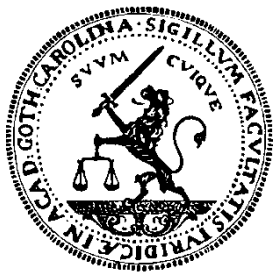

FACULTY OF LAW
Lund University

Jenny Forsberg

A Skinny Label

The intersection of EU competition law and patent law, and the abuse of dominance by the enforcement of second medical use patents

LAGM01 Graduate Thesis

Graduate Thesis, Master of Laws program
30 higher education credits

Supervisor: Hans Henrik Lidgard

Semester of graduation: Autumn semester 2015

Contents

Summary

EU competition law is the safeguard of the functioning of the internal market, and not many fields of law other than patent law can delimit the scope of competition law. A patent's value is based upon an exclusive right to the invention and product as protected by the patent. The value stems from the monopoly to the market, namely, an exclusiveness to produce, market, offer and sell the product for a limited time-period. Such an exemption from competition law is unique, and the intersection of the two fields of law creates a dynamic field that nurses a competitive market.

A pharmaceutical patent is unique in its character and position in relation to other patents. It is only within the sphere of pharmaceutical patents where an already known and previously patented active substance can be protected multiple times. The possibility stems from the exemption to novelty in the *EPC*, known as second medical use. Second medical use patents have recently caused a stir around EU when utilised in infringement proceedings against generic companies, producing products to compete with the originally patented product, i.e. the reference medicinal product.

Skinny labelling stimulates competition on the market of the reference medicinal product. Simplified, a skinny label is when the indication that is protected by a second medical use patent has been erased from, e.g., the label, leaflet or packaging. Such a removal facilitates the launch of generic products on the reference medicinal product's market without infringing the valid second medical use patent. Skinny labelling is consequently a direct articulation of the balance struck between competition law and patent law.

Since the patented and generic products are based on the same active substance, substitution is possible based on the active substance. Such substitution has occurred, and led lawsuits around Europe. Relevant questions arising from such substitution, and following lawsuits, are (i) can the patent holder of a second medical use patent righteously claim infringement of its patent by the generic product, and file a lawsuit against the generic pharmaceutical company, and (b) could such an infringement proceeding against the generic pharmaceutical company constitute an abusive expansion of the patent's scope of protection, and consequently violate Article 102 *TFEU*?

The dynamics of EU competition law and patent law is a rather well scrutinised area of law, but the problem of skinny labelling shines some light on new aspects of the intersection that needs to be clarified and settled. The thesis is studying the possible limitation imposed on a second medical use patent holder when scrutinising the problem from a competition law perspective. A balance must be struck between the two fields of law and there are different solutions to find such equilibrium, and this thesis provides one of them.

Sammanfattning

Den EU-rättsliga konkurrensrätten har till syfte att skydda den inre marknaden och dess funktion, och det är inte många andra rättsområden utom patenträtten som kan avgränsa dess tillämpningsområde. Värdet i ett patent ligger i den försäkran om ensamrätt till uppfinningen som är patentskyddad. Värdet härrörs från patentinnehavarens monopol till marknaden och ensamrätten till att producera, marknadsföra, utbjuda och sälja produkten. Detta undantag från konkurrensrättens tillämpningsområde är unikt för patenträtten, och brytpunkten mellan de båda skapar ett dynamiskt område som värnar en marknad som är konkurrenskraftig.

Läkemedelspatent har en säregen ställning och utformning jämfört med andra patentområden. Det är enbart inom läkemedelspatent som en redan tidigare känd och patenterad substans kan patenteras igen. Undantaget från nyhetskravet är fastställt i *EPC,* och är känt som en andra medicinsk indikation. Sådana patent har skapat uppståndelse runt om i EU i det senaste då de använts i intrångsåtal mot generiska läkemedelsföretag som ämnat producera läkemedel för att konkurrera med det tidigare patenterade läkemedlet, i.e. referens läkemedlet.

Skinny labelling genererar konkurrens på marknaden för referens läkemedlet. Ett *skinny label* är då den andra medicinska indikationen, som fortsatt är patenterad, tas bort från exempelvis generikans märke, bipacksedel eller paket. Genom att ta bort den fortsatt patentskyddade indikationen så kan generikan konkurrera med referens läkemedlet marknad utan att göra intrång i det fortsatt giltiga andra medicinska indikationspatentet. Därav är s*kinny labelling* ett direkt uttryck för ett försök att finna balansen mellan patenträtten och konkurrensrätten.

Produkterna är baserade på samma aktiva substans och därav utbytbara. Det är just utbytbarheten som har gett upphov till stämningsansökningarna runt om i Europa. Relevanta frågor som uppstår vid sådant utbyte är (a) kan en patenrättsinnehavare till ett andra indikationspatent rättmätigt hävda att ett intrång har skett av den generiska produkten, och därav väcka talan mot generika företaget, och (b) skulle en sådan intrångstalan mot det generiska läkemedelsföretaget kunna anses vara en skadlig expansion av patentets skyddsomfång och därav anses vara en överträdelse av Artikel 102 av *Europeiska funktionsfördraget*?

Balansen mellan EU-konkurrensrätten och patenträtten är ett relativt välutredd rättsområde, men *skinny labelling* lyfter nya aspekter att diskutera och förtydligas. Uppsatsen utreder den potentiella begränsning som kan åläggas patentinnehavare till andra medicinska indikationspatent då problemet belyses ur ett konkurrensrättsligt perspektiv. En balans mellan dem båda måste hittas, och det finns olika lösningar för att hitta en sådan brytpunkt. Denna uppsats redogör för en av dem.

Preface

Before taking the leap over the finishing line into the future, I would like to take a moment and thank all of those who have supported me throughout the years spend at Lund University.

Firstly, I would like to emphasise my appreciation to my supervisor Hans Henrik Lidgard, who has been a true inspiration and role model throughout my Master studies. I thank you for the time and effort in supervising me, and I look forward to discuss the topic further with you in the future.

My appreciation also extends to Xavier Groussot as professor and lecturer at the European Business Law Master at Lund University, but also as team coach in the European Law Moot Court. A special thanks is also extended to Justin Pierce, lecturer at the Master and team coach of the moot court competition. Thank you both for inspirational lectures, for constantly challenging my way of thoughts and for the time and effort put into the moot court competition. You have been a true inspiration, and I will forever be grateful.

Furthermore, I would like to thank all my close friends and family for supporting over the years, for your understanding and for always being there. I would also like to thank all my dear fellow students at the European Business Law Master at Lund University for making my last years in Lund truly wonderful.

Lastly, I want to take the opportunity to thank all my dear colleagues at Setterwalls Malmö. A special thanks goes to the IP and competition law team for taking the time to discuss questions raised while working on the thesis. Thank you all for being a great support, inspiration and friends, and I hope that our paths will meet again.

Jenny Forsberg

Abbreviations

API	Active pharmaceutical substance
CFREU	*Charter of Fundamental Rights of the European Union,* OJ C 326, 26.10.2012, p. 391–407
CJEU	Court of Justice of the European Union
EMA	European Medicines Agency
EPC 1973	*Convention on the Grant of European Patents***,** 1973, *1065 U.N.T.S. 199*, 5 October 1973, entry into force 7 October 1977
EPC alt. *EPC 2000*	*European Patent Convention*, 15th edition September 2013
EPO	European Patent Office
EU	European Union
GAD	Generalised anxiety disorder
GDP	Gross domestic product
Guidance paper	*Communication from the Commission — Guidance on the Commission's enforcement priorities in applying Article 82 of the EC Treaty to abusive exclusionary conduct by dominant undertakings (Text with EEA relevance),* OJ C 45, 24.2.2009, p. 7–20
INN	International non-proprietary name
Medicinal product directive	*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*, OJ L 311, 28.11.2001, p. 67–128
MRP	Mutual recognition procedure

