled that the Bolar exemption does not apply to the activities of third-party manufacturers, i.e. to the supply of active ingredients for studies and trials to be conducted by third-party manufacturers of generics.<sup>70</sup> The German Regional Court of Düsseldorf had already ruled in 2012 that acts of provision by third parties only fall under the privileged status, if at all, under certain restrictive conditions.<sup>71</sup>

The Düsseldorf Higher Regional Court (OLG) took a different view: in 2013, in the context of a question referred to the CJEU, it found that an excessively narrow interpretation of the Bolar exemption would run counter to the purpose of the provision.<sup>72</sup> According to the OLG, it was sufficient for the supplier to make sure before the act of provision that

‘[...] according to all the circumstances (to be enquired into by him if necessary), there is no reasonable doubt that the active substance provided is used exclusively for privileged market authorization studies’.<sup>73</sup>

According to case law of the Higher Regional Court, indicators of this are in particular the focus of the company supplied, the quantity of the active ingredient provided, the imminent expiry of patent protection as well as positive or negative experiences with the customer in the past. The supplier must also take measures that effectively counteract any unlawful use of the active ingredient provided other than in a privileged marketing authorization procedure. This can be achieved by a legally binding agreement in which the customer undertakes to use the active substance provided solely for the agreed purpose. Whether and to what extent it is also necessary to come to an agreement on a contractual penalty in the event of non-compliance with such an undertaking would still need to be clarified in detail, though experience has shown that such undertakings are only negotiable to a limited extent. As this question arose from the interpretation of the EU Directive, the Higher Regional Court referred a corresponding question to the CJEU for a preliminary ruling. However, the legal dispute was later settled, and the referral was withdrawn.

In Germany (as in other European countries), it is therefore still unclear whether third parties who do not themselves fall under one of the privileges of Sec. 11(1) to (3) Patent Act are liable for supplying the active ingredient. Particularly problematic is the situation where the supplier can only supply components or starting materials that a generics manufacturer needs in order to produce a patented medicinal product. Broadly speaking, the supplier fulfils the criteria for indirect patent infringement

<sup>66</sup> *ibid.*

<sup>67</sup> Research tools are products and processes that are used to research other objects. Their purpose is therefore limited to carrying out research work. This includes, for example, laboratory equipment or so-called drug targets for use in screening procedures, see Holzapfel, ‘Keine Entschädigung für mittelbare Erfindungsbenutzungen?’ (n 32) 10 (11).

<sup>68</sup> See also Haedicke (n 40) ch 7, para 21; Holzapfel, ‘Keine Entschädigung für mittelbare Erfindungsbenutzungen?’ (n 32) 10 (16 f).

<sup>69</sup> See, for example, *Proveris Sci Corp v Innovasystems Inc*, 536 F3d 1256 (Fed Cir 2008) and *Allele Biotechnology & Pharms., Inc. v Pfizer, Inc.* No 20-CV-01958-H-AGS, 2021 WL 1749903 (S.D. Cal. 4 May 2021).

<sup>70</sup> Polish Supreme Court, decision of 23 October 2013, IV CSK 92/13; see also Thorsten Bausch, ‘You must Bolar alone: Polish Supreme Court confirms exclusion of third-party manufacturers from the Bolar exemption’ (*Kluwer Patent Blog*, 7 November 2013) <<https://patentblog.kluweriplaw.com/2013/11/07/you-must-bolar-alone-polish-supreme-court-confirms-exclusion-of-third-party-manufacturers-from-the-bolar-exemption/>> accessed 23 May 2024.

<sup>71</sup> Regional Court Düsseldorf, 4a O 282/10, [2013] BeckRS 1711 – *Experimental privilege, placing on the market*.

<sup>72</sup> Higher Regional Court Düsseldorf, I-2 U 68/12, [2014] GRUR-RR 100 – *Marktzulassungsprivileg*.

<sup>73</sup> *ibid* 100 (107).

pursuant to Sec. 10 Patent Act.<sup>74</sup> However, according to Sec. 10(3) Patent Act,

‘Persons performing the acts referred to in Sec. 11 nos. 1 to 3 [...] are deemed, within the meaning of subsection (1), not to be persons entitled to exploit the invention’.

