Specialeafhandling

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Titel: Bolar Exemption and Third Party Suppliers. Comparison of legal approaches and case law in the United Kingdom, Germany, Denmark and Poland

Emnebeskrivelse: An analysis of different implementations of reaserch use and Bolar exemptions in Europe in the wider context of third party suppliers of active pharmaceutical ingredients. Discussion of relevant case law from four different jurisdicitions: the United Kingdom, Germany, Denmark and Poland.

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Abstract

The purpose of this thesis is to analyze the scope and implementation of the Bolar exemption in four specific jurisdictions: the United Kingdom, Germany, Denmark and Poland, and place it subsequently in the wider context of third party suppliers of active pharmaceutical ingredients. This is achieved by using the traditional legal dogmatic approach and the comparative analysis approach.

To understand the role of the Bolar exemption it is necessary to look at the research use exemption, which precedes and complements the Bolar exemption. The most significant case law from the United Kingdom and Germany is analyzed in this context. It has been outside of the scope of this work to discuss the research use exemption in the United States, however, the case of *Roche v Bolar Pharmaceuticals* is briefly looked at in the context of the introduction of the Bolar exemption in the European Union.

The main body of this thesis focuses on the Bolar exemption in Europe, as introduced by the Directive 2001/83, as amended by the Directive 2004/27, with a specific emphasis on its applicability to third party suppliers of active pharmaceutical ingredients. The key issue in this context is whether third party supply of active patent protected ingredients to generic companies can be privileged under the Bolar exemption. The outcome of the case of *Astellas v Polpharma* is discussed in this context. The Polish Supreme Court and the Regional Court in Dusseldorf have ruled that commercial third party activities of advertising and supplying such ingredients to generic manufactures constitute patent infringement and thus do not fall within the scope of activities permissible under the Bolar exemption. The Higher Regional Court in Dusseldorf, however, was willing to consider some factors, which would make it possible for the third party supplier to be covered by the Bolar exemption. The Higher Regional Court also referred questions to Court of Justice of the European Union (CJEU) but withdrew its referral before the Court had a chance to introduce some clarity into the exact scope of permissible activities under the Bolar exemption. In the discussion part of this thesis it is considered what a hypothetical ruling of the CJEU would be as well as practical advice is given to third party suppliers and generic manufacturers as how to avoid patent infringement.

This thesis concludes with reinstating the status quo regarding the Bolar exemption and third party suppliers of active pharmaceutical ingredients. It also offers a more general discussion of the Bolar exemption and some thoughts about its future.
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Chapter 1. Introduction

1.1 The pharmaceutical industry

The pharmaceutical sector is highly regulated with many sector-specific laws. It is also driven by research and development (R&D). The main reason for such specific laws is the long-standing tension between the two major players on the supply side of the pharmaceutical industry. On one side are originator companies who develop new innovative drugs, while on the other are generic companies who sell copy versions of such drugs.¹ The generic companies produce drugs, which contain the same active pharmaceutical ingredients as their original counterparts. They can therefore be used to treat the same diseases but come at a much cheaper price. Both actors sometimes buy active pharmaceutical ingredients from specialised companies (third party suppliers), save in those cases where they themselves can produce the necessary amount of the active ingredients.²

When an innovative pharmaceutical company develops a new drug, it is placed on the market under a brand name and can be prescribed by doctors to patients. For as long as the drug enjoys patent protection, it can only be manufactured and sold by its inventor and patent holder, namely the pharmaceutical company. The patent protection provides a compensation for the very high costs of R&D and offers monopoly for the patent holder, but at the same time, being limited in time, encourages further innovation.

The second player in the pharmaceutical industry, generic companies, enter the market with their products that are equivalent to the originator (innovative) products first upon the expiry of the patent on those innovative medicinal products. The generic products are much cheaper than the originator products, which encourages competition on the pharmaceutical market and benefits the customers, who can receive the same treatment at a much lower price. The monopoly enjoyed by the patent holder and his exclusive patent rights are over once the generic drug is released onto the market.

1.2. Patent protection

Since the pharmaceutical sector is one of the main users of the patent system, \(^3\) the process of obtaining a patent and a market authorisation will be shortly described here.

The investment made by inventors (here, the pharmaceutical companies) in developing new products, obtaining a market authorisation and then producing such products needs to be somehow returned. The necessary exclusivity attractive enough to encourage R&D and innovation is provided by the patent system. Protection of a patent provides the desired award for the time and money spent on innovation. The protection is limited in time, and therefore encouraging the company to bring the innovation to market as quickly as possible and ensuring that the company continues to innovate. \(^4\)

Exclusive patent rights protect patented products against any third party unauthorized making, using or selling of these products. In some countries, the unauthorized import of products protected by patents or resulting from a patented process, likewise constitutes an infringement of exclusive patent rights. Accordingly, 'absent an exception, all research on or with patented inventions — including non-commercial and non-profit research by universities as well as research and development by commercial firms — constitutes patent infringement'. \(^5\)

Patent rights have a limited duration, with the global minimum of twenty years from the filing date. \(^6\) The new product, way of manufacture or a process described in the patent application must be something that is new and innovative and which has not been formerly disclosed. The latter is a test of novelty, made by comparing the claims of the patent applicant against the body of published literature in the field, including previously issued patents (the so-called 'prior art'). The purpose of this process of examination is to make sure that one can only claim patent rights to something that does not already exists and has not been subject to a patent application before. \(^7\)

In order to obtain a patent, it is necessary to file an application, usually with the patent office of the country where the innovator works. An application must include a detailed description of the invention and explain to a person skilled in the art how it can be carried out. \(^8\) The invention cannot be obvious to a person ordinarily skilled in the art (the so-called non-obviousness test). There exists an international application procedure managed by the World Intellectual Property Organization.


\(^4\) Ibid, p. 48


\(^6\) See for example Article 33 of the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS), available at http://www.wto.org/english/tratop_e/trips_e/t_agm3c_e.htm#5


\(^8\) Cook Trevor, 'Pharmaceuticals Biotechnology ad the Law', 2nd edition, published by Lexis Nexis, 2009, United Kingdom, p. 28
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(WIPO) under the Patent Cooperation Treaty (PCT). This procedure allows for many early stages of patent application procedure to be centralised in a form of a single procedure. This thesis does not, however, discuss the procedural issues in detail or issues of enforcement.

1.3. Market authorisation

In accordance with EU Directive 2001/83 (hereafter, referred to as ‘the Directive’) and EU Regulation 726/2004 governing medicinal products, in order to legally place a medicinal product on the market in the European Union or the European Economic Area, a marketing authorisation must first be obtained from a competent authority. Applications filed for new medicinal products containing new active substances are called ‘full applications’, whereas applications for products containing previously used and authorized active substances are described as ‘abbreviated’ or ‘abridged’ applications.

Directive 2001/83 contains the relevant provisions and provides the different legal bases for making a marketing authorisation application:

- A full application according to Article 8 of the Directive, to be accompanied by a dossier of information covering pharmaceutical (physico-chemical, biological or microbiological) tests, preclinical (toxicological and pharmacological) tests, clinical trials and any relevant published literature
- An abridged application (derogation from Article 8 above) according to Article 10 of the Directive, used for generic medicines and biosimilar medicinal products
- An abridged application (derogation from Article 8) according to Article 10a of the Directive, used for applications relying on well-established medicinal use supported by bibliographic literature
- An abridged application (derogation from Article 8) according to Article 10b of the Directive, used for applications for new fixed combination products
- An abridged application (derogation from Article 8) according to Article 10c of the Directive, used for applications based on informed consent from a marketing authorisation holder for an authorised medicinal product.

When making an application for a marketing authorisation to place a medicinal product on the market, the applicant provides the scientific data to support the product’s quality, efficacy and safety. The relevant competent authority, like for example, the Medicines and Healthcare Products Regulatory Agency in the United Kingdom, then evaluates the data. However, most of the drugs, which come onto

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the market, contain active ingredients, which have been previously tested and approved in other forms or for other companies. The Directive 2001/83 allows in these circumstances for the 'abridged' or 'abbreviated' application procedure to be used, so that companies do not have to repeat the clinical tests and trials on the ingredients already approved. Abridged application procedures are used by generic companies, who can avoid carrying out the expensive and time-consuming full trials by relying on at least some of the clinical data submitted by the original applicant for marketing authorisation in connection with the original medicinal product. It is, however, still necessary for generic companies to demonstrate that the generic version of the product is bioequivalent to the approved reference medicine.

There are different procedures for making an application for a marketing authorisation: the centralized procedure, the mutual recognition procedure and the decentralized procedure. It is, however, beyond the scope of this thesis to explain these procedures in more detail.

1.4. The research use exemption

As mentioned above, patent right are exclusive rights. This means that the patent holder has the exclusive right to use and exploit his patent. One important exception to patent rights that has been recognized by most patent laws in the world is the use of a patented product or process, without the consent of the patent owner, for certain research and experimental purposes. Such exemptions may be either expressed in a form of a specific provision in the law, or be created by the courts. The research use exemption is built on the idea that 'a key public policy purpose underlying patent laws is to facilitate the dissemination and advancement of technical knowledge and that allowing the patent owner to prevent experimental use during the term of the patent would frustrate part of the purpose of the requirement that the nature of the invention be disclosed to the public'. Experimental activity such as clinical trials, is of considerable significance for the pharmaceutical sector, where in order to obtain a market authorisation a series of tests and experiments must be conducted.

A strict enforcement of patent rights without exceptions for research may hinder scientific innovation along with the useful follow-on innovation in any industry, also the pharmaceutical industry. The absence of research exemption would result in the patent holder enjoying a full patent monopoly as his generic competitors are not be

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13 Cook Trevor 'A European Perspective as to the Extent to which Experimental Use, and Certain Other Defences to Patent Infringement, Apply to Differing Types of Research. A Report for the Intellectual Property Institute.', March 2006, p. 4
able to undertake pre-market research and development necessary to create a feasible product that can be brought to market as soon as the original patent expires. Since the patent rights are exclusive, the generic drug manufacturers cannot – except for under the research exemption – begin their studies and trials using a patented ingredient or substance until the original patent expires. Otherwise, generic companies would be infringing patent rights. Absent the exemption, the original inventor and patent holder would get an extension to his exclusive patent rights for the time it takes for the generic manufacturer to acquire the results and tests necessary to obtain a marketing authorisation.

One of the underlying purposes of patent protection is encouraging new innovations and rewarding innovators. However, the patent system should not be biased towards compensating originators at the expense of follow-on inventors or scientific researchers. The patent system should not impede the ability of the generic manufacturers to improve the original inventions. The reward given to the original inventor should not be so strong as to provide an exclusive long-term protection and thereby prevent the ability of others to conduct basic research on the patented products. 15

1.5. Bolar exemption

A special form of the research use exemption is the co-called Bolar exemption, named after a famous US case involving a party called Bolar. 16 Under this exemption generic drug manufacturers can conduct clinical trials on products still under their patent protection in order to obtain a marketing approval. This use of the patent protected invention does not therefore constitute patent infringement.

The scope of the Bolar exemption differs between the various EU Member States. The fundamental principle is enshrined in Article 10(6) of the Directive 2001/83 and has been consistently implemented in the Member States. It allows generic drug manufacturers to conduct the necessary clinical trials and studies, which are needed for obtaining a marketing authorisation based on active pharmaceutical ingredient and processes protected by patents, before such patents expire. There is, however, an unresolved question of whether the scope of protection of Bolar exemption covers the production, advertisement and supply of active pharmaceutical ingredients by third party suppliers to generic drug manufacturers. This thesis seeks, from a European perspective, to discuss the scope of the Bolar exemption and place it in the wider context of third party supply of active pharmaceutical ingredients to generic drug manufacturers.

There is no doubt, that the scope of the Bolar exemption has significant practical implications. Generic companies are often much smaller than the innovative drug

15 Cook Trevor 'A European Perspective as to the Extent to which Experimental Use, and Certain Other Defences to Patent Infringement, Apply to Differing Types of Research. A Report for the Intellectual Property Institute.,' March 2006, p. 4
16 Roche Products v. Bolar Pharmaceuticals, 733 F.2d 858 (Fed. Cir. 1984)
manufacturers and are therefore unable to produce the active pharmaceutical ingredients necessary for clinical trials and the production of their own products. This leads to generic companies being dependent on third party supply of active pharmaceutical ingredients.

1.6. Research questions

After setting the scene for this thesis with a brief introduction to the pharmaceutical industry, the patent system and the two exemptions to the exclusive patent rights, the two research questions underlying this thesis that need to be identified are:

1. How far does the protection of the Bolar exemption extend, as implemented by the legislation and interpreted by the case law in the United Kingdom, Germany, Denmark and Poland?
2. Is the supply of patent protected active pharmaceutical ingredients by a third party to a generics company, intended for use in the clinical trials necessary to obtain a marketing authorisation, exempt from patent infringement under the European Bolar exemption?

1.7. Legal method

This thesis has been researched and written using two legal methods: the traditional legal dogmatic approach and the comparative analysis approach. The legal dogmatic approach has been chosen for describing and investigating patent law rules applicable in the cases, where generic or innovative pharmaceutical companies wish to obtain a marketing authorisation for a new medicinal product using data generated in clinical trials conducted on third-party patented products or active ingredients. It is also this approach, which is used to assess the significance of these legal rules for the pharmaceutical and generic industries and the patent system in general.