Paris Convention	*Paris Convention for the Protection of Industrial Property*, as last revised at Stockholm, 21 UST 1583, 828 UNTS 305
Remedy directive	*Directive 2007/66/EC of the European Parliament and of the Council of 11 December 2007 amending Council Directives 89/665/EEC and 92/13/EEC with regard to improving the effectiveness of review procedures concerning the award of public contracts*
SmPC	Summary of product characteristics
SPC	Supplementary Protection Certificate
SSNIP	Small but Significant Increase in Price
TEU	*Consolidated version of the Treaty on European Union*, OJ C 326, 26.10.2012, p. 13–390
TFEU	*Consolidated version of the Treaty on the Functioning of the European Union*, OJ C 326, 26.10.2012, p. 47–390
TRIPs	*Agreement on Trade-Related Aspects of Intellectual Property Rights*, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, THE LEGAL TEXTS: THE RESULTS OF THE URUGUAY ROUND OF MULTILATERAL TRADE NEGOTIATIONS 320 (1999), 1869 U.N.T.S. 299, 33 I.L.M. 1197 (1994)
Unitary Patent Regulation	*Regulation (EU) No 1257/2012 of the European Parliament and of the Council of 17 December 2012 implementing enhanced cooperation in the area of the creation of unitary patent protection*, OJ L 361, 31.12.2012, p. 1–8
UPC Agreement	*Agreement on a Unified Patent Court*, OJ C 175, 20.6.2013, p. 1–40

1 Introduction

1.1 Background

Patent law and competition law are two areas of law that are of vital importance to the European Union ("EU") and its economic development. Whilst competition law protects the free movement of goods and services and keeps competition undistorted, patent law shields inventions from infringements, i.e. the entry of a competing product on the market. The two might seem as conflicting but creates, when balanced, a dynamic market.

Patent law is, internationally, a semi-harmonized area of law. The first international convention on patent was the *Paris Convention*[1], signed and ratified 1883 with now 176 contacting parties.[2] Most national legislators have used the *Paris Convention* as guidance, and the *Paris Convention* is the backbone of international treaties and conventions. Patent law is not harmonised by EU law. However, international conventions, to which all Member States are signatories, have streamlined the Member States' national legislation on patents. All Member States of the EU are members to the European Patent Office ("EPO") and the *European Patent Convention*[3] ("*EPC*"), an extensive collaboration on patents. EPO is not incorporated in the EU system, but is causing indirect harmonisation of Member States' patent systems since the *EPC* prescribes that all signatories must utilise *EPC*'s principles of patentability in their national patent law.[4] Consequently, the difference between the EU Members States is the approach taken by the national courts to infringement and revocation claims. However, such differentiation can be troublesome.

EU competition law is a fully harmonised area of EU law and has since the early years of the Coal and Steal Union been developing. The Union's objective was to prevent war by establishing a common market for goods

[1] *Paris Convention for the Protection of Industrial Property*, as last revised at Stockholm, 21 UST 1583, 828 UNTS 305 ("Paris Convention").
[2] See WIPO, *Contracting parties to the Paris Convention*.
[3] *European Patent Convention*, 15th edition September 2013 ("EPC"). For the previous version, see, *Convention on the Grant of European Patents***,** 1973, 1065 U.N.T.S. 199, 5 October 1973, entry into force 7 October 1977 ("EPC 1973").
[4] See Part II Chap I EPC. See also Article 4quater Paris Convention; Article 27 (1) *Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, THE LEGAL TEXTS: THE RESULTS OF THE URUGUAY ROUND OF MULTILATERAL TRADE NEGOTIATIONS 320* (1999), 1869 U.N.T.S. 299, 33 I.L.M. 1197 (1994) ("TRIPs"). First, the invention must be new to the market, secondly, it must consist of an innovative step and, lastly, that it is capable of industrial application.

with free movement over the borders. [5] The first step towards EU was taken by the establishing of institutions in a supranational manner, such as the Court of Justice and the High Authority. The Court of Justice of the European Union ("CJEU"), who made famous rulings in the 60's and 70's such as the *Hoffman-La Roche*[6] and *Consten & Grundig*[7], early ruled on the dynamic of EU competition law and intellectual property law. The objective of the EU, as stated in Article 3 of the *Treaty on European Union*[8] ("*TEU*"), is an internal market with "highly competitive social market economy". The CJEU has further held that the main objective of the internal market is an open market with undistorted competition, only limited by objective justifications.[9]

Inventions are essential for the EU in order to be able to compete globally. This is acknowledged in *Europe 2020*[10] where the Commission proposes the target to reinvest 3 % of EU's GDP in research and development in order for the EU to evolve into an "Invention Union".[11]

A patent's importance stems from the protection of the exclusive rights to an invention. The exclusive rights constitute an incentive for innovators to invent by the return that the exclusive right to the commercial use of the invention awards them. The costs, risks and time effort to innovate would be too high without such a protection. Various EU treaties safeguard patent law and other intellectual property rights. Article 17 of the *Charter of Fundamental Rights of the European Union*[12] ("*CFREU*") stipulates that "[i]ntellectual property shall be protected" and Article 36 of the *Treaty of the Functioning of the European Union*[13] ("*TFEU*") constitutes that the protection of intellectual property is exempted from the prohibition of quantitative restrictions. Such provision expresses a limitation on the scope of competition. However, the protection for intellectual property extends even further. Article 118 *TFEU* prescribes that, in the context of ensuring the establishing and functioning of the internal market, intellectual property right shall be provided with a uniform protection throughout the EU.

---

[5] See Paul Craig & Gráinne De Burca, G., *EU Law: Text, cases and materials* (Oxford University Press, 2011), pp 4 ff.
[6] Judgment in *Hoffmann-La Roche v Commission*, C-85/76, 1979 461 ("Hoffmann-La Roche").
[7] Judgment in *Consten & Grundig v Commission*, C-56/64, 1966 429 ("Consten & Grundig").
[8] *Consolidated version of the Treaty on European Union*, OJ C 326, 26.10.2012, p. 13–390 ("TEU").
[9] Judgment in *Europemballage and Continental Can v Commission*, Case 6/72, 1973 215, para 26 ("Continental Can"); Judgment in *France Télécom SA v Commission*, Case C-202/07 P, ECR I-2369, ("France Télécom SA") para 105.
[10] *EUROPE 2020: A strategy for smart, sustainable and inclusive growth*, COM(2010) 2020 final, 3 March 2010 ("EUROPE 2020").
[11] Ibid, p 5.
[12] *Charter of Fundamental Rights of the European Union*, OJ C 326, 26.10.2012, p. 391–407 ("CFREU").
[13] C*onsolidated version of the Treaty on the Functioning of the European Union*, OJ C 326, 26.10.2012, p. 47–390 ("TFEU").

Pharmaceutical patents form a category of patent law of significant importance, and are distinctive from all other patents by their nature. The same active pharmaceutical ingredient ("API") can be patented multiple times thanks to the concept of first and second medical use patents. A second medical use patent grants a patent for the discovery of that an already protected API can be used to treat another disease, i.e. to treat another indication.[14] Consequently, second medical use patent is privileged with an eased novelty prerequisite.

The acceptance of a second medical use patents creates an overlap in the time of single right to use the substance in part, since the protection of it is prolonged even if in somewhat with narrower scope. Skinny labelling is levelling the playfield between patent right holders and generic producing pharmaceutical companies. A generic product is a chemically identical and equivalent product to the previously patent protected product. A generic product launched with a skinny label has excluded the patented indication from its label, packaging, leaflet etc. in order not to infringe the valid patent of the second medical use product. Consequently, the evasion of patent infringement stems from not actively marketing the generic pharmaceutical and excluding information that might indicate substitutability.

The tension between competition law's undistorted market and patent law's exclusivity to patented products is, however, noticeable when examining the case law on the concept of skinny labelling. Skinny labelling is in its simplicity the balance of the two fundamental rights of the EU: the right to property and the right to conduct business. The utopia is that the two realms of law harmoniously coexist and limit each other.

The patent holder's exclusive right is exempted from competition rules in order to stimulate invention. However, EU competition law – if used in an abusive manner by a dominant undertaking – limits patent law. There have been some adjudications by Member States' courts on skinny labelling, all giving contrarious rulings. However, there are indications that more disputes are emerging. None of the judgments is discussing the aspect of the restraints that competition law and Article 102 *TFEU* might impose on a patent holder. Such lack of acknowledgement of the complexity of the problem is a shortage inherent in the all examined judgments. Hence, it is of importance to examine skinny labelling in the light of not only patent law, but also EU competition law.

