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Skinny Labelling and (Indirect) Infringement of Second Medical Use Patents in Europe

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Abstract

Once patent protection of a drug substance expires, generic companies can sell a generic form of a drug, which typically has development and market approval costs that are a tenth of those of the original drug, allowing generic companies to sell the drug at a fraction of the original's price. Pharmaceutical companies, therefore, wish to extend the patent life of their drugs for as long as possible to maintain exclusivity and thereby high profits. This extension is made possible through second medical use patents, which allow a company to protect a novel aspect (e.g. new use/indication, dosage, patient group) of an already known drug. Generic companies are then allowed to sell their generic drug under a skinny label, wherein the novel use, dosage or patient group is excluded from the label. However, even if generic companies use a skinny label, they could still be liable for patent infringement under certain circumstances, as described below. For example, if a third party, such as a doctor, used the drug for an indication protected by a second medical use patent, the generic company could be indirectly liable for the infringement.

This so-called indirect infringement is a source of great legal uncertainty because the enforcement of European patents is a national issue and does not fall under the centralized rules of the European Patent Convention. Hence, national courts decide patent infringement matters based on national laws, which often lack clear rules on indirect patent infringement. Thus, not only is the individual outcome of an indirect infringement trial uncertain, but courts of member states could rule entirely differently. Recently, courts of member states of the EPC have issued interesting decisions in this field. These offer essential guidance for future rulings in Europe and might lead the way to a more uniform handling of indirect patent infringement matters.

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1. Introduction

A patent is a legal monopoly that is granted by the state to an individual or company. It allows its owner to exclude all other parties from using, producing, and selling the patented product for a limited amount of time, 20 years in most countries. In order for an invention to be patentable it must be useful, novel, and include an inventive step. Thus, it has to be different from anything that is known up to the time of application ("prior art"), and it must not be an obvious invention for the expert in the field. Finally, it has to be commercially exploitable, an additional requirement, which applies to patents in Europe, but not in the US. In exchange for the grant of the patent, the invention must be published, and thus made available to the general public.[1]

Most countries have individual patent laws incorporated in their legal systems which allow them to grant patent rights within their state territory. In addition to national laws, multiple international treaties exist to facilitate gaining patent protection in more than just one country and to harmonize the patenting process. The most important treaties include the worldwide Patent Cooperation Treaty (PCT) and the European Patent Convention (EPC). The EPC is special as it unifies the patenting systems for all member states, and a patent granted through the EPC is protected under national law in each of the member states.[2]

There are various theories on the economic and legal grounds for patent protection, such as for example the natural rights theory and the utilitarian model. In any case, legal patent protection is essential for protecting intellectual property and for incentivizing invention by rewarding the inventor with a temporary monopoly allowing

[1] Wiebe (ed.), *Wettbewerbs- und Immaterialgüterrecht*, 3rd edn., 2016, pp. 53-60; Kucsko, *Geistiges Eigentum*, 2003, p. 922.
[2] G. Paterson, *The European Patent System*, 2nd edn., London, Sweet&Maxwell, 2001, pp. 3-23.

him to exclude others from using his new and innovative product. Patent law is also intended to promote technical, and thus economic, progress and is intended to incentivize publication of a new invention without the risk of unauthorized copying by third parties.[3]

Development of a new drug takes about 10 years and often costs over 2 billion dollars.[4] Protection of intellectual property through patents thus is of utmost importance and pharmaceutical companies are always searching for ways to avoid the so-called "patent cliff." Once patent protection runs out, the drop in earnings is massive. Therefore, it is key to a company's survival to extend the period of patent protection, and nowadays this is often done through secondary patents. These secondary patents most importantly include patents for new therapeutic uses, also called secondary medical use patents.[5]

1.1 The European Patent

The European Patent Convention (EPC), an instrumental step towards a unified Intellectual Property legal system, was adopted in Munich, Germany on October 5, 1973 and entered into force on October 7, 1977.[6] It was revised by the Act Revising the Convention on the Grant of European Patents on November 29, 2000 (EPC 2000), which is the current version in effect that entered into force December 13, 2007.

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[3] Machlup, *die wirtschaftlichen Grundlagen des Patentrechts,* GRUR Int, 1961, p. 373; Baier, *die herkömmlichen Patentrechtstheorien und die sozialistische Konzeption des Erfindungsrechts*, GRUR Int 1970, p. 1.

[4] S. Peters and P. Lowy, *Tufts CSDD Assessment of Cost to Develop and Win Marketing Approval for a New Drug Now Published*, http://csdd.tufts.edu/news/complete_story/tufts_csdd_rd_cost_study_now_published, 2016 (accessed 25 November 2016).

[5] N. Dagg, *Second Medical Use*, http://whoswholegal.com/news/features/article/30569/second-medical-use, 2013 (accessed 20 November 2016).

[6] G. Paterson, *The European Patent System*, 2nd edn., London, Sweet & Maxwell, 2001, p. 3.