Chapter 2 and 3 concentrate on the law applicable under research use and Bolar exemptions and provide for a descriptive analysis of the rules in primary legal sources such as the UK Patents Act and the German Patent Law. The rules are reviewed objectively. In order to comment on the significance of the rules, relevant case law is considered in which Courts have interpreted the above-mentioned exemptions. Where appropriate, legal commentary and travaux préparatoires have been used. These chapters set the scene for the main body of the thesis. Both chapters however end with a brief discussion and conclusion on the rules applicable. Chapter 4 and 5 form the main body of this work. Chapter 4 focuses on the only case law interpreting the scope of the Bolar exemption in Europe with the special focus on third party suppliers. This has the aim of investigating how far the protection of this exemption extends and what kind of activities are exempted from infringement. Chapter 5 discusses various political implications of the rules described in the previous chapters. These legal rules and their interpretation are looked at more critically than descriptively in this chapter. Chapter 6 concludes the thesis. The last
two chapters of this thesis form the analytical part of the work, while the first four a more descriptive one. This distinction however is not absolute because Chapter 2, 3 and 4 each contain its own conclusion and discussion, and these have certain analytical elements.

The second legal method used is the comparative analysis approach. Common law rules in the United Kingdom are compared to civil law rules in Germany and Denmark. The similarities and differences between the systems are emphasized with the aim of exposing different interpretations of the same research use and Bolar exemptions. As this thesis is written in Denmark, a reference to Danish law and its interpretation of the two exemptions is included. Additionally, in Chapter 3, Bolar exemption in Poland is outlined due to a Polish case being discussed and analysed later in Chapter 4. The comparative analysis approach exposes different solutions to the same problems shared by the various jurisdictions. These concerns are discussed and solutions compared. Chapter 5 seeks to point out strengths and weaknesses of the different implementations of the Bolar exemption. The comparative analysis in Chapter 2 is used to discuss differing interpretation of the law through case law in the United Kingdom and Germany, while in Chapter 3 the approach is used to contrast the different national implementation of Article 10(6) of the Directive. The sources used for researching and writing this thesis are statutes (legislation), precedent (case law), government guidelines, preparatory works, scholarly articles, academic books and commentaries, online blogs and updates.

1.8. Organisation of the thesis

The thesis starts with a short introduction to the scene of pharmaceutical industry, and the topics of medicines, marketing authorisations, research use exemption and Bolar exemption. Chapter 1 ends with the outline of the research question and a description of the legal method used to research and write this thesis.

Chapter 2 introduces the research use exemption and its origins in the Community Patent Convention. It then described the way the exemption has been implemented in the United Kingdom, Germany and Denmark and compares the way it has been interpreted by the courts in these jurisdictions.

Chapters 3, 4 and 5 constitute the main body of the thesis. Chapter 3 describes the origins of the Bolar exemption in Europe, the legislative history of this provision and its implementation, focusing on four specific jurisdictions, namely the United Kingdom, Germany, Denmark and Poland. Special attention is paid to the very recent amendment made to the English research use exemption, which has the effect of broadening the scope of the Bolar exemption. A comparison of approaches in these four jurisdictions is made. Poland is included in Chapter 3 for the reasons of transparency. The following chapter, Chapter 4, describes and discusses a decision of a Polish court in a Polish case decided on the scope of Bolar exemption under the Polish law.
Chapter 4 focuses on the case of *Astellas v Polpharma*, the only case to date, which concerned the scope of the Bolar exemption and specifically, whether it applies to third-party suppliers of patent-protected active pharmaceutical ingredients. The case was tried in court of both Poland and Germany; therefore decisions from both Polish and German courts are described in Chapter 4, as well as the questions referred by the Dusseldorf Court to the Court of Justice of the European Union (CJEU). These court decisions are the only judicial interpretation of the scope of the Bolar exemption to date.

Chapter 5 consists of the discussion on the issues arising from the previous chapter: firstly, what would a hypothetical ruling from the CJEU in the *Astellas* case be and why, and secondly, what practical advice can be given to third party suppliers delivering patented active ingredients to pharmaceutical companies so that they can avoid infringing patent rights.

Chapter 6 concludes the thesis. It contains the outline of the issues discussed and summarizes the conclusions made in the different chapters. It also offers a more general discussion of the Bolar exemption, reflections on the problems and the significance of the exemption for the pharmaceutical industry and some thoughts on future developments.
Chapter 2. Research use exemption

2.1 Introduction

Most European countries have adopted into their national laws the exemption found in Article 31(b) of the Community Patent Convention of 1975, which was transposed into Article 27(b) of the Community Patent Convention as adopted by the Agreement Relating to Community Patents of 1989,\textsuperscript{17} in a wording very similar or identical to that of the Article:

' The rights conferred by a Community patent shall 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'

Article 27(b) is a statutory implementation of the so-called research use exemption and its interpretation under national laws of United Kingdom, Germany and Denmark will be discussed in this Chapter. This exemption consists of two elements or limbs: 'experimental purposes' and 'relating to subject-matter of the invention'. Most of the case law, including the cases discussed below, relate to safety and efficacy studies, or clinical trials, of pharmaceuticals undertaken in order to satisfy the requirements of a regulatory authority, namely what constitutes 'experimental purposes'. The main focus of the case law has been on whether or not such clinical studies and trials constitute 'experiments' rather than whether they are conducted in relation 'to the subject matter of the invention'.\textsuperscript{18} For the research use exemption to fully apply it is necessary that both limbs of the exemption apply to the activity in question. However, the discussion on the second limb ('relating to the subject matter of the invention') is beyond the scope of this thesis.

2.2. United Kingdom

The UK Patents Act 1977 contains two exemptions from patent infringement relating to research and experimental use. The first one, discussed in this section is the research use exemption, enshrined in section 60(5)(b) of the Act. It allows the use of a patented invention for research purposes relating to the subject matter of the invention. The second exemption is the Bolar exemption in section 60(5)(i) of the Act, introduced into UK legislation as a result of the Directive 2001/83. The UK Bolar exemption is discussed in detail in Chapter 3, paragraph 3.4.1.

The Patents Act 1977, chapter 37, section 60(5) mirrors in its wording Article 27(b) of the Community Patent Convention, and states that:

\textsuperscript{17} Agreement Relating to Community Patents, 89/695/EEC, done at Luxembourg on 15 December 1989, Official Journal L 401, 30/12/1989 p. 0001 - 0027
\textsuperscript{18} Cook Trevor 'A European Perspective as to the Extent to which Experimental Use, and Certain Other Defences to Patent Infringement, Apply to Differing Types of Research', A Report for the Intellectual Property Institute', March 2006, p. 27
‘an act which, apart from this subsection, would constitute an infringement of a patent for an invention shall not do so if:
(a) it is done privately and for purposes which are not commercial;
(b) it is done for experimental purposes relating to the subject matter of the patented invention.’  

There has been much dispute on the scope and the interpretation of the above research exemption. For example, would the research need to be conducted with only restricted access or openly or ‘publicly’ in order for it to be non-commercial? Does the publication of the scientific results automatically make the research ‘non-private’ and thus commercial, and hence exclude it from the scope of the exemption?

The Court of Appeal had considered the issues of research and trials into a patent protected product, purpose of any such research and when it can be said to infringe the patent, in the case of Monsanto v. Stauffer.  

‘trials carried out in order to demonstrate to a third party that a product works, or in order to amass information to satisfy a third party, whether a customer or body […], that the product works as its maker claims are not […] to be regarded as acts done ‘for experimental purposes’”.

The case concerned field trials undertaken by Stauffer using a herbicide known to infringe Monsanto’s patent. The trials were conducted in order to obtain the equivalent of a marketing authorisation for Stauffer’s product. There was no legal requirement of a prior authorisation before a product could be placed on the market in 1985. Instead, a non-statutory ‘clearance’ was operated. It was the trials directed at obtaining this clearance that were in question.

The case established that the research use exemption would not cover activities performed for the purpose of obtaining a regulatory approval. However, experiments performed to find out something new may be exempted ‘in so far as they relate to the subject matter of the invention’. The Court recognized that all activities performed by companies have ‘commercial interests in view and that this fact alone did not defeat the research use exemption’. In the example given by the Court, ‘an experiment limited to determining capacity to manufacture a quality product commercially in accordance with the patent specifications would be covered

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19 This section also contains the Bolar exemption, discussed below in Chapter 3.
20 Monsanto Co. v. Stauffer Chemical Co. [1985], FSR 55; RPC 515
21 Ibid. at 542 per Lord Justice Dillon
22 Marketing authorisation and the requirement of conducting the necessary trials were first introduced by Council Directive 91/414 of 15 July 1991 concerning the placing of plant protection products on the market
23 Edwards Wildman 'Experimental use and Bolar exemptions in the EU – how far do these provisions extend?', available at http://www.edwardswildman.com/insights/publicationdetail.aspx?publication=8ac4f036-2979-44b8-b04f-7768c78bacba
by the exemption’. Accordingly, an act can in fact have an ultimate commercial purpose. The Court explained its reasoning by comparing the wording of sub-paragraph (b) to that of (a):

'The distinction between the wording of sub-head (a) and the wording of sub-head (b) in section 60(5) indicates that experimental purposes in sub-head (b) may yet have a commercial end in view...'  

In order to limit the scope of the exemption, the Court defined the word ‘experiment’ as ‘trials carried out in order to discover something unknown or to test a hypothesis or even to find out whether something which is known to work in specific conditions (...)’ But tests carried out in order to gather information to satisfy a third party, whether a customer or a regulatory body, or demonstrate to a third party that a product works do not qualify as acts done ‘for experimental purposes.’ Preliminary work, directed at issues such as whether one can actually perform the invention or improve on it, would however be covered by the exemption.

The Court recognized a potential difficulty in always determining the trial’s purpose. A trial may also have a mixed purpose. It is therefore for the courts to define the purpose of the particular activity in each case. Generally, where the aim of a trial is mixed (partly research and partly commercial use), English law will most probably favour a narrow approach that considers the trials and its aim to be infringing.

On the facts and the evidence before it, and keeping in mind that field trials need to have an experimental purpose and aim at finding something unknown about the product, the Court found that field trials conducted by the defendant were not experimental and thus an infringement of patent holder’s exclusive rights. It was not clear from the evidence presented to the Court what the defendants still wanted to find out about their product that was not already known.

Although Monsanto concerned a matter not related to the pharmaceutical products, the general wording of the judgment meant it also applied to trials on and for pharmaceutical products. The decision has never been overruled by a higher UK Court.

Accordingly, whereas section 60(5)(a) allows for unauthorized individuals or organizations to engage in research on or with the patented invention, so long as the research is private and non-commercial, section 60(5)(b) only permits unauthorized

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25 Monsanto Co. v. Stauffer Chemical Co. [1985], RPC 515, at 538
26 Monsanto Co. v. Stauffer Chemical Co. [1985], RPC 515, at 538
27 Monsanto Co. v. Stauffer Chemical Co. [1985] RPC 515, at 542.
28 Ibid.
29 Ibid at 542.
31 Cook Trevor 'A European Perspective as to the Extent to which Experimental Use, and Certain Other Defences to Patent Infringement, Apply to Differing Types of Research. A Report for the Intellectual Property Institute', March 2006, p. 38
individuals to engage in research on the patented invention that takes the form of experiments and not clinical trails or demonstrations to third parties. \(^{33}\) Thus, in order to provide a true exemption for clinical trials performed for the purpose of obtaining data necessary for a marketing authorisation a separate statutory provision needed to introduce a regulatory review exemption into UK patent law (discussed in detail in Chapter 3 below).

No further analysis of the research use exemption took place in Europe until the decision of the German Federal Supreme Court described below.

2.3. Germany

Research use exemption in Germany is, like the English exemption, modelled on Article 27(b) of the Community Patent Convention. It has been implemented into German law by §11(2) of the German Patent Law, which states:

'The effects of the patent shall not extend to:

1. acts done privately and for non-commercial purposes;
2. acts done for experimental purposes relating to subject matter of the patented invention; ...' \(^{34}\)

Even though the provision looks practically the same as the one in England, the German courts have interpreted it differently in two very important case involving clinical trials.

2.3.1. Clinical Trials \(^{35}\)

The specific issue before the Court was whether the exemption in §11(2) applied to a wide range of safety and efficacy clinical trials conducted on the protein gamma-interferon, which was believed to have therapeutic potential as a medicinal product. The patent holder did not at the time himself secured a marketing authorisation for the use of the patented substance in any indications. \(^{36}\)

The German Federal Supreme Court reversed the decision of the Dusseldorf Appeal Court and held that the use of a patented active pharmaceutical substance in clinical trials, whose purpose was obtaining data necessary for a marketing authorisation application for a new medicinal product for a second, not-yet patented use of the patented active substance was allowed under the research use exemption.


\(^{34}\) German Patent Law §11(2), full text in English available at http://www.wipo.int/wipolex/en/text.jsp?file_id=126259. This provision also includes the Bolar exemption provision, discussed below in Chapter 3.

\(^{35}\) Klinische Versuche (Clinical Trials) (1997) RPC, 623 (Federal Supreme Court of Germany)

\(^{36}\) Cook Trevor 'A European Perspective as to the Extent to which Experimental Use, and Certain Other Defences to Patent Infringement, Apply to Differing Types of Research', A Report for the Intellectual Property Institute, March 2006, p. 29
The German Federal Supreme Court stated:

'The wording of the Act when examined naturally rather indicates that §11(2) of the Patent Act in principle exempts all experimental acts as long as they serve to gain information and thus to carry out scientific research into the subject-matter of the invention, including its use (...) Since the provision makes no limit, either qualitative or quantitative, on the experimental acts, it cannot matter whether the experiments are used only to check the statements made in the patent or else to obtain further research results, and whether they are employed for wider purposes, such as commercial interests...'

Like the English court in Monsanto, the Federal Supreme Court held that §11(2) of the Patent Act is concerned with the purpose of the activity, rather than the type of activity taking place. The court gave a broad interpretation to the word 'experiment', holding that it includes 'any procedure for obtaining information irrespective of the intended use of the information, provided that the experiment relates to the subject matter of the invention'. As evidenced by the passage quoted above, the Court was of the opinion that statutory language contains neither quantitative nor qualitative limits on the experiments that can be conducted under the exemption. As a result, all experiments, which satisfy the initial requirement of an experimental purpose, will fall within the scope of §11(2), irrespective of how the results of these experiments are subsequently used.