Although the Bolar provision should fall within the scope of application of Sec. 10(3) Patent Act due to the clear wording of Sec. 10(3) Patent Act, which explicitly covers the ‘acts referred to in nos. 1 to 3’, this appears problematic in view of Sec. 11(2b) Patent Act, which historically came into force much later than Sec. 10(3) Patent Act. This uncertainty poses considerable legal risks for suppliers and customers alike, particularly in the pharmaceutical sector. At least according to the prevailing opinion, acts of provision by third parties should be permissible in principle.<sup>75</sup> It is only unclear under which conditions this should be possible. However, these conditions, i.e. ultimately the degree of diligence required of the supplier (and possibly the customer), are sometimes set too high by the courts. If, for example, suppliers are required to demonstrate their own interest in researching the subject matter of the invention, this is unlikely to correspond to the reality on the supplier market and would impose an unreasonably high burden upon the respective supplier.<sup>76</sup>

In France and Spain, this issue has not yet been clarified by the courts, although the French and Spanish Bolar exemption could be interpreted broadly to mean that third parties should also benefit from it. There is also no case law on this in Belgium and the Netherlands. In Switzerland, an extension to third parties would appear to be possible under certain circumstances.<sup>77</sup>

#### e) Medical devices and plant protection products

While the US exemption rule applies to both generics and new medicinal products<sup>78</sup> and medical devices,<sup>79</sup> the European Bolar exemption does not cover medical devices.<sup>80</sup> Rather, these are governed by a separate Medical Devices Regulation (EU) 2017/745, which does not, however, contain a provision comparable to the Bolar privilege.<sup>81</sup> An analogous application is also out of the question, at least according to the prevailing opinion. It is true that the boundaries between medical devices and medicinal products are becoming increasingly blurred, with the result that it can

be difficult to make a precise distinction in certain cases. However, in contrast to medicinal products, there is no approval process for medical devices requiring the performance of lengthy and costly clinical trials. In view of the different regulatory requirements and the different authorization timelines compared to medicinal products, it therefore appears appropriate that the permissibility of experimental acts on and using medical devices is not privileged by Sec. 11(2b) Patent Act.<sup>82</sup>

Plant protection products are also not covered by the European Bolar exemption. It could be argued that the Bolar exemption is indeed also applicable to veterinary medicinal products in accordance with Art. 13(6) of Directive 2004/28/EC or 2001/82/EC, and that these protect non-human organisms in the same way as plant protection products and therefore have a similar protective purpose. However, the wording of Art. 10(6) of EU Directive 2004/27/EC or 2001/83/EC, which explicitly refers to medicinal products and not plant protection products, argues against the applicability of the Bolar privilege.

#### f) Authorization batches (products made in the course of regulatory testing)

It has also not yet been clarified (as far as the author is aware) whether batches of medicinal products lawfully manufactured in accordance with the Bolar regulation may be commercially exploited after the relevant patent has expired. The sale of these batches has been met with concern due to the fact that their manufacture was only legitimate based on a privilege granted in order to obtain regulatory approval. Hence, sales of batches outside of the approval procedure during the patent term are in any case excluded. This begs the question as to whether there is an enduring connection between the privileged manufacture of the batches during the patent term and their sale after the patent has expired. In other words, whether merely the point in time of placing the product on the market within the meaning of Sec. 9 sentence 2 No. 1 Patent Act is decisive, or whether the purpose-related manufacturing privilege exercised before the expiry of the patent (Sec. 11(2b) Patent Act) also leads to a purpose limitation of all subsequent acts of use of the privileged manufactured product even after the expiry of the patent.

In principle, patent protection ends when the patent expires. However, the patent proprietor does not lose the claims that he has acquired against third parties, such as infringers of his patent, during the term of the patent.

It cannot be directly inferred from the wording of Sec. 11(2b) Patent Act that the Bolar exemption should lead to a restriction on use after expiry of the impeding patent. However, the Bolar exemption must be measured against the so-called three-step test pursuant to Art. 28 para. 1 in conjunction with Art. 30 TRIPS. As mentioned in para. 22, Art. 30 requires that:

‘Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.’