The European Patent Organization (EPO) is responsible for the administration of the EPC. The EPO is the organization in charge of the centralized procedure that leads to the grant of a "European Patent." Qualified personnel at the EPO carry out the individual steps of the patenting procedure, including examination of the subject matter of the application, conducting a search of prior art and writing up a search report, publication of the application, and guiding and undertaking the opposition procedure.[7]

In the case of a successful application, a European Patent is granted for a period of 20 years from the date of filing. This European Patent has the same effects as a national patent, and from the date of the grant the European Patent is recognized under the individual national laws with regard to the maintenance and enforcement of the rights of the patentee. The EPC thus provides a centralized grant procedure for its member states, but the right granted is in fact a fragmented bundle of national rights. Currently, it is therefore very time consuming and expensive to sue patent infringers since trial procedures have to be undertaken individually in the concerned member states and the decisions of one court are not binding on other states. Additionally, there is no legal certainty for litigants since the national courts could reach different decisions. This problem and other issues are addressed by the Unitary Patent, the first piece of the European Patent Package, but this legislation will not be applicable until the Agreement on a Unified Patent Court becomes legally binding, which will occur once a certain number of member states ratify the contract. [8]

This date is yet to be determined, and may have been pushed further in the future by the exit of the United Kingdom from the European Union. Thus for the foreseeable

[7] A. Ilardi, *The New European Patent*, Oxford & Portland, Oregon, Hart Publishing, 2015 p. 10.
[8] Unitary Patent & Unified Patent Court, https://www.epo.org/law-practice/unitary.html (accessed on 18 November 2016).

future, patent matters must be dealt with under the EPC. This means that infringement claims have to be assessed under national law, and, unfortunately, there is not a Europe-wide solution to infringement matters.

1.2 Second Medical Use Patents

Once the primary patent, containing the product claims, has expired, a second medical use patent can be obtained in order to extend the patent protection for a drug. A second medical use patent thus protects a previously unknown effect of an already known product. This is not only applicable to second medical uses, but can also include first uses (i.e. the primary patent only protected the product but no specific uses) or further uses since an unlimited number of further uses can be subject to a patent as long as they fulfill the requirements for patentability.[9]

The term second or further medical use refers to the use of a known pharmaceutical composition for the treatment of a previously entirely unknown indication[10] for the treatment of a previously known indication but in a new patient group or new dosage form or with a new dosage regime.[11]

A well-known example for this type of patenting strategy is Pfizer's Viagra. It was originally intended as a cardiovascular drug, but later studies showed its effect in Male Erectile Dysfunction (MED). Pfizer then filed a subsequent patent application to protect the use of Viagra for treatment of MED, i.e. a second medical use patent.[12]

[9] G. Paterson, *The European Patent System*, 2nd edn., London, Sweet & Maxwell, 2001, p. 518.
[10] Indication is the medical term for the condition to be treated by a drug, for example diabetes is an indication for insulin.
[11] A. Hess, *Second Medical Use Patents – The European/Swiss Perspective*, http://aippi.org/wp-content/uploads/2015/08/Pres_Pharma_2_AHess_020913.pdf, AIPPI Helsinki 2013 (accessed 20 November 2016).
[12] L. Tottie and R. Wiklund, *Second Medical Use Claims – What's the Commercial Value?*, http://www.valea.eu/en/news/2013/second-medical-use-claims-whats-commercial-value, (accessed 1 February 2016).

Under Article 53(c) EPC 2000, methods of treatment for humans or animals are not patentable, but "this provision shall not apply to products, in particular substances or compositions, for use in any of these methods"[13], which, according to some, is basically a self-evident statement that was added out of excessive caution[14]. Article 53(c) (formerly Article 52(4) EPC 1973) was added to the EPC to prevent a common fear from becoming a reality; namely, that physicians and veterinarians would be prevented from using state of the art treatment methods, such as CPR for example, because of patent protection.

Article 54(5) EPC 2000[15] further adds that substances and compositions that are used in such a method do not lack the patent criteria of novelty, even if the substance or composition itself is part of the state of the art, as long as the use of the substance or composition for such a method is not part of the state of the art. Thus, the novelty of a second medical use patent is derived from its new application. This accords with Article 54(5) and the basic principle of novelty:

"A claimed invention lacks novelty unless it includes at least one essential feature which distinguishes it from the state of the art. When deciding upon the novelty of a claim, a basic initial consideration is therefore to construe the claim in order to determine its technical features".[16]

Together, these two Articles, 53(c) and 54(5), clearly show that a new pharmaceutical use of an already known product or drug can be patented.

[13] Article 53(c) EPC 2000, Convention on the Grant of European Patents (European Patent Convention) of 5 October 1973 as revised by the Act revising of 17 December 1991 and the Act revising the EPC of 29 November 2000, 16th edition of June 2016.
[14] G5/83 EISAI/Second medical indication O.J. EPO 1985, 64.
[15] Article 54(5) EPC 2000, Convention on the Grant of European Patents (European Patent Convention) of 5 October 1973 as revised by the Act revising of 17 December 1991 and the Act revising the EPC of 29 November 2000, 16th edition of June 2016.
[16] G2, 6/88 MOBIL OIL/BAYER/Friction reducing additive O.J. EPO 1990, 93, 114.

1.2.1 Types of claims

Claims are the heart of the patent. Article 84 EPC states that:

"The claims shall define the matter for which protection is sought. They shall be clear, concise and supported by the description."[17]

For the patent protection of pharmaceutical compositions product claims are most commonly used. These claims are set in the form of "X for use as a medicament", thus protecting a pharmaceutical composition X for a certain but broad use, namely as a medicament. For second medical use claims, however, a different claim design must be used. Before the revision of the EPC, under the EPC 1973, only a first medical use could be protected through a purpose-limited product claim, i.e. a product claim that is limited by the use in a treatment. A second medical use patent was considered to lack novelty when based on a purpose-limited product claim. Medical use patents also could not be based on process claims for treatment, because that would fall under the prohibition of Article 52(4) EPC 1973, which excludes methods of treatment.[18]

Back then, this problem was resolved using Swiss-Type claims, also referred to as purpose-limited *process* claims. Such a claim protected the use of a pharmaceutical composition for the manufacture of a medicament for a new medical indication[19]. Since this claim aims to protect the production of the drug for a specific indication,