[14] See Article 54(4) and (5) EPC. See Chapter 2.4 for a more detailed examination.

1.2 Purpose

The advancement of skinny labelling cases around the globe, as well as the rising number of cases in the EU, amplifies the importance to address the potential clash between patent law and competition law. For example, a second medical use patent must enjoy the full protection for its discovery of the new use, but should remain limited to the indication as such. Moreover, a generic product to the originally patented product on the API, i.e. the reference medicinal product, must enjoy the protection of competition law and be able to enter the market without restraints to market, offer, import, produce and sell its product.

The thesis studies the dynamic of EU competition law and pharmaceutical product's granted patent protection. The limitation that Article 102 *TFEU* imposes on a second medical use patent holder – and the consequences such a limitation results in if the patent holder claims infringement of the patent – will be scrutinised. The basic problem is the substitutability of the two pharmaceutical products. The two pharmaceuticals might be interchanged and the generic product dispensed for the medications as protected by the second medical use patent by a third party even if the protected indication was carved out from e.g. the list of contents, the packaging or the leaflet. An indication is the symptom that the substance aims at treating.

The thesis will focus on discussing two interrelated questions, namely

- Can the patent holder of a second medical use patent righteously claim infringement of its patent by the generic product, and file a lawsuit against the generic pharmaceutical company?
- Could such an infringement proceeding against the generic pharmaceutical company constitute an abusive expansion of the patent's scope of protection, and consequently violate Article 102 *TFEU*?

1.3 Method

The thesis is examining how EU competition law can restrict a patent holder's rights granted by a second medical use patent. Consequently, the thesis will apply a EU competition law perspective to the addressed conflict of law, rather than a patent law perspective. Such perspective is more appropriate in relation to the problem area and to answer the posed questions in a concise and clear manner. This study consists of mainly two sections, namely, a descriptive section and an analytic section. In order to accomplish an adequate scrutiny of the legal situation, an in-depth examination of the fields of patent and EU competition law must first be made before a well-founded discussion and analysis can be conducted. Such a critical discussion will include both law and case law, mainly stemming from the CJEU and EU but also EPO and its Boards of Appeal.

The general method applied to this thesis is the legal dogmatic method. The method seeks to clarify and establish the meaning of the applicable law or the researched and specified field of law. In regard of this thesis, the relevant field of law is the intersection of EU competition law and patent law, and specified to the dynamics of EU competition law and the use of second medical use patents. The method is the means to interpret the universally recognised sources of law, i.e. legislation, preparatory work, case law and legal doctrine.[15] However, EU law is superior to the national legislation when primary law or secondary EU law has been implemented in the Member State.[16]

Due to the EU law perspective as applied to the study, the EU legal method must also be regarded. The method establishes the norm hierarchy of EU law and is of vital importance in order to understand the legal system as discussed in this thesis. The superior norm in the hierarchy is primary law, such as the *TEU* and *TFEU*. Next is secondary EU law and principles of law. The law of the CJEU is subordinated the secondary law, and followed by the *travaux préparatoires*, the Opinion of the Advocate General and, lastly, the legal doctrine.[17]

The thesis will be, to a certain extent, interdisciplinary in the sense that policy documents and arguments as such will be scrutinised and applied in the discussion and analysis. This is a part of the EU that cannot be overlooked, especially not when assessing why certain regulations come into play. Such policy arguments are often articulated in the preamble of EU regulations and directives. Due to the incorporation in the legislative documents, such objectives are occasionally utilised when interpreting legislative documents.

1.4 Materials

The published literature on skinny labelling is not extensive, and mainly limited to articles in legal papers and blogs on intellectual property law. However, the dynamic of competition law and intellectual property law has been studied and especially so when concerns patents.

The basis for the study is the competition provisions prescribed by the *TFEU* and the guiding principles of Union law, such as proportionality and non-discrimination. Secondary law documents, such as regulations and directives are also discussed both within the field of competition law and

[15] See Fredric Korling & Mauro Zamboni, *Juridisk metodlära* (Studentlitteratur, 2013), pp 21 ff; Bengt Lehrberg, *Praktisk juridisk metod* (Iusté, 7th ed, 2014), p 203; Aleksander Peczenik, *Juridikens teori och metod: en introduktion till allmän rättslära* (Fritze, 1995), pp 17f; pp 35 ff.
[16] See Christian Dahlman, *Rätt och rättfärdigande* (Studentlitteratur, 2011), pp 21 ff.
[17] See Jörgen Hettner & Ida Otken-Eriksson, *EU-rättslig metod – teori och genomslag i svensk rättstillämpning* (Norstedts Juridik, 2nd ed, 2011), pp 40ff; p 188 f.

within the emerging field of EU patent law. International conventions and agreements will be scrutinised to the extent necessary. Such conventions are e.g. the *EPC* and the *Agreement of a Unified Patent Court*. Case law stemming both from the CJEU, Member States' courts and international organisations decision-making bodies will be scrutinised and analysed.

The thesis will study and apply numerous competition law judgments by the CJEU. Case law such as *Consten & Grundig*[18], *Hoffmann-La Roche v Centrafarm* [19] and *IMS Health v NDC Health*[20] will be scrutinised and constitute the framework of discussion. However, the main case of study will be *Astra Zeneca v Commission*[21].

The case law stemming from the Boards of Appeal of the EPO will also be scrutinised to establish the current general principles of patent law. Presently, such case law is the precedence of patent law in Europe. There is not an extensive pool of adjudications on skinny labelling, but the disputes are emerging. This thesis is examining and analysing three selected national court judgments on skinny labelling and second medical use patents.

As abovementioned, the material on skinny labelling, and to some extent pharmaceutical patents, is finite and mainly based on Internet sources such as blogs and articles. The main publishers of articles and other materials are law firms. Even if such material is given an objective outlook, one must stay critical to such articles since they might have an underlying objective. Hence, the three judgments that are discussing skinny labelling will be utilised as the basis for the discussion and analysis on the dynamic of competition law and pharmaceutical patents.

The legal doctrine is essential for a thorough examination of the problem-area of the study. Consequently, the thesis will take into account and discuss the work of prominent scholars and practitioners in the field of EU competition law and intellectual property rights, such as Jonathan D.C. Turner, Guy Tritton, Marianne Levin and Bengt Domeij, among others. Such works will be utilised as a foundation for discussion and analysis.

[18] See Consten & Grundig, supra n 7.
[19] Judgment in *Hoffmann-La Roche v Centrafarm*, 102/77, 1978 1139 ("Hoffmann-La Roche v Centrafarm").
[20] Judgment in *IMS Health v NDC Health*, C-418/01, ECR I-5039 ("IMS Health v NDC Health").
[21] Judgment in AstraZeneca v Commission, C-457/10 P, e.r. ("AstraZeneca").

1.5 Delimitations

The thesis will be limited to study pharmaceutical patents in relation to Article 102 *TFEU* with a focus on the prerequisite *abuse* in order to assure an adequate and focused discussion of the posed questions. A focus on the intersection of EU competition law and patent law will be a necessity for a sufficient discussion on if the limitation of a patent holder's right is acceptable and justified by the objectives of EU law.

In order to conduct an eloquent discussion on EU law and pharmaceutical patents, certain aspects from other sources of law other than Article 102 *TFEU* must also be mentioned, even if done so in brief. The study will therefore examine the EU directives on public procurement and the remedies available for an aggrieved party. Two new procurement directives were published in 2014 repealing the previous ones from 2004. The study is based on the new directives and the provisions prescribed there within. Public procurement is a vital part of the pharmaceutical sector, and consequently of importance for this study. Authorities purchase pharmaceuticals through procurement procedures, and public procurement is the ultimate form to ensure that the market remains undistorted when authorities enter into transactions. However, the examination of EU procurement law will be held short, only discussing the fundamental principles of procurement law to the benefit of a concentrated discussion.