<sup>74</sup> Ulrich Worm and Oliver Guski, ‘Analoge Anwendung des Zulassungsprivilegs auf Medizinprodukte? Zu den Grenzen von Versuchshandlungen an und mit patentierten Medizinprodukten’ [2011] MittPatA 265 (270).

<sup>75</sup> cf. Bukow in Haedicke and Timmann (n 43) s 13, para 26 f; Martin Fährndrich and Winfried Tilmann, ‘Patentnutzende Bereitstellungshandlungen bei Versuchen’ [2001] GRUR 901 (902 f); Worm and Guski (n 74) 265 (270); *Experimental privilege, placing on the market* (n 71); *Marktzulassungsprivileg* (n 72) 100.

<sup>76</sup> See in detail: Marco Stief and Tobias Matschke, ‘Das Versuchs- und Bolar-Privileg im Bereich der mittelbaren Patentverletzung’ [2021] GRUR 1241.

<sup>77</sup> See also CMS law tax future, ‘CMS Expert Guide on Bolar Provisions’ (n 62).

<sup>78</sup> See *Merck KGaA v Integra Lifesciences I Lt* 545 US 193 (2005).

<sup>79</sup> cf. *Eli Lilly and Co v Medtronic* 496 US 661 (1990).

<sup>80</sup> For the US exception, see *ibid*.

<sup>81</sup> See Jakob Wested and Timo Minssen, ‘Research and Bolar Exemptions in the U.S. and Europe: Recent Developments and Possible Scenarios’ (30 August 2018) 9 <[https://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=3236127](https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3236127)> accessed 23 May 2024.

<sup>82</sup> Worm and Guski (n 74) 265 (266, 271).

The Bolar exemption must therefore be handled restrictively.

The Bolar exemption permits the use of the patent insofar as this is required for a marketing authorization under Regulation (EC) No. 726/2004.<sup>83</sup> Not only the manufacture but also the subsequent utilization, for example exploitation or even mere possession, is permitted as long as and insofar as it comes under the privilege of the Bolar exemption, i.e. is for the purpose of obtaining marketing approval.

Since the purpose limitation applies to all activities and not only to the manufacture, it appears only consistent that any subsequent change of purpose with regard to the privileged activity be prohibited. Whenever an authorization batch is kept after approval has been granted with the intention of exploiting it commercially later on, the purpose of the authorization shifts towards a purely commercial intention and accordingly the exemption no longer applies with retroactive effect. As a result, authorization batches whose production was lawful pursuant to the Roche-Bolar regulation may only be used for purposes that are necessary for the approval procedure, and the surplus quantity not or no longer needed for obtaining marketing approval must be destroyed unless it can be sold to, or a license can be obtained from, the (former) patentee, both of which appear rather unlikely. It should be noted that the restrictions described here only apply to authorization batches that were manufactured within the patent term. It goes without saying that they do not apply to any other batches or to authorization batches that were manufactured after the patent expires.

While this leads to rather unsatisfactory results, both economically and in terms of health policy, it can be assumed that a significant part of a manufactured authorization batch will be used during the authorization procedure – e.g. by delivery to the authorization authority or by being used in the clinical trials. The economic ‘damage’ to the manufacturer – generally a generics manufacturer according to the meaning and purpose of Sec. 11(2b) Patent Act – is therefore likely to be limited.

### III. Intention to harmonize the Bolar regulations in the EU Member States

#### 1. Possible advantages of harmonizing the Bolar exemption

The different handling of the Bolar exemption in the EU countries has led to legal uncertainty and confusion among developers of generics, biosimilars, originator products and active pharmaceutical ingredients (APIs)<sup>84</sup> with regard to its scope of application. This is particularly problematic given the risk that investments in the development and production of APIs will be relocated outside Europe<sup>85</sup> because of these uncertainties.<sup>86</sup>

