PATENTS

Safe harbors in Europe: an update on the research and Bolar exemptions to patent infringement

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Though the major European Union member states all have research and Bolar exemptions in their patent laws, the scope and effect differs considerably from country to country.

The strength and economic importance of patent protection in the pharmaceutical and biotech industries is commonly known. The scope of a patent owner's monopoly is, however, not unlimited. The patent laws of many countries have certain 'safe harbor provisions'—rules that allow acts that would otherwise be considered patent infringement. Here, we discuss two particular safe harbors: the so-called research exemption and the Bolar exemption. The research exemption excludes scientific research from patent infringement, whereas the Bolar exemption relates to clinical trials performed in the context of generic or biosimilar drug development and approval. The term Bolar exemption stems from *Roche Products v. Bolar Pharmaceutical*[1] in which the US Court of Appeals for the Federal Circuit held that Bolar could not benefit from the research exemption to conduct bioequivalency studies and therefore infringed Roche's patent. Shortly after the decision, the Hatch-Waxman Act was adopted, which allows generic studies and trials in the current system.

As there still is no single European patent law and court system, different European countries have their own sets of rules for patent infringement safe harbors. Moreover, this area of the law is constantly evolving. For example, questions regarding the Bolar exemption were referred to the European Union's highest court, the European Court of Justice, and several European countries including the United Kingdom, Belgium and Spain have adopted or are in the process of adopting new legislation in this area.

This article highlights the most recent developments regarding research and Bolar exemptions in Belgium, France, Germany, Italy, Spain, the Netherlands and the UK, and aims to provide up-to-date practical insights into what is exempted in each country.

The research exemption

The exclusive right of a patentee typically covers all uses of a patented product or method. A research exemption exempts from infringement certain research activities that would otherwise qualify as patent infringement. Research exemptions do not have a common basis in European law, in contrast to the Bolar exemption. In an international law context it can be noted that the World Trade Organization's Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) sets the limits for what member states can exempt from infringement. TRIPS Article 30 states, "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."

As a consequence, each European country has its own specific rules that determine the scope of the research exemption. We will now explore the various research exemptions and their scope in different European countries. We discuss whether the research exemption allows research 'on' patented subject matter (e.g., to find improvements) or also research 'with' patented subject matter (e.g., using a patented research tool). We also investigate whether it makes a difference if the research is performed in academia or within a company.

Belgium. Belgium arguably has the broadest research exemption of all the countries examined in this study. Under Article XI.34, §1, b) of the Code of Economic Law the exclusive rights deriving from a patent do not extend to "acts on and/or with the patented invention for scientific purposes." The research exemption under Belgian patent law therefore covers all "acts" (not only experiments) performed "for scientific purposes" on as well as with the patented invention. It was the Belgian legislators' intention to enlarge the scope of this exemption when the patent legislation was amended in 2005 to transpose the EU Biotechnology Directive[2]. In view of the legislators' intention legal scholars agree that the exemption covers the use of a patented research tool[3,4] if this tool is used "for scientific purposes." However, the exact scope of the research exemption remains unclear[5].

As made clear during parliamentary discussions, the notion of scientific purposes covers not only activities with a purely scientific or academic purpose, but also activities with a mixed (scientific and commercial) purpose, as long as the commercial purpose does not prevail[3]. Examples of such exempted activities include, "the development of new applications, a better therapeutic effect, a more efficient manufacturing method, a new administration form, a new indication."

Recent case law has confirmed that the simple fact that the alleged infringer may

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Table 1 The scope of the research exemption in several European countries

Covered by research exemption?	Research 'on'	Research 'with'	Use of research tool	Academia exempted?
Belgium	Yes	Yes	Yes	No
France	Yes	No	No	No
Germany	Yes	No	No	No
Italy	Yes	Yes	Yes	No
Spain	Yes	No	No	No
The Netherlands	Yes	No	No	Yes
UK	Yes	No	No	No

have a commercial intent does not exclude the application of the research exemption[6]. Where the research takes place (at a university or within a company) is not relevant—only the purpose of the research matters[5].

France. In accordance with article L.613-5 of the French intellectual property code under b) there will be no infringement of a patent if the invention is used for experiments "on the subject matter of the patented invention." There are two elements for this exemption to apply: there must be an experiment (presumably to gain knowledge) and the experiment must be performed on the subject matter of the invention. Thus, using the invention for experimentation unrelated to the invention (i.e., to gain knowledge on something else) is not exempted. In the case law, it has been held that the publicity surrounding an infringing product was sufficient to deprive the defendant of the experimental-use defense. Also, when commercial offers are made to potential customers, this defense cannot be used. Experiments with patented medicines for the purpose of finding new modes of administration should not constitute infringement.