It is inevitable to study the fundamental right as prescribed by the *CFREU*. However, these principles and rights will be discussed and examined continuously all through the thesis, rather than scrutinised in an own subchapter.[22] This is also the main reason why the thesis will study and discuss *Europe 2020*. The policy document is the foundation of the ten years' strategy of the EU and can give guidance on the purpose of all legislation stemming from later than its publishing. The correct understanding of *Europe 2020* is as an interpretation tool, a tool that even the CJEU also utilises, but cannot be scrutinised in its entirety in the study.[23]

As regards patent law, the study focuses on pharmaceutical patents and the use of skinny labelling by generic companies. The EU patent regulation, *Unitary Patent Regulation*[24], is emerging. The study will examine the

[22] The scope and strength of the Article 16 CFREU and the right to conduct business is thoroughly discussed in "Weak Right, Strong Court - The Freedom to Conduct Business and the EU Charter of Fundamental Rights" by Xavier Groussot, Gunnar Tor Petursson & Justin Pierce (2014) 01/2014 *Lund University Legal Research Paper Series*. See also Judgment in Scarlet *Extended v. SABAM*, Case C-70/10, ECR I-11959, para 47-49. Right to intellectual property cannot restrict right to conduct business if deemed under secondary law.

[23] See e.g. Opinion by Advocate General Kokott in Judgment in *European Commission v Kingdome of the Netherlands*, C-368/10, e.r., para 36; Judgment in *Giersch and Others,* C-20/12, e.r., para 54.

[24] *Regulation (EU) No 1257/2012 of the European Parliament and of the Council of 17 December 2012 implementing enhanced cooperation in the area of the creation of unitary patent protection*, OJ L 361, 31.12.2012, p. 1–8 ("Unitary Patent Regulation").

regulation, and the *Agreement on a Unified Patent Court*[25] ("*UPC Agreement*") in order to establish what the future holds. It would be of little interest to examine skinny labelling in the sole aspect shadow of *EPC* when a new area of EU law is emerging. The future existence of a EU patent law system makes the question of how to find the equilibrium between patent law and competition law even more relevant.

Even if the EU system of patent law is emerging, all of the existing case law is based on the regulations of EPO and the provisions of *EPC*. Naturally, the study must examine the patent system as provided under the *EPC* and discuss its impact on skinny labelling. For the sake of clarity, it must be pointed out that the *EPC* was modernised in 2000 and if not stated otherwise, by reference to *EPC 1973*, the use of the abbreviation *EPC* will refer to the version from 2000.

The provisions regarding second medical use patents were amended by the introduction of the new *EPC*. Previous to the amendment, second medical use claims had been accepted by the case law of the EPO Boards of Appeal in contradiction to the actual wording of the *EPC 1973* but are now accepted as valid patent claims under the new convention. However, the amendment changed the form of claims, from Swiss type claims to EPC 2000 claims. This change is essential for the study, and is therefore examined in a subchapter. The legal scholars and practitioners of Europe are disagreeing upon how the new wording of claims has affected the scope of protection. This could be a topic for a thesis in itself, and cannot possibly be covered by the scope of this thesis. The study on this specific issue is therefore limited to examining what the Boards of Appeals of the EPO has stated in its decisions.

The second medical use and skinny label case law is limited to three different national courts' decision adjudicating disputes on the same API, namely, pragabalin. The claimant is Warner-Lambert, a branch of the Pfizer group, who has filed lawsuits in multiple EU Member States for patent infringement of its second medical use patent. A British, a French and a German court adjudicate the examined decisions. The focus of the examination to the same patent and the same claimant generates a possibility to contrast the different courts' solutions to the dispute in an effective and interesting manner. The discussion and conclusions drawn from the judgments can be more concise and more balanced by such a limitation.

[25] *Agreement on a Unified Patent Court* ("UPC Agreement"), OJ C 175, 20.6.2013, p. 1–40.

1.6 Disposition

The thesis is divided into two parts, one descriptive section and one analysing section. The second chapter, scrutinizing the EU competition law system, commences the descriptive section. This chapter focuses mainly on Article 102 *TFEU* and abuse of dominance, but also includes a brief closing subchapter on public procurement, and is meant to give the reader the knowledge necessary to analyse the intersection of competition and patent law. The subchapter on Article 102 *TFEU* focuses especially on the prerequisite *abuse* after a general introduction to the provision. A study of the *AstraZeneca* judgment is conducted in a separate subchapter.

The third chapter examines the realm of patent law. The chapter consists of subchapters on the existence of patent law in the EU and the relevant aspects of patent law on pharmaceutical inventions. The chapters means to give the reader a basic knowledge of patent law in order to follow the discussion in the fourth and fifth chapter. The chapter is concluded by a study of the pregabalin judgments in the United Kingdom, France and Germany. These judgments will be utilised as a foundation for the discussion and conclusions in the following chapters.

The fourth chapter is devoted to the scrutiny and analysis of the intersection of EU competition law and patent law. The discussion takes its starting point in analysing the *AstraZeneca* judgment, followed by a scrutiny of the balance between the patent holder's and the generic companies' rights. Such an analysis will take its start in discussing the new type of second medical use claim, the EPC 2000 claim, which is followed by an in-depth discussion on the pregabalin judgments. The fourth chapter is concluded by a discussion on how to strike a balance between competition law, second medical use patent holders' and generic companies' objectives and rights as provided by EU law.

The fifth chapter concludes the thesis with final remarks and conclusions on the findings from the discussion.

2 EU Competition law

2.1 Introduction

Competition law is a fully harmonised area of law within the EU. It is mandatory for national adjudicators to interpret their competition law in the light of the EU law. EU competition law strives to safeguard an open and competitive market. Competition law has multiple objectives. For example, one underlying objective is to establish economic efficiency and welfare.[26] Furthermore, the *TEU* articulates the strive to establish a highly competitive social market economy, as well as the objective to ensure that the internal market remains undistorted.[27]

Article 101 and 102 *TFEU* are the substantive provisions of EU competition law. The two articles enforces and safeguards the functioning of the internal market, as held in the *EcoSwiss v Benetton* judgment.[28] Article 101 *TFEU* is prohibiting the use of agreements for anticompetitive purposes. Such actions include price fixing, tying and bundling, and the use of rebates in a distortive manner.[29] Article 102 *TFEU* regulates the behaviour of a dominant undertaking on the market. Conducts where a dominant undertaking abuses its position on the market are in violation of EU law.

EU competition law is to some extent limited. EU law recognises the existence and right to property ownership.[30] Article 36 *TFEU* exempts intellectual property rights from competition law's applicability.[31] Consequently, the *TFEU* stipulates that free movement, and competition, can be restricted if justified to protect intellectual property rights.

This chapter will study Article 102 *TFEU* with focus on the concept of *abuse*. The first subchapter will conduct a brief and general introduction to Article 102 *TFEU* followed by a scrutiny of the prerequisite *abuse* and the likelihood of intellectual property right to be utilised in an abusive manner. The chapter will, lastly, scrutinise the *AstraZeneca v Commission* judgment.

---

[26] See David Bailey & Vivien Rose (eds), *Bellamy & Child: European Union Law of Competition* (Oxford Uiversity Press, 5th ed., 2014), [1.013]. See also Judgment in *TeliaSonera Sverige*, C-52/09, ECR I-527, ("*TeliaSonera*") para 22; Judgment in *Roquette Frères*, C-94/99, ECR I-11037, para 42.

[27] See Bailey & Rose, supra n 26, [1.011] – [1.012].

[28] See Judgment in *EcoSwiss China Time Ltd v Benetton International NV*, C-126/97, ECR I-3055, para 36.

[29] See Jonathan Faull & Ali Nikpay (eds), *Faull & Nikpay: The EU Law of Competition* (Oxford University Press, 3rd ed, 2014), [3.24] – [3.26].

[30] See Article 345 TFEU.