The desire for a harmonized extension of the scope of the Bolar exemption can be justified by the fact that, in addition to the legal certainty thereby established, competition could also be strengthened, and a significant contribution could be made to the objectives of affordability of medicinal products and thus also to improved patient access. A harmonized scope of application of the Bolar exemption within the EU should not only lead to a fairer distribution of API investments across the Member States, but also to a wider choice of European API suppliers. Due to the restrictions on patent protection through the Bolar privilege, more investment in R&D could also be expected.<sup>87</sup> Extending the scope of the Bolar exemption to all medicinal products and marketing authorizations in all countries would also be economically beneficial for the European pharmaceutical industry as a whole, as it would bring down legal costs, reduce the need for duplicate trials to support marketing authorizations in different jurisdictions and streamline the strategic planning process.<sup>88</sup>

#### 2. The pharma package of the EU

Calls for harmonization of the Bolar exemption within the EU Member States are growing – including from the EU Commission.<sup>89</sup> On 27 April 2023, the EU Commission presented a proposal<sup>90</sup> for the reform of pharmaceutical legislation in the EU.<sup>91</sup> The aim is to fundamentally revise pharmaceutical legislation. The proposal can be split into a Directive on the creation of an EU code relating to medicinal products for human use, and a proposal for a regulation establishing EU procedures for the authorization and monitoring of medicinal products for human use and for establishing rules for the European Medicines Agency. According to the Commission, this reform, the most far-reaching in 20 years, would also impact (through Art. 85 of the draft Directive) the Bolar exemption: according to Art. 85 lit. a) of the draft Directive,<sup>92</sup> acts of use for studies, trials and other activities carried out to obtain data for an application for the following procedures are to be privileged:

- an authorization for the placing on the market of generics, biosimilars, hybrids or biohybrid medicinal products and for subsequent changes;
- health technology assessment within the meaning of Regulation (EU) 2021/2282;
- pricing and costs reimbursement.

In particular, the assessment of health technologies, including pricing and reimbursement of costs, is now explicitly addressed under the wording in Art. 85 with reference to the new Regulation (EU) 2021/2282 on the

<sup>87</sup> *ibid.*

<sup>88</sup> De Coninck and others (n 38) 2.

<sup>89</sup> 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’ COM(2023) 192 final, 2023/0132(COD), 26 April 2023.

<sup>90</sup> *ibid.*

<sup>91</sup> For details on the new draft Directive, see: Marco Stief and Gisela Grabow, ‘Quo vadis Arzneimittelrecht – ein Überblick zur Überarbeitung der EU-Arzneimittelvorschriften’ [2023] PharmR 317.

<sup>92</sup> This article is based on the wording of the EU proposal published on 26 April 2023. The wording and the number of articles could still change in the course of the legislative process.

<sup>83</sup> BT Drucks. 15/5316, p 48; see also Scharen (n 35) s 11 para 10; for Regulation (EC) 726/2004 [2004] OJ L136/1.

<sup>84</sup> Active pharmaceutical ingredients or APIs are chemicals or biologics that have an additional therapeutic benefit in a drug.

<sup>85</sup> cf Medicines for Europe, ‘The Bolar’ (*Medicines for Europe*, April 2021) <<https://www.medicinesforeurope.com/wp-content/uploads/2021/11/Factsheet%20on%20Bolar%20Exemption%20-%20Medicines%20for%20Europe%20-%20Apr%202021.pdf>> accessed 23 May 2024.

<sup>86</sup> *ibid.*



assessment of health technologies, which is due to enter into force in 2025.

The wording of the draft Directive is more precise than the vague wording of the 'practical follow-up requirements' in the current formulation of the Bolar exemption in Art. 10(6) of Directive 2004/27/EC or 2001/83/EC (see II.3.), which requires judicial clarification to make it more precise and hence places the legal risk on generics manufacturers and their contractual partners. The clear wording is intended to provide more legal certainty for developers of generics, biosimilars and APIs. The EU Commission's draft is very similar to the stakeholder recommendations from the generics industry, including those of *Medicines for Europe*.<sup>93</sup>

Article 85 lit. b) of the draft also to a large extent privileges activities that are carried out exclusively for the purposes mentioned under letter a), namely 'the submission of the application for a marketing authorization and the offer, manufacture, sale, supply, storage, import, use and purchase of patented medicinal products or processes, including by third party suppliers and service providers'.