The issue of research tools has never been expressly ruled upon by French courts. However, based on the case law in France, any commercial activity will in principle prevent reliance on the exemption. As a result, the use of patented research tools for the purpose of carrying out research should lead to infringement.

In theory, academic institutions could seek to rely on the exception according to paragraph (a) of L 613-5 with regard to acts performed privately and for noncommercial purposes. However, the reliance on this exemption is exceedingly rare and clearly is only relevant to private citizens acting within their homes. Academic research should thus not be exempted *per se* from patent infringement.

Germany. The legal basis under German patent law for the experimental use exemption can be found in § 11 of the Patent Act (PA). Thus, § 11 no. 2 PA explains: "The rights conferred by the patent shall not extend to acts done for experimental purposes, relating to the subject matter of the patented invention," also known as the "experimental use privilege." An "act done for experimental purposes" is every planned action to resolve uncertainties regarding the subject matter of the patented invention or to produce new findings and insights about it, and that applies regardless of the purpose the findings are ultimately intended to serve[7,8]. Therefore, there need not be a purely scientific motivation, so that even commercial interests are not harmful. At least before the introduction of § 11 no. 2 b) PA (the Bolar exemption), this could also include experiments by which the safety and efficacy of a pharmaceutical composition is to be tested in human clinical trials, with the aim of collecting data for regulatory drug approval[8]. Regarding the experimental purpose, both acts of use that are carried out to verify technical information in a patent specification or to explore the effects of a substance, as well as those for finding new, previously unknown applications can be included hereunder[7]. Bioequivalence studies, on the other hand, due to their lack of an experimental purpose in the meaning of § 11 no. 2 PA, are excluded from the experimental use exemption[9].

An act is "relating to the subject matter of the patented invention" if the subject matter of the invention is the object of the experimental act, for the purpose of obtaining additional knowledge[7,8]. Because of this characteristic, experiments 'on' the invention but not 'with' the invention are covered by the exemption. To date, the German courts have not decided whether research tools are covered by the experimental use exemption or the regulatory approval exemption. The literature tends to oppose the idea of such inclusion by the experimental use exemption[10–15] as well as the regulatory approval exemption[13,14,16]. Although the primary argument against the experimental use exemption is that an experiment with a research tool is normally not based on the patented subject matter, as is required under § 11 no. 2 PA, the decisive argument against a regulatory approval exemption pursuant to § 11 no. 2 b) PA is that an inclusion under the experimental use exemption or the regulatory approval exemption would threaten to nullify the patent protection for research tools, as they are specifically developed for the purpose of conducting experiments and research[10,13,14]. Such discussions usually do not differentiate between academic and economic research.

Italy. In Italy, the experimental use of patented subject matter is governed by article 68(1)(a) of the Italian Intellectual Property (IP) Code, which, in principle, exempts from infringement activities undertaken for experimental purposes. "The exclusive rights arising from the patent, regardless of the scope of the invention, do not shield from: (a) activities carried out… for experimental purposes, even if aimed at obtaining, also in foreign countries, a marketing authorization for a pharmaceutical and at performing the resulting practical fulfillments, including the preparation and use of the pharmaceutically active raw materials strictly necessary therefore."

Since 1970, Italian case law consistently maintains that all experimental activities (carried out both in academia or in a business) on the subject matter of a patented invention are lawful to the extent they are acquiring knowledge, thus promoting scientific research on the subject matter thereof[17,18]. As long as these criteria are met, research, including the use of patented research tools, will be exempted from patent infringement.

Spain. Article 52 (1)(b) of the Spanish Patent Act (SPA) provides for the experimental use exemption together with a Bolar exemption as follows: "The rights conferred by the patent shall not extend to: …acts carried out for experimental purposes related to the subject-matter of the patented invention, in particular the studies and tests carried to obtain regulatory approval of generic drugs, either in Spain or abroad, and the subsequent practical requirements, including preparation, obtention and use of the active principle for this purpose." Although the research and Bolar provisions are joined in one and the same article, the Spanish Supreme Court has confirmed that the experimental use exemption and the Bolar exemption have a different nature and a different aim.

A new patent act is in the final stage of the legislative process, pending approval in parliament. Under the latest version of the draft law, the experimental use exemption and the Bolar clause are split up into two different provisions. This approach is consistent with the case law and the most authoritative scholars[19]. In accordance with Article 61 (1) of the draft

law: "The rights conferred by the patent shall not extend to: … (b) Acts carried out for experimental purposes related to the subject-matter of the patented invention. (c) Studies and tests necessary to obtain the marketing authorization for medicines in Spain or outside of Spain, including the preparation, obtention and use of the active substance for those aims."

As the case law currently stands, in principle, the experimental use exemption should be interpreted narrowly and covers research 'on' the patented invention but not research 'with' the patented invention. Acts carried out for experimental purposes should be aimed exclusively at improving or consolidating the inventive technical rule in itself in order to benefit from the research exemption.

Whether the research exemption covers the use of a patented research tool or not has not been an issue in Spain. Taking into account that the interpretation of the scope of the experimental use exemption should be strict, if the patented research tool was not the subject matter of the research but it was used to do research on other inventions the research would most likely not be covered by the research exemption. In this respect, whether the research has been performed in academia or in business is not relevant as neither the current legal provisions nor the draft law limits the application of the research exemption in this respect.

The Netherlands. In accordance with article 53(1) of the Dutch Patent Act (DPA), the patent owner has the exclusive right "to make, use, put on the market or resell, hire out or deliver the patented product, or otherwise deal in it in or for his business, or to offer, import or stock it for any of those purposes"[20] or, in the case of a process patent, "to use the patented process in or for his business or to use, put on the market, or resell, hire out or deliver the product obtained directly as a result of the use of the patented process, or otherwise deal in it in or for his business, or to offer, import or stock it for any of those purposes." In accordance with article 53(3) DPA, "The exclusive right shall not extend to acts solely serving for research on the patented subject matter, including the product obtained directly as a result of using the patented process."

First of all, the phrase "in or for his business" in defining the exclusive rights of the patentee is to be interpreted broadly. As a consequence, only strictly private or academic acts are excluded from patent infringement.

The research exemption as defined in article 53(3) DPA is limited to research of the patented subject matter. This is reflected in the wording of the applicable statute and has been confirmed in the case law. It was held that the research exemption is to be interpreted in a narrow way. This means that research on the patented subject matter in a commercial setting is allowed only if the intent of the research is in accordance with the overarching objectives of the DPA, for example, to advance science. The use of a patented research tool would normally not be covered by the research exemption because it would be research 'with' patented subject matter, unless the research tool itself would be investigated (research 'on') and with an intent that can be reconciled with the objectives of the DPA.

United Kingdom. The statutory basis for the UK experimental use exemption can be found in s.60(5)(b) of the Patents Act 1977. This provides that: "(5) An act which, apart from this subsection, would constitute an infringement of a patent for an invention shall not do so if… (b) it is done for experimental purposes relating to the subject-matter of the invention." The exemption applies only to research carried out to find out something unknown about the invention but will include experiments, for example, to see how the invention will work in specific conditions or in combination with other factors[21]. The exemption will generally cover only experimentation having a real and direct connection with the subject matter of the invention found in the claims of the patent that would otherwise be infringed[22]. The exemption will not apply to the use of a patented research tool unless the purpose of the research is to learn something new about the research tool itself, though there may be an exception for research tools used for the purposes of a "medicinal product assessment."

Research may be conducted with some ultimate commercial aim in view and still claim the benefit of the experimental use exemption, provided that the preponderant purpose of the study is research to find out something new relating to the subject matter of the invention[23]. Other than in that regard, no distinction is drawn between those researchers in academia and business.

Table 2 The scope of the Bolar exemption in several European countries

Covered by Bolar exemption?	Generic trials	Innovator trials	Phase 4 trials[a]	For non-EU approval?
Belgium	Yes	No	Yes	No
France	Yes	Yes	Yes	Yes
Germany	Yes	No	Yes	Yes
Italy	Yes	Yes	Yes	Yes
Spain[b]	Yes	Yes	Yes	Yes
The Netherlands	Yes	No	Yes	No
UK	Yes	Yes	Yes	Yes

[a]Except for Italy, in all jurisdictions where phase 4 trials are exempted, it is required that such trials are necessary to obtain marketing approval. [b]Under the draft Patent Law.

The Bolar exemption

EU Directive 2001/83/EC, as amended by Directive 2004/27/EC, relating to medicinal products for human use[24] (the Community Medicines Code or CMC) aims to harmonize European rules for the trade of medicines. Article 10 relates to the marketing approval procedure for generic and biosimilar medicines. Article 10(6), generally referred to as the Bolar exemption, states that "conducting the necessary studies and trials…and the consequential practical requirements shall not be regarded as contrary to patent rights or to supplementary protection certificates for medicinal products." Thus, in principle, acts carried out in the process of getting a generic or biosimilar product approved are exempt from patent infringement. It should, however, be noted that the CMC is a European Community directive which, by its nature, has to be implemented into the national laws of the member states. In fact, as a result of implementing the CMC, different EU member states have adopted different rules and policies, giving rise to significant complexity and, as a consequence, legal uncertainty. Moreover, as the legal basis for the Bolar exemption is a European Community directive, the European Court of Justice has the final say in its interpretation and in defining its scope.

Belgium. Legislators almost literally transposed Article 10(6) CMC into its national laws. The Bolar exemption has been inserted in Article 6bis, §1, last paragraph of the Belgian Medicines Act[25] and provides manufacturers of generics and biosimilars with a defense to patent infringement when gaining regulatory approval. Studies, tests and trials, as well as all the consequential practical requirements, are thus exempted under the Bolar exemption to the extent that they are necessary for making an application for a marketing authorization using the abridged, hybrid or biosimilar application procedure.

As there is not much case law in Belgium on this exemption, its scope remains unclear[26].

Neither the Belgian Medicines Act nor the preparatory works give more details about the specific activities that fall within the scope of this exemption. It is, in any case, generally accepted that, in order to rely on the Bolar exemption, the tests performed should be linked to obtaining data that are required to be supplied to the regulatory authorities. Moreover, it is clear that the manufacturing, importing and processing of the active material for the necessary studies are also exempted. Whether suppliers may invoke this exemption is not clear yet.

The preparation and printing of promotional material relating to generic products before patent expiry do not constitute a patent infringement; however, the publishing and distribution of these materials before patent expiry are considered to be infringing[27]. In this regard, the court explicitly confirmed that acts of premarketing fall outside the scope of the Bolar exemption. Moreover, the Brussels Court of Appeal confirmed that the Bolar exemption also covers pricing and reimbursement applications[28].

Given the wording of the Bolar exemption, which refers only to abridged applications, hybrid applications and biosimilar applications, only studies and trials in view of such applications are exempted from patent infringement. Whether phase 4 clinical trials are covered is not certain, but we consider that a mandatory, post-authorization (efficacy) study with a clear regulatory purpose and imposed as an obligation by the regulatory bodies also falls within the scope of the Bolar exemption. Such a clinical trial would be considered necessary to comply with the regulatory conditions relating to the marketing authorization, as well as a consequential practical requirement of the regulatory approval process.

Regulatory approval for originator products is not covered. Also, the territorial scope of the Bolar exemption is limited to regulatory data needed to obtain Belgian or EU marketing authorizations. Furthermore, with regard to innovator clinical trials, most Belgian legal scholars tend to consider that clinical trials carried out with a view to obtaining a marketing authorization to commercialize the allegedly infringing product have a commercial purpose and, therefore, also do not fall within the scope of the research exemption[29,30]. However, one author argues that phase 1 and phase 2 trials are always exempted from patent protection because "the primary objective of such tests is to obtain scientific information on the efficiency and harmlessness of the tested medicine"[31]. This author also argues that, as a rule, phase 3 trials will also be exempted as this phase, too, "aims at defining with precision the exact conditions for administering the medicine," and only indirectly aims at commercialization, as "it is not uncommon to see a phase 3 interrupted due to the occurrence of serious secondary effects"[31]. This position seems debatable; as discussed above, the only relevant criterion is whether or not a commercial or scientific purpose prevails. There is, however, no case law yet on this matter.

France. Here, it was accepted by the courts that bioequivalence tests for the purpose of obtaining a marketing authorization did not constitute industrial or commercial acts and thus were exempted from patent infringement[32]. Upon implementation of the CMC into the French intellectual property code, a specific exemption was added to the law, dealing expressly with marketing authorizations. Article L 613-5 ICP exempts "(d) the studies and trials which are necessary in order to obtain a marketing authorization for a medicinal product, as well as any acts which are necessary to carry out such studies and trials and to obtain the authorization."

As to the scope of the Bolar exemption, article L 613-5 does not define marketing authorizations and does not refer to the CMC or even to the notion of generics. Thus, the French law that implemented these provisions has no such limitations. As a result, as the law does not differentiate between trials for generic marketing authorizations and trials for any marketing authorizations, such a distinction is not relevant. In addition, case law already predominantly construed all experiments performed for the purpose of obtaining a marketing authorization as covered by the general experimental use exemption. However once the authorization is obtained, any further production is unlikely to constitute research and would thus infringe. In this regard, phase 4 reporting could be more controversial as it arises after the grant of the marketing authorization. If the experimental acts necessary for such reporting are clearly required for holding a marketing authorization, then they should be exempted as an extension of the steps required to obtain one. The territorial scope of the Bolar exemption in France may be an ambiguous issue. Nevertheless the scope of the original exemption and the clear policy of French courts not to limit research and generics make it likely that conducting studies and trials in France to obtain regulatory approval outside of the EU will be exempted from patent infringement. This has been recently confirmed in the High Court of Paris[33].

Germany. Pursuant to § 11 no. 2 b) PA (the Bolar exemption), "the effect of a patent shall not extend to studies and trials, and the resulting practical requirements that are necessary for obtaining authorization to place a medicinal product on the market in the European Union, or for obtaining authorization for a medicinal product in the member states of the EU or in third countries," also known as the "regulatory approval privilege."

This provision goes beyond the experimental use exemption in so far as the experiments aimed at acquiring new knowledge do not necessarily have to relate to the subject matter of the patented invention[34] so that, in principle, both experiments "on" and experiments "with" the invention may be covered by this exemption. Nevertheless, at least in the field of research tools, it is being discussed whether an extension of the exemption to experiments "with" the invention should be excluded in order to achieve appropriate results. In contrast to § 11 no. 2 PA, bioequivalence trials may also benefit from this exemption status[34].

According to the wording of the law, neither the experimental use exemption nor the regulatory approval exemption differentiates between generic manufacturers or other parties. However, the regulatory approval exemption was specifically introduced to enable a faster market entry of generic products[35]. Thus, its applicability is, at least de facto, limited in most cases to the actions of generic manufacturers.

"Practical requirements resulting therefrom" are any use of the patented teaching, which creates the conditions for conducting a privileged study or a exempted experimental use[34]. What is decisive therefore is which requirements the regulatory authority lays down for the issuance of a permit or approval.

Typically, phase 1, 2 and 3 trials can be covered by the experimental use or regulatory approval exemption. Even phase 4 studies can fall within the exempted conditions, particularly if such a study has been called for by the licensing authority, provided that the limits identified by case law are observed (i.e., a privilege is excluded where the experiment constitutes means of enforcing competitive purposes because, for example, there is no reference to the technical teaching, or these trials are carried out with the intention to seriously disrupt or hinder the patentee's own product sales).

Italy. Implementation of the CMC in Italy has led to inclusion of the Bolar exemption into the research exemption in Article 68(1)(a) of Italian IP Code. The scope of the experimental use exemption in Italy is not limited to generic trials or to any specific phase of testing (phase 4 clinical trials are included). Furthermore, the experimental use exemption covers clinical trials for regulatory approval abroad, without distinction between EU and non-EU countries.

The only instance in which the exemption does not apply is when experiments are carried out in connection with activities solely aimed at infringement before the expiration of the relevant patent or SPC[36]. For instance, it has been held that certain production tests (i.e., the insertion of a patented active ingredient in certain capsules in order to test their marketability) were outside the scope of the experimental use exemption, as clearly preparatory to the upcoming infringement of the patent on the active ingredient. Furthermore, the exemption does not apply if experimental activities are coupled with infringing behaviors.

Spain. In Spain there has been little guidance from the courts regarding the Bolar exemption. In contrast to the current provision, the amended provision in the new draft patent law does not seem to be limited to marketing authorizations for generic medicines. Accordingly, it may be deduced that once the new patent act comes into force, the Bolar exemption will cover any trial, whether relating to a generic or not. With respect to the territorial scope of the exemption, both the existing and the draft laws refer to marketing authorizations "in Spain or abroad," so conducting trials in Spain to gather data for submission to a foreign regulatory authority would be exempted from patent infringement.

As to the question of which specific types or phases of clinical trials would be covered, neither Article 52, paragraph (1), letter b) of the current SPA nor Section 61 (1) (c) of the new draft law limit the application of the Bolar exemption to one or more specific phases of clinical trials. Based on the case law, it can be argued that phases 1, 2 and 3 will be covered by the Bolar exemption, as these trials must be conducted before obtaining the marketing authorization. In the case of post-marketing studies conducted under phase 4, this is not clear. In any event, it would depend on the specific circumstances of the case, in particular the purposes of the study and its compulsory or voluntary character.

It is to be noted that both the SPA and the new draft law refer generally to 'trials' without distinguishing between preclinical trials and clinical trials. However, Article 10 of the CMC expressly includes preclinical trials under the scope of the Bolar exemption; therefore, it can be argued that preclinical trials are also included under the scope of both the current SPA and the draft law.

The Netherlands. In accordance with article 53(4) DPA, "the performance of necessary studies, tests and experiments in connection with the application of article 10(1) to (4) CMC and the ensuing practical requirements shall not be deemed to constitute an infringement of patents relating to medicinal products for human use or medicinal products for veterinary use, respectively." Article 53(4) was introduced into the DPA on the occasion of the implementation of the CMC. The article refers directly and explicitly to the directive in defining the scope of the exemption.

Before implementation, the Dutch Supreme Court had taken a narrow interpretation of the research exemption and held that clinical trials to obtain generic marketing approval and providing samples to the regulatory authorities did constitute patent infringement[37]. In view of the explicit wording of the DPA and also in view of the narrow interpretation in general of patent law exemptions, it seems likely that the scope of the Bolar exemption will be limited to the wording of the law, that is, limited to studies and trials for generic (and biosimilar) medicines in accordance with the Medicines Directive. That would also imply that studies and trials conducted to obtain marketing authorizations outside of the EU would be considered patent infringement. As to whether or not phase 4 trials are covered by the Bolar exemption, in the absence of any case law to this effect, it will most likely depend on all facts and circumstances of the case. If such trials are considered necessary to obtain (or maintain) regulatory approval, they should be exempt.

United Kingdom. Prior to October 1, 2014, the UK had implemented a narrow Bolar-like exemption, which applied only to studies undertaken for the purposes of obtaining a marketing authorization under the abridged procedure for generic medicines. Those conducting clinical trials of nongeneric medicines previously had to rely on the experimental use exemption, and there was a lack of clarity as to whether that exemption would protect late-stage trials (which, arguably, had a predominantly commercial rather than research purpose).

On October 1, 2014, the Legislative Reform (Patents) Order 2014 came into force. This introduced a broader Bolar exemption into the UK Patents Act 1977 covering "anything done in or for the purposes of a medicinal product assessment which would otherwise constitute an infringement of a patent for an invention." "Medicinal product assessment" means any testing, course of testing or other activity undertaken with a view to providing data for the purposes of obtaining a marketing authorization (whether in the UK or elsewhere), complying with any regulatory requirement imposed in relation to such an authorization, or enabling a government or public authority to assess the suitability of a medicinal product for the purpose of determining whether to use it or recommend its use in the provision of healthcare.

The new Bolar exemption operates by deeming that, for the purposes of s.60(5)(b) (i.e., the experimental use exemption), such activities are "to be regarded as done for experimental purposes relating to the subject-matter of the invention." The new Bolar exemption therefore covers all clinical trials conducted for the purposes of a medicinal product assessment and is not limited to those relating to generic medicines. The narrower Bolar-like exemption for generic medicines also continues to be in effect[38]. Phase 1, 2 and 3 trials are covered by the new Bolar exemption, as are phase 4 (post-marketing) studies to the extent that they are mandated by the relevant regulator. The new Bolar exemption expressly covers trials conducted for the purposes of obtaining a marketing authorization outside of the UK. No distinction is made between EU and non-EU countries.

It is also interesting to note that, although it purports to operate within the framework of the existing experimental use exemption, in contrast to the usual position under those provisions, the new Bolar exemption covers "anything done in or for the purposes of a medicinal product assessment" and therefore also appears to exclude from infringement the use of a patented research tool, provided that the research tool is used in the course of a relevant study. The UK Intellectual Property Office has issued a guidance note that reinforces this interpretation, although it states that "a license agreement would be needed to use a research tool once the [medicinal] product is commercialized"[39].

In the course of implementing the Legislative Reform Order, the UK Government was required to consider whether the new provisions would "remove any necessary protection" or "prevent a person exercising any right or freedom that they might reasonably expect to continue to exercise." The UK Government considered that the new provisions did not have such an effect as "The changes do not exempt commercial activities which a patentee could reasonably expect to continue exercising and do not remove any necessary protection as a third party will still require a licence from the patent holder in order to use a patented product for commercial activities"[40], and "any third party seeking to use a patented product commercially would still require a licence from the patentee. The proposals do not prevent anybody from exercising a right which they might expect to continue exercising, namely the commercial exploitation of a patent"[41].

Although those conclusions are arguably correct with regard to patents covering the medicinal product(s) being studied, they offer

no consideration whatsoever to patents covering research tools that may be used in the course of the protected studies. One can envisage that some research tools will find use predominantly or exclusively in the context of medicinal product assessments and that, once those studies are completed, use of the research tools will no longer be required. If the new provisions apply so as to exempt the use of research tools from infringement, the effect will be that some patentees are deprived of substantially the entire benefit of their patents. This does not appear to be consistent with the UK Government's assessment of the impact of the new provisions. Owing to their recent implementation, there has not yet been any judicial interpretation of the new provisions.

Unified Patent Court Agreement

Europe currently does not have a single patent or a common patent court system. This will change dramatically once the unitary patent system[42] and the Unified Patent Court (UPC) system come into force.

The Agreement on a UPC[43] defines the rights conferred by a patent and the limitations to those rights. In accordance with article 27 UPC Agreement, the rights conferred by a patent do not extend to "(a) acts done privately and for non-commercial purposes; (b) acts done for experimental purposes relating to the subject-matter of the patented invention; […] and (d) the acts allowed pursuant to Article 13(6) of Directive 2001/82/EC (1) or Article 10(6) of Directive 2001/83/EC (2) in respect of any patent covering the product within the meaning of either of those Directives; […]"

As for the research exemption, the 'relating to' wording resembles the wording of the UK law and therefore a UK-style approach might be taken. It remains to be seen whether academia will be able to benefit from the 'non-commercial purposes' exemption of article 27 (a) UPC. As to the Bolar exemption, the UPC Agreement (like the DPA) refers clearly to the CMC, so it may well be that the scope of the exemption will be limited to studies and trials for generic or biosimilar drugs for obtaining marketing approval in Europe. In the end, it will be up to the UPC and/or the ECJ to rule on the scope of the exemptions.

Conclusion and discussion

When it comes to patent law, Europe is certainly not a single jurisdiction with uniform rules. All of the EU member states we discuss have a research exemption and a Bolar exemption in their patent acts, but the scope and effect thereof differs considerably.

In Belgium, the research exemption covers research 'with' a patented product or method, as long as this is done for scientific purposes. Italy has a similar provision in its IP code. The other countries have limited the scope of the research exemption to research 'on' the patented product or method. For research tools, this means that the use of these should be exempted in Belgium and Italy (assuming that the 'scientific purpose' requirement is met), whereas in Germany, France, the Netherlands and the UK, researchers would infringe. In most countries, except for the Netherlands, it does not matter whether you are in academia or not.

A similar picture applies for the Bolar exemption. Despite the fact that the Bolar exemption finds its origin in the common European CMC, there are significant differences in how different member states have implemented the directive. The Bolar exemption in Belgium, Germany and the Netherlands is limited to studies and trials necessary for obtaining generic or biosimilar EU marketing approval, whereas in France, Italy, the UK and Spain, once the new law comes into force, studies and trials with innovator medicines should also be exempted. Where it concerns the territorial scope, Belgium and the Netherlands are the narrowest. Trials to obtain marketing authorizations outside the EU do not constitute patent infringement in the other countries investigated in this article.

There are many interesting issues to be resolved that we have not discussed. One such question is whether third parties can also rely on the Bolar exemption. In this respect, the Düsseldorf (Germany) Court of Appeal had requested a preliminary ruling as to whether or not a third-party (commercial) supplier of a patented active substance for use in generic trials can benefit from the Bolar exemption and if so, under which circumstances[44]. Unfortunately, the case was settled and the ECJ never got to answer this important question. Undoubtedly, there are more to come.

COMPETING FINANCIAL INTERESTS
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All of the authors have contributed equally to this work. For further information, see http://www.bolar.eu. This article is in no way intended to provide legal advice. The views expressed are solely the personal views of the authors and not their firms' or clients' views. No liability is accepted for any statement in this article.

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