[17] Article 84 EPC 2000, Convention on the Grant of European Patents (European Patent Convention) of 5 October 1973 as revised by the Act revising of 17 December 1991 and the Act revising the EPC of 29 November 2000, 16th edition of June 2016.
[18] P. England, *First and Second Medical Use Claims*, https://united-kingdom.taylorwessing.com/synapse/ip-medical-use-claims.html, 2015 (accessed on 25 November 2016).
[19] G5/38 EISA/Second medical indication O.J. EPO 1985, 64.

and not just the use of the drug for a specific indication/treatment, it does not fall under Article 52(4) EPC 1973.[20]

Since the revision of the European Patent Convention, purpose-limited *product* claims are now allowed under Article 54(5) EPC 2000 for second and further medical use patents too. Therefore, these patents can now use the claim format "use of medication X for the treatment of disease Y" too. The purpose-limited product claim is applicable for all patents dating from December 13, 2007 and replaces the Swiss-type claims.[21] This means that for the upcoming years, purpose-limited product and Swiss-type claims will coexist for second medical use patents.[22]

1.3 Skinny Labelling

In order to sell a medicinal product or a pharmaceutical drug on the EU market the product must receive marketing authorization. This can be achieved for all EU member states via the centralized authorization procedure, in which a single application is filed with the European Medicines Agency (EMA).[23]

In accordance with Article 10 of European Parliament and Council Directive 2001/83/EC of 6 November 2001 (consolidated version : 16.11.2012),[24] generic suppliers can obtain marketing authorizations for generic versions of a drug without

[20] G. Paterson, *The European Patent System*, 2nd edn., London, Sweet&Maxwell, 2001, p. 518.
[21] G 2/08, Abbott Respiratory LLC/Nicotinic acid compositions for treating hyperlipidemia, 19 February 2010.
[22] A. Hess, *Second Medical Use Patents – The European/Swiss Perspective*, http://aippi.org/wp-content/uploads/2015/08/Pres_Pharma_2_AHess_020913.pdf, AIPPI Helsinki 2013 (accessed 20 November 2016).
[23] European Medicines Agency (EMA), Authorisation of Medicines, http://www.ema.europa.eu/ema/index.jsp?curl=pages/about_us/general/general_content_000109.jsp (accessed on 26 November 2016).
[24] Article 10 of the Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community Code Relating to Medicinal Products for Human Use, Official Journal L – 311, 28/11/2004, p. 67 – 128.

generating their own safety and efficacy data once the original maker's exclusivity has expired.[25]

The EMA must receive the product information together with the application. The product information must include the package leaflet for patients and the labeling for the product, which is called the "Summary of Product Characteristics" (SmPC). In the SmPC, the indicated medical uses and dosages must be included. If the product is generic, the SmPC must include the same information as the original product, hence, all indications, even those protected by a second medical use patent, have to be listed. Therefore, a generic drug cannot be sold without infringing the reference drug if its patent lifetime has been extended through a second medical use patent. The company producing the generic drug would be allowed to produce and sell the drug, since the base patent of the reference drug has expired, but it would be liable for direct infringement of the second medical use patent.

This practice means that pharmaceutical companies could potentially exclude generic drugs from the market indefinitely, since the number of further medical uses applicable for patent protection is theoretically unlimited. Therefore, Article 11 of the Directive allows companies applying for authorization of a generic product to exclude indications or other information, for example dosages or forms of administration, which are protected by patents, from the Summary of Product Characteristics of the generic drug. This process is called "carving-out" or "skinny labeling".

The European Medicines Legislation, however, does not provide rules for further deletions or changes for other kinds of information, such as safety information or

[25] T. Cornwell, *Data Exclusivity for Medicinal Products in Europe*, https://www.taylorwessing.com/synapse/regulatory_dataexclusivity.html, 2016 (accessed 27 November 2016).

contraindications, situations in which the drug should not be used because it might harm the patient, which could also be part of medical use patents. Generally, the applicant is required to settle this issue of carving-out non-central information individually with each member state concerned, since there is no EU-wide regulation.

While this practice avoids the problem of pharmaceutical manufacturers potentially excluding generic companies from market access indefinitely, it creates other problems.

In recent years it has become more and more common to prescribe medications for off-label use. In a significant number of EU member states, it is mandatory for physicians to prescribe the generic drug if possible, or for pharmacists to hand out the generic drug if it also covers the indication that the prescription is for. Arguably, this is economically necessary in order for the social healthcare systems to survive. Obviously, however, these acts can amount to direct or indirect patent infringement and render the generic drug manufacturer or even the physician or pharmacist liable for infringement.[26]

The issue of second medical use patents is a delicate and vital one that is in need of a balanced solution from the courts. As tensions in the field rise, so do the number of trials; leading to the development of preliminary case law in some European states.

1.4 Infringement of Second Medical Use Patents

Liability for patent infringement can stem from manufacturing, using, applying, selling, or marketing a patent protected invention within the territory of the patent protection. Import of products manufactured elsewhere into the patent territory also constitutes

[26] P. England and K. Osgerby, *Carve-Outs and Skinny Labelling*, https://united-kingdom.taylorwessing.com/synapse/ti_skinnylabelling.html, 2013 (accessed on 15 November 2016).

patent infringement. The patent owner, however, can grant permission to perform any of said acts, typically through a license.