This is a non-exhaustive catalogue of examples. This regulatory technique is reminiscent of the provisions of the SPC manufacturing waiver in Regulation 2019/933, which in addition to the main subject matter of the regulation is also intended to privilege 'any related act strictly necessary for manufacture in the Union [...]'.<sup>94</sup>

It is not clear from the draft Directive whether acts carried out in the context of an application for marketing authorization outside the territory of the EU are also exempt. It can be assumed that the national legislators will therefore have some leeway with regard to the territorial scope, which would actually be contrary to the purpose of harmonization.

In addition, this exemption should also apply to related activities of third parties who have a contractual relationship with the manufacturer.<sup>95</sup> Contractual partners of the applicant who carry out clinical trials or activities within the meaning of Art. 85 lit. b) in the context of the Bolar exemption should therefore also be privileged. In this respect, the new Bolar regulation would open up a wider scope of application than the previous regulations, according to which it was at least arguable whether, for example, mere suppliers of the applicant could also invoke the Bolar regulation.<sup>96</sup> The clarification in the new regulation in the Commission's draft is therefore to be welcomed. However, it remains unclear under which conditions the supply to third parties is exempt.

By clarifying and broadening the scope of the exemption, the EU Commission aims to harmonize the previously fragmented application of Bolar exemptions in the EU and in this way facilitate market access for generics. A more comprehensive Bolar exemption with clearer wording provides more legal certainty for developers of generics, biosimilars and APIs. In this respect, the EU Commission seems to be largely in agreement with the policy recommendations of *Medicines for Europe*.<sup>97</sup>

On 13 February 2024, the Legal Affairs Committee of the European Parliament published its opinion on the European Commission's proposal for a directive, in which the Committee endorses the proposed Bolar exemption in Art. 85 of the draft. The Legal Affairs Committee stated its approval of the Commission's objective of ensuring greater harmonization and legal certainty in the application of the Bolar exemption in order to promote health research and encourage generics without compromising the intellectual property rights of patent and/or supplementary protection right holders.<sup>98</sup>

Furthermore, it discussed whether any kind of measures commonly referred to as patent linkage should be explicitly prohibited under the new Bolar exemption as proposed in the pharma package. In its Report on competition enforcement in the pharmaceutical sector, the Commission wrote:

'Patent linkage refers to the practice of linking the granting of marketing authorization, the pricing and reimbursement status, or any regulatory approval for a generic medicinal product to the status of a patent (application) for the originator reference product. Under EU law, it is not allowed.'<sup>99</sup>

In the Commission's view, patent linkage is unlawful under EU law.<sup>100</sup> Nevertheless, in several EU Member States, both marketing authorization and patent linkage still exist. One consequence of patent linkage is that it undermines the Bolar provision by preventing generics and biosimilars from entering the market from day one.<sup>101</sup> *Medicines for Europe* is therefore demanding that the revised Bolar clause should explicitly state that its scope encompasses all regulatory and administrative procedures (such as marketing authorizations, price and reimbursement listings, tender bids, etc.) necessary to ensure the effective market entry of off-patent products from day one.<sup>102</sup> It remains to be seen how this will develop.

#### IV. Effects of the UPC Agreement (2013/C 175/01)<sup>103</sup> on the research and Bolar privilege

In addition to the EU Commission's proposal for the reform of pharmaceutical legislation, changes will also result – at least with regard to the Bolar exemption – from the regulations on the new European unitary patent that came into force in June 2023.

<sup>98</sup> European Parliament, Committee on Legal Affairs, Opinion on of the Committee on Legal Affairs 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 February 2024) <[https://www.europarl.europa.eu/doceo/document/JURI-AL-758884\\_EN.pdf](https://www.europarl.europa.eu/doceo/document/JURI-AL-758884_EN.pdf)> accessed 15 May 2024.

<sup>99</sup> European Commission, 'Pharmaceutical Sector Inquiry – Final Report' 130 (8 July 2009) <[https://competition-policy.ec.europa.eu/system/files/2022-05/pharmaceutical\\_sector\\_inquiry\\_staff\\_working\\_paper\\_part1.pdf](https://competition-policy.ec.europa.eu/system/files/2022-05/pharmaceutical_sector_inquiry_staff_working_paper_part1.pdf)> accessed 20 June 2024.

<sup>100</sup> *ibid* p 315.