[31] Article 36 TFEU provides: "The provisions of Articles 34 and 35 shall not preclude prohibitions or restrictions on imports, exports or goods in transit justified on grounds of public morality, public policy or public security; the protection of health and life of humans, animals or plants; the protection of national treasures possessing artistic, historic or archaeological value; or the protection of industrial and commercial property. (…)"

2.2 Article 102 TFEU

2.2.1 General

Article 102 *TFEU* reads as follows:

> Any abuse by one or more undertakings of a dominant position within the internal market or in a substantial part of it shall be prohibited as incompatible with the internal market in so far as it may affect trade between Member States. (…)

An undertaking must, in order to infringe Article 102 *TFEU*, fulfil four criteria. Firstly, it must be an undertaking; secondly, this undertaking must be in a dominant position on the relevant market; thirdly, the dominant undertaking must conduct an abusive behaviour; and fourthly and last, the abusive conduct must affect trade between Member States.

The definition of an undertaking is the same in Article 101 and 102 *TFEU*, and has been defined by extensive case law.[32] It was established in the judgment of *Höfner* that:[33]

> [i]t must be observed, in the context of competition law, first that the concept of an undertaking encompasses every entity engaged in an economic activity, regardless of the legal status of the entity and the way in which it is financed

The decision on whether or not an entity is conducting an economic activity is based on functions performed by the entity and the characteristic features of the entity. The actual intent, or whether the entity is making profit or not is irrelevant. The characteristic features of an undertaking is that it offers goods and/or services to the market and that such an activity, at least hypothetically, can generate profit.[34]

A dominant position has been defined by the CJEU in multiple cases. The CJEU define dominant position by its judgment in *Hoffmann-La Roche* as:[35]

> The dominant position (…) relates to a position of economic strength enjoyed by an undertaking which enables it to prevent effective competition being maintained on the relevant market by affording it the power to behave to an appreciable extent independently of its competitors, its customers and ultimately of the consumers.

---

[32] See Faull & Nikpay, supra n 29, [3.27].
[33] See Judgment in *Höfner and Elser v Macrotron GmbH*, C-41/90, ECR I-1979, para 21.
[34] See Judgment in *Firma Ambulanz Glöckner v Landkreis Südwestpfalz*, C-475/99, ECR I-8089, para 19; Judgment in *FENIN v Commission*, C-205/03 P, ECR I-6295, para 25; Judgment in *Albany International BV v Stichting Bedrijfspensioenfonds Textielindustrie*, C-67/96, ECR I-5751; Judgment in *Pavlov v Stichtting Pensioenfonds Medische Specialisten*, Joined Cases C-180/98, C-181/98, C-182/98, C-183/98, C-184/98, ECR I-6451, para 201.
[35] See *Hoffmann-La Roche*, supra n 6, para 38. See also Judgment in *United Brands v Commission*, Case 27/76, 1978 207 ("*United Brands*"), para 65.

The Commission has established some guiding thresholds in their *Guidance Paper*[36]. The *Guidance Paper* is not legally binding, but provides undertakings with a greater clarity and predictability on how the Commission will deem certain conducts and market structures when it is conducting its investigation of a potential violation by undertakings. An undertaking with less than 40 % of the market-shares is assumed as not dominant.[37] However, the thresholds are not absolute and can vary between markets, industries and products and it is underlined in the *Guidance paper* that the dominance must be assessed in relation to the relevant market.[38] Therefore, it is necessary to establish the relevant market of the undertaking.

The market definition is "a tool to identify the boundaries of competition between firms."[39] The assessment of the relevant market is split up in a two-step assessment: one on the product market and one on the geographical market. The product market must be established first in order to determine the geographical market. In order to do so, it must be established which products or services that are close to substitutes to the product or service in question. The objective is to identify the actual competitors that have the capacity to constrain the dominants undertaking's behaviour on the market.[40]

Products that are substitutable to the product of the dominant undertaking form the relevant product market.[41] The substitutability is measured by the demand and supply substitution and cross-elasticity on the market.[42] In the judgment in *Hoffmann-La Roche,* the Court stated the following regarding the relevant product market:[43]

> The concept of the relevant market in fact implies that there can be effective competition between the products which form part of it and this presupposes that there is a sufficient degree of substitutability between all the products forming part of the same market in so far as a specific use of such products is concerned.

The test applied to measure the demand substitution is the SSNIP test. SSNIP stands for *Small but Significant Increase in Price*.[44] The test is utilised worldwide in order to detect the relevant market and defines the

---

[36] *Communication from the Commission — Guidance on the Commission's enforcement priorities in applying Article 82 of the EC Treaty to abusive exclusionary conduct by dominant undertakings (Text with EEA relevance)*, OJ C 45, 24.2.2009, p. 7–20 ("Guidance Paper").
[37] See Ibid III.A.14.
[38] See Ibid III.A.13.
[39] *Commission Notice on the definition of relevant market for the purposes of Community competition law*, OJ C 372, 9.12.1997 ("Commission notice"), p. 5–13, [2].
[40] See Ibid [10] – [12].
[41] See Bailey & Rose, supra n 26, [4.027].
[42] See Alison Jones & Brenda Sufrin, *EU Competition Law; Text, cases and materials* (Oxford University Press, 4th ed, 2014), pp 66 f.
[43] See *Hoffmann-La Roche*, supra n 6, para 28. See also Judgment in *AKZO v Commission*, C-62/86, ECR I-3359, para 51; Judgment in *L'Oréal v De Nieuwe AMCK*, Case 31/80, ECR 3775, para 25; Judgment in *Bronner v Mediaprint*, C-7/97, ECR I-7817, para 33.
[44] See Jones & Sufrin, supra n 42, p 67.

relevant market by establishing the maximal profitable price a hypothetical monopolist could charge before its customer would change to another product. It is executed by the hypothetical increase of 5-10 % in price and examination of customers' hypothetical behaviour to such a change. If the customers would switch to another available product, that substitutable product will be included in the relevant market. The test is conducted until a small but significant increase in price would remain profitable for the undertaking.[45] Some other variables can be utilised to establish the relevant product market as well. For example, the product characteristics might erase the substitutability between the products,[46] customers' preferences can also make two fully substitutable products belong to two different markets,[47] or the fact that it would be too costly for a customer to switch to another product, or other hindrance by other barriers to the market.[48]

Whilst demand-side substitution focuses on how the consumer would react on a price increase, supply-side substitution focuses on the alternative suppliers that are active on the market. Such estimation is based on how many alternative suppliers that would reorganise its production, start to produce and sell products competing with the dominant undertaking's product if the price were to be increased.[49] The CJEU underlined in *Continental Can* that the supply-side substitution forms an essential part in the establishing of the relevant market.[50]

The geographical market is defined by the assessment of market shares between the undertakings in different regions, the price differences and trade flows. The geographic market can be local, national, regional, EU-wide or global.[51] The judgment of *United Brands*[52] set out that the geographic market is a "clearly defined geographic area in which [the product] is marketed and where the conditions of competition is sufficiently homogenous for the effect of economic power".[53]

Furthermore, the abusive behaviour must "may affect trade between Member States" in order to violate Article 102 *TFEU*. The conduct must disrupt the flow over the borders or interfere with the structure of the competition on the market to an *appreciable* extent.[54] However, each element of the behaviour does not need to affect trade, it is the overall impact of the behaviour and the overall strategy that is assessed.[55] It must be

[45] See Commission notice, supra n 39, [17].
[46] See *Hoffmann-La Roche*, supra n 6, para 28. See also Bailey & Rose, supra n 26, [4.029].
[47] See e.g. Judgment in *CEAHR v Commission*, Case T-427/08, ECR II-2805, para 90. See also Bailey & Rose, supra n 26, [4.032].
[48] See Commission notice, supra n 39, [42]. See also Bailey & Rose, supra n 26, [4.033].
[49] See Bailey & Rose, supra n 26, [4.046].
[50] See *Continental Can,* supra n 9, [29]; [35].
[51] See Commission notice, supra 39, para 28-31.
[52] See *United Brands,* supra n 35.
[53] See Ibid para 11.
[54] See Jones & Sufrin, supra n 42, pp 283 f.
[55] See *Commission Notice - Guidelines on the effect on trade concept contained in Articles 81 and 82 of the Treaty (Text with EEA relevance)*, OJ C 101, 27.4.2004, p. 81–96 ("Commission guidelines"), p 17.

possible for the authorities to "foresee with a sufficient degree of probability (…) that the agreement or practice may have an influence, direct or indirect, on the pattern of trade".[56] It is not necessary that the conduct affects the whole of one Member State and the whole of another. A conduct can be deemed to be affecting trade between Member States even if it only affects a part of a Member State, "provided that the effect on trade is appreciable."[57]

2.2.2 The Concept of Abuse

The essence of the prohibition of abusive conduct in Article 102 *TFEU* is to protect competition on the merits and to safeguard consumers. An undertaking using its dominance to foreclose the market and hinder competition on the merits is in breach of Article 102 *TFEU*. EU competition law does not prohibit dominant undertakings, as long as they compete on the merit. However, undertakings are penalised if distorting competition by the abuse of dominance.[58] Abusive behaviour can be e.g. predatory pricing, entry barriers and exclusionary conducts.[59]

The concept of abuse was defined by the CJEU in the judgment of *Hoffmann-La Roche* as:[60]

> the behaviour of an undertaking in a dominant position which is such as to influence the structure of a market where , as a result of the very presence of the undertaking in question , the degree of competition is weakened and which , through recourse to methods different from those which condition normal competition in products or services on the basis of the transactions of commercial operators , has the effect of hindering the maintenance of the degree of competition still existing in the market or the growth of that competition.