For the member states of the European Patent Convention (EPC), a European Patent is granted by the European Patent Office (EPO). Thus, the application procedure for a European Patent is centralized, but enforcement is the legal responsibility of each individual country. The European Patent Office has no legal competence to handle or decide infringement matters.[27] This concept is clearly stated in Article 64(3) EPC:

> "Any infringement of a European patent shall be dealt with by national law."[28]

This situation can obviously lead to very different outcomes in court proceedings in the individual member states of the EPC. In the future, this issue should be resolved by the Unitary Patent which will also introduce a Unified Patent Court, but only for the member states of the European Union. The possibility of extending the UPC to further member states of the EPC that are not part of the EU is under discussion.

However, as the Unitary Patent is not yet applicable, and a date for its entry into force is not yet determined, infringement matters are still dealt with under the current patent legal system. This national approach to patent enforcement of the EPC has unfortunately produced a fragmented system with the possibility of contrary decisions in the case of patent-related litigations that occur simultaneously in multiple member

[27] G. Paterson, *The European Patent System*, 2nd edn., London, Sweet&Maxwell, 2001, p. 577.
[28] Article 64(3) EPC 2000, Convention on the Grant of European Patents (European Patent Convention) of 5 October 1973 as revised by the Act revising of 17 December 1991 and the Act revising the EPC of 29 November 2000, 16th edition of June 2016.

states[29]. Obviously, this is an unsatisfying situation for patent owners, as it makes enforcement of patents difficult, expensive, and legally uncertain.

Before the EPC entered into force, there was no unified patent system in Europe and potential patent owners had to apply for patent protection in each country individually. Also there was no common approach to the extent of protection and enforcement of patents, and thus no agreement as to what exactly constituted infringement of a patent. Thus, national patents of an invention comprising of almost identical wording could lead to very different levels of protection under the different national laws.[30]

With the implementation of the EPC, basic rules for the extent of protection of a patent and the interpretation of claims were introduced. Article 84 and Rule 29(1) EPC emphasize the central importance of the claims, since these rules state that the claims alone define the invention to be patented in terms of its technical features. Article 69(1) EPC further determines that the claims should be the main aspect of the patent considered by a national court when determining the extent of protection, and that the description and drawings only have a subsidiary role in this context.[31]

1.4.1 Direct and Indirect Patent Infringement

As mentioned above, direct infringement occurs when someone makes, produces, uses, imports, sells, or offers to sell a patent protected invention within the legal territory of the patent without permission from the patent owner. Most legal systems have specifications on direct infringement in their national patent laws, and numerous trials concerning direct infringement have yielded substantial case law.

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[29] M. Mejer and B. van Pottelsberghe de la Potterie, *Economic Incongruities in the European Patent System*, ECARES working paper 2009-003, January 2009.
[30] G. Paterson, *The European Patent System*, 2nd edn., London, Sweet&Maxwell, 2001, p. 573.
[31] G. Paterson, *The European Patent System*, 2nd edn., London, Sweet&Maxwell, 2001, p. 310 and p. 575.

With regard to indirect infringement, the situation is less clear, and indirect infringement is not specifically included in all national patent laws. However, especially since infringement of second medical use patents has been a growing issue in the past years, the amount of case law on this issue has steadily increased.

If someone contributes to acts of direct infringement or facilitates the infringing acts of another, he can be liable for indirect infringement, also called secondary liability. In the area of pharmaceuticals, this usually happens through contributory infringement. Key aspects of this type of infringement are: material contributions to the act of direct infringement by a third party, i.e. providing the means to enable the infringement, and knowledge of the infringing act performed by the third party. Through this mechanism, the providing party can be held accountable for the infringing acts of a third party as long as they provided essential means with the knowledge that their contribution would amount to acts of infringement, even though they themselves did not actively infringe. The first legal disputes and corresponding court decisions on secondary infringement occurred in the United States and these decisions have laid the ground for future dispute resolutions in other parts of the world.[32]

Indirect infringement is still a developing legal element that is mainly shaped through case law. Within the past few years, there have been some interesting court decisions, which most likely will shape the way indirect infringement will be generally handled in the future.

2. Case Law in Europe

[32] *Gershwin Publ'g Corp. v. Columbia Artists Mgmt.*, 443 F. 2d 1159 (2d Cir. 1971) and *Sony Corp. of America v. Universal City Studios, Inc.*, 464 U.S. 417 (1984).

Obviously, there is no general case law in Europe or the European Union. The national courts are not bound by the decisions of courts from other countries, as there is no basis for such authority. Nevertheless, decisions from courts within the European courts are not overlooked, and sometimes are even used as guidance and as reference for argumentation.

Since the European Medicines Legislation allows the applicant for a marketing authorization of a generic drug to exclude from the product leaflet those indications or dosage forms which are protected by patents, it was thought that usage patents could only be directly infringed. In other words, only if the package leaflet of the medicinal product includes patent protected indications, modes of administration, or dosage forms could it infringe a second medical use patent.

However, a prominent decision, *Grimme v Scott*, from the UK Court of Appeal points in a different direction. Grimme Maschinenfabrik GmbH & Co KG, which owns a patent for potato separator machinery with rubber rollers, filed an infringement suit against Derek Scott (Scotts Potato Machinery). The case was based on the grounds that even though Scott's machine was sold with steel rollers, the ultimate user could easily adapt the machine with rubber rollers and thus the steel rollers simply were means of eluding Grimme's patent. In the court's decision, it ruled that a person or company can be liable for indirect patent infringement if "means essential" to a patented invention are supplied, and if the supplier knows or should have known, since it was obvious, that the "ultimate users will intend to do acts amounting to

infringement".[33] Even though this was not a pharmaceuticals case, it was thought that it would pave the way for similar decisions in the world of pharmaceutical patents.[34]

Furthermore, the Lord Justices Jacob and Etherton addressed the importance of guidance by relevant decisions of courts of other European countries in their *Grimme v Scott* ruling. Especially in the area of patent law, when a decision of general importance has been reached by a court of another member state of the European Patent Convention, such decision carries weight in the United Kingdom and should also matter in the other member states. Particularly, they found that "an important decision in one Member State may well be of strong persuasive value in all the others, particularly where the judgment contains clear reasoning on the point". Therefore, courts across Europe should "try to follow the reasoning of an important decision in another country" and "only if the court of one state is convinced that the reasoning of a court in another Member State is erroneous should it depart from a point that has been authoritatively decided there".[35] [36]

Therefore, this paper will take a close look at recent decisions and ongoing litigation in three different Member States of the European Patent Convention. In doing so, the similarities and discrepancies will be highlighted in order to predict possible implications for direct and indirect infringement of second medical use patents in Austria.