<sup>101</sup> *Medicines for Europe*, 'The Anti-Competitive effects of patent linkage' (*Medicines for Europe*, May 2019) <<https://www.medicinesforeurope.com/wp-content/uploads/2021/03/Medicines%20for%20Europe%20Position%20Paper%20On%20Patent%20Linkage%20-%20May%202019.pdf>> accessed 15 May 2024.

<sup>102</sup> *Medicines for Europe*, 'Revision of the pharmaceutical legislation' (*Medicines for Europe*, July 2023) <<https://www.medicinesforeurope.com/wp-content/uploads/2024/01/Medicines-for-Europe-Position-paper-Pharmaceutical-Legislation-FINAL-1.pdf>> accessed 15 May 2024.

<sup>103</sup> Agreement on a Unified Patent Court [2013] OJ C175/01.

<sup>93</sup> cf *Medicines for Europe*, 'The Bolar' (n 85).

<sup>94</sup> Regulation (EU) 2019/933 of the European Parliament and of the Council of 20 May 2019 amending Regulation (EC) No 469/2009 concerning the supplementary protection certificate for medicinal products.

<sup>95</sup> *ibid* Recital 9.

<sup>96</sup> See II.5.d) above.

<sup>97</sup> cf *Medicines for Europe*, 'The Bolar' (n 85).

A unitary patent, or a 'European patent with unitary effect' (to give its full title), is a property right that offers uniform patent protection in all EU Member States that have ratified the UPCA. In this way, the entire territory of these states is covered by just one patent, renewal fees must only be paid for this one patent, and both invalidity and infringement proceedings are decided with unitary effect by the Unified Patent Court (UPC), which has exclusive jurisdiction. At the time of writing, 17 EU countries are participating in the agreement.<sup>104</sup> The 'classic' European patent, on the other hand, once granted, can be considered a 'bundle' of patents in the member states of the European Patent Convention (EPC), which include the 17 EU countries that have ratified the UPCA. Said bundle of patents is broken down into individual national patents after validation in the corresponding EPC member states.

The UPC, which was introduced parallel to the unitary patent, is a new multinational court that deals centrally with both infringement and invalidity of a 'classic' European patent (bundle patent)<sup>105</sup> and infringement and invalidity of a unitary patent. The UPC has exclusive jurisdiction for unitary patents, but it will replace the national courts for 'classic' European patents altogether after a transitional period. This means that the UPC will take its place alongside the existing national courts, which will only deal with infringement and invalidity of corresponding national patents in the individual country.

With the introduction and implementation of a centralized patent system in the form of the Agreement on a Unified Patent Court (UPCA), Art. 27 of the Agreement regulates the experimental and Bolar privilege under the heading 'Limitations of the effects of a patent'. Under this provision, the rights conferred by a unitary patent do not extend, *inter alia*, to

b) 'acts done for experimental purposes relating to the subject-matter of the patented invention' (experimental privilege)

nor to

d) 'the acts allowed pursuant to Article 13(6) of Directive 2001/82/EC<sup>106</sup> or Article 10(6) of Directive 2001/83/EC,<sup>107</sup> in respect of any patent covering the product within the meaning of one of these Directives' (Bolar privilege).

Accordingly, with regard to Art. 27 lit. b) UPCA, the scope of application of the research exemption will depend on how the courts interpret the word 'relating'.<sup>108</sup>

Accordingly, persons seeking generic medicinal product authorization can carry out the studies and tests required for the authorization without the consent of the patent proprietor, also where the regulations on the unitary patent apply. However, Art. 27 lit. d) UPCA represents a

restriction of the scope of application of the Bolar exemption to generics and biosimilars. This is clear at least from the wording of the provision, which refers to Art. 13(6) of Directive 2001/82/EC and Art. 10(6) of Directive 2001/83/EC, which contain such a restriction (see II.3.). According to Art. 217(3) of the EU Draft, 'references to the repealed Directives 2001/83/EC [...] shall be construed as references to this Directive'. Therefore, Art. 27(d) of the UPCA might refer to the new Art. 85 of the EU Draft once it enters into force. Accordingly, unlike in Germany, Spain, France, the UK and Switzerland, the UPC-Bolar exemption no longer applies to innovative medicinal products or new indications, as is already the case in Belgium and the Netherlands (see II.5. a)). Furthermore, it is also geographically restricted to marketing authorizations in the EU. Unlike in the past, at least in Germany, Spain, France, the UK and Switzerland, but already in Belgium and the Netherlands (see II.5.b)), studies may therefore no longer be conducted that relate to marketing authorization procedures outside Europe (e.g. marketing authorization procedures in the USA).<sup>109</sup>