The term abuse is an objective concept. It is not the use of a dominant position that is the essential prerequisite, but rather to which extent the effect of a conduct disrupts competition on the market and competition on the merits.[61] The abuse is not dependent on the undertaking's subjective intent.[62] On that note, a conduct may be deemed abusive by the Commission even if the undertaking does not obtain any advantages from the conduct, financial or competitive.[63] The definition of abuse, as previously established, was altered in 2012 by the judgment in *Post Danmark*.[64] The CJEU added in the test of abuse that Article 102 *TFEU* "applies, in

[56] See Ibid p 23.
[57] See Ibid p 21.
[58] See Jones & Sufrin, supra n 42, pp 272 f.
[59] See Guidance paper, supra n 36, IV.A – D.
[60] See *Hoffmann-La Roche*, supra n 6, para 91.
[61] See Ibid. See also *TeliaSonera*, supra n 26, para 67; Judgment in *Tomra v Commission,* C-549/10 P, n.y.r., para 17; Opinion of Advocate General Kirschner in Judgment *Tetra Pak Rausing SA v Commission*, T-51/89, ECR II-309, para 64.
[62] See Judgment in *Clearstream v Commission,* T-301/04, ECR II-3155, para 142 – 144.
[63] See Judgment in *SELEX v Commission*, T-155/04, ECR II-4797, para 108.
[64] Judgment in *Post Danmark*, Case C-209/10, EU:C:2012:172.

particular to the conduct of a dominant undertaking, (…), that has the effect, to the detriment of the consumers, of hindering the maintenance of the degree of competition".[65]

There is a possibility that a conduct can evade violation of Article 102 *TFEU*. However, this requires that such an exemption can be objectively justified. According to case law and the *Guidance Paper,* two criteria must be met: the action taken by the dominant undertaking must be necessary, and it must achieve efficiency gains.[66] The *Guidance Paper* sets out that the conduct must be "objectively necessary", proportionate, and must be determined on the basis of external factors. An abusive conduct might be considered necessary for health and safety reasons. However, the Commission states firmly that:[67]

> proof of whether conduct of this kind is objectively necessary must take into account that it is normally the task of public authorities to set and enforce public health and safety standards. It is not the task of a dominant undertaking to take steps on its own initiative to exclude products which it regards, rightly or wrongly, as dangerous or inferior to its own product

The dominant undertaking may evade the penalisation under Article 102 *TFEU* if the effects arising from the conduct can be counterbalanced by advantages, which would also benefit the consumer, i.e. negative effects of the abuse might be overweight by efficiency gains from the conduct.[68] However, the Commission has set out four cumulative criteria to be fulfilled. Firstly, the conduct must relate to the actual conduct, secondly, the conduct must be indispensable for the efficiency gains realisation, thirdly, the gains must overweight all negative effects on competition and consumer welfare, and fourthly, the conduct cannot eliminate effective competition.[69] The dominant undertaking bears the burden of proof. However, the test for proving efficiency gains was defined and utilised by the CJEU in its recent *Post Danmark II* judgment. The CJEU stated that:[70]

> it is for the dominant undertaking to show that the efficiency gains likely to result from the conduct under consideration counteract any likely negative effects on competition and consumer welfare in the affected markets, that those gains have been, or are likely to be, brought about as a result of that conduct, that such conduct is necessary for the achievement of those gains in efficiency and that it does not eliminate effective competition, by removing all or most existing sources of actual or potential competition

---

[65] See Ibid para 44.
[66] See Guidance paper, supra n 36, [30].
[67] See Ibid [29]. See also Judgment in *Hilti* v *Commission,* T-30/89, ECR II-1439 ("*Hilti v Commission*"), para 118 – 119; Judgment in *Tetra Pak International* v *Commission (Tetra Pak II)*, T-83/91, ECR II-755, para 83 – 84; 138.
[68] See Judgment in *Post Danmark II*, C-23/14, 6 October 2015, n.y.r., ("*Post Danmark II*"), para 48; compare to Judgment in *Post Danmark*, supra n 64, para 42. See also judgments in *British Airways v Commission*, C-95/04 P, ECR I-2331, para 86; *TeliaSonera*, supra n 26, para 76.
[69] See Guidance paper, supra n 36, [30].
[70] See *Post Danmark II*, supra n 68, para 49.

Intellectual property rights can be used in a manner that constitutes an abusive manner and, thus, penalised under Article 102 *TFEU*.[71] Article 102 *TFEU* has increased in significance after the *Regulation 1/2003*.[72] Article 3 *Regulation 1/2003* states that national competition authorities must apply Article 102 *TFEU* to banned conducts under the article even in sole national matters.

2.2.3 Abuse of dominance by use of intellectual property right

Patents can enhance a dominant position and contribute as a factor to that the undertaking is found dominant on the market. However, the mere existence of such rights cannot in itself constitute a dominant position.[73] The exercise of intellectual property rights is lawful, as long as in coherence with Article 36 *TFEU,* and cannot constitute an abuse in themselves.[74]

There must be a clear link between the abusive use of the right and the dominant position of the undertaking in order for the intellectual property right to be an abuse.[75] Intellectual property rights will most of the time amount to a barrier to market entry. However, it is of importance to differentiate between the foreclosure of the market due to the rightful use of the right and the barriers to entry due to abusive behaviour. A patent constitutes a part of the product but is not the product itself.[76] Consequently, the market will be a bit bigger than the patent in most cases.

It is not an abusive act to refuse to license or supply intellectual property in itself. However, it is abusive if the refusal prevents new products to enter the market or limits technical development to the expense of the consumers. CJEU affirmed this in the *IMS Health v NDC Health* judgment.[77]

The dispute in *IMS Health v NDC Health* was based on the refusal to license copyright to a competitor, and whether that could be considered abuse of dominance. IMS Health is supplying pharmaceutical companies with sales

[71] See Jones & Sufrin, supra n 42, pp 558 ff.
[72] *Council Regulation (EC) No 1/2003 of 16 December 2002 on the implementation of the rules on competition laid down in Articles 81 and 82 of the Treaty (Text with EEA relevance),* OJ L 1, 4.1.2003, p. 1–25 ("Regulation 1/2003"). See also Jones & Sufrin, supra n 42, p 287.
[73] See Compare Judgment in *EMI v CBS*, Case 51/75, ECR 1976-811; Judgment in *RTE and ITP v Commission*, Joined cases C-241, 242/91 P, ECR I-808, para 46 ("Magill") with Judgment in *Parke, Davis and Co. v Probel, Reese, Beintema-Interpharm and Centrafarm***,** Case 24/67 *1968 55*; *Hilti v Commission*, supra n 67, para 93. See also Guidance paper, supra n 36, [17].
[74] See Jonathan D.C. Turner, *Intellectual property and EU competition law* (Oxford University Press, 2010), p 85.
[75] See Ibid p 86.
[76] See Guy Tritton, *Tritton on intellectual property in Europe* (Sweet & Maxwell, 2014), p 1605.
[77] See *IMS Health NDC Health*, supra n 20.

data in a "brick" structure where each brick correspond to a designated geographical area.[78] In 2000, after discovering some competitors' usage of the structure, IMS Health obtained an injunction from a German court.[79]

NDC Health filed a complaint to the European Commission claiming abuse of dominance under Article 102 *TFEU*. The Commission ordered IMS Health to grant a license, but the President of the Court of First Instance later suspended the decision.[80] IMS Health brought actions against NDC Health for usage of the structure, and the German court decided to stay the proceedings and refer questions to the CJEU.

It is an abusive behaviour, explicitly exemplified in Article 102 (b) *TFEU*, to create a market barrier for new products or to limit technical development. The notion of "new product" is a balance of the value of protection for intellectual property rights and the interest of free competition and right to conduct business.[81] As held in *IMS Health v NDC Health* judgment, free competition prevails if the "refusal to grant a license prevents the development of the secondary market to the detriment of consumers."[82] Notably, the undertaking aspiring to enter the market cannot "duplicate the goods or services already offered on the secondary market", but must produce new products for which there is potential consumer demand.[83]

The fact that an undertaking is protecting its intellectual property right by preventing unlicensed users to make use of its products does not constitute an abuse under Article 102 *TFEU*. However, to frustrate or delay a licensing of the right might be an abuse;[84] to register a trademark used by its competitors in other Member States might constitute an abuse.[85] Furthermore, to give misleading representation numerous times in order to acquire an extended patent protection and preserve supplementary protection in respect of medicines are abusive conduct.[86]

---

[78] See Ibid, para 4.
[79] See Case COMP D3/38.044 – NDC Health v IMS Health: Interim measures, OJ 2002 L 59, p.18, art. 1.
[80] See Judgment in *IMS Health v Commission*, T-184/01 R, ECR II-3193.
[81] See Article 16 and 17 of the CFREU.
[82] See *IMS Health v NDC Health*, supra n 20, para 48.
[83] See Ibid para 49.
[84] See *Hilti v Commission*, supra n 67.
[85] See *Osram/Airam*, Eleventh Report on Competition Policy (1981), [97].
[86] See Judgment in AstraZeneca, COMP/A 37.507/F3 ("*AstraZeneca – Commission decision*"), para 626. See also Judgment *AstraZeneca v Commission,* T-321/05, ECR II-2805 ("*AstraZeneca – General Court*"); *AstraZeneca*, supra n 21.

2.2.4 AstraZeneca v Commission

2.2.4.1 Background

The Commission imposed a fine of EUR 60 million on AstraZeneca plc and AstraZeneca AB ("AstraZeneca") for abuse of dominant position.[87] The decision was appealed to the General Court, and was finally settled by judgment of the CJEU.[88]

The decision stems from AstraZeneca's attempt to expand its monopoly on the EU market for the market of Losec by misuse of patent regulations. Losec is a brand name and most commonly used on the European market for the omeprazole-based pharmaceutical product used in treatments of gastrointestinal conditions liked with hyperacidity and proactively inhibit acid secretion into the stomach. The product was the first product on the market to act directly on the proton pump, i.e. the enzyme in the parietal cells along the stomach walls. Accordingly, Losec decreases the acid production when patients medicate with it.[89]

AstraZeneca was claimed to have misled multiple national patent offices and national courts in order to obtain a supplementary protection certificate ("SPC"), to prolong the protection of the patent for Losec. Furthermore, AstraZeneca had withdrawn the market authorisation for Losec by deregistration, arguably to make market entry harder for generic companies.

2.2.4.2 Commission Decision and General Court

In 1999, the generic undertakings Generics (UK) Ltd and Scandinavian Pharmaceuticals Generics AB complained to the Commission and claimed that AstraZeneca's actions prevented generic products of omeprazole to enter the market.[90] The Commission found that AstraZeneca had committed two abuses, and consequently breached Article 82 *EC* [now 102 *TFEU*].

The first abuse consisted of misleading representations to national patent offices and the Member States of the European Economic Area's courts. AstraZeneca tried to induce the national patent offices of Belgium, Denmark, Germany, the Netherlands, the United Kingdom and Norway, and national courts in Norway and Germany, to deliver a supplementary protection certificate to which it was not entitled.[91]

The second abuse consisted of AstraZeneca's deregistration of the market authorisation in Sweden, Denmark and Norway. Such a withdrawal was conducted in order to make the launch of generic products on the market more difficult or at least delay it, and prevent parallel import of Losec to this

[87] See *AstraZeneca – Commission decision*, supra n 86, p 198.
[88] See *AstraZeneca*, supra n 21.
[89] See *AstraZeneca – Commission decision*, supra n 86, pp 5 ff.
[90] See Ibid pp 5 ff.
[91] See Ibid, pp 32 ff.

area.[92] The Commission decided to fine AstraZeneca for abusive behaviour on the market to a sum of EUR 60 million.[93]

The General Court upheld the Commission decision in its entirety. However, the General Court found the Commission to error in evaluating the second abuse of dominance, namely, in the assessment of the parallel import of Losec. The General Court held that the Commission had failed to establish that the withdrawal was capable of restricting the parallel import and argued that the conduct was not objectively of a nature to exclude the imports and competition.[94] The fine was reduced to EUR 52,5 million.[95]

2.2.4.3 Court of Justice of the European Union

Considering the first abuse, the CJEU upheld the judgment in its entirety but seized the opportunity to clarify the test utilised when assessing misleading statement to a patent office.

The CJEU underlined that representation in itself cannot constitute an abuse, regardless of its anti-competitive effects on the market. Representation can only lead to an abusive conduct if it is designed to unlawfully obtain an exclusive right and that "those representations are actually liable to lead the public authorities to grant the exclusive right applied for."[96] Subsequently, the CJEU deemed the representation as a fact of the case, but not the central issue at hand. The central issue for the CJEU was the intent to mislead and intent to conduct an abusive behaviour.

Regarding the second abuse, AstraZeneca argued that the withdrawal of the market authorisation of Losec was merely an exercise of their right conferred upon them by EU law. An exercise of a right could not be prohibited, in AstraZeneca's view, at the same time as legally granted. The CJEU countered with the fact that, firstly, there was no objective justification for AstraZeneca to withdraw those registrations.[97] Secondly, the withdrawal could not legitimately protect an investment in such a way that it came within the scope of competition on the merits.[98] Thirdly, the CJEU clearly stated that the illegality of an abusive conduct by a dominant undertaking could not be justified by the lawfulness of the behaviour under other areas of law.[99] The CJEU established that a dominant undertaking has a special responsibility, which implies that:[100]

---

[92] See Ibid p 61.
[93] See Ibid p 198.
[94] See *AstraZeneca – General Court,* supra n 87, para 901; 905.
[95] See Ibid para 931.
[96] See *AstraZeneca,* supra n 21, [106].
[97] See Ibid [130].
[98] See Ibid [131].
[99] See Ibid [132]. The paragraph provides: "the illegality of abusive conduct under Article [102 TFEU] is unrelated to its compliance or non-compliance with other legal rules and, in the majority of cases, abuses of dominant positions consist of behaviour which is otherwise lawful under branches of law other than competition law."
[100] See Ibid.

> it cannot therefore use regulatory procedures in such a way as to prevent or make more difficult the entry of competitors on the market, in the absence of grounds relating to the defence of the legitimate interests of an undertaking engaged in competition on the merits or in the absence of objective justification.

The CJEU furthermore refused the argument that the exercise of a right lawfully afforded by EU law could not amount to an abuse, or only amount to an abuse in exceptional cases, and held that[101]

> The fact that the exercise of such options by an undertaking in a dominant position is limited or made subject to conditions in order to ensure that competition already weakened by the presence of that undertaking is not subsequently undermined is in no way an exceptional case and does not justify a derogation from Article 82 EC, unlike a situation in which the unfettered exercise of an exclusive right awarded for the realisation of an investment or creation is limited.

The CJEU shows by its adjudication an eagerness to widen the scope of the concept of abuse, and making the test of objective justifications more strict. Furthermore, the other essential aspect of the judgment is the Court's statement that nothing apart from competition on the merits is allowed, and anything else should be considered an abuse of dominance.

[101] See Ibid [150]. Compare to Ibid [142].

2.3 EU public procurement law

All governmental authorities around Europe have to purchase pharmaceuticals through public procurement procedures. If a public insurance schemes is in place that funds the healthcare entities directly or indirectly, those entities must utilise tender procedures as governed by EU law for supply of medicaments. Even sickness insurance funds and healthcare entities are included if receiving funds from the government in any way.[102] This chapter will quickly run through the basic aspects of EU procurement law in order to give a better understanding of the procedure and the remedies available for an aggrieved party.

Three directives govern EU public procurement law.[103] The directives consist of substantial changes in comparison to the previous ones that they repealed, and an implementation on the *Europe 2020* goals and influenced by the Mario Monti Report *A New Strategy for the Single Market*[104].[105] The directives are still under implementation in the Member States.[106] The directives, both previous and current, lay the foundation for the public procurement law in the Member States.[107]

The directives prescribe which procurement procedures that are approved of under different circumstances, and how selection and award criteria can be formulated.[108] For example, the selection and award criteria must be precise and advertised, and tender offer shall be disregarded if it does not fulfil the advertised criteria.[109] The public procurement directives are governed by three fundamental principles of EU law, namely, equal treatment, proportionality and transparency. These principles are the pillars that public

[102] See Marc Martens & Nicolas Carbonelle, *White paper: Public procurement of medicinal products - Common legislation but diverging implementation approaches throughout the EU,* p 4.
[103] See *Directive 2014/24/EU of the European Parliament and of the Council of 26 February 2014 on public procurement and repealing Directive 2004/18/EC*, OJ L 94, 28.3.2014, p. 65–242 (”Classic directive”); *Directive 2014/25/EU of the European Parliament and of the Council of 26 February 2014 on procurement by entities operating in the water, energy, transport and postal services sectors and repealing Directive 2004/17/EC*, OJ L 94, 28.3.2014, p. 243–374 (”Utilities directive”); and *Directive 2014/23/EU of 26 February 2014 on the award of concession contracts*, OJ L 94, 28.3.2014, p. 1–64 (“Concession directive”).
[104] Mario Monti, "A New Strategy for the Single Market", Report to the President of the European Commission, 9 May 2010.
[105] See e.g. Ibid pp 6 ff.
[106] E.g. the legislative act implementing the new rules on public procurement will be brought to voting by the Swedish Parliament in the spring 2016, see SOU 2014:25 “*Nya regler om upphandling*”. See also, for more general comments, Christoffer Bovis, *EU Public Procurement Law* (Elgar European Law, 2nd ed, 2012), pp 6 ff.
[107] See Martens & Carbonelle, supra n 103.
[108] See e.g. Classic directive*,* supra n 103, Article 58 & 67; Utilities directive*,* supra 102, Article 80 & 82.
[109] See e.g. Classic directive, supra n 103, Article 56; Article 67 (4-5); Whereas 89. See also Bovis, supra n 106, p 219 ff.

procurement rests upon, and visible both through the wording of provisions and explicitly mentioned in the preambles.[110]

However, the *Remedy directive*[111] ensures compliance with the procurement rules and affords the aggrieved party effective means for redemption due to a fault conducted in the tender procedure.[112] Remedies can be both pre- and post-contractual. The pre-contractual remedies offer a possibility for a national court to set aside the award of the contract, if the procedure is found unlawful.[113] Alongside the nullification of contract, the aggrieved party can claim damages because of harm suffered due to the loss of contract.[114] Two options are ultimately at hand if the award of the contract is set aside, either the contract is awarded to the runner-up in the tender or to redo the tender procedure following procedural regulations. Post-contractual remedies consist of a right to damages and that the award of contract will be deemed ineffective.

The directives are the ground rules for procurement procedures. The new directives are currently being implemented in Member States' legislations. The *Remedies directive* is already, and will remain, implemented in Member States' legislation and will continue to be applicable to all procurement procedures covered by the applicability of the procurement directives. Tender procedures on pharmaceuticals are governed by these rules, and offers the remedies to turn to when a party has been faultily aggrieved.

[110] See Ibid Article 76 & Whereas 1.
[111] *Directive 2007/66/EC of the European Parliament and of the Council of 11 December 2007 amending Council Directives 89/665/EEC and 92/13/EEC with regard to improving the effectiveness of review procedures concerning the award of public contracts,* OJ L 335, 20.12.2007, p. 31–46 ("Remedies directive").
[112] See Remedies directive, Article 1.
[113] See Ibid Article 2 & 2d.
[114] See Ibid Article 2.

3 Patent law

3.1 Introduction

Patent law has roots stretching back to the informal system of the Renaissance's Italy. The Italian glass blowers spread the use of patents to the rest of Europe to protect their skills.[115] The international conventions on patents are extensively developed.[116] The importance to protect inventions increased in the wake of the industrialisation. Effective protection of the inventions was hindered by the diversified and ineffective legal systems. The first international convention on patent was the *Paris Convention,* which was signed 1883 after ten years of conferences and drafts.[117] The *Paris Convention* has influenced the international system of patent law, and most patent law systems around the globe stem from the convention.[118]

The EPO supervises the *EPC,* and is not a EU institution but consists of an additional eleven non-EU members.[119] The CJEU has held that international conventions and treaties to which it is a signatory cannot create rights for individuals to rely upon before the Court. However, it was held in *Monsanto v Cefetra*[120] that EU law was to be interpreted to the furthest extent possible in the accordance with the *TRIPS*.[121] Case law by the EPO has also been taken into account in judgments by the CJEU.[122] Subsequently, the EU does not remain unaffected by the international patent systems and *Europe 2020* states that it is of importance for the EU to safeguard invention, in order to compete globally and stimulate investors in European companies.[123] Furthermore, the pharmaceutical sector is one of the major industries in the EU and its competitiveness is important for the economic development.[124]

A patent is valid for 20 years. After the expiry, any company who sees fit can enter the market.[125] This chapter will study pharmaceutical patents with focus on second medical use patents and skinny labelling. The first subchapter will focus on EU and the development of the unitary patent law system, whilst the following subchapters will study pharmaceutical patents and, lastly, scrutinise the pregabalin judgments.

---

[115] See Thomson & Reuters, "The History of Pantent".
[116] See Marianne Levin, *Lärobok i immaterialrätt* (Norstedts Juridik, 10th ed, 2011), pp 29 ff; Tritton, supra n 76, pp 68 ff.
[117] See *Paris Convention,* supra n 1.
[118] See e.g. TRIPs, supra n 4; the Patent Cooperation Treaty, June 19, 1970, 28 U.S.T. 7645, 1160 U.N.T.S. 231 reprinted in 9 I.L.M. 978 (1970); and the EPC, supra n 3.
[119] See Tritton, supra n 76, pp 90f; pp 123ff.
[120] See Judgment in *Monsanto v Cefetra*, C-428/08, ECR I-6765.
[121] See Ibid para 72.
[122] See e.g. Judgment in *Daiichi Sankyo and Sanofi-Aventis Deutschland*, C-414/11, e.r..
[123] See EUROPE 2020*,* supra n 10, pp 3f.
[124] See European Federation of Pharmaceutical Industries and Associations, *The Pharmaceutical Industry in Figures – Key data 2013*, p 3.
[125] See TRIPs, supra n 4, Article 33.

3.2 The European Union and Patent Law

3.2.1 The Unitary Patent System

The EU law on patents is in the starting pits. There were only two legislative measures in force on patents up until 2012.[126] There has been an on-going process to harmonise the national legislations on patents since 1965, when presenting the first draft on a harmonised patent law.[127] The striving for a unitary patent regulation had years of political deadlocks and disagreements.[128]

The *TEU,* the *TFEU* and the *CFREU* introduced multiple provisions safeguarding and strengthening the stand of patent law and intellectual property in general in the EU. Not only does the Article 36 *TFEU* exempt the intangible rights from the prohibition of quantitative restrictions, but it is also stipulated in Article 118(1) *TFEU* that:

> In the context of the establishment and functioning of the internal market, the European Parliament and the Council, (…), shall establish measures for the creation of European intellectual property rights to provide uniform protection of intellectual property rights throughout the Union and for the setting up of centralised Union-wide authