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# European Exemptions from Patent Protection: An Overview of the Research Exemption, the Bolar Exemption, and the Supplementary Protection Certificate (“SPC”) Waiver in Europe

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## Abstract

Patent law protects innovation by granting inventors exclusive rights, but strict enforcement can sometimes hinder technological progress. To balance innovative incentives with public interests, exceptions like the research exemption and the *Bolar* exemption have been established in the European Union (“EU”). More recently, the SPC waiver was introduced to ease market entry for generics and biosimilars in the EU. This article explores how these European mechanisms adjust the reach of patent protection to promote both innovation and access to affordable medicines.

## Introduction

The European patent system is based on the principle that the patent holder is granted an exclusive right to use their invention for a limited period of time. This exclusive right is intended to create incentives for innovation by enabling the patent holder to recoup their investments in research and development (“R&D”) by granting them a temporary monopoly over their invention. At the same time, it generally prohibits third parties from using the protected invention without consent. However, this protection is not without limits: in order to strike a balance between the need to protect innovation, freedom of research and the public interest, European patent law and national legal systems provide exceptions to patent protection.

Particularly important in this context are the so-called research exemption, which allows scientific studies on the patented invention, and the so-called *Bolar* exemption, which allows studies for the approval of generics and biosimilars to be carried out even before a patent expires. Since 2019, these exemptions have been supplemented by the SPC waiver, which, provided certain conditions are met, allows the manufacture and storage of such products during the term of a supplementary protection certificate. These restrictions raise a number of legal, methodological and practical questions, which are explored in this article.

Although these exemptions are rooted in the European legal framework,

they are also of considerable practical relevance to non-European research and development (“R&D”) companies. In practice, research in at least most industry sectors no longer takes place in national silos. A particularly illustrative example is the pharmaceutical and life sciences sector, where cross-border cooperation is typically – though not always – essential due to the high levels of investment required for development, research, and clinical testing of new drugs. Because of this transborder character of modern R&D work, it is important for all parties involved to familiarise themselves with the respective foreign patent protection exemptions, in order to verify whether and to what extent certain research and clinical testing may be performed without the risk of infringing third parties’ patents or without the need to acquire special licenses or to conduct costly and elaborate freedom-to-operate analysis.

This article also provides an overview of a comparatively new European patent exemption, that applies to so-called SPCs, namely patent term extensions granted in Europe for pharmaceutical patents. This introduction of the SPC Waiver in Europe represents a novel legal mechanism to address concerns about the overreach of extended patent exclusivity for pharmaceutical patents. In light of discussions about pharmaceutical patent reform in Australia, the European experience may offer useful insights into how

innovation incentives may be balanced with timely market entry for generics and biosimilars.

## The Research Exemption

To enable scientifically motivated research on patented inventions, many legal systems provide for exceptions to patent exclusivity for experimental activities, subject to certain conditions being met: The research exemption allows third parties to use a patented invention for research purposes under certain conditions, in particular when the purpose is to acquire new knowledge.

### *History of the Research Exemption*

The concept of the research exemption has its roots in United States case law. Unlike in European legal systems, where such exemptions are codified in statute, the US research exemption developed through judicial decisions. As early as 1813, Justice Joseph Story stated in *Whittemore v Cutter*<sup>1</sup> that purely scientific research does not constitute an infringement of patent rights. In subsequent case law, the courts consistently emphasised that non-commercial research activities and experimental activities that are not aimed at making a profit or at manufacturing or selling products do not, in principle, constitute an infringement of exclusive patent rights.<sup>2</sup> This line of reasoning was continued in subsequent case law for decades before the US Court of Appeals made a significant restriction in 2002 with its *Madey v Duke University* decision.<sup>3</sup> It ruled that the

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research exemption does not apply if the research act in question serves a recognizable economic interest.

With the continuing harmonisation of European patent law, the need for a statutory experimental exception also became increasingly important in Europe. The *Preliminary Draft Convention on a European Patent Law* of 1962<sup>4</sup> contained a provision in art 20(3) according to which acts for experimental purposes were to be excluded from patent protection. This provision was incorporated in revised form in art 31 of the *Community Patent Convention* (“CPC”) of 1975 and adopted in art 27 CPC in 1989 without any changes being made to its substance. Although the Convention never entered into force, it served as a reference model for many national implementation measures.<sup>5</sup> All EU Member States have meanwhile incorporated corresponding exemptions into their national legal systems, albeit with varying regulatory content and scope.<sup>6</sup>

At the level of international law, art 30 of the *TRIPS Agreement*<sup>7</sup> forms the central basis for the permissibility of such exceptions. The provision permits exceptions to the exclusive right under patent law, provided that they (1) are confined to specific, limited situations, (2) do not unreasonably conflict with the normal exploitation of the patent (3) safeguard the legitimate interests of the patent proprietor and third parties (three-step test).<sup>8</sup>

## **The German Research Exemption**

In Germany, key structural elements of the CPC<sup>9</sup> were adopted in the German *Community Patent Act* in 1981, including the provisions relating to research exemptions.<sup>10</sup> Section 11 of the German *Patent Act* 1975 (“Patent Act”) contains a number of restrictions on exclusive rights under patent law. The research exemption under section 11(2) concerns acts which “relate to the subject matter of the patented invention” and serve an

experimental purpose. The decisive factor here is that the research is carried out *on* the invention, not *using* it. To be more precise: all experiments that serve to research the invention are permitted, although the invention itself may not be used to obtain knowledge in another area. This distinction is particularly relevant in clinical studies.

The reach of this provision was delineated by the German Federal Court of Justice (“BGH”) in two fundamental decisions from 1995 and 1997. In *Clinical Trials I*<sup>11</sup> (1995), the BGH clarified that the primary criterion for the applicability of Section 11(2) German Patent Act is the gaining of knowledge – not the intended use of the data obtained. An experimental act does not fall outside the scope of application just because it (also) facilitates a later approval process. Even a commercial background does not preclude the experimental exception as long as the focus is on research.<sup>12</sup>

This line of reasoning was pursued in *Clinical Trials II*<sup>13</sup> (1997). In that case, a company had conducted clinical trials for the purpose of obtaining regulatory approval data for a drug. Here, too, the court recognised the experimental use exception, so long as the studies delivered insights into the patented invention. However, bioequivalence studies were excluded, as their aim was not to obtain new insights, but to establish interchangeability with a reference product.<sup>14</sup> The decision continues to have a significant impact on the line of demarcation vis-à-vis the *Bolar* exception introduced seven years later at European level.

## **The Bolar Exemption**

In the field of pharmaceutical research, the general research exemption is supplemented by the *Bolar* exemption. This exemption under patent law allows generics and biosimilar manufacturers to carry out clinical

studies and other preparatory activities required for marketing authorisation while a patent is still in force. The aim is to enable immediate market access after the expiry of the property right (“Day-1-Entry”). Without such an exemption, the necessary studies could only begin after the expiry of the protection, which would effectively prolong the monopoly position of the patent holders and delay the availability of affordable successor products.<sup>15</sup>

## **The US Bolar Exemption**

The *Bolar* exemption has its origins in US law and arose as a legislative reaction to a fundamental decision of the United States Court of Appeals for the Federal Circuit in 1984 in *Roche v Bolar*,<sup>16</sup> to which it also owes its name. *Bolar* had used a substance patented by *Roche* to conduct clinical trials in advance of the expiry of the patent preparatory to obtaining marketing approval for a generic drug. The court held that such actions constituted unauthorised use of the patented invention. Consequently, the use of the protected substance in the context of clinical trials was deemed to constitute patent infringement.

This ruling led to considerable legal uncertainty for manufacturers of generic drugs and jeopardized their ability to prepare for market entry in a timely manner after patent expiry. The US Congress responded in the same year with new legislation enacting the *Drug Price Competition and Patent Term Restoration Act* of 1984, better known as the *Hatch-Waxman Act*. It introduced 35 USC § 271(e)(1) to facilitate access to clinical research ahead of marketing approval. The provision stipulates that the making, using, selling or importation of a patented invention does not constitute patent infringement if the act is reasonably related to obtaining regulatory approval.

United States case law has clarified the scope and limits of this exception

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in several landmark decisions. In *Eli Lilly v Medtronic*<sup>17</sup> (1990), the Supreme Court clarified that the term “patented invention” in s.271(e)(1) also extends to medical devices. In subsequent decisions, the US Supreme Court confirmed that the provision allows for a broad interpretation.<sup>18</sup> All activities that are reasonably related to preparations for regulatory approval are covered – including preclinical research, provided they are geared towards a later FDA<sup>19</sup> application.<sup>20</sup> However, basic research without any product relevance is excluded.<sup>21</sup>

The broad US *Bolar* exemption has thus served as a model for comparable regulations in other legal systems, particularly in the EU.

## ***The European Bolar Exemption*** *Origin and legislative background at European level*

Originally developed in the US, the *Bolar* exemption was initially met with considerable skepticism in Europe.<sup>22</sup> In particular, it was criticised for being an unreasonable restriction of the exclusive rights to which the patent holder was entitled. Nevertheless, a growing awareness of the competition-enhancing effects of this regulation eventually led to a turnaround in European legal policy. In 2004, European Directive 2004/27/EC included a separate *Bolar* exception in art 10(6) of Directive 2001/83/EC:

Conducting the necessary studies and trials with a view to the application of paragraphs 1, 2, 3 and 4 and the consequential practical requirements shall not be regarded as contrary to patent rights or to supplementary protection certificates for medicinal products.

This was intended to ensure timely market entry after patent expiry and at the same time strengthen the competitiveness of the European pharmaceutical industry, particularly in a global context.<sup>23</sup>

## *Implementation in EU Member States*

The EU Directive was subsequently implemented by all Member States within a few years. However, as it is a Directive, the national legislators were given leeway in the specific details of implementation. This has led to considerable divergence within the EU, both in terms of the content of the regulations and the interpretation of the respective national *Bolar* provisions.