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[33] *Grimme Maschinenfabrik GmbH & Co KG v Derek Scott* (t/a/ Scotts Potato Machinery), Court of Appeal (Civil Division), High Court of Justice, London [2010] EWCA Civ 1110.
[34] P. England and K. Osgerby, *Carve-Outs and Skinny Labelling*, https://united-kingdom.taylorwessing.com/synapse/ti_skinnylabelling.html, 2013 (accessed on 15 November 2016).
[35] *Grimme Maschinenfabrik GmbH & Co KG v Derek Scott* (t/a/ Scotts Potato Machinery), Court of Appeal (Civil Division), High Court of Justice, London [2010] EWCA Civ 1110.
[36] S. Parker, *UK - Grimme v Scott / Appeal*, EPLAW Patent Blog, [web blog] http://www.eplawpatentblog.com/eplaw/2010/10/uk-grimme-v-scott-appeal.html, 2010 (accessed on 15 November 2016).

2.1 Infringement of Second Medical Use Patents in the UK

Several recent, pertinent cases concern the drug pregabalin, which was marketed by Warner-Lambert under the tradename Lyrica for three indications epilepsy, generalized anxiety disorder (GAD), and neuropathic pain. The pregabalin parent patent expired in October 2013, but Warner-Lambert filed a second medical use patent containing Swiss-type claims, which was granted for neuropathic pain, one of the three original indications.[37]

The most important claims of Warner-Lambert's second medical use patent are:

1. *Use of [pregabalin] or a pharmaceutically acceptable salt thereof for the preparation of a pharmaceutical composition for treating pain.*
2. *Use according to claim 1 wherein the pain is neuropathic pain.*

After the expiration of the patent in October 2013, Actavis prepared for launch of a generic pregabalin product, called Lecaent, under a skinny label, meaning that the generic producer carved out neuropathic pain from their labeling. Actavis' marketing authorization for a skinny label was granted on February 16, 2015, and the product was launched the next day. Warner-Lambert (now Pfizer) then sued Actavis for patent infringement on the grounds of "inevitable" off-label use of those generics for pain indications. Actavis then counter-claimed for revocation, i.e. for annulment of

[37] L. Whetton and P. Campbell, *Warner-Lambert v Actavis – Do We Have an Effective System for Enforcing Second Medical Use Patents in the UK?*, http://www.jakemp.com/en/knowledge-centre/briefings/topical-briefings-2/warner-lambert-v-actavis-enforcing-second-medical-use-patents-in-the-uk, 2015 (accessed on 20 November 2016).

Warner-Lamberts pregabalin patent. This lawsuit is called *Warner-Lambert Company LLC v Actavis Group PTC EHF & Ors*[38].

The trial was conducted by Judge Arnold who rejected the *Grimme v Scott*-approach in his preliminary decision in January 2015. His argument was simply that the claims in Warner-Lambert's pregabalin patent are Swiss-type claims, which are process claims protecting the manufacture of the patented drug. Obviously, wholesalers and pharmacists, which are the ultimate users in this case, will not use the generic pregabalin to manufacture a pharmaceutical composition of pregabalin for the treatment of neuropathic pain. However, this was not the end of the lawsuit. For easier understanding, the analysis of the subsequent trial will be divided into direct infringement and indirect infringement argumentations.

2.1.1 Direct Infringement

Since the Lyrica patent claims are Swiss-type claims, Judge Arnold assessed the matter under section 60(1)(c) Patents Act 1977, as direct infringement, because indirect infringement as outlined in the *Grimme v Scott* decision would only apply if the defendant were supplying a manufacturer. Actavis was not supplying a manufacturer, but rather was itself the manufacturer, and could therefore only directly infringe Warner-Lambert's patent. Section 60(1)(c) Patents Act 1977 defines infringement as "any product obtained directly by means of [the claimed] process".

Judge Arnold concluded that the word "for" in the Swiss-type claim (use of substance X for producing a medicament **for** the treatment of Y) requires subjective intention on part of the manufacturer. The manufacturer thus has to purposely intend to

[38] *Warner-Lambert Company LLC v Actavis Group PTC EHF & Ors,* Patents Court (Chancery Division), High Court of Justice, London [2015] EWHC 72.

manufacture the medicament to be used for treatment of the patent protected condition in order to be liable. As there was no evidence brought forth on subjective intent on behalf of Actavis to use Lecaent for neuropathic pain, Judge Arnold held that there was no direct infringement.

However, the Court of Appeal disagreed with Judge Arnold's reasoning, since there is no particular reason why the word "for" should imply a requirement of subjective intent. Making subjective intent a prerequisite for direct infringement would mean that the party suing for patent infringement would have to prove the infringer's intent to use the drug for the patented condition, which would be a very difficult task. Instead, the Court of Appeal suggested that the word "for" in the Swiss-type claim means that the manufacturer would have to know or should have known since it was obvious that the product would be used for the patented purpose, but the patentee does not have to prove specific intent on behalf of the infringer. This approach is similar to the test for indirect infringement, but in the view of the Court of Appeal, the fact that they reached a similar conclusion demonstrates that the test is practicable.[39] The direct infringement issue was thus allowed to proceed to trial.

2.1.2 Indirect Infringement

After *Grimme v Scott*, it was generally thought that the principle established in this decision, that "a person or company is liable for indirect infringement if they supply 'means essential' to a patented invention, when they know or it is obvious that the

[39] P. England and K. Osgerby, *Carve-Outs and Skinny Labelling*, https://united-kingdom.taylorwessing.com/synapse/ti_skinnylabelling.html, 2013 (accessed on 15 November 2016).

ultimate users will intend to do acts amounting to infringement"[40] would also apply to second medical use patents.[41]

In his first decision[42] in the Warner-Lambert case, however, Judge Arnold dismissed the indirect infringement claims before trial, since the claims of the Lyrica patent were Swiss-type claims, i.e. process claims, which meant that in order for Actavis to be liable for indirect infringement, the ultimate user would have to use the patented product to produce a pharmaceutical composition. As the end users in this case were wholesalers and pharmacists who definitely would not use Lecaent for manufacturing, indirect infringement is not possible and therefore was dismissed.

However the Court of Appeal held differently. They used the wording "to put the invention into effect" of Section 60(2) Patents Act 1977 to hold that the focus should not lie on the manufacturer alone, but should rather be seen as a combination of acts of different people. After all, it fits within the wording to say that the product is put into effect if it is manufactured by someone who then supplies it to the next person who uses it for the patent protected condition. The court held that if the manufacturer supplies the product with the requisite knowledge that ultimate users will infringe the patent, he provides the means for direct infringement and should thus be liable for indirect infringement. The Court of Appeal also supported its decision by citing similar court decisions in the Netherlands and Germany, where indirect infringement was found at that stage of trial. Already in the *Grimme v Scott* decision, the Court of Appeal noted the importance of court decisions of other Member States of the European Patent Convention.

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[40] *Grimme Maschinenfabrik GmbH & Co KG v Derek Scott* (t/a/ Scotts Potato Machinery), Court of Appeal (Civil Division), High Court of Justice, London [2010] EWCA Civ 1110.
[41] P. England and K. Osgerby, *Carve-Outs and Skinny Labelling*, https://united-kingdom.taylorwessing.com/synapse/ti_skinnylabelling.html, 2013 (accessed on 15 November 2016).
[42] *Warner-Lambert Company, LLC v Actavis Group PTC EHF and Actavis UK Ltd and Caduceus Pharma Ltd*, Patents Court (Chancery Division), High Court of Justice, London [2015] EWHC 249.

The Court of Appeal thus remanded the indirect infringement claim to the lower court for trial.

2.1.3 Preliminary Final Decision

The trial of this case was heard in June, 2015, and a decision was reached and published in September.

Warner-Lambert's infringement claim against Actavis was unsuccessful because Judge Arnold held the patent invalid with respect to the corresponding claims, pain and neuropathic pain, because the invention was insufficiently disclosed. Nevertheless, Judge Arnold outlined his opinion on indirect infringement. He decided that Actavis is not liable for infringement under the Court of Appeal's reasoning. The test brought forward by the Court of Appeal, namely that manufacturer and ultimate user have to be seen in cooperation, would require intent to use Lecaent for the patented indication of neuropathic pain by the downstream users. After all, for direct infringement, intent is required on behalf of the manufacturer. For indirect infringement, though, only knowledge, not intent, must be proved. Therefore, the element of intent is required on behalf of the ultimate user. Since there was no evidence that doctors, pharmacists, or wholesalers intended to use Lecaent for neuropathic pain, Actavis could not be liable for patent infringement.[43]

2.2 Infringement of Second Medical Use Patents in the Netherlands

[43] D. Smyth, '*BREAKING NEWS Full decision out in the Lyrica case, and it's a whopper'*, The IPKAT [web blog], http://ipkitten.blogspot.co.at/2015/09/breaking-news-full-decision-out-in.html, 2015, (accessed on 20 November 2016).

A similar trial took place in the Netherlands in January 2015, in which Novartis sued Sun Pharmaceuticals Industries for patent infringement[44]. Novartis holds a second medical use patent for the treatment of osteoporosis. Sun Pharmaceuticals allegedly infringed this patent by selling the same pharmaceutical compound under the name zoledronate, even though Sun Pharmaceuticals excluded the indication for osteoporosis of its Summary of Product Characteristics (SmPC), in accordance with Article 11 of the EU Directive, in order to gain market approval for the treatment of paget's disease.

In the first trial, Sun Pharmaceuticals was held liable for indirect infringement because it was found that the quantity of zoledronate that was placed on the market vastly exceeded the number of paget's disease patients. To the court, this was an unambiguous sign that Sun Pharmaceuticals knew that zoledronate would be used for the patent protected indication osteoporosis, and was thus acting with bad intent when it manufactured the drug.

Interestingly, the court also said that simply carving out an indication protected by a second medical use patent is not enough to avoid the risk of indirect infringement. The entity responsible for the skinny label medicament should take additional steps, such as careful information of protected indications and making agreements with health practitioners, hospitals, pharmacists, and wholesalers to prevent infringement.

The District Court of The Hague, however, decided the issue differently in November 2015. In particular, it ruled that there was no indirect infringement by Sun Pharmaceuticals. The second medical use patent of Novartis contained Swiss-Type claims, which according to the District Court are purpose-limited process claims

[44] *Novartis AG v Sun Pharmaceutical Industries* (Europe) BV C/09/460540 / KG ZA.

inevitably including the phrase “in the preparation of a medicament”. Since zoledronate is a ready-to-use product, the ultimate users cannot infringe the patent since they will not use the zoledronate to produce a drug. Novartis argued that the preparation of the medicament should be seen as the same as the manufacture of the product, but according to the District Court, a readily prepared product can never be the central component of an invention defined in a Swiss claim.

This dispute is likely to continue, especially as direct infringement has not been addressed in this trial, and the District Court allowed Novartis to validate its claim further.

2.3 Infringement of Second Medical Use Patents in Germany

For most of these cases in Germany, direct infringement is applicable because generic drug companies included the patent protected indication in the Summary of Product Characteristics, i.e. the label. This is enough to prove that the drug was produced with the intent to use it for the indication protected by the second medical use patent. In German patent law, this praxis is called “sinnfällige Herrichtung”[45]. In English, manifest arrangement. But this praxis is not only applicable for cases where the protected indication is mentioned in the label. If it can be proven that the infringer aimed for the patented purpose, manifest arrangement can also be shown through the formulation, dosage, or the manner of provision of the drug.

Two recent cases show that if the patent protected second medical use is not indicated in the label of the generic drug, then the manner of the marketing of the drug must be very closely linked to the protected indication in order to fall under

[45] Düsseldorf District Court, docket number 4a 0 12/03, 24 February 2004, GRUR-RR 2004, 193 – *Ribavirin*; Düsseldorf Court of Appeal, docket number 2 U 54/11, 31 January 2013 – *Cistus Incanus*; Düsseldorf District Court, docket number 4a O 145/12, 14 March 2013 – *Chronic Hepatitis C.*

manifest arrangement[46]. Even though sales people, employed by the manufacturer of the generic drug, told customers that the drug could be used for the patent protected indication and the manufacturing company distributed marketing materials such as flyers that also mentioned the patented second medical use, the courts decided that the manufacturer was not liable for direct infringement. The courts reasoned that the marketing materials and comments made by sales people were not directly linked to the products in these cases, and it is thus not certain whether the customer would have performed acts amounting to infringement because of the information provided through flyers and salesmen. Therefore, the courts determined that the generic drug was marketed in a way that did not infringe the second medical use patent and the manufacturer was thus not liable for direct infringement.

Under the German Patent Act,[47] a physician can be liable for patent infringement if he or she prescribes the drug for off-label use, as physicians are not exempted from Article 139 of the German Patent Law. So, should, as in the cases described above, a physician prescribe the generic drug for the patent protected second medical use, he himself could be liable for direct patent infringement. To date, however, there have been no such cases in Germany where the patentee sought to act against a physician or pharmacist for handing out the generic drug.

Notably, indirect infringement was not claimed in either of the two cases. Possibly because according to established German case law, a party can only be liable for indirect infringement if it offers and supplies a drug with the intent that it be used for

[46] Düsseldorf Court of Appeal, docket number 2 U 54/11, 31 January 2013 – *Cistus Incanus*; Düsseldorf District Court, docket number 4a O 145/12, 14 March 2013 – *Chronic Hepatitis C.*
[47] Section 139 German Patent Act, as published on 16 December 1980 (Federal Law Gazette 1981 I p. 1), as last amended by Article 1 of the Act of 19 October 2013 (Federal Law Gazette I p. 3830).

the patent protected indication, which can be very difficult to prove[48]. Offering and supplying the product for other indications than the protected ones therefore cannot amount to indirect infringement.

Thus, in Germany in order to be liable for indirect infringement it must be shown that the manufacturer must have known, or that it was obvious, that the (generic) drug was intended to be used for the indication protected by a second medical use patent[49]. So far there are no court decisions in Germany that detail the evidence necessary to show subjective intent, so it is not yet clear whether indicators, such as production numbers that are higher than the number actually needed to treat a specific patient group would be enough proof to establish a link.

Should the patentee be successful with an indirect infringement claim, he can request injunctive relief, but only concerning the patent protected second medical use indication. The drug may still be sold for the other indications, hence enabling potential further acts of infringement not by the manufacturer, but also by the ultimate users. The aggrieved patentee can also sue for damages, but the indirect infringer only has to pay for damage caused by direct infringement. The aggrieved party thus has to prove the acts of direct infringement and the amount of damage caused, which can be very difficult to calculate.

3. Legal Situation in Austria

[48] Düsseldorf District Court, docket number 4a 0 12/03, 24 February 2004, GRUR-RR 2004, 193 – *Ribavirin.*

[49] Section 10 German Patent Act, as published on 16 December 1980 (Federal Law Gazette 1981 I p. 1), as last amended by Article 1 of the Act of 19 October 2013 (Federal Law Gazette I p. 3830).

The legal framework is laid out in the Austrian Patent Act[50] from 1970, which has since been modernized a couple times. The forms of relief that the aggrieved party can seek in court are determined in Section 147 and the following paragraphs of the Austrian Patent Act and include damages, injunction prohibiting further use, and revocation, and can even make the infringer criminally liable according to Section 159 of the Austrian Patent Act.[51]

The effects of the patent and the rights it grants its owner are statutorily regulated in Section 22 of the Austrian Patent Act. Section 22(1) refers to direct infringement whereas Section 22(3) refers to indirect infringement of a patent.

Section 22(1): "The patent shall entitle the patentee to exclude others from industrially producing the subject matter of the invention, putting it on the market, offering it for sale or using it or importing or possessing it for the said purposes. The effect of the patent shall not extend to studies and trials as well as to the consequential practical requirements, as far as they are necessary to obtain a permission, authorization or registration for putting on the market pharmaceutical products."

Section 22(3): "The patent shall further have the effect that any third party, without the consent of the patentee, shall be prohibited from offering or delivering means relating to an essential element of the invention for use of the invention to others than those persons entitled to use the invention, if the third party knows, or if it is obvious due to the circumstances, that the means are suited and intended to be used for the use of the invention."

[50] Patentgesetz (PatG) 1970 BGBl 1970/259.
[51] Wiebe (ed.), *Wettbewerbs- und Immaterialgüterrecht*, 3rd edn., 2016, pp. 53-60; Kucsko, *Geistiges Eigentum*, 2003, p. 922.

There are only few, but well established, cases on direct infringement in Austria.

The Austrian Supreme Court (OGH) highlighted in the Isoflavone case[52] that second medical use claims (in this case a Swiss-type claim) are only infringed if it has been shown that the intended purpose of the invention, i.e. the respective medical indication, is indeed achieved to a substantial extent.

In this case, the patent contained a Swiss-type claim protecting the use of isoflavone phyto-oestrogen extract for the manufacture of a pharmaceutical product for treatment of specific indications. The defendant sold a food supplement which was intended to alleviate similar conditions since it also contained isoflavone.

The Supreme Court decided that due to the Swiss-type claim, the scope of protection of the patent was restricted to the manufacture of a pharmaceutical composition using isoflavone. Thus, only the act of manufacturing such a product could infringe the patent.

So far there is no jurisprudence for “skinny labelling” in Austria, however, according to recent case law within the European Community, as discussed above, indirect infringement has been generally dismissed in cases where a generic company had taken all reasonable steps within its power to prevent using a drug for the patented indication. Liability for indirect infringement was further negated if there was insufficient proof that the product was intended to be used for the patented purpose on behalf of the manufacturer.

Since Section 22(3) of the Austrian Patent Act also requires the manufacturer to have known or to have constructive knowledge that the means provided by the manufacturer will be used for the patent protected use, it is highly likely that the

[52] OGH 09.02.2010, 17 Ob 35/09k.

Austrian Courts will follow the approach developed by the UK Courts. It is therefore likely that Austrian Courts will demand proof of intent on behalf of the manufacturer and will not hold liable for indirect infringement those who took all feasible steps to avoid direct infringement downstream through wholesalers and ultimate users.

4. Steps to Avoid Indirect Infringement

Since in Austria so far there is no jurisprudence on indirect infringement, it is unclear what exactly the requirements for liability will be. No one can exactly predict how the courts will judge individual acts of parties involved and what will be accepted as proof of infringement.

However, it is expected that the Austrian Courts will adopt an approach similar to, for example, the UK Courts, and it is thus advisable for companies to undertake the measures suggested in the Warner-Lambert decision [53] and in the Sun Pharmaceuticals decision[54] to avoid indirect infringement.

It is essential to provide pharmacists, physicians, and even health authorities with the information that the generic drug is not indicated for the patented second medical use. Further, it would be beneficial to already include the fact that the label excludes certain indications in promotional materials, such as leaflets. Special care should also be taken when instructing the sales team in order to ensure that they are aware that the drug is not to be used for a certain patented indication, and that they can then answer questions from potential customers regarding this matter correctly.

[53] *Warner-Lambert v Actavis*, Patents Court (Chancery Division), High Court of Justice, London [2015] EWHC 2548.
[54] *Novartis AG v Sun Pharmaceutical Industries* (Europe) BV C/09/460540 / KG ZA.

As no such cases have been decided in Austria so far, there is no legal certainty as to whether these measures will be enough to avoid liability for indirect infringement. But working to ensure that downstream parties will not use one's product in a patent infringing way may forestall claims that one should have known or it must have been obvious that downstream users used the product in an infringing way.

5. Conclusion

As the number of second medical use patents has grown in recent years, so has the potential for conflict with regard to indirect patent infringement. There have been some memorable cases in the past years, starting with *Grimme v Scott* which set the ground rules for establishing liability for indirect infringement, as well as the cases mentioned above in three member states of the EPC, which will serve as guiding examples for similar cases in other European states.

Interestingly, the defendant was not held liable for indirect infringement in any of the cases discussed above. Primarily, this was due to two reasons. First, the patents upon which the infringement claims were based consisted of Swiss-type claims. This claim form is also called purpose-limited process claim, and these types of patents protect the process of manufacturing a certain pharmaceutical composition for the treatment of a certain disease or symptom. As the ultimate users in these cases were physicians and pharmacists and not manufacturers, they could not infringe since the infringing act is the production of the drug and not its use or application.

However, this was not the end of the story because the trial in the United Kingdom introduced the idea of a specially designed test for indirect infringement which would look at the manufacturer and ultimate user to check whether they were acting in

unison. If the manufacturer knew or should have known that the ultimate user intends to use the product for the patent protected indication, the manufacturer will be liable for indirect infringement. The ultimate user, who uses the product in an infringing way, would be liable for direct infringement, but so far no case in Europe is known where a patent owner sued the ultimate user.

The second reason for why no party was held liable for indirect infringement lies with the element of proof. A claimant must prove that the manufacturer knew or should have known that downstream users would perform acts amounting to infringement, and moreover must prove that ultimate users actually used the product in an infringing way and that they did so intentionally. Lack of sufficient proof was a compelling reason to rule in favor of the defendant.

Even though so far there have been no rulings in favor of claimants, it is advisable for generic companies to take action to avoid liability for indirect infringement by giving careful information to ultimate users and documenting those exchanges. After all, courts of other member states of the EPC could decide this issue entirely differently, and rulings could change once the Swiss-type claims expire.