In support of its decision the Court considered general public policy issues involved in the exemption. The Court stated that 'further technical development is in the public interest and is the aim of patent law'. The reason for conferring the exclusive patent rights is the recognition for a particular contribution to technical knowledge and industry as well as provision of remuneration for the inventor, also to be regarded as encouragement of further contributions. Since patent law 'aims at promoting technical progress' and stimulating innovation for, but not at inhibiting research and development in an unreasonable way, 'it would be inconsistent with this purpose to exclude experimental acts, which serve research and further technical development. From the viewpoint of the further technical development in the general interest, which is the aim of patent law, it is therefore appropriate to exempt clinical trials and investigations with active substances experimental acts as long as these experiments are directly aimed at obtaining information'.

Accordingly, acts performed to determine the effects of an active pharmaceutical substance or to ascertain its new medical uses have been interpreted to be within the scope of the German research use exemption. This also means that,

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38 Ibid. at 638.
39 Ibid. at 639.
40 Ibid. at 643. Quoted in Cook Trevor 'A European Perspective as to the Extent to which Experimental Use, and Certain Other Defences to Patent Infringement, Apply to Differing Types of Research', A Report for the Intellectual Property Institute, March 2006, p. 30
41 Klinische Versuche (Clinical Trials) I [1997] RPC. 623, at 646.
unauthorized uses of the patented invention for purposes of obtaining data necessary for regulatory review and approval are within the scope of §11(2). It is noteworthy since the language of the German §11(2) is almost identical to that of section 60(5)(b) of the UK Patent Act, which has been interpreted by the UK courts in a much stricter fashion in Monsanto.

2.3.2. Clinical Trials II 42

In Clinical Trials II another protein, erythropoietin, was protected by a patent. It had known therapeutic value as a medicinal product. The defendant had produced the same protein as the patent holder but used a different procedure. He then used the patented protein in clinical trials with three purposes: verification of certain animal test results; generation of data necessary for obtaining an official pharmaceutical permission to market the product; and comparison of certain properties of the patented protein against his own version. 43

The German Federal Supreme Court held that the generation of clinical data legitimately required to obtain a marketing approval could qualify for the research use exception, as long as the research is not performed solely to demonstrate bioequivalency but can be also considered as aimed at discovering something unknown about the pharmaceutical substance or product in question. 44 The only requirement is that the trials conducted must be directed towards the generation of information. Clinical trials are also permitted when conducted for the same indication as that of the patent-protected product. It does not matter whether the information generated by clinical trials and research is used afterwards for obtaining a marketing approval. In the words of the Court:

‘... The wording of §11(2) of the Patent Act, (...) as well as its meaning and purpose speaks for the fact that clinical research in which the digestibility and effectivity of a pharmaceutical contained in a protected active agent are tested on human beings is exempted even in the event that these tests were undertaken with the purpose of obtaining data necessary for the obtainment of legal pharmaceutical authorisation. This does not in any way mean that research activities of any and every sort are exempted (...)’ 45

Just like the Court of Appeal in Monsanto, the Court defined the range of permissible activities by making a distinction between what will and will not qualify as an experiment. 46 Therefore, experiments must relate to ‘technological theory’ and cannot be conducted in ‘a volume that would no longer be justifiable’ on research

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42 Klinische Versuche (Clinical Trials) II, [1998] RPC 423 (Federal Supreme Court of Germany)
46 Ibid at 434.
grounds. 47 Experiments carried out with the purpose of ‘persistently disturbing or hindering the inventor’s distribution of his product’ or ‘accomplishment of competitive purposes’ or aiming at clarification of ‘commercial facts such as the needs of the market, acceptance of process, and possibilities of distribution’ will not be permissible. 48

The Court also held that commercial purpose would not ‘from the outset turn the commercial activity into an impermissible patent infringement.’49 Article 27(b) of the Community Patent Convention does not mention any limits for experiments with commercial goals, and the Court seemed to have implied that if the legislators wished to have set such limits they would have included them in the text of the Convention. 50

2.3.3. Conclusion – German position

Initially only experiments aimed at finding new, unknown uses were exempted under the German research exemption (decision in Clinical Trials I). However, after the decision in Clinical Trials II, experiments were also permitted directed at finding data on characteristics and effects of the patented active substance within the limits of the indications already known (the so-called indication experiments). The following trials and tests are thus permissible today under §11(2) of the German Patent Act:

- finding indications and contra-indications within and beyond known fields of application,
- analyzing the pharmaceutical form and dosage of an active substance to discover a cure for or to relieve certain illnesses,
- finding clinically-relevant differences over other products, in particular the effectiveness and tolerance thereof as well as
- testing by plant protection authorities in field trials of a patented active substance of a plant-treatment agent. 51

The limitation placed by the Court on the applicability of the research exemption was that only those tests that are directed at the technical findings of the patented invention are harmless but not those aiming exclusively at satisfying a commercial interest. Obtaining technical or scientific findings may not only be a secondary purpose of the trial on the patented invention. Furthermore, the experiments may only be carried out to an extent and in a volume justifying the research purpose. 52

48 Ibid.
49 Ibid, at 434
52 Ibid.
As a result of the above case law, Germany is perceived as being one of the more open-minded countries in Europe with regard to the research use exception in general, and with regard to clinical trials conducted with the aim of finding new indications for old substances or for obtaining marketing authorisations for patented indications that are still protected. 53

A few years after the German Federal Supreme Court had rendered its Clinical Trials II decision, Germany along with other European countries adopted a Bolar-type regulatory approval exemption, which complements the existing research use exemptions. The Bolar exemption is described in more detail in Chapter 3 below.

2.4. Denmark

A research use exemption is recognised under Danish Patent Act in Article 3(3), subpoint 3, which states:

‘3. The exclusive right shall not extend to: (…) (3) acts done for experimental purposes relating to the subject matter of the patented invention’.

The exemption came into force with §1 of Executive Act No. 264 introduced on 8 June 1978. It is evident from the explanatory notes that the exclusive patent rights do not apply to activities carried out as experiments on the subject matter of the patented invention. The provision corresponds therefore to Article 27(b) of the Community Patent Convention. 54 It is to be noted that at the time of introduction of the research use exemption in its present form, it was not allowed to patent medicinal products, but only processes for their manufacture. Obtaining a product patent for a medicinal product became first possible from 1 December 1983, when the Executive Order No. 450 of 16 September 1983 was passed.

Danish research use exemption does not make a distinction concerning the nature of the organization conducting the experimentation or research. It is therefore irrelevant whether the organization is commercial or a non-profit entity. In other words the exemption is not restricted to non-commercial purposes. The Danish law does not define the concepts ‘experimental use’ or ‘research’. 55

54 Folketingstidende 1977-1978, Supplement A, columns 2020-2021
Thereby, it is also possible to undertake the so-called ‘reverse engineering’ and other similar analysis of the patented invention, though always on the condition that the activity is undertaken for experimental purposes.

There is to date no Danish case law on the scope or interpretation of the research use exemption, but it should be assumed that the exemption is to be interpreted narrowly. An example of a court’s interpretation can however be found in Norwegian law. The majority of the Norwegian Supreme Court found that the exemption only gives a right ‘to generate new knowledge’ and should be construed narrowly. The Court emphasized that the research use exception and the right to acquire new knowledge does not mean that a research institution can exploit such knowledge commercially by selling the new product based on the acquired knowledge without being liable for a patent infringement. One should distinguish between research work on one hand and the exploitation of the patented invention, or the commercial exploitation of essential means of the patented invention on the other hand. It is interesting to note that this decision had a dissent. Two out of five justices of the Supreme Court found that the work of the research institute fell within the research use exemption and that delivering the results of that work was also covered by the exemption.

2.5. Comparative analysis

In order to fully grasp the importance and the reasons behind the introduction of the Bolar exemption into EU law, it is necessary to look at and to analyse the scope and interpretation of the research use exemption in Europe. It provides a valuable insight into the challenges faced by both the generic and innovative drug manufacturers wishing to undertake clinical trials using patent-protected substances or products. The scope of the research use exemption differs throughout Europe, as demonstrated by the example of England and, to certain extend, Denmark on one hand representing the narrow interpretation, and Germany on the other embodying the broad interpretation.

To a large extend, the scope of the defence depends on the way ‘experimental purpose’ or ‘experiments’ are defined. According to Monsanto if it can be shown that the purpose of the activity was to discover something unknown or to test a

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56 Reverse engineering is the process of extracting design or knowledge information from any man-made product in order to duplicate or enhance the original product.


hypothesis, it would be regarded as an experiment. It can however be the case that purposes for which tests and trials are carried out may sometimes be mixed and in some cases difficult to discern. The definition of 'experimental purposes' adopted by Monsanto is generally agreed upon. The Federal Supreme Court of Germany employed a similar definition in Clinical Trials I, i.e. any systematic procedure aimed at obtaining new information is considered an experiment within the meaning of section 11(2) of the German Patent Act. It seems appropriate to say that according to Clinical Trials decisions an act will be deemed to be experimental if it seeks to generate new information but the act will not classify as an experiment if it seeks to do no more than verify existing knowledge. Furthermore, the Supreme Federal Court of Germany emphasized that the term 'experimental purposes' is broadly construed and the only limitation of relevance is actually whether such experimental purposes relate to the 'subject-matter of the invention'. This would even extend to research into possible new uses of a patented invention or substance, and even if there is an associated commercial purpose to the experimentation.

There is no definition of the concepts 'experimental use' or 'research' under the Danish law, or any case law interpreting the scope of the research use exemption. Some guidance can perhaps be found in Norwegian law and a Supreme Court decision, which found that the exemption only gives a right 'to generate new knowledge' and should be construed narrowly. It seems therefore, that the scope of the Danish research use exemption resembles that of the English section 60(5)(b) more than the German §11(2).

With respect to the range of permissible activities that can be performed under the research use exemption, Germany provides for the broadest interpretation permitting a fair amount of commercial-orientated activities. Thus, it may well be that clinical trials performed exclusively to gather information are not covered by the §11(2) exception. But the Federal Supreme Court was of the opinion that the ultimate purpose of the studies and experimental acts is not decisive. Thus tests aimed at commercial exploitation of the results may also be carried out. This is somewhat in contrast to the English interpretation of the provisions on experimental use. Even though the English Court of Appeal has not completely rejected the idea of a commercial purpose, it warned that the idea should be treated with caution. Since section 60(5)(b) of the Patents Act does not mention the need or experimental purposes to be non-commercial, it is possible that experimental acts can be carried out which may ultimately lead to a commercial benefit. An issue worth considering in this context is the difficulty in drawing lines between commercially and non-

61 Monsanto Co. v. Stauffer Chemical Co. [1985] RPC 515, at 515.
62 Ibid, at 542 per LJ Dillon
64 Klinische Versuche (Clinical Trials) I [1997] RPC. 623
65 Klinische Versuche (Clinical Trials) II [1998] RPC 423
commercially motivated uses in today’s research landscape. On the one hand, it would not make any sense to limit the exemption to academic research only; universities acquire considerable revenue from patent licensing and business corporations often sponsor university research. On the other hand, business corporations, which normally are seen as the actors with purely commercial interests, are increasingly engaged in performing basis research and funding such research in universities and other academic settings. As mentioned above, the German interpretation of the exemption is more liberal in regards to the purpose of the experiments being commercial. The Court in Clinical Trials I said that it would not matter whether the experiments are carried out for wider purposes than research, for example commercial purposes. Clinical Trials II have confirmed this view and further added that the commercial orientation does not from the outset turn the experimental activity into an impermissible infringement of patent rights.

It seems like the issue of commercial motives behind experimental use has to yet be considered by the English courts in detail. It has however been suggested that it is more likely to fall outside the scope of the research use exemption. In 2009, the English Patents Court seems to have somewhat accepted the general approach as advocated for by the Clinical Trials I and II cases, but modified it slightly by suggesting that the assessment of whether ‘experimental use’ exists ‘should involve the considerations whether the immediate purpose of the transaction in question is to generate revenue’. There is no doubt that this issue will become more pressing given the tendency of public institutions that have traditionally relied on the research use exemption, such as universities, to commercialize their research results.

Under the Danish research use exemption there is no differentiation between a commercial or non-commercial (non-profit) nature of the organization undertaking the experiments. The exemption is similarly not restricted to non-commercial purposes. As an example of activity falling within the scope of the exemption reverse engineering has been mentioned in literature along with other similar analysis of the patented invention. The only condition is that the activity is conducted for experimental purposes, regardless of whether these are commercial or not. By being open to commercial purposes, the scope of the Danish exemption resembles that of the German §11(2) of the Patents Act, as interpreted by the Court in Clinical Trials I and II.

One of the most problematic aspects of the Monsanto decision is its exclusion of ‘trials carried out in order to amass information to satisfy a third party, whether a customer or a [regulatory] body (...) that the product works as its maker claims’ from the scope of the exemption. As explained in the introduction, generic and innovative

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68 Ibid.
69 Inhale Therapeutic Systems v Quadrant Healthcare [2002] RPC 419, at 463
70 Corevalue Inc v Edwards Lifesciences [2009] FSR 8, at para. 77
companies often use patented medicine or active ingredients to conduct the trials and studies necessary to obtain a marketing authorisation for their new product. Due to the narrow interpretation of the exemption in Monsanto, these kinds of trials and tests have been interpreted as falling outside the scope of the research use exemption in the UK. This view has been confirmed in another case, Auchincloss v. Agricultural & Veterinary Supplies, 71 decided 12 years after Monsanto. Auchincloss established that making a product for the purpose of obtaining official marketing authorisation is an infringement of the patent covering the product. The argument of the Court was that the trials carried out to gather information to support an attempt to gain an authorisation for a new use of a patented product (to be used once the patent has expired) were for commercial rather than scientific purposes. The Court of Appeal reasoned, applying Monsanto, that the sample (manufactured as a result of the trials) was made to obtain official approval and not to discover something unknown or test a hypothesis. Its manufacture was therefore not done for experimental purposes. The Court then went on to state that if the sample ‘had been produced during genuine experiments and been used for such experiments, it would have concluded that such experiments were done in relation to the subject matter of the invention’. Some authors, including Trevor Cook, derived from the above observation a tacit acceptance of the principle established by the German Federal Supreme Court in Clinical Trials ‘that supplying data to a regulatory body does not deprive the activity which gave rise to such data from the benefit of the defence for experimental purposes relating to the subject matter of the invention, provided that such activities were indeed experimental and did related to such subject matter.’ 72 This interpretation is certainly consistent with the decision in Clinical Trials I and II but it is doubtful whether the Court of Appeal meant for its comment to symbolize some kind of softening of approach towards experimental activities undertaken to obtain a regulatory approval for a product.