### *The German Bolar Exemption under s.11(2)(b) German Patent Act*

In Germany, art 10(6) of the Directive was implemented by the introduction of Section 11(2)(b) German Patent Act, which has been in force since September 2005.<sup>24</sup> In terms of content, the German provision goes beyond the requirements of the Directive.<sup>25</sup> It not only privileges actions related to the authorisation of generics and biosimilars but also extends to innovative medicinal products. According to s.11(2)(b) of the German Patent Act, all studies and trials that are objectively necessary to obtain a marketing authorisation under pharmaceutical law or a comparable official approval are permitted. Of particular practical importance in this context is the conduct of clinical trials within the meaning of s.24b of the German *Medicinal Products Act*, which are considered a mandatory part of the approval procedure.<sup>26</sup>

Compared to the general research exemption under s.11 No 2 of the German Patent Act, which only privileges acts relating to the patented invention, the *Bolar* exemption covers a broader area. It encompasses not only the examination of the invention itself, but also its use in the practical implementation of marketing authorisation studies. This means that all preparatory measures that are objectively necessary to obtain marketing authorisation for a medicinal product are privileged.

Furthermore, the scope of application of the German regulation is not limited to marketing authorisation procedures within the EU. Authorisation procedures in third countries are also covered by the exception, provided that the relevant studies are carried out in the EU. The decisive factor is always whether the action in question is objectively necessary for the preparation of a specific approval procedure.<sup>27</sup>

### *Bolar Regulations in other EU Member States*

While countries such as Germany, France, Spain, and, incidentally, the United Kingdom and Switzerland, interpret the *Bolar* exemption broadly and extend it not only to generic manufacturers but also to originator products and also include authorisation procedures outside the EU, other countries take a more restrictive approach. In the Netherlands and Belgium<sup>28</sup> in particular, the exception is defined much more narrowly: there, it is limited to activities in connection with the approval of generics and biosimilars and applies exclusively to approval procedures within the EU.<sup>29</sup>

## ***Legal Uncertainties Regarding Bolar***

As already mentioned, there are major differences in the interpretation and scope of the *Bolar* exception within the Member States. The resulting differences in national law lead to considerable legal uncertainty in cross-border situations. For example, in many cases it is unclear which specific activities fall under the respective national *Bolar* exemption and which companies are entitled to invoke the privilege. The lack of uniformity raises questions that have not yet been conclusively clarified either under EU law or by national supreme courts.

### *Third Party Suppliers under Bolar*

In European practice, it has not yet been conclusively clarified whether suppliers of active pharmaceutical

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ingredients or excipients who are not themselves involved in the marketing authorisation procedure under pharmaceutical law can also invoke the *Bolar* exemption. This question was already the subject of court proceedings in Germany and Poland in 2012 and 2013, namely in *Polpharma v Astellas Pharma*. While the Düsseldorf Regional Court denied the applicability of *Bolar* to mere suppliers of active pharmaceutical ingredients in 2012,<sup>30</sup> the Court of Appeal took a more differentiated view in 2013<sup>31</sup>: under certain conditions – such as exclusive supply for marketing authorisation purposes and effective organisational safeguards – a supplier may also be privileged. A referral by the Court of Appeal to the European Court of Justice (“ECJ”) came to nothing, as the proceedings ended in a settlement. In the same year, the Polish Supreme Court<sup>32</sup> denied the applicability of *Bolar* to third party suppliers, even in the case of contract manufacturing.

The issue was also recently brought before the highest court level in Italy. In July 2024, the Italian Supreme Court<sup>33</sup> had to rule on the scope of the Italian Bolar regulation<sup>34</sup> in *Boehringer Ingelheim v Sicor and Teva*. Specifically, the question was whether a contract manufacturer commissioned by a generics manufacturer that is not itself involved in the marketing authorisation process can benefit from the protection afforded by the Italian exemption provision. The Court affirmed this in principle but imposed clear conditions. Production must be carried out on the specific and verifiable instructions of a company that is itself involved in the marketing authorisation process. A mere intent or formal declaration that production is related to authorisation is not sufficient. The contract manufacturer’s own commercial exploitation – such as advertising or distribution – is not permitted. In the case in question, *Sicor and Teva* had already started production and advertising the active

ingredient without a specific order from a generics manufacturer.<sup>35</sup>

## Research Tools under Bolar

Particularly controversial and yet unresolved is the question of whether the research exemption and the Bolar exemption can also be applied to the use of patented research tools. The issue becomes particularly relevant when such tools are used in experimental studies, for example to gain new scientific insights or in the context of bioequivalence studies. As far as can be seen, this issue has not yet been addressed by European courts nor ruled on by the highest courts.

Research tools, e.g. devices, substances or methods that are primarily used to conduct scientific or medical research, are by definition intended for experimental use.<sup>36</sup> If their use in the context of scientific or marketing authorisation-related studies were generally covered by the research exception or the *Bolar* exemption, this could in effect lead to a significant restriction of their protection under patent law. Since the main field of application of such inventions lies precisely in research, a far-reaching exemption would considerably reduce their commercial exploitability, with the result that patent applications for research tools might no longer become worthwhile.<sup>37</sup>

In US law, too, the applicability of the *Bolar* exemption under s.271(e)(1) 35 USC to research tools is assessed differently. The case law is not uniform in this respect. Some courts reject a corresponding application of the privilege to research tools.<sup>38</sup>

## The Bolar Exemption in the EU Pharma Package

To remedy inconsistent and fragmented application in the Member States and to facilitate market access for generics and biosimilars, the European Commission presented a draft Directive as part of the planned EU Pharmaceutical Reform on 26 April 2023,<sup>39</sup> which also includes a

revision of the *Bolar* exemption in art 85.<sup>40</sup> Article 85 of the draft Directive envisages a significant expansion of the scope of the current art 10(6) of Directive 2001/83/EC.

## Original Proposal of the EU Commission

The wording of art 85 of the Proposal originally submitted by the Commission reads:

*Patent rights, or SPCs [...] shall not be regarded as infringed when a reference medicinal product is used for the purposes of:*

- (a) *studies, trials and other activities conducted to generate data for an application, for:*
  - (i) *a marketing authorization of generic, biosimilar, hybrid or bio-hybrid medicinal products and for subsequent variations;*
  - (ii) *health technology assessment as defined in Regulation (EU) 2021/2282;*
  - (iii) *pricing and reimbursement*
- (b) *the activities conducted exclusively for the purposes set out in point (a), may cover 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 exception shall not cover the placing on the market of the medicinal products resulting from such activities.*

Article 85(a) of the draft Directive therefore proposes to significantly extend the scope of the *Bolar* exemption. In future, not only activities in connection with the authorisation of generics and biosimilars are to be privileged, but also those relating to hybrid and biohybrid medicinal products. In addition, activities relating to health

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technology assessment in accordance with Regulation (EU) 2021/2282, pricing and the clarification of reimbursement issues are also to be included.

Article 85(b) also extends the privileged scope of action to a wide range of specific preparatory acts prior to marketing authorisation. Not only are the application and official communications expressly covered, but also the offering, manufacturing, selling, supplying, importing, storing, using and acquiring of the relevant patent-protected medicinal products or manufacturing processes – expressly now also by contractual third parties and external service providers. However, it remains unclear whether and to what extent supplies to third parties are also covered by the exemption and whether the exemption also extends to marketing authorisation procedures outside the European Union.

## *Amendments by the EU Parliament*

In the course of its deliberations, the European Parliament made several amendments to the Commission’s draft, some of which are editorial in nature and some of which are substantive changes. The wording of art 85<sup>41</sup> as amended by the EU Parliament now reads as follows:

*Patent rights, or SPC [...] shall not be regarded as infringed when necessary studies, trials and other activities are conducted for the purpose of:*

- (i) *obtaining a marketing authorization and subsequent variations;*
- (ii) *conducting a health technology assessment as defined in Regulation (EU) 2021/2282;*
- (iii) *obtaining pricing and reimbursement approval; and*

*(iiia) the subsequent practical requirements associated with such activities.*

*The activities conducted exclusively for the purposes set out in the first paragraph, shall cover as relevant the submission of the application for a MA 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 exception shall not cover the placing on the market of the medicinal products resulting from such activities.*

The reintroduced, vague wording “practical requirements” had already been criticised in terms of legal clarity, as it is unclear which specific actions are covered.

In addition, the reference to “reference medicinal products” was removed from the text of the Directive. The explicit mention of “generic, biosimilar, hybrid or bio-hybrid medicinal products” in art 85(1)(a) (i) was also deleted. What remained was product-neutral wording. This adjustment suggests that original medicinal products, i.e. innovative products, could also come within the scope of the exception.

Another relevant aspect concerns the replacing of the phrase “activities conducted to generate data” with the more general term “other activities”. This change is justified, given that price negotiations or applications for reimbursement eligibility, for example, do not necessarily serve the purpose of generating data. The new version thus broadens the understanding of the term but does not eliminate all demarcation difficulties.<sup>42</sup>

If the Commission’s proposal on art 85(1)(b) is accepted, this would be an important step towards greater legal certainty for generics manufacturers and their suppliers. At the same

time, the circle of privileged market participants would be expanded, which is likely to be perceived as disadvantageous from the perspective of originator companies.

Despite the proposed simplification for generics and biosimilar manufacturers, the proposed extension – for example to price and reimbursement procedures – has also met with criticism on the grounds that the proposed changes are too far-reaching and could unduly restrict the rights of patent holders. Among other things, such extension could restrict the ability of patent holders to obtain preliminary injunctions before generics enter the market. As such proceedings could in future be privileged, ‘imminent’ patent infringement would no longer apply in many cases.<sup>43</sup>

Also new is the European Parliament’s proposal to introduce art 85a, which specifies that procedures and decisions in connection with the *Bolar* exception are to be treated independently of patent law issues. This could mean that patent claims may not be invoked to refuse or delay approval procedures.