It is clear from the wording of Art. 27 UPCA that national law which has implemented the Bolar exemption with a wider scope of application than that described in Art. 10(6) of Directive 2004/27/EC or 2001/83/EC is currently not compatible with Art. 27 UPCA.<sup>110</sup> Although the UPC will have to take national law into account when interpreting the UPCA (Art. 24 lit. e) UPCA), it remains to be seen which interpretation the UPC will tend towards in general (narrow or broad).

Moreover, according to its wording, the Bolar exemption provided for in Art. 27 UPCA only permits the use of patents that specifically protect the product ('patent covering the product'). Therefore, according to the wording, the use of patented so-called research tools already appears to be excluded. It seems as if Art. 27 UPCA does not allow the use of patented diagnostic or toxicological tests that are required for receiving marketing approval.

It is not uncommon for specific tests to be required for pre- and clinical trials in order to determine the suitability of the active substance and generate the data required for approval. At least in some cases, the use of these tests is mandatory or prescribed, either from a technical or a regulatory perspective, to generate the data required for approval. It is needless to say that patent applications are regularly filed to protect such tests. However, if tests ultimately required for gaining approval may not be used due to existing patent protection, it may no longer be possible to carry out the approval procedure.

Considering that the research exemption privileges the use of patented inventions for research purposes only, this exemption would not apply in cases wherein a patented assay needs to be used in order to get approval, since such use would not serve to further develop the patented invention but would be aimed solely at complying with the prescribed approval procedure. Accordingly, if at all, such use could be privileged under the Bolar exemption.

<sup>104</sup> Austria, Belgium, Bulgaria, Denmark, Estonia, Finland, France, Germany, Italy, Latvia, Lithuania, Luxembourg, Netherlands, Malta, Portugal, Slovenia, Sweden.

<sup>105</sup> Unless the bundle patent has been withdrawn from the jurisdiction of the UPC by declaration (so-called 'opt-out').

<sup>106</sup> Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products [2001] OJ L311/1 with all subsequent amendments.

<sup>107</sup> *ibid* 67.

<sup>108</sup> cf Lavoix, 'UPC and the Bolar exemption – Unitary Patent and Unified Patent Court' (Lavoix, 28 September 2022) <<http://blog.lavoix.eu/2022/09/28/upc-and-the-bolar-exemption-2/>> accessed 27 May 2024.

<sup>109</sup> cf Anthony Tridico, Jeffrey Jacobstein and Leythem Wall, 'Facilitating generic drug manufacturing: Bolar exemptions worldwide' (WIPO Magazine, 2014) <[https://www.wipo.int/wipo\\_magazine/en/2014/03/article\\_0004.html](https://www.wipo.int/wipo_magazine/en/2014/03/article_0004.html)> accessed 27 May 2024.

<sup>110</sup> Mignolet and others in Desautettes-Barbero and others (n 57) 496.

However, similar to the discussion regarding research tool patents, the question arises whether this would undermine the patent protection granted for such patents, since it would exempt the only or (at least most important) scope of application of the patented technology. On the other hand, it must be asked whether such patents should be allowed to effectively block the use of the Bolar exemption by in effect forcing the generics company to hold back its application for a regulatory approval until after the patents required for testing have expired. It appears contradictory that the Bolar exemption permits use of the patented product, e.g. the active pharmaceutical ingredient, while not allowing one to also use patents granted for particular testing procedures or assays, in particular if such testing is mandatory or prescribed either from a technical or a regulatory perspective in order to generate the data required for approval. This would in effect thwart the purpose and intention of the Bolar exemption, which is to allow for and to ensure a day-one entry. A solution to the apparent dilemma of ensuring the effectiveness of the Bolar exemption while at the same time not disregarding the value of such patents could also be found by requiring the respective patent owner to grant a compulsory license. A possible parallel to the principles of standard essential patents (SEPs) could be drawn for the licensing of generics. Similar to SEPs, generics manufacturers should have the opportunity to obtain approval for their generic product and not be blocked by patents merely protecting specific testing procedures required for the approval of a generic product. From an economic point of view, a compulsory license may possibly be the best way of catering to the legitimate interest of the owner of such patents in capitalizing on its patented technology. The questions are, of course, how to calculate the correct reference and the amount of the (appropriate) license fee to be paid and whether a compulsory license procedure can be implemented quickly enough in order not to endanger a day-one market entry.

Until the first binding decisions have been rendered by the UPC in this regard, several uncertainties will remain regarding the exact scope of exemption offered by Art. 27. It appears rather likely that more than one referral to the CJEU will be necessary to clarify the exact scope of application.

## V. Outlook/legal assessment

There are currently three (potential) regulations under discussion in the EU: the national regulations (see II.4.), the UPC regulation in Art. 27 lit. d) UPCA (see IV.) and the prospective new regulation in the draft Directive (see III.). The application of the correct Bolar exemption depends on the type of patent. While for national patents only the national Bolar rule in the respective country is applicable, Art. 27 lit. d) UPCA is applicable to unitary patents. In the case of ‘classic’ European patents, on the other hand, it depends on whether the legal dispute is brought before the UPC. In such a case, Art. 27 lit. d) UPCA also applies; otherwise, the national Bolar provisions apply. Consequently, in the event of an ‘opt-out’ (excluding the competence of the UPC for infringement and invalidity of a ‘classic’ European patent), the national Bolar provisions also apply.

Moreover, it appears that the scope of application of the Bolar exemption in the UPCA is no longer keeping pace with national developments.<sup>111</sup> This impression is reinforced by the EU Commission’s new proposal of 26 April 2023. While the EU Commission is in favor of facilitating the earlier market entry of generics and biosimilars in order to stimulate competition and thereby achieve price reductions, it does not appear to make sense that the UPCA – which was enacted far earlier – restricts the scope of the Bolar exemption by limiting it to generics and biosimilars and limiting it to situations where European approval is sought.

Another interesting question is how the fate of the Bolar exemption will be affected by the implementation of the pharmaceutical reform proposed by the EU Commission. The draft proposes a significant expansion of the scope of the exemption with regard to the group of persons benefiting from the exempted activities. As the Commission’s proposal is essentially limited to generics and biosimilars (Art. 85 lit. a) of the draft Directive), friction between the Member States regarding the exemption of new medicines cannot be ruled out. Furthermore, questions regarding the application of the Bolar exemption to studies intended for marketing authorizations outside Europe remain unresolved.

Since Art. 27 lit. d) UPCA also refers to the Human Medicinal Products Directive, an additional provision in the proposed reform could automatically result in an extended UPC-Bolar exemption.<sup>112</sup> However, it is not inconceivable that the UPC will interpret this provision broadly in order to incentivize the carrying out of clinical trials in Europe, particularly at a time of strong competition with Asia.<sup>113</sup> Until the first binding decisions are handed down by the UPC in this regard, some uncertainties regarding the scope of application will therefore remain.

Finally, it remains to be seen when the Bolar exemption will be uniformly implemented in all EU countries, particularly with regard to the challenges that the UPCA poses. In any event, the Bolar exemption will remain an important topic for the pharmaceutical and health care sector in Europe.

<sup>111</sup> See England, ‘Upgrading the single market: updating the Bolar exemption’ (n 47).

<sup>112</sup> cf András Kupecz, Ann Henry and Sarah Tylor, ‘Unified Patent Court: strategic considerations for life sciences companies’ (*IAM*, 18 August 2022) <[www.iam-media.com/guide/global-life-sciences/2022/article/unified-patent-court-strategic-considerations-life-sciences-companies](https://www.iam-media.com/guide/global-life-sciences/2022/article/unified-patent-court-strategic-considerations-life-sciences-companies)> accessed 27 May 2024.

<sup>113</sup> Mignolet and others in Desautettes-Barbero and others (n 57) 512.