There is no legal commentary or case law in Denmark which provide guidance on whether experiments conducted for the purpose of acquiring an official regulatory or marketing authorisation would be exempted under Article 3(3), subpoint 3 of the Danish Patents Act.

It is important to note that the research use exemption in the UK (section 60(5)(b)) has recently been changed to include performance of clinical trials for the purpose of obtaining a marketing authorisation in its scope. The new exemption, which also and its implementation are described in detail below in Chapter 3.

The interpretation and scope of the research use exemption in Europe remain rather erratic. The exemption functions across European jurisdictions without any degree of harmonisation. Sadly, there has been no chance or scope for any guidance on the matter of the research exemption from the ECJ. This is due to the current limited

71 Auchincloss v Agricultural & Veterinary Supplies Ltd [1997] RPC 649 (Patents Court) and [1999] RPC 397 (Court of Appeal)
72 Cook Trevor 'A European Perspective as to the Extent to which Experimental Use, and Certain Other Defences to Patent Infringement, Apply to Differing Types of Research', A Report for the Intellectual Property Institute, March 2006, p. 40
scope of harmonisation of patent law under Community law, Biotechnology Directive being the only area of law to date harmonised on the European level.\textsuperscript{73} It was the desire to remove the uncertainty, as described and discussed in this section, surrounding the research use exemption, along with its varying scope throughout the EU, that led to the introduction of the EU Bolar provision in the field of pharmaceuticals.

\textsuperscript{73} Directive 98/44 of 6 July 1998 on the legal protection of biotechnological inventions, OJ L 213, 30.7.98, p. 13
Chapter 3. The EU Bolar Exemption

3.1. Introduction

Different national patent laws, as interpreted by national courts, govern the research use exemption in Europe. As described above in Chapter 2, especially with regard to clinical trials, the scope of the research use provisions is unclear. Some countries, such as Germany, provide a broad exemption for clinical trials, while others, such as the UK, have an exemption with a narrower scope.

In order to harmonise the law in this area and to strengthen the European pharmaceutical industry (especially the generics sector), the EU introduced a new exemption in Article 10(6) of the ‘Community code relating to medicinal products for human use’: ⁷⁴

‘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 provision is modelled on its forerunner from the United States, which is discussed in more detail below in section 3.3. It is strictly speaking only a “Bolar-type” provision, as it is not identical to its American counterpart.

The road to the introduction of a Bolar exemption into European law was a rather complicated one. The purpose of this kind of exemption was to address the uncertainty about the scope of application of the research use exemption, discussed in Chapter 2 of this thesis.

In 1996, the European Parliament made a proposal for an exemption equivalent to the Bolar exemption in the US. ⁷⁵ This proposal was unsuccessful, because most of the Member States considered it unlikely that such an exemption would comply with Article 30 of the World’s Trade Organization’s Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). ⁷⁶ The research use of patented products remained governed according to national patent laws. It is therefore not surprising that the extent to which experiments were permitted differed between the Member States. The research use exemption in Europe originates in Article 27(b) of the Community Patent Convention as adopted by the Agreement Relating to Community


⁷⁶ Article 30 of TRIPS 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”
Bolar Exemption and Third Party Suppliers
Anna A. Pacyk Nielsen

Patent of 1989.\textsuperscript{77} Despite this common origin, approaches and interpretations taken by the Member States and their courts, differed greatly in various countries, most notably in the United Kingdom and in Germany, as discussed above in sections 2.2, 2.3 and 2.5.

The reason behind the introduction of the Bolar exemption into EU law through the Directives 2001/83 and 2004/27 was a case brought by the European Community (EC) against Canada before the World Trade Organization (WTO).\textsuperscript{78} The EC challenged the Canadian Patent Act, in particular the lack of protection of inventions in the area of pharmaceuticals under the relevant provisions of the Act. The Canadian Patent Act allowed for making and stockpiling of patent-protected medicinal products for a period of six months before the expiry of the patent. The EC claimed that Canada’s legislation was incompatible with its obligations under the TRIPS Agreement, because it did not provide for the full protection of pharmaceutical inventions for the whole duration of the patent protection term.\textsuperscript{79} The contested section of the Canadian Patent Act stated, \textit{inter alia}, that:

\begin{quote}
‘it is not an infringement of a patent for any person to make, construct, use or sell the patented invention solely for uses reasonably related to the development and submission of information required under the law of Canada, a province or a country other than Canada that regulates the manufacture, construction, use or sale of any product’.\textsuperscript{80}
\end{quote}

Thus, a regulatory approval and a stockpiling exemption existed under the Canadian law. Thereby it was allowed that a generic manufacturer, without the consent of the patent holder, used a patented invention firstly, to carry out necessary tests and trials to obtain marketing approval of a generic product before the relevant original patent expired; and secondly, to manufacture and stockpile the approved generic product for a period of up to six months before patent expiry.

Canada defended its legislation, arguing that both of the provisions challenged by the EC are ‘limited exemptions’ to the exclusive patent rights and are therefore compatible with Article 30 of the TRIPS Agreement. The WTO Panel found that the manufacturing and stockpiling exemption applied six months before the expiry of the patent is not a ‘limited exemption’ to the rights of the patentee and was therefore not covered by the exception in Article 30 of the TRIPS Agreement.

In contrast, the regulatory approval exemption was covered by the exception in Article 30 and was thought to be a ‘limited exemption’ as long as it was confined to


\textsuperscript{79} As envisaged by Articles 27.1, 28 and 33 of the TRIPS Agreement

\textsuperscript{80} Canadian Patent Act, Section 55.2(1), R.S.C., 1985
behaviour necessary to fulfil the requirements of the regulatory approval (marketing authorisation) process and ‘no commercial use was made of resulting products, even though the approval processes may require substantial amounts of test production to demonstrate reliable manufacturing’.  

The EU has accepted the decision of the WTO and designed the new rules in amending Directives 2001/83 and 2004/27 so that, the patent protection of a particular drug will not lead to an unnecessary delay of the marketing authorisation procedure that a generic manufacturer must comply with in order to satisfy the requirements of pharmaceutical legislation in the EU.

It is interesting to note that a general rule in a number of EU countries prior to the Canada – Patent Protection of Pharmaceutical Products case was that the required clinical trials and studies necessary for obtaining a marketing authorisation for a generic product could only take place after the expiry of the original patent. This legislation has severely impaired the ability of generic manufacturers to enter the market immediately after the expiry of the patent on the original medicinal product. It could take two years or longer before a generic product could lawfully be placed on the market in those countries. It thus happened often that generic manufacturers undertook clinical trials in countries outside of the EU where different rules applied or where the original reference medicinal products were not patent-protected. It was likewise common prior to May 2004 when 10 new member states joined the European Union that the development and production of generic medicine before the expiry of a patent tended to take place in then outside of the EU countries such as Hungary, Poland and Slovenia. This was due to the circumstances described above as well as the uncertainty with regard to the applicability and the scope of the research use exemption within the EU.

During the review of pharmaceutical regime, the European Commission focused therefore on striking the right balance between the interests of the innovative drug producers and those of the generics manufacturers. At the end of the review process, the Commission came to the conclusion that generic companies should be allowed to conduct trials necessary for obtaining a marketing authorization during the patent term of the original product.

This conclusion led to the introduction of the Directive 2001/83/EC and the amendment made thereto on March 31, 2004 to Article 10, point 6 of the Directive (quoted at the beginning of this section). It exempts from patent infringement the

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83 Ibid.
necessary studies and trials conducted with a view to generating the data required to obtain marketing authorization for a generic or biosimilar medicinal product.


The intention of the European Commission when drafting the Directive was to allow for marketing authorisation procedures during the term of a patent within the European Economic Area, so that generic drugs can be put on the market immediately after the expiration of the patent by demonstrating bioequivalence to an existing authorised medicinal product. On another aim of the Commission was to ensure that the clinical trials and studies, that are required in preparation for the application of a generic drug, no longer have to be conducted outside the Community for legal reasons.

Furthermore, recital 14 of Directive 2004/27 touches upon the aim as it underlines the necessity to favour manufacturers of generic drugs. It reads:

‘Since generic medicines account for a major part of the market in medicinal products, their access to the Community market should be facilitated in the light of the experience acquired.

Article 10(6) of Directive 2001/83/EC introduces the principle into European law in the light of which ‘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’ if they are performed for the purpose and in the course of obtaining a marketing approval for a generic or biosimilar medicinal product. The EU Bolar exemption is therefore by its wording limited to being applicable only in respect of obtaining marketing authorizations in the EU, for generic medicinal products or biosimilar/bioequivalent products.

The Directive sets a minimum standard for exemption and being a part-harmonization tool is given effect through the introduction of appropriate amendments to the national laws of EU Member States, including the German Patentgesetz (Patent Act) § 11(2)(b), the UK Patents Act section 60(5)(i), the Danish Patents Act Article 3(3) subpoint 4 (iv) and the Polish Prawo własności przemysłowej (Industrial Property Law)(Art 69 (1)(iv)).

It is clear that a party wishing to carry out trials necessary for obtaining marketing

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84 Communication from the Commission to the Council, the European Parliament, the Economic and Social Committee and the Committee of the Regions ‘A Stronger European-based Pharmaceutical Industry for the Benefit of the Patient – A Call for Action’, COM (2003) 383 final, p. 20
authorisation for a generic medicine is allowed to manufacture the needed quantity of the product under the Bolar exemption. What is however disputed is whether or not the manufacture and supply of such a product by a third party can fall within the ambit of the Bolar provision. This issue is discussed in detail in the following Chapter 4 and 5. Despite the Directive’s intention to harmonize European law, the exemption created its own uncertainty, especially in relation to what is meant by ‘trials’.

It is important to note that the European Bolar exemption supplements but does not replace the research use exemption described above in Chapter 2.

The limitation in the scope of the EU Bolar exemption can be seen from the way in which the provision interacts with other aspects of the pharmaceutical legislative regime, in particular regulatory data protection. Regulatory data protection offers a strong protection for the innovative drug manufacturers because it prevents their generic counterparts from using and referring to the original results of pre-clinical tests and clinical trials for the making of their own application for marketing authorization. Directive 2004/27 brought an important change to this regime. It introduced an eight-year period of data protection plus a two-year period of marketing protection (which then can further be extended by one year if, during the data protection period, the holder of the marketing authorization obtains an authorization for one or more new therapeutic indications). This means that for a period of ten or eleven years the original drug enjoys market exclusivity and a generic drug cannot be placed on the market during that period. In order not to place generic manufacturers at such a great disadvantage, the same Directive introduced the EU Bolar exemption. This simultaneous introduction of the new data protection regime and the Bolar exemption can be seen as a compromise between the generics and innovative industries.

3.3. Roche Products v Bolar Pharmaceutical

The case of Roche v Bolar Pharmaceuticals led to the introduction of the statutory regulatory review exemption into the US law. This exemption has been the model for the European ‘Bolar’ exemption (named after the US case), even though the European version is slightly different and is therefore only a Bolar-type exemption. Even though the US research use and Bolar exemptions are outside the scope of this thesis, the Bolar case itself provides an interesting background to the European exemption and is therefore worth mentioning.

Roche was the owner of the patent for flurazepam-HCl, the main active ingredient of the sleeping pill Dalmane. Bolar wanted to submit an application for a marketing authorisation, similar to the European abbreviated application, for a comparable drug containing the same active pharmaceutical ingredient and do so upon the expiry of Roche’s patent. The application required Bolar to show that it had a

87 Barnden Marina, ‘EU Bolar exemption is not so simple’, No. 182 Managing Intellectual Property, 2008, p.57
88 Art 1(8) of the Directive 2004/27,
89 Barnden Marina, ‘EU Bolar exemption is not so simple’, No. 182 Managing Intellectual Property, 2008, p.57
90 Roche Products v. Bolar Pharmaceuticals [1984] 733 F.2d 858 (Federal Circuit Court)
bioequivalent product and thus enable a speedy approval procedure by the US Food and Drug Administration. A short time before the expiry of the patent, Bolar obtained some of the active ingredient from a foreign manufacturer and began the studies necessary for obtaining a marketing authorisation pursuant to the abbreviated procedure.  

Roche filed a suit for patent infringement. At first instance, the Court held that no infringement had taken place because of the ‘experimental’ nature of Bolar’s works. The Court of Appeal for the Federal Circuit, however, disagreed with Bolar’s argument that its work fell within the scope of the common law research use exemption and instead ruled that the exemption was to be interpreted narrowly. The exemption was not to apply to experiments, which serve a commercial interest. Accordingly, experiments conducted for use in an abbreviated application for a market authorisation could not take place prior to the expiry of a patent.

In its judgement the Court stated:

‘We cannot construe the experimental use rule so broadly as to allow a violation of the patent laws in the guise of ‘scientific inquiry’, when that inquiry has definite, cognizable, and not insubstantial commercial purposes.’

The Court went on to state that Bolar’s intended ‘experimental’ use was solely for business purposes and not for amusement, and the unlicensed experiments conducted with a view to the adaption of the patented invention to the experimenter’s business is a violation of the rights of the patentee to exclude others from using his patented invention.

The Federal Circuit Court deciding Roche has therefore rejected to judicially create a regulatory review exception. Shortly after, the Congress passed the Drug Price Competition and Patent Restoration Act of 1984 (referred to as ‘Hatch-Waxman Act’). The Act added §271(e)(1) to the U.S. Patent Act’s definition of patent infringement:

‘It shall not be an act of infringement to make, use, or sell a patented invention (other than a new animal drug or veterinary biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Act of March 4, 1913))

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93 Roche Products v. Bolar Pharmaceuticals, at 863
94 Ibid.
solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs. 95

When adopting the provision, Congress was concerned that the Bolar decision had been decided wrongly and unfairly because of ‘the ability of patent holders to dominate research into and development of competitive alternatives during the patent term’, which would eventually end in the improper extension of the exclusive patent rights beyond the patent term. 96

This is the same concern as the one expressed by the European Commission, the generic industry and the commentators at the time of introduction of the regulatory approval exemption into European law.

3.4. The implementation of the Bolar exemption in Europe

As described in paragraph 3.2. above, Article 10(6) of Directive 2001/83/EC as amended, defines the minimum scope of the Bolar exemption. It requires EU Member States to exempt from patent infringement all studies and trials necessary for obtaining a marketing authorisation for a generic medicinal product. The Directive refers in its wording only to authorisations for generic medicines and does not explicitly mention clinical trials designed to secure authorisations for innovative medicinal products.

EU Member States have taken different approaches when implementing Article 10(6). Some States, such as the United Kingdom until recently, chose to follow the wording of the Directive closely, while others such Germany and Denmark, have implemented the provision as exempting all clinical trials, both for generic and innovative drugs. The implementation of the Bolar exemption in four jurisdictions (United Kingdom, Germany, Denmark and Poland) will be described and compared in this Chapter.

3.4.1. United Kingdom

The implementation of the Bolar exemption in the United Kingdom provides an interesting case study due to the recent amendment of the law. It is noteworthy that the amendment was in fact made to the research use exemption, namely section 60(5) of the Patents Act 1977, but it directly affects the scope and interpretation of the Bolar exemption, which is why it is discussed under this section.

3.4.1.1. The pre-October 2014 position

The Directive’s Article 10(6) has been implemented into English law by section 60(5) of the Patents Act 1977:

(5) an act which, apart from this subsection, would constitute an infringement of a patent for an invention shall not do so if:

(...) it consist 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 2011/82/EC or paragraphs 1 to 4 of Article 10 of Directive 2011/83/EC [the regulatory approval processes of the two directives], or

(ii) any other act which is required for the purpose of the application of those paragraphs.’

Section 60(5) lists therefore circumstances in which certain acts, which would otherwise constitute an infringement of a patent, are regarded not to be. The provision is very similar to the wording of the Directive itself, and thus may be interpreted by analysis of the legislative history and commentary to the Directive. It represents the narrow approach to implementation of the Bolar exemption and therefore only clinical trials necessary for obtaining a marketing authorisation for a generic medicinal product are exempted under the UK law.

The Medicines and Healthcare Products Regulatory Agency (MHRA) and the UK Intellectual Property Office (UKIPO) issued a useful guidance on the interpretation and the scope of the Bolar exemption in the UK. 97 This guidance is not a binding legal document but provides assistance to, for example, courts in their interpretation of the scope of the exemption. The MHRA listed those activities that, in its view, would be covered by the exemption:

‘i.) the carrying out of chemical and biological synthetic processes suitable for the making, disposal or keeping of the active substance(s) including the manufacture or the import of batches in quantities sufficient to provide material for preparing investigative batches of the medicinal product and to validate the processes to the satisfaction of the competent authorities

ii.) the development, testing and use of the associated analytical techniques for the above

iii.) the development of the final pharmaceutical composition and manufacturing processes for the medicinal product to be marketed including the making, disposal or keeping or import of product batches in quantities sufficient to conduct the necessary pre-clinical tests, clinical and bioavailability trials and stability studies of the medicinal product and to validate the processes to the satisfaction of the competent authorities

iv.) the development, testing and use of the associated analytical techniques for the above

v.) the manufacture and supply to the competent authorities of samples of active substances, their precursors, intermediates or impurities and of finished product samples

vi.) the compilation and submission of a marketing authorisation or Variation application and application for a marketing authorisation.

The exemption would however not include 'the manufacture, packaging and testing of the active substance or finished product not required for conducting the tests and trials necessary for gaining an authorisation'. The guidance also excludes stockpiling from the scope of the Bolar exemption.

It is clear from the above list that the MHRA considers that section 60(5)(i) covers all activities that are necessary to support an application for a generic marketing authorization. Activities that are not a condition of such authorisation will not be covered (such as comparability studies done for the purposes of a decision on pricing).

The wording of the UK Bolar exemption is restrictive in terms of the type of application covered. In the words of the guidance:

'It is our view that the non-infringing study and trial activities could be carried out as from the date of the proposed amendment to patent legislation in the UK... as long as those activities are for the purposes of submitting an application under Article 10 paragraphs 1, 2, 3 and 4 of the 2001 Directive.'

Since innovative drug manufacturers could not rely on the Bolar exemption when conducting the clinical trials and studies, they were forced to rely on section 60(5)(b) of the Act (the research use exemption). This was considered to be an obstacle to clinical trials taking place in the UK.

3.4.1.2. The new position

The restrictive interpretation of the Bolar exemption in the UK made it difficult for innovative pharmaceutical companies to conduct their research and development in the UK. They would choose to conduct their pharmaceutical research somewhere else with a more favorable environment, because of the legal uncertainty in the UK caused by the decision in Monsanto, with regards to whether

99 Ibid.
100 The list is also cited in Cook Trevor, 'Pharmaceuticals Biotechnology ad the Law', 2nd edition, published by Lexis Nexis, 2009, United Kingdom, p. 547
101 Barnden Marina, 'EU Bolar exemption is not so simple', No. 182 Managing Intellectual Property, 2008, p.58
clinical trials and related activities fall within the scope of section 60(5)(b) of the Patents Act. The uncertainty and the financial burden of the pre-October 2014 regime were especially related to the need to assess or to remove the risk of patent infringement before commencing clinical trials in the UK. The risk of patent infringement gave rise to costs connected with 'the need to undertake legal analysis of the patent landscape and clearing the path by challenging the validity of existing patents before the Courts, or patent applications before patent offices'.

Following the recommendation for clarification of the scope of the research exemption from Andrew Gowers' Review of Intellectual Property, the Intellectual Property Office (IPO) has undertaken the first round of informal consultations in 2008. The Bolar exemption was initially excluded from the scope of the consultation but the respondents suggested that including an expanded version of the Bolar exemption into the definition of research use would achieve the desired aim of exempting all clinical trials.

The second informal consultation followed in 2011. At this point, the UK Government has declared its commitment to ensure that the intellectual property system supports the pharmaceutical sector. Responses from stakeholders have shown that the UK legislation at the time did not strike the right balance between the rights of a patentee and the need to carry out clinical trials on new products. Stakeholders wanted to be able to conduct clinical trials without having to worry about infringing a third party's patent. Respondents also expressed concern about the lack of certainty as to which activities are exempt from infringement. There was almost unanimous agreement that change is required.

On 24 October 2012 the IPO launched formal consultation on proposed changes to legislation relating to clinical trials conducted in the UK. The aim stated in the proposal was to eliminate the uncertainty and the financial burden on the pharmaceutical companies undertaking clinical trials, both caused by the narrow interpretation of the research use exemption and the Bolar exemption. As the result of the responses received, the Government decided that the Patents Act should be changed to include an exemption from infringement for activities involved in preparing or running clinical trials involving innovative drugs for the purpose of

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obtaining a marketing authorisation in any country. Furthermore, the exemption should also cover activities involved in health technology assessment (HTAs). In the UK, HTAs are required before the National Institute for Health and Clinical Excellence (NICE) can recommend a medicinal product for use by the National Health Service.

The Legislative Reform (Patents) Order (hereafter, the Order) introduced the changes described above to section 60 of the Patents Act 1977 (meaning of infringement). As a result, after paragraph (6C) paragraph (6D) has been inserted—

'(6D) 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.'

Even though the Order makes changes to the research use exemption in section 60(5)(b) of the Patents Act, rather than expanding the Bolar exemption under section 60(5)(i) of the Act, the result of the amendment is to allow companies to use a patented product when conducting clinical trials and testing in order to provide the necessary information for a marketing authorisation application. The change achieved has therefore an effect equivalent to a broad implementation of the Bolar exemption. Testing activity performed to obtain a marketing authorisation for a medicinal product abroad is covered by the amendment, as long as the aim of the activity is medicinal product assessment. The same is true of the use of patented medicine as a comparator. The new provision, however, does not apply to commercial activities, such as sale, commercial supply, or manufacture in preparation for sale or supply. A licence, or other agreement, is required from the patent holder before a product can be sold or supplied commercially. The provision does not apply retrospectively, which means that only activities carried out

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112 Medicinal product assessment is defined in paragraph 6E of the Order as ‘any testing, course of testing or other activity undertaken with a view to providing data for any of the following purposes—
(a) obtaining or varying an authorisation to sell or supply, or offer to sell or supply, a medicinal product (whether in the United Kingdom or elsewhere);
(b) complying with any regulatory requirement imposed (whether in the United Kingdom or elsewhere) in relation to such an authorisation;
(c) enabling a government or public authority (whether in the United Kingdom or elsewhere), or a person (whether in the United Kingdom or elsewhere) with functions of—
(i) providing health care on behalf of such a government or public authority, or
(ii) providing advice to, or on behalf of, such a government or public authority about the provision of health care, to carry out an assessment of suitability of a medicinal product for human use for the purpose of determining whether to use it, or recommend its use, in the provision of health care.
after 1 October 2014 will be exempt from patent infringement.\textsuperscript{114}

According to the Guidance Note issued by the UK Intellectual Property Office, the following activities are considered to be in the scope of the new exemption (the exact scope will be a decision for the Courts):

- Activities carried out to provide data on new medicines to UK or non-UK regulatory authorities
- Post approval studies to comply with UK or non-UK regulatory requirements
- Activities carried out to amend a UK or non-UK authorisation for a medicine
- Activities done to obtain a UK or non-UK authorisation for a new indication of an existing drug
- Any tests or studies required by UK or non-UK regulatory bodies
- Activities carried out for the purposes of obtaining full authorisation in the EU of a generic drug or biosimilar i.e. where the abridged procedure exempted by section 60(5)(i) of the Patents Act (the ‘Bolar exception’) is not used
- Activities carried out to provide data for obtaining regulatory approval outside of the EU for a generic or biosimilar product\textsuperscript{115}

Changes to the Patents Act brought the UK patent law into line with the law in Germany, whose Bolar exemption is regarded to be industry friendly. This is a welcome development as it brings certainty and harmonization originally intended by the Directive, a step closer.\textsuperscript{116}

\textbf{3.4.2. Germany}

In Germany, the Bolar exemption has been implemented by adding subparagraph 2(b) to §11 of the German Patent Act:

‘§11 The effects of the patent shall not extend to:

(...) 2(b) studies and trials and the resulting practical requirements necessary for obtaining a marketing authorization to place a medicinal product on the market in the European Union a marketing approval for a medicinal product in the Member States of the European Union or in third countries.’

The provision has been in force since 6 September 2005 and is an example of the broad implementation of the Bolar exemption. By virtue of its wording the provision exempts studies and trials necessary for obtaining a marketing authorization for a medicinal product in any EU Member State, as well as in third countries outside of the EU’s territory. Its scope includes ‘studies and trials and the resulting practical


\textsuperscript{115} Ibid.

requirements, such as the making, the import, the possession and the use of patent protected substances if and insofar as necessary for obtaining a marketing approval in a certain jurisdiction’.\footnote{Taylor Wessing, ‘Not all Bolar exemptions are the same’, September 2013, available at http://www.taylorwessing.com/synapse/september13.html} Moreover, the wording indicates that the exemption will cover activities undertaken by both generic and innovative drug manufacturers, and similarly, in relation to both generic and new medicine.\footnote{Bausch Thorsten, Foerstl Urs, Komper Michael, Lederer Christian, Schussler Andrea, Witte Herbert; AIPPI, Germany Report Q202, p. 2, available at https://www.aippi.org/download/committees/202/GR202germany_en.pdf} \textsection{11(2)(b) offers therefore a very broad Bolar privilege.}

There had been no published German case law examining the precise limits of the Bolar exemption until recently when the Dusseldorf Regional Court and the Higher Regional Court of Dusseldorf had to deal with the question of whether the offer and supply of patent protected active pharmaceutical ingredient by a third party to a generic company is an activity privileged under the Bolar exemption. This case gave rise to vivid discussions on the scope of the Bolar exemption. The reasoning of the Dusseldorf courts confirms to a certain degree, that the scope of the German Bolar exemption is to be given a generous interpretation. A detailed description of the case and the discussion of the courts’ decisions are contained in section 4.4. below.

3.4.3. Denmark

At the time of introduction of the EU package reforming European pharmaceutical legislation, the Bolar provision was considered to be included in the Danish law by interpretation, and the Minister for Economic and Business Affairs therefore found it acceptable to postpone express implementation until the next revision of the Patent Act.\footnote{CMS, ‘Bolar Provision and Regulatory Data Exclusivity in Europe’ Denmark, p.12, 2007, available at http://www.cms-cmck.com/Hubbard.FileSystem/files/Publication/3ed51f5e-7615-44dc-a399-076a7ccc3745/Presentation/PublicationAttachment/2a4563f5-b970-4fa2-9d61-0bac21c0b232/BolarProvisioninEU.pdf}

On 24 January 2007 the Minister for Economic and Business Affairs, Bendt Bendtsen, proposed a draft bill to Parliament for various amendments to the Patents Act, including the introduction of rules for permissible actions taken in connection with obtaining a market authorisation for medicinal products. The draft bill contained a new addition to Article 3(3), which lists acts that are not considered as infringement to exclusive patent rights. This new addition is an express implementation of the Bolar provision into Danish law.