The European Council is currently examining these proposals. Trilogue negotiations between the Commission, Parliament and Council will then take place. The new Directive is expected to be adopted in 2026, followed by an implementation period of 18 months.<sup>44</sup>

## ***The UPCA Bolar Exemption***

With the launch of the Unified Patent Court (“UPC”)<sup>45</sup> on 1 June 2023, a harmonised EU-wide *Bolar* exemption under art 27(d) of the Agreement on a Unified Patent Court (“UPCA”)<sup>46</sup> also applies. The applicable *Bolar* exemption is determined by the type of patent: national rules apply to national patents, while unitary patents are governed by art 27(d) UPCA. This exemption refers to art 10(6) of Directive 2001/83/EC and

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privileges studies for the marketing authorisation of generics and biosimilars within the EU. It does not cover studies on innovative medicinal products, marketing authorisations outside the EU or activities of third party providers. Article 26(3) UPCA also excludes indirect infringers from the exception. Compared with the national regulations and the proposed art 85 of the EU pharmaceutical package, the UPCA *Bolar* regulation is significantly more restrictive. It remains to be seen whether the UPC will interpret this in a strict or practice-oriented manner.

## The SPC Waiver

The EU adopted Regulation (EC) No 469/2009<sup>47</sup> which introduced SPCs in 2009. These can extend patent protection by up to five or five and a half years.<sup>48</sup> This was in response the impact of the marketing authorisation procedure which can reduce the economic life of pharmaceutical patents.

However, the resulting extension of protection led to structural disadvantages for generics and biosimilar manufacturers based in the EU, as they – unlike manufacturers outside the EU – were prohibited from production during the term of the SPC. Third party manufacturers, on the other hand, were able to manufacture their products during the protection period and launch them on the EU market immediately after the certificate expired. To remedy this, Regulation (EU) 2019/933,<sup>49</sup> introduced the “SPC Manufacturing Waiver”.<sup>50</sup> Under certain conditions (art 5(2) of the SPC Regulation), this allows making for the purpose of export to third countries and storage for market entry in the EU in the last six months before the SPC expires. Unlike EU Directives, Regulation 2019/933 is directly applicable in the EU in accordance with art 288 of the Treaty on the Functioning of the European Union (“TFEU”).

Even before the introduction of the manufacturing waiver, generics and biosimilar manufacturers were able to invoke the research exemption and *Bolar* exemption. Although the *Bolar* exemption clearly goes beyond the research exemption, it does not permit commercial sales either, but ultimately only the use of the manufactured pharmaceutical products in the context of clinical trials and, of course, only making in the quantity necessary to carry out the required clinical trials. The provisions of the SPC waiver now go one step further and, as stated in the recitals to the regulations,<sup>51</sup> also allow commercial activities in order to create a level playing field for the biosimilar and generics industry in the EU.

## Content and Scope of art 5(2) SPC Regulation

Article 5(2)(a) Regulation (EU) 2019/933 differentiates between two privileged situations: the “manufacturing waiver” (art 5(2)(a) (i)) permits the making of a product or a medicinal product containing that product during the entire term of the SPC for the sole purpose of export to countries where there is no corresponding protection. The “Stockpiling Waiver” (art 5(2)(a) (iii)) allows the making and storage of a corresponding medicinal product in the Member State of making within the last six months prior to the expiry of the certificate in order to enable immediate market entry in the EU.

In addition, art 5(2)(a)(ii) and (iv) also give preferential treatment to “related acts”, i.e. acts other than the making itself, but which are necessary for the making. These include, the possession, import, use and chemical manufacture of the active substance.<sup>52</sup> This also applies to the activities of third parties who have a contractual relationship with the manufacturer.<sup>53</sup> The related acts must meet the same requirements as the relevant exemption.

The regulation applies directly in the EU Member States and – taking

into account national implementing Acts – also in the European Economic Area (“EEA”) and the European Free Trade Association (“EFTA”) states of Iceland and Norway. Liechtenstein is excluded due to the lack of an SPC regime.<sup>54</sup> Extraterritorial effect in third countries – in particular with regard to foreign intellectual property rights – is expressly not envisaged by the Regulation and would be incompatible with the territoriality principle of industrial property protection.<sup>55</sup> The regulatory content is therefore limited to acts within the EU or EEA.

In terms of timing, the waiver only applies to protection certificates that were applied for from July 1, 2019. For certificates already applied for but not yet effective, the regulation also applies, but only from July 2, 2022.<sup>56</sup>

## Obligations of the Manufacturer

In contrast to the *Bolar* privilege, the use of the SPC manufacturing and stockpiling waiver is contingent on specific notification, labelling and due diligence obligations. Any breach of these obligations leads to the loss of the privilege and may constitute an SPC violation.<sup>57</sup>

## Notification Obligations

According to art 5(2)(b) of the SPC Regulation, the manufacturer is obliged to notify the competent authority of the Member State of manufacture and the holder of the certificate at least three months before the start date of the privileged action. The notification must be documented and contain all information listed in art 5(5). In Germany, the German Patent and Trademark Office (“DPMA”) is the competent authority within the meaning of art 9(1) SPC Regulation.<sup>58</sup>

## Duties of care

According to art 5(2)(e) SPC Regulation, the manufacturer must take appropriate steps to ensure that all contractually involved third parties are adequately informed



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about the scope of the waiver and the limits of the placing on the market. The inclusion of corresponding information in the contract – e.g. vis-à-vis exporters or warehouse keepers – extended to third parties in contractual relationship with the manufacturer.

## Labelling Requirements

According to art 5(2)(d) of the SPC Regulation, products manufactured for export to third countries must be labelled with a standardised logo in accordance with Annex I on the outer packaging and, where possible, on the primary packaging. For EEA exports, the label must be adapted accordingly.<sup>59</sup> In addition, art 5(8) stipulates that exported medicinal products may not bear unique identifiers within the meaning of Delegated Regulation (EU) 2016/161. According to recital 21, compliance with all labelling requirements is a prerequisite for the exemption to be effective. It is unclear whether the requirement of “affixing” requires permanent labelling or whether, for example, removable labels are sufficient.

## Conclusion

The various exceptions to patent protection, such as the research privilege, the *Bolar* exemption and the SPC waiver, serve as regulatory instruments for fine-tuning the balance between the interests of patent holders and the needs of the general public. In the pharmaceutical sector in particular, these regulatory mechanisms must be regularly reviewed to determine whether they still adequately reflect changing economic and social realities. Neither excessive protection that delays market access nor overly broad exceptions that undermine investment incentives for research and development are compatible with a functioning healthcare system. These exceptions are an expression of a fundamental legal principle: patent protection is

not an end in itself but serves as a means of promoting innovation and must be restricted where it runs the risk of defeating its very purpose.

The tension between patent protection and its exceptions has tangible consequences, especially in the cross-border context of pharmaceutical research and development, where differing legal frameworks can create significant operational challenges for companies from Australia and New Zealand that engage with the European market. They must carefully adapt their R&D operations to avoid conflicts between differing national interpretations of what is legally permissible. Even minor inconsistencies in the scope of research or regulatory use exemptions can lead to costly disputes – particularly where conduct deemed lawful in one jurisdiction triggers liability in another. In the worst-case scenario, such inconsistencies may even vitiate the results of research or clinical trials to the extent that they become impermissible for regulatory purposes, rendering the underlying investments futile.

In light of these challenges, a comparative look at the European approach to patent exceptions may offer valuable insights for jurisdictions such as Australia and New Zealand when it comes to regulating patent exceptions. Similar to the European SPC system, Australian regulations provide patent term extensions of up to five years for certain pharmaceutical patents under section 70 of the *Patents Act* 1990 (Cth) (“*Patents Act*”), aiming to offset delays in the launch for a medicinal product due to the marketing approval process.

Section 70 of the *Patents Act* may likewise result in extended periods of market exclusivity, without any corresponding mechanism such as the European SPC Waiver system. As already explained, the reason for the introduction of the SPC Waiver

in Europe was the growing awareness that EU manufacturers of generics and biosimilars were at a considerable competitive disadvantage compared to non-EU manufacturers.

- 1 *Whittemore v Cutter* 29 Fed Cas. 1120 (CCD. Mass 1813) (No 17, 600).
- 2 See, e.g., *Sawin v Guild* 21 Fed Cas 554, No 12,391 (CCD Mass. 1813); *Poppenhusen v Falke* 19 F Cas. 1048, 1049 (CCSDNY 1861) (No 11, 279).
- 3 *Madey v Duke* 307 F3d 1351 (Fed Cir. 2002).
- 4 For details on the history of its development, see: Philipp Moritz Lührs, ‘Die Entstehung des Reichspatentgesetzes von 1877 und der Versuch eines europäischen Patentrechts von 1962 im Vergleich’ (2018) 247, available at (Web Page) <<https://docserv.uni-duesseldorf.de/servlets/DerivateServlet/Derivate-53851/Die%20Entstehung%20des%20Reichspatentgesetzes%20von%201877%20und%20der%20gescheiterte%20Versuch%20eines%20europ%C3%A4ischen%20Patentrechts%20von%201962%20im%20Vergleich.pdf>>.
- 5 See in detail: Henrik Holzapfel, ‘Das Versuchsprivileg im Patentrecht und der Schutz biotechnologischer Forschungswerkzeuge’ (2003) 53.
- 6 See selection: András Kupecz et al, ‘Safe Harbors in Europe: An Update on the Research and *Bolar* Exemptions to Patent Infringement’ (2015) 33(7) *Nature Biotechnology* 710.
- 7 *Agreement on Trade-Related Aspects of Intellectual Property Rights*, opened for signature 15 April 1994, 1867 UNTS 299 (entered into force 1 January 1995), annex 1C (“TRIPS Agreement”).
- 8 See in detail: Matthias Lamping et al, ‘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, available at <[https://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=2500784](https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2500784)> (accessed 18.04.2025).
- 9 *76/EEC: Convention for the European patent for the common market* OJ L 17 26.01.1976.
- 10 See in detail: Henrik Holzapfel, ‘Das Versuchsprivileg im Patentrecht und der Schutz biotechnologischer Forschungswerkzeuge’ (2003) 53.



# European Exemptions from Patent Protection: An Overview of the Research Exemption, the Bolar Exemption, and the Supplementary Protection Certificate (“SPC”) Waiver in Europe

- 11 *Klinische Versuche I*, Bundesgerichtshof [German Federal Court of Justice], X ZR 99/92, 11 July, 1995 reported in GRUR 1996, 109.
- 12 *Klinische Versuche I*, Bundesgerichtshof [German Federal Court of Justice], X ZR 99/92, 11 July, 1995 reported in GRUR 1996, 109, 115.
- 13 *Klinische Versuche II*, Bundesgerichtshof [German Federal Court of Justice], X ZR 68/94, 17 April, 1997 reported in NJW 1997, 3092.
- 14 *Marktzulassungsprivileg*, Oberlandesgericht Düsseldorf [Higher Regional Court Düsseldorf], I-2 U 68/12, 5 December 2013 reported in GRUR-RR 2014, 100, 102.
- 15 European Commission, Commission Staff Working Document Impact Assessment, 28.5.2018, SWD (2018) 240 final, 15, available at (Web Page) <<https://ec.europa.eu/docsroom/documents/29463>>.
- 16 *Roche Products, Inc. v Bolar Pharmaceutical Co., Inc.*, 733 F.2d 858, Fed Cir (1984).
- 17 *Eli Lilly and Co v Medtronic*, 496 US 661, 671 (1990).
- 18 *Isis Pharms v Santaris Pharma A/S*, No 3:11-CV-2214-GPC-KSC, 2014 WL 794811 (SD Cal 27 Feb, 2014).
- 19 Food and Drug Administration.
- 20 *Edwards Lifesciences v Meril Life Scis PVT. Ltd.*, No 19-CV-06593-HSG, 2020 WL 6118533, \*4 (ND Cal Oct 16, 2020).
- 21 See in detail: Jeanna Wacker et al, ‘Navigating the Murky Waters of the Hatch-Waxman Safe Harbor’, *Kirkland & Ellis LLP*, 21.09.2022, (Online Article) <<https://www.kirkland.com/publications/article/2022/09/navigating-the-murky-waters-of-the-hatch-waxman-safe-harbor>> (accessed 20.04.2025).
- 22 See WTO Dispute Settlement Procedure: World Trade Organization, ‘Canada - Patent Protection of Pharmaceutical Products’ WT/DS114/R (Online Statement, 17 March 2000) <[https://www.wto.org/english/tratop\\_e/dispu\\_e/dispu\\_e7428d.pdf](https://www.wto.org/english/tratop_e/dispu_e/dispu_e7428d.pdf)> (accessed 23.04.2025).
- 23 Ulrich Gassner, ‘Unterlagenschutz im Europäischen Arzneimittelrecht’ (2004) *GRUR Int* 983, 990; Manja Epping and Ina Gerstberger, ‘Europa auf dem Weg zu “BOLAR” - Ein regulatorisches Korrektiv des Versuchsprivilegs?’ (2003) *PharmR* 257, 262.
- 24 Bundestag printed paper 15/5316, 1, 29.
- 25 Cf. Uwe Scharen, ‘§ 11 German Patent Act’, in Georg Benkard (ed), *Patentgesetz* (12th edition 2023) ch 11 [10].
- 26 Thomas Kühnen, ‘Handbuch der Patentverletzung’, (16th edition 2024), ch E [1121].
- 27 Thomas Kühnen, ‘Handbuch der Patentverletzung’, (16th edition 2024), ch E [1122].
- 28 The Belgian *Bolar* exemption in art 6bis s. 1 of the Belgian *Medicinal Products Act* 1964 does not explicitly include originator studies, but under art XI.34 §1.b of the Belgian Code of Economic Law.
- 29 See overview of the national *Bolar* exception of the EU Member States (selection): Marco Stief, ‘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’ (2024) *GRUR Int* 824, 828.
- 30 Landgericht Düsseldorf [Regional Court Düsseldorf], 4a O 282/10, 03 July 2012 reported in BeckRS 2013, 1711.
- 31 *Marktzulassungsprivileg*, Oberlandesgericht Düsseldorf [Higher Regional Court Düsseldorf], I-2 U 68/12, 5 December 2013 reported in GRUR-RR 2014, 100.
- 32 Sąd Najwyższy [Polish Supreme Court], IV CSK 92/13, 23 October, 2013.
- 33 Corte Suprema Di Cassazione [Italian Supreme Court], No. 18372, 5 July 2024.
- 34 Art 68 I lit. b *Codice della Proprietà Industriale*.
- 35 See in detail: Marco Stief, ‘*Bolar* Exemption: Status quo und Ausblick unter Berücksichtigung der Entscheidung des italienischen Obersten Gerichtshofs vom 5.7.2024’ (2024) *GRUR-Prax*, 595.
- 36 Cf. Henrik Holzapfel, ‘Die patentrechtliche Zulässigkeit der Benutzung von Forschungswerkzeugen’ (2006) *GRUR* 10, 11.
- 37 Cf. Henrik Holzapfel, ‘Die patentrechtliche Zulässigkeit der Benutzung von Forschungswerkzeugen’ (2006) *GRUR* 10, 116f.