It became Article 3(3), subpoint 4(iv) in the new Patents Act and provides an exception for:

‘acts delimited to the subject-matter of the patented invention which are necessary for obtaining a marketing authorisation for a medicinal product for humans or animals in the EU, in an EU member state or in other countries.’
According to the explanatory notes to Article 3(3), subpoint 4, the acts necessary for obtaining a marketing authorisation include clinical trials, studies, examinations and other related procedures. The acts must relate to the patent in question, namely the medicinal product. If the actions performed under the Bolar exemption require the use of for example research tools, which are protected under a separate patent, the use of such tools can only take place after the patent holder has given permission thereto.

Access to perform the acts described above is open to both generic manufacturers who want to introduce a copy drug to the market upon the expiry of the original patent, as well as to companies that - in order to send a new original drug onto the market - must meet the documentation requirements accompanying the grant of marketing authorizations. The provision is not limited to particular acts necessary for obtaining a marketing authorisation in any specific country. The criterion of necessity relates to the requirements applicable in any country where the manufacturer wishes to obtain a marketing authorisation.\(^\text{120}\) Thus the Danish provision appears to relate to all applications for marketing authorisations in any country (i.e. not just abridged applications and not just for EU countries).\(^\text{121}\)

The Bolar exemption in Danish law has therefore the same scope as the Bolar exemption in German law. The justification for choosing the broad implementation is the possibility of a more extensive conduct of pre-clinical and clinical trials in Denmark, which is beneficial for the research community and forms the basis for improvements of existing products and development of new drugs.\(^\text{122}\)

3.4.4. Poland

Bolar exemption was formalized under Polish law even before the Directive 2001/83 came into force or was implemented by any of the Member States (Poland was not a member of the EU until May 2004). Article 69 (1)(iv) of the Polish Industrial Property Law was effective from 22 August 2001.\(^\text{123}\) It excludes from patent infringement:

(iv) ‘The exploitation of an invention to a necessary extent, for the purpose of performing the acts as required under the provisions of law for obtaining registration or authorisation, being, due to the intended use thereof, requisite for certain products to be allowed for putting them on the market, in particular those being pharmaceutical products.’

\(^\text{120}\) Lindgreen Nicolai, Skovsbo Jens og Thorsen Jesper 'Patentloven med kommentarer', p. 184, 1st edition, Jurist og Økonomforbundets Forlag, 2012
\(^\text{122}\) Forslag til lov om ændring af patentloven, LF 2006-2007.1.120
The provision does not state which ‘law’ is being referred to in respect of medical products but it is understood to extend at least to the laws of any EU or EEA Member State. 124

The wording itself of Article 69(1)(iv) is broad in scope and allows all activities necessary for obtaining a marketing authorisation, including pre-clinical and clinical trials conducted by generic drug manufacturers. 125 Likewise, it is to be expected that the Article permits the production of samples of the active ingredient for stability and bioequivalence tests on the generic product. The Polish Supreme Court was presented with an opportunity to interpret the scope of the Bolar exemption in the Astellas case. This decision and its implications are discussed in section 4.3 below.

3.4.5. Comparative analysis

The aim of the Directive 2001/83 was to introduce Bolar exemption into European law - a defence to patent infringement for those matters, such as bioequivalence and stability testing, which generic manufacturers applying for a marketing authorisation under paragraph 1, 2, 3 and 4 of Article 10 of the Directive must undertake. The scope of the exemption under the Directive is limited to trials conducted by generic manufacturers wanting to introduce a generic medicinal product onto the market in the EU or any EU Member State. As this Chapter described, different implementations of the Bolar exemption have been adopted by the Member States.

Germany and Denmark have from the start adopted the same broad implementation of the exemption. Under §11(2)(b) of the German Patent Act and Article 3(3), subpoint 4 of the Danish Patents Act, the defence applies to all applications for marketing authorisations in all countries. In other words, all tests and trials for authorisations for both generic and innovative pharmaceutical products fall within the scope of the exemption. The tests can be conducted inside or outside the EU for obtaining a marketing authorization for a medicinal product in any EU Member State, as well as in third countries outside of the EU’s territory. There is no exhaustive list of activities permissible under the exemption in Germany or Denmark but it is understood that all activities necessary for obtaining a marketing approval will be exempted. The key word in this context will always be ‘necessary’.

Initially, the approach adopted in the United Kingdom was much narrower than the one in Germany and Denmark. It only allowed manufacturers to carry out the necessary bioequivalence tests for generic medicinal products. This implementation proved to be an obstacle to clinical trials being performed in the UK and the Government decided to introduce a new paragraph (6D) into section 60(5) of the UK Patent Act. This amendment, effective from 1 October 2014, brought the UK approach in line with the broad implementation of the Bolar exemption in Germany.

and Denmark. Despite the amendment being made to the research use exemption and not the Bolar exemption in the UK, its effect is the expansion of the Bolar defence. The new exemption applies to both innovative and generic drugs, just like its counterparts in Germany and Denmark. Generic and innovative manufacturers are now able to rely on the new provision to exempt a range of activities relating to regulatory requirements in any jurisdiction, inside and outside of the EU.  

The new paragraph (6E), cited in footnote 112 above, clarifies that testing activity with a view to providing data for obtaining an authorisation or other associated regulatory compliance anywhere in the world falls within the scope of the new exemption. The UK Intellectual Property Office has also issued a non-exhaustive list of activities permissible under the new ‘Bolar’ exemption (for the full list of activities, see section 3.4.1.2. above). Despite it being a non-binding guidance, it gives a good idea of how broad the scope of the new exemption is.

The previously very different implementations of the Bolar exemptions in the UK on one hand, and Germany and Denmark on the other, are now practically identical. The Bolar exemption under the Polish law likewise represents a broad implementation of the Directive, albeit not as broad as the new UK provision, and the German and Danish provisions. It applies to any act required for obtaining a marketing approval, relating to both generic and innovative medicines, but it seems that it will only apply to acts required for market authorisations obtainable in the EU.  

It should be noted that the Bolar exemption has in fact existed under the Polish law since August 2001. Poland first joined the EU in 2004 and before that was a very attractive location for European generic companies to conduct their clinical trials. The only judicial discussion on the extend of the Bolar exemption in Europe is the subject of Chapter 4 below.

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Chapter 4. Third party suppliers and the Bolar exemption

4.1. Introduction
As described in sections 1.5 and 3.2. above, the Bolar exemption was introduced into European law in order to balance the exclusive rights and data exclusivity of innovative medicines’ patent owners with the desire to encourage healthy competition and easy access to the pharmaceutical market for generic manufacturers upon the expiry of the original patents. In more practical terms, those conducting trials and research often need to acquire ingredients and materials necessary for conducting their experiments from third parties. Those third parties produce, advertise and supply the patent protected ingredient to generic manufacturers shortly before the expiry of the patent. This situation poses a dilemma – are such third party activities of advertisement and supply covered by the Bolar exemption, if the supplied ingredient is used solely for conducting trials necessary to obtain a marketing authorisation for a generic product? The courts of Poland and Germany examined this question in 2012. The answers provided and the uncertainties created are discussed in this and the following Chapter.

4.2. Astellas v Polpharma

Polpharma S.A. Pharmaceutical Works vs Astellas Pharma brought to the Polish and German courts the issue of whether a third party supplying patent-protected active pharmaceutical ingredients to generic drug manufacturers for testing purposes would be covered by the Bolar exemption. The core of the problem faced by the courts was whether the Bolar exemption applies only to the testing entity or also to a third party’s manufacturing and selling of the active substance to the testing entity but not itself participating in any of the testing activity.

The Polish Supreme Court and the Regional Court of Düsseldorf, Germany have both held that the activities of a third party manufacturer are not exempted under the Bolar exemption. Along with the differing implementation of Art 10(6) of the Directive, it remained unclear what is actually meant by the phrase ‘consequential practical requirements’. In the process of lawmaking it has been clarified that the entity undertaking the testing is allowed to produce the patented substance itself for its trials and studies, but it remained uncertain whether the active substance could also be produced and sold by a third party manufacturer.

\[128\] German judgement of the Regional Court in Dusseldorf, judgment of July 26, 2012, 4a O 282/10 and the Polish decisions: the Appeal Court in Gdansk, judgment of June 26, 2012, court docket IX GC 76/11 and Supreme Court’s judgment of October 23, 2013, court docket IV CSK 92/13
\[130\] Regional Court in Dusseldorf, judgment of July 26, 2012, 4a O 282/10
without infringing the rights of the patentee. 131

The facts of the case were the following: Polpharma S.A. Pharmaceutical Works (Polpharma), a Polish manufacturer manufactured a patent protected active ingredient solifenacin succinate and supplied it to generics companies. One of such companies was Haxal in Germany. Polpharma advertised solifenacin succinate for sale on its website as well as in various professional pharmaceutical magazines, such as the Generics Bulletin and SCRIP. The advertisement did not state that the active ingredient would only be supplied for the use in clinical trials necessary for obtaining a marketing authorisation. Astellas Pharma (Astellas) was a Japanese company, which owned a European patent for solifenacin succinate. It sued Polpharma for patent infringement in Poland and in Germany.

Polpharma’s main argument was that the acts of advertisement and supply fell within the Bolar exemption because the addressees of the advertisement and the purchasers of the active ingredient would only use it in the course of their clinical trials necessary for obtaining a marketing authorisation. 132 Furthermore, Polpharma claimed that the ingredients would only be delivered on the condition that they would be used solely for testing purposes. These arguments were challenged by Astellas.

4.3. The Polish litigation
The Polish Supreme Court has in October 2013 133 reaffirmed the decision of the Court of Appeal in Gdansk, 134 and ruled that Astellas patent has been infringed by Polpharma. The Supreme Court has dismissed the appeal, holding that the Bolar provision, formalised under Polish law in Article 69(1)(iv) of the Industrial Property Law (IPL), applied only to generic drug manufacturers carrying out the necessary clinical trials themselves, and cannot be extended to third party suppliers merely selling the active pharmaceutical ingredient for use in trials carried out by others. 135

According to the Appeal Court in Gdansk it was not relevant to ascertain whether the purchasers of solifenacin succinate actually intended to use the ingredient in experimental research, or for other purposes. The Court emphasised that Polpharma as the seller was unable to control whether the purchaser used the purchased active ingredient solely for the purposes that the Bolar exemption covers. According to the Appeal Court the acts covered by the Bolar exemption can only be performed by the

party applying for a marketing authorisation. The purpose for which the third party obtained the patent-protected ingredient was therefore irrelevant, and Polpharma could not have had control over how its customers used the patented substance.

The Supreme Court agreed with the above and reasoned that the Bolar exemption should be interpreted narrowly due to its nature as an exception to the general rule of patentee’s exclusive rights. Only if the manufacturer of the active ingredient itself were to seek a marketing authorisation would the manufacturing activities fall within the Bolar exemption. The criterion to go by was whether the activities are sufficiently closely linked to the purpose of the Bolar exemption. The Court also pointed out that the manufacture of a patent-protected active ingredient for the purpose of selling is not an action necessary for obtaining a marketing authorisation. Only such necessary actions would fall within the protection of the Bolar exemption. Polpharma’s only goal was the supply of the active ingredient to a third party, which is an action of a purely commercial nature and one, which is not necessary for obtaining a marketing authorisation for a generic product. The Court held therefore that Polpharma infringed the exclusive patent rights of Astellas.

Article 69(1)(iv) of the Polish IPL provides that a patent is not infringed by ‘the exploitation of an invention to a necessary extent, for the purpose of performing the acts as required under the provisions of law for obtaining registration or authorisation, being, due to the intended use thereof, requisite for certain products to be allowed for putting them on the market, in particular those being pharmaceutical products’. It has been argued in legal commentary to the Act that Article 69(1)(iv) does not explicitly impose any specific limitations on the number of persons involved in the exploitation of an invention. This interpretation is consistent with the 23 June 1977 resolution issued by 7 Supreme Court judges, who indicated that a subcontractor manufacturing a patented product on the basis of a third party request does not exploit an invention.

The wording of Article 69(1)(iv) is broad in scope and allows all activities necessary for obtaining a marketing authorisation, including pre-clinical and clinical trials conducted by generic drug manufacturers. Likewise, it is to be expected that the Article permits the production of samples of the active ingredient for stability and bioequivalence tests on the generic product. There is nothing in the wording of the

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137 Judgment of October 23, 2013, court docket IV CSK 92/13, p. 7
138 ibid, p. 9
140 V PZP 1/77 Resolution 23 June 1977
Article suggesting that the generic drug manufacturer alone should produce the above-mentioned samples of the active ingredient. In the majority of cases, the generic company is not the manufacturer of the active pharmaceutical ingredient. It seems therefore inappropriate that a generic drug manufacturer cannot import or purchase from a third party the active pharmaceutical ingredient needed for conducting the clinical trials that are necessary for obtaining a marketing authorisation.

The Supreme Court’s decision that production and/or offering of the patented active pharmaceutical ingredient by suppliers that had not directly applied for their own marketing authorisation should be considered as patent infringement seems contrary to the wording of the Bolar exemption under the Polish law. The Court seems to have disregarded the fact that the generic drug manufacturers purchasing the active pharmaceutical ingredient intended to use it solely for the purpose of obtaining a marketing authorisation. The Supreme Court had not only dismissed Polpharma’s appeal, but also refused to refer the case to the Court of Justice of the European Union for a preliminary ruling regarding the interpretation of the Bolar exemption. Polpharma asked for answer of the following question:

‘Is the manufacture of patented substances permissible under Article 10(6) of Directive 2004/27/EC if the privileged purpose is conducted by a third party? And, if the answer is yes, what conditions must be fulfilled by a third party so that the supply falls within the requirements of the Directive?’

The decision of the Polish Supreme Court gave rise to wide disapproval. The main criticism is that the decision denies generic companies that are unable to manufacture the active ingredient themselves the opportunity to launch a new product into the market immediately on the expiry of the original patent. When introducing the Bolar exemption into Polish law, the main purpose of the legislator was to enable market entry for generic companies and ensure competition between innovative pharmaceutical companies and the generic manufacturers resulting in cheaper medicine available for patients. A strict interpretation of the Bolar provision undermines this purpose. Given the wording of the Article 69(1)(iv), the Court could have interpreted the provision in a way that would not generally exclude third party suppliers of active pharmaceutical ingredients from the Bolar exemption under Polish law.

This judgment may have severe economic consequences for generic companies in Poland, as it forces them either to produce the active pharmaceutical ingredient


themselves or to buy it directly from a patent holder. Considering that the Bolar exemption aims to facilitate production of generic drugs, the Supreme Court's interpretation may undermine the main purpose of this provision.\textsuperscript{147} The judgment of the Supreme Court is final and although there is no common law system in Poland, the decision will probably become a guideline for the Polish courts deciding on patent infringement by third party suppliers in the future.

4.4. The German litigation

As mentioned above, Polpharma had supplied solifenacin succinate to a generic company based in Germany named Hexal. Polpharma claimed that the supply had been made subject to the condition that Hexal AG uses the active ingredient for the sole purpose of conducting the studies necessary for obtaining a marketing authorisation.\textsuperscript{148}

The German court of first instance (Dusseldorf Regional Court) found that third party suppliers could only benefit from the protection of the Bolar exemption if they themselves conducted the clinical trials. The Court admitted that the wording of §11(2)(b) does not exclude acts of deliveries of third parties for trials conducted by customers.\textsuperscript{149} However, according to the Court and the systematic approach of the Patent Act and a legal interpretation consistent with Article 10(6) of the Directive, such acts can only be admissible in exceptional circumstances.\textsuperscript{150} Therefore, the supply of the active ingredient by a third party with only a commercial interest in mind would not fall within the Bolar exemption. The supplier would instead need to directly participate in the trials or have some specific interest in the results, beyond commercial reasons. The Court has expressed this most clearly in the following paragraph:

'The balance which §11 of German Patent Act wants to achieve between the interests of the patentee and the public would be jeopardized to the detriment of the patentee and would therefore be inequitable if supply by third parties would be privileged according to §11(2) or (2)(b) of the German Patent Act only because the customer can invoke these privileges. In cases where the third party cannot be seen as a co-organizer of the trials and studies and does thereby not have a genuine interest in these trials and studies, the main interest of the third party will be the turnover generated by the supply business and thereby the commercial exploitation


\textsuperscript{148} Rigby Barbara, ‘CJEU to provide guidance on the scope of the Bolar exemption’, available at \url{http://www.dehns.com/site/information/industry_news_and_articles/cjeu_to_provide_guidance_on_scope_of_bolar_exemption.html}

\textsuperscript{149} Astellas v Polpharma, I-2 U 68/12 Dusseldorf Higher Regional Court, judgment of 5 December 2013 at p.8, available at \url{http://www.taylorwessing.com/fileadmin/files/docs/Polpharma-Astellas_Beschluss_OLG-Düsseldorf__ENG.pdf}

\textsuperscript{150} Ibid.
Both parties, Astellas and Polpharma, have appealed this decision to the Higher Regional Court of Dusseldorf.\textsuperscript{152}

As described in Chapter 3, the Bolar exemption is implemented into German law by §11(2)(b) of the German Patent Act. It provides that clinical trials and resulting practical requirements necessary to obtain market authorisation for pharmaceuticals in the European Union or third states, are not considered patent infringements. This exemption applies to both innovative and generic drugs. The Higher Regional Court of Dusseldorf made a strict legal interpretation based on the wording of the German Bolar provision and on the legislator’s intention to facilitate market entry for generic drug manufacturers.\textsuperscript{153} The Court also looked at the German provision in the light of Article 10(6) of the Directive. This led to the conclusion that under certain circumstances the Bolar exemption may cover third party suppliers.

The Court reasoned that commercial third party’s acts of delivery are principally also subject to the marketing authorisation privilege pursuant to §11(2)(b) of the Patent Act and Article 10(6) of Directive 2001/83/EC. However, when a third party commits an act of delivery, it must be able to assume, that the delivered active pharmaceutical ingredient will indeed exclusively be used for privileged trials and studies. In this context, the relevant considerations to be made are: ‘the profile of the supplied company, the small amount of the delivered active ingredient, the imminent expiration of patent protection for the active ingredient in question and the already acquired experience concerning the reliability of the supplied customer’.\textsuperscript{154} Additionally, the third party itself has to take precautionary measures in order to avoid non-privileged use of the delivered active ingredient. These measures will differ depending on whether the third party merely offers or supplies the patented ingredient. In case of offering it suffices to clearly indicate that only small quantities of the product will be delivered and merely for the purpose of marketing authorisation studies. In case of delivery, the third party and the customer will have to enter into an agreement of use that is subject to an adequate contractual penalty. In individual cases with particular circumstances other measures

\textsuperscript{151} Der von § 11 PatG bezweckte billige Ausgleich zwischen den Interessen des Patentinhabers und denen der Allgemeinheit ginge einseitig zu Lasten des Patentinhabers und wäre insoweit unbillig, wenn Bereitstellungshandlungen Dritter allein deswegen gemäß § 11 Nr. 2 oder 2b PatG privilegiert wären, weil sich der Abnehmer für seine Handlungen auf die Prüfleugierung berufen kann. Denn in Fällen, in denen der Dritte nicht als Mitveranstalter der Studien und Versuche angesehen werden kann und er somit kein eigenes Interesse an den Studien und Versuchen hat, wird für ihn regelmäßig das mit der Bereitstellung verbundene Umsatzgeschäft, mithin die gewerbliche Verwertbarkeit der Erfindung, von entscheidendem Interesse sein.’

\textsuperscript{152} Astellas v Polpharma, I-2 U 68/12 Dusseldorf Higher Regional Court, judgment of 5 December 2013 at p.8, available at http://www.taylorwessing.com/fileadmin/files/docs/Polpharma-Astellas_Beschluss_OLG-Düsseldorf__ENG.pdf


might be required.\textsuperscript{155}

The Court stated that the wording of §11(2)(b) does not refer to the individual who files the application for marketing authorization, but merely to the purpose of the conducted trials and studies. Thus, third party deliveries can be included within its scope. For its application, it is merely decisive that the trials and studies as well as the therefore necessary deliveries ("practical requirements), whoever might have delivered them, serve to obtain a marketing authorisation for a pharmaceutical product.\textsuperscript{156}

In regards to Article 10(6) of the Directive, the Court likewise observed that the wording does not prevent third party delivery acts, and does not focus on the individual who files the application, but stipulates that it is the purpose of the conducted trials and studies that is the relevant criterion based on which the privilege is extended.\textsuperscript{157}

The argument of the Higher Regional Court in Dusseldorf is in accordance with the purpose of the Bolar exemption and leads to economically appropriate results. Market access should not be made unnecessary difficult for smaller generic manufacturers who do not have in-house production of all necessary active ingredients, and are therefore dependent on third party suppliers. An opposite conclusion would lead to larger generic manufacturers being arbitrarily favoured. This would in turn be contrary to the general aim of the Directive and the Bolar provision, which is that of facilitating the entry of generic products into the European market.\textsuperscript{158}

4.4.1. Questions referred to the CJEU

The Higher Regional Court felt that some clarification from the Court of Justice of the European Union (CJEU) is required on the issue of third party suppliers and the scope of the Bolar exemption. §11(2)(b) of the German Patent Act implements Article 10(6) of the Directive. Due to the decree of implementation and the principle that the national court, to the full extent of its discretion under national law, is required to interpret laws that were enacted in order to implement a European Directive in the light of the wording and the purpose of the Directive, the Dusseldorf Court believed it necessary to file a request for a preliminary ruling as the wording of §11(2)(b) of the German Patent Act and Article 10(6) of the Directive is

\textsuperscript{155} Ibid.
\textsuperscript{157} Ibid., pp. 20-21
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not clear and several interpretations are equally possible.\textsuperscript{159}

The following questions have thus been referred to the CJEU:

1. ‘Must Art. 10(6) of Directive 2001/83 be interpreted as meaning that those acts of delivery are also excluded from patent protection by which a third party offers or delivers a patented active substance to a manufacturer of generic products for purely commercial reasons, which the manufacturer of generics intends to use for studies or trials in order to obtain a marketing authorisation or approval within the meaning of Art. 10(6) of Directive 2001/83?’

2. ‘If this first question is to be answered in the affirmative:

(a) Does the privileged status of the third party depend on whether the manufacturer of generics supplied indeed uses the provided active substance in privileged studies or trials within the meaning of Art. 10(6) of Directive 2001/83? In such a case, does the exclusion from patent protection also apply if the third party is unaware of its customer’s intended privileged use and has not ascertained whether this is the case?

Or does the privileged status of the third party merely depend on whether, at the time of the act of delivery, the third party can rightly assume that, judging all of the circumstances (i.e. profile of the supplied company, small amount of the provided active substance, imminent expiration of the patent protection of the relevant active substance, experience gained concerning the customer’s reliability), the supplied manufacturer of generics will use the provided active substance for privileged trials and studies in the context of a marketing approval only?\textsuperscript{163}

(b) In the context of its act of delivery, is the third party obliged to take separate precautions to ensure that its customer will indeed use the active substance for privileged trials and studies only or do the precautionary measures of the third party differ, depending on whether the patented active substance is merely offered or actually delivered?’\textsuperscript{160}


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Chapter 5. Discussion

It was hoped that the CJEU would provide some much-needed clarification on the scope of the European Bolar exemption with regard to the supply of patented active ingredients. Unfortunately, the questions referred by the German court will remain unanswered. Astellas withdrew the lawsuit pending before the Higher Regional Court in Dusseldorf with the result that the action has been dismissed. Both the Regional Court in Dusseldorf and the Polish Supreme Court have concluded that a third party supplier cannot benefit from the protection of the Bolar exemption only because its customer uses the purchased product exclusively for experimental or Bolar purposes. An opposite conclusion would lead and result in unrestricted trade with patent protected substances. Even though far from the anticipated clarification, these decisions still provide judicial interpretation of the scope of the Bolar exemption, and strengthen the position of the patent owner.

The questions asked by the Dusseldorf court to the CJEU, as quoted above in section 4.4.1., related to the issue of whether or not acts of advertising and supply of a patented active ingredient to a generic manufacturer are exempted from patent infringement, where the generics manufacturer plans to use the ingredient for trials necessary to obtain a marketing authorisation, but the acts of advertisement and supply are purely commercial activities. Other questions asked concerned the state of knowledge of the supplier and issues such as if it mattered whether the customer actually used the purchased ingredient in privileged trials and if the supplier has the obligation to take active precautions to ensure that the active ingredient will indeed be used for privileged trials only.

This Chapter contains a discussion on the issue of third party suppliers and the question of whether their activities can and in fact, should be exempted from patent infringement by the Bolar exemption. In the second part of this Chapter, practical advice and some useful suggestions on how to avoid patent infringement are made to third party suppliers, who wish to advertise and supply patent protected pharmaceutical ingredients to generic companies.

5.1. A hypothetical CJEU ruling – Astellas v Polpharma

The Regional Court in Dusseldorf and the Polish Supreme Court have both held that a third party supplier cannot benefit from the protection of the Bolar exemption when advertising or selling patent protected active ingredients. The Higher Regional Court in Dusseldorf was prepared to accept that third party suppliers might be protected from patent infringement but only in exceptional cases and under special circumstances. An interesting question is thus, what would the CJEU have held, had it had the chance to give its opinion in *Astellas v Polpharma*?

The main purpose of the Bolar exemption is to make it easier for the generic products to enter the market immediately upon the expiry of the relevant original patent. If the CJEU were to have followed the strict approach of the Polish Supreme Court, the ability of generic companies not able to manufacture their own active pharmaceutical ingredients to launch their products immediately after the expiry of the relevant patent would be heavily obstructed. 162

Given the intention of Article 10(6) of the Directive and the rationale behind it, it would be reasonable to assume that the CJEU would have decided in favour of generic companies. The wording of the provision does not as such exclude supply activities of third parties. Instead, the decisive factor for whether or not an activity can benefit from the protection of Article 10(6) is the connection of the delivery of the active ingredient to the purpose of using it for clinical trials exempted under the Bolar exemption. Such connection needs to be interpreted based on the history of origins and the legislative interpretation for the relevant provision. 163

The rationale for Article 10(6) is to facilitate marketing authorisation trials while patent protection is still in force in order to ensure competitiveness between generic and innovative drug manufacturers on the market. Furthermore, the Commission stated that it considered it necessary that generic manufacturers are able to enter the market right after the expiry of the original patent to ensure open competition in the pharmaceutical sector. Moreover, marketing authorisation trials and studies should no longer be conducted outside the EU due to legal obstacles. 164 Given the fact that many generic manufacturers do not produce active ingredients themselves, it is possible that the CJEU would have concluded that many market authorisation trials could not be carried out without the commercial supply of the ingredients by third parties. 165

This said, it must be remembered that the interests of the patent owners have to be considered by the CJEU as well. A too liberal interpretation of the Bolar exemption would result in diminishing the value of patent protection enjoyed by the innovative drug companies. This in turn would hinder innovation and incentives for conducting the costly research and development. Therefore, it is essential that when an opportunity arises, the CJEU interprets Article 10(6) in a fair and balanced way. Setting out certain safeguards to ensure the proper use of the active ingredient would be one of the ways of striking an appropriate balance between the interests of generic and innovative companies.

163 Ibid.
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It is worth mentioning that the questions referred to the CJEU by the Higher Regional Court in Dusseldorf were framed in rather narrow terms, referring only to generics, whereas the Bolar exemption also covers biosimilar and sometimes also innovative medicinal products. In view of the importance of this exemption in the European pharmaceutical law, it is only a matter of time before a similar case is brought before the courts again and similar questions are referred to the CJEU.

It is also interesting to note that the Guidance Note issued by the UK Intellectual Property Office in connection with the amendment made to section 60(5) of the Patents Act, states that the act of supplying a drug to a third party for use in a marketing authorisation is not covered by the new broad exception and, like other commercial use, will still require a licence from the patent holder.

5.2. Practical advice for third party suppliers

It is regrettable that the referral to the CJEU has been withdrawn before the Court had a chance to define the scope of the Bolar exemption in more clear and uniform terms. The offering and sale of patented pharmaceutical active ingredients by third parties will remain a grey area until a judgement from the Court of Justice of the European Union will help to clarify it. The reality is, however, that many generic manufacturers are not able to produce themselves the active ingredients necessary for conducting the clinical trials so they are forced to buy them from third parties instead. Is there a way to avoid patent infringement in these situations? Is it possible for third parties to supply active pharmaceutical ingredients to generic companies without running the risk of infringing patent rights? Here are some suggestions as to how that could be achieved.

The main argument for why third party supply is considered to be contrary to the purpose of the Bolar exemption is its commercial nature. Third parties sell the patent protected active ingredients to generic companies and even if the quantity is small and if the customer claims that the ingredient will be used exclusively for the performance of clinical trials necessary for a marketing authorisation, third parties selling the ingredient have no genuine interest in the clinical trials undertaken, other than economic benefit. Without the direct interest in the privileged trials, the suppliers and their activities cannot be protected by the Bolar exemption. However, third party suppliers and generic manufacturers could avoid this by cooperating in conducting the trials. A combined interest in the trials and in obtaining a marketing authorisation should be expressed. Thus, the suppliers would no longer have a purely commercial interest; instead they would be co-organisers of the studies and trials and could prove an active, genuine and non-commercial interest. This

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cooperation between the generic manufacturer and the third party supplier could also take the form of a joint venture or partnership. It would be advisable that a written agreement is concluded between the parties, clearly stating the terms of the cooperation, common goals and the shared interest in the clinical studies conducted for privileged marketing authorisation purposes.

A good alternative to the above suggestion would be for the generic manufacturer to purchase the third party supplier, or its assets, in order to obtain the active ingredient or product and at the same time, benefit from the protection of the Bolar exemption. This would be a persuasive approach aiming at avoiding patent infringement.

If the parties did not want to act in consortium, other methods could be used in order to avoid infringement of patent rights. The Higher Regional Court in Dusseldorf has provided some guidelines on this issue. One solution would be for the supplier to make sure that no reasonable doubt remains as to the exclusive use of the active ingredient for privileged marketing authorisation purposes. According to the Court, the supplier would need to ask for it if necessary. It would therefore be up to the supplier to enquire and preferably obtain a written confirmation that the supplied ingredient will only be used for Bolar purposes. In this context, it would be wise to consider a number of factors.

One of the decisive factors here would be the business focus of the purchaser on generic medicine, in other words, the purchaser should be a manufacturer of mostly generic medicinal products. Other relevant factors would be small amounts of delivered active ingredient (just enough to manufacture the products for clinical trials), the imminent expiry of the original patent making it plausible to grant a generic marketing approval, and the positive and negative experiences regarding the reliability of the purchaser.

Additionally, the supplier would have to take effective measures to avoid wrongful use of the active ingredient. This could be done by entering into an agreement which obliges the generic manufacturer to use the supplied ingredient for purposes of obtaining a marketing authorisation only, or by making it clear in advertisements that the active ingredient can only be delivered for trials conducted for such purposes. In the case of selling the active pharmaceutical ingredient, the purchaser would be expected to give a warranty, enforceable by a contractual penalty that the ingredient is only used for the purposes covered by the Bolar exemption (thus, clinical trials and studies necessary for obtaining a marketing authorisation). Penalty could exist in a form of payment to patent proprietor for each case of non-compliance. 168

The above suggestions are some of the practical solutions a supplier could find relevant to consider when entering into a business relationship with a generic manufacturer. Taking these factors into considerations will minimize the risk of infringing patent rights and will maximize the likelihood of a third party supplier being protected by the Bolar exemption. It should however be remembered that there is no uniform interpretation of the scope of the Bolar exemption, which means that the above suggestions might be adequate and satisfactory in some countries but lead to patent infringement in others implementing the Bolar exemption in narrower terms. For example, as described above, in Poland, third party suppliers, which are only selling the patented active ingredients for use in trials conducted by others risk being charged with patent infringement. In Germany, however, a third party supplier meticulously applying the guidelines suggested by the Higher Regional Court in Dusseldorf would be likely to benefit from the protection of the Bolar exemption. It has to be noted that the Dusseldorf court’s decision is not a binding precedent in Germany and therefore other German courts could still find patent infringement of a third party supplier delivering active ingredients to generic companies.
Chapter 6. Conclusion

This thesis sought to discuss from a comparative European perspective the history and the scope of the Bolar exemption and subsequently place it in the wider context of third party supply of active pharmaceutical ingredients to generic drug manufacturers.

Pharmaceutical industry cannot exist and function optimally without its two most important actors on the supply side, namely the innovative pharmaceutical companies and the generic companies. The innovative companies conduct research, develop and sell new original drugs and in return enjoy exclusive patent rights for a limited period of time. During this time, generic drug manufacturers cannot use or sell the patented product without the consent of the patent holder. There are two exceptions to this rule. First exception applies when the patented ingredient of substance is used by the generic companies for experimental purposes and relates to the subject matter of the invention. This is the research use exemption, discussed in Chapter 2. It delimits the scope of the exclusive right granted by a patent to a patent owner. It forms the background for the subsequent discussion of the Bolar exemption. The uncertainty created in Europe as to the interpretation of the research use exemption and the controversial decisions in Monsanto and Clinical Trials I and II have led to a weak European generics sector, not able to enter the market due to restriction on trials conducted on patented ingredients. Generic companies would instead of performing their research in Europe take it outside of the EU, where the research use exemptions were broader or where a patent did not protect the original medicine. The main problem in Europe was the unclear position on whether clinical trials necessary for abridged procedures were exempted under the research use exemption. As described in Chapter 2, the English Court of Appeal in Monsanto was not convinced clinical trials conducted to obtain a marketing authorisation fell within the scope of the research use exemption. German courts were willing to accept that the trials are in fact within the protection of the research use exemption and that a commercial interest or purpose did not prevent activities from being ‘experimental’. Nevertheless, the exemption and its confines were unclear and seemed to favour originators rather than the generic manufacturers.

The reason for discussing the research use exemption and its limitations in this thesis was to present its relationship with the main subject of this thesis, the Bolar exemption. These two exemptions are interrelated to a certain degree and one would have difficulty fully appreciating the history and the scope of the Bolar exemption without first understating the research use exemption.

Before turning to third party suppliers, the implementation of the Bolar exemption in the United Kingdom, Germany, Denmark and Poland was discussed. The introduction of Bolar exemption into European law has helped clarify many of the questions that have occupied European courts in the past, especially the issue of whether the research use exemption applies to trials and experiments performed in
order to obtain a marketing authorisation. The Bolar exemption gives generics manufactures the possibility to undertake 'studies and trials and the resulting practical requirements necessary for obtaining a marketing authorization to place a medicinal product on the market' before the expiry of a patent. The problem with the Bolar exemption, however, is that its scope remains uncertain in regard to what trials are considered necessary for obtaining an authorization and how far back in the research and supply chain the exemption will apply. 169

The most interesting conclusion from the comparison of Bolar implementations in Chapter 3 was the recent amendment made to the UK Patent Act aligning the UK position with the interpretations adopted by Germany and Denmark. This change of approach in the UK shows that a broad implementation is desirable in the pharmaceutical industry, as it leads to cheaper access to drugs, promotes competition in the market and enables further research and development.

Some of the uncertainty created by the Bolar exemption is associated with the meaning and interpretation of the phrase 'resulting practical requirements'. It has been generally accepted that making the necessary preparations by the generic companies themselves, such as producing the necessary quantity of an active pharmaceutical ingredient falls under the scope of the Bolar exemption. However, what remained unresolved was whether commercial manufacturers of active pharmaceutical ingredients are allowed to advertise, produce and sell these to the generics companies seeking marketing authorization. The Polish Supreme Court and the courts in Dusseldorf have ruled that commercial third party activities of advertising and supplying such ingredients to generic manufactures constitute patent infringement and thus do not fall within the scope of activities permissible under the Bolar exemption. The Higher Regional Court in Dusseldorf was willing to consider some factors, which would make it possible for the third party supplier to be covered by Bolar exemption. The Court opined that it is the supplier's duty to ensure that the ingredient is properly used under the Bolar exemption by looking at the particular circumstances of the individual case and through different levels of safeguards, depending on whether the suppliers merely advertises the ingredient or actually sells it. 170 The Higher Regional Court also referred questions to CJEU but unfortunately withdrew its referral before the Court had a chance to introduce some clarity into the exact scope of permissible activities under the Bolar exemption.

One can speculate on how the CJEU would have decided the issue of third party suppliers but considering that the policy behind the Bolar exemption was to encourage the performance of clinical trials and the prompt entry of generic products to the market, there seems to be no reason in discouraging those trials by

making it impossible to obtain the essential means for their performance. ¹⁷¹ Since the generic manufacturer is in fact allowed to produce the active ingredient himself, what legitimate interest does a patent holder have in preventing the generic company from buying the ingredient from a third party? There might be situations where the generic company is unable to produce the patented product, due to for example the company’s size, and the patent holder is unwilling to supply it on reasonable commercial terms. It is then only possible to perform the exempted trials by buying the product or ingredient from a third party supplier. In the absence of commercial sale, the disadvantage suffered by the patent holder is no greater than if the generic company itself produced the product necessary for trials. ¹⁷²

For now, generic companies along with third party suppliers will have to comply with different national laws established in each Member State. Activities of advertisement and supply undertaken by third party suppliers and based on a ‘pure economic interest’ will likely be judged as patent infringement not protected by research use and Bolar exemptions. Another solution would be for companies seeking to rely on the protection of the Bolar exemption to always use the minimum amount of active ingredient needed for the trials and to maintain detailed registers to prove it. It would be similarly desirable that the tests performed are evidently linked to obtaining data necessary for obtaining a marketing authorisation. ¹⁷³

I would propose that in order to promote fair competition, cheap access to medicine and further innovation the European law should be amended to permit either the patent holder or a third party to supply the patented active ingredients for profit, as long as this is done for Bolar purposes of obtaining a marketing authorisation.

On a future more general note, it is expected that the exact scope of the Bolar exemption will remain a hot topic, as the unitary patent system is soon to become reality. Article 27(d) of the Agreement on the Unified Patent Court ¹⁷⁴ introduces the Bolar exemption into the unitary patent system by direct reference to Article 10(6) of the Directive (the narrow exemption as implemented by the UK until October 2014).

¹⁷² Ibid.
¹⁷⁴ Agreement on a Unified Patent Court, 16351/12, 11 January 2013, PI 148 COUR 77 ‘Art 27 – Limitations of the effects of a patent
The rights conferred by a patent shall not extend to any of the following: (...) (d) the acts allowed pursuant to Article 13(6) of Directive 2001/82/EC or Article 10(6) of Directive 2001/83/EC in respect of any patent covering the product within the meaning of either of those Directives (...)’
Bibliography

Primary sources (in chronological order)


Canadian Patent Act, R.S.C., 1985


Communication from the Commission to the Council, the European Parliament, the Economic and Social Committee and the Committee of the Regions ‘A Stronger European-based Pharmaceutical Industry for the Benefit of the Patient – A Call for Action’, COM (2003) 383 final


Forslag til Lov om Ændring af Patentloven, LF 2006-2007.1.120

Lov 2007-04-30 nr. 399 om Ændring af Patentloven (med noter)
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Agreement on a Unified Patent Court, 16351/12, 11.01.2013, PI 148 COUR 77


Case law (in chronological order)

Wykładni Prawa Wynalazczej Zawartej w Uzasadnieniu Uchwały 7 Sędziów Sudu Najwyższego z dnia 23 czerwca 1977 r. V PZP 1/77, OSNCP 1977, z. 10, poz. 173

Roche Products v. Bolar Pharmaceuticals [1984] 733 F.2d 858

Monsanto Co. v. Stauffer Chemical Co. [1985] FSR 55; R.P.C. 515


Torbjørn Kvassheim v. Research Foundation Stiftelsen SINTEF [2009], Norwegian Supreme Court, 22 December 2009, Case No. 2009/694, HR-2009-2402-A

Astellas Pharma Inc. v Polpharma SA Pharmaceutical Works [2012], Dusseldorf Regional Court, 26 July 2012, Case No. 4a O 282/10

Astellas Pharma Inc. v Polpharma SA Pharmaceutical Works [2013], Polish Supreme Court, 23 October 2013, Case No. IV CSK 92/13


Astellas Pharma Inc. v Polpharma SA Pharmaceutical Works, Request for a Preliminary Ruling from the Oberlandesgericht Düsseldorf (Germany), 13 December 2013, C-661/13

Secondary sources (in alphabetical order)


Barnden Marina, ‘EU Bolar exemption is not so simple’, No. 182 Managing Intellectual Property (2008), pp. 56-60


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Edwards Wildman ‘Experimental use and Bolar exemptions in the EU – how far do these provisions extend?’, available at http://www.edwardswildman.com/insights/publicationdetail.aspx?publication=8ac4f036-2979-44b8-b04f-7768c78bacba


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