- 38 E.g., *PSN Illinois v Abbott Labs*, No 09 C 5879, 2011 WL 4442825 (ND Ill Sept 20, 2011); *Allele Biotechnology & Pharms. v Pfizer*, No 20-CV-01958-H-AGS, 2021 WL 1749903 (SD Cal May 4, 2021); See in detail on the safe harbor in the US: Jeanna Wacker et al, ‘Navigating the Murky Waters of the Hatch-Waxman Safe Harbor’, *Kirkland & Ellis LLP*, 21.09.2022, (Online Article) <<https://www.kirkland.com/publications/article/2022/09/navigating-the-murky-waters-of-the-hatch-waxman-safe-harbor>> (accessed 20.04.2025).
- 39 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), 26.04.2023.
- 40 Communication from the Commission - Reform of pharmaceutical legislation and measures to combat antimicrobial resistance, COM(2023) 190 final, 3f.
- 41 See legislative resolution of the European Parliament of April 10 2024, COM(2023)0192 - C9-0143/2023 - 2023/0132(COD), 287f, available at (Web Page) <[https://www.europarl.europa.eu/RegData/seance\\_pleniere/textes/adoptes/definitif/2024/04-10/0220/P9\\_TA\(2024\)0220\\_EN.pdf](https://www.europarl.europa.eu/RegData/seance_pleniere/textes/adoptes/definitif/2024/04-10/0220/P9_TA(2024)0220_EN.pdf)>.
- 42 Cf. Christian Meyer and Gisela Grabow, ‘EU seeks harmonization of privilege for generic market entry’, *Managing IP*, 09.01.2025, (Online Article) <<https://www.managingip.com/article/2e9idap95k1fotg86i1vk/sponsored-content/eu-seeks-harmonisation-of-privilege-for-generic-market-entry>> (accessed 20.04.2025).
- 43 So Brian Cordery, Rachel Mumby, ‘The new *Bolar* provisions and their potential impact on European PI landscape’ (April 16, 2025) *Kluwer Patent Blog*, <<https://patentblog.kluweriplaw.com/2025/04/16/the-new-bolar-provisions-and-their-potential-impact-on-european-pi-landscape/>> (accessed 23.04.2025).
- 44 Brian Cordery, Rachel Mumby, ‘The new *Bolar* provisions and their potential impact on European PI landscape’ (April 16, 2025) *Kluwer Patent Blog*, <<https://patentblog.kluweriplaw.com/2025/04/16/the-new-bolar-provisions-and-their-potential-impact-on-european-pi-landscape/>> (last accessed on April 23, 2025).
- 45 See overview of the UPC: Marco Stief, ‘Das einheitliche Patentgericht und das Einheitspatent (1.Teil)’ (2024), *A&R* 197; Marco Stief, ‘Das einheitliche Patentgericht und das Einheitspatent (2.Teil)’ (2024), *A&R* 233.
- 46 Agreement on a Unified Patent Court, 2013/C 175/01.
- 47 Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products, OJ L152/1.
- 48 The duration of the SPC corresponds to the period that elapses between the filing date of the patent and the granting of marketing authorisation, minus five years. However, there is a maximum term of five years. This may exceptionally be extended by 6 months in accordance with Regulation (EC) No. 1901/2006 if the SPC relates to a medicinal product for children for which data have been submitted in accordance with a pediatric investigation plan (PIP).
- 49 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, OJ L135/1.
- 50 See in detail on the SPC waiver: Marco Stief, ‘SPC manufacturing and stockpiling waiver - part 1’ (2024) (19)9 *JIPLAP* 695 and Marco Stief, ‘SPC manufacturing and stockpiling waiver - part 2’ (2024), 19(10) *JIPLAP* 754.
- 51 See Recital 5-9 Regulation (EU) 2019/933.
- 52 Recital 9 Regulation (EU) 2019/933.
- 53 Recital 9 Regulation (EU) 2019/933.
- 54 Recital 2 Regulation (EU) 2019/933.
- 55 Marco Stief, ‘SPC manufacturing and stockpiling waiver - part 1’ (2024) (19)9 *JIPLAP* 695, 698f.
- 56 Recital 26f Regulation (EU) 2019/933.
- 57 See Recital 13 Regulation (EU) 2019/933.
- 58 Recital 14 Regulation (EU) 2019/933.
- 59 See Decision of the EEA Joint Committee No 197/2022 of 10 June 2022 amending Annex XVII (Intellectual Property) to the EEA Agreement [2022/1897], art 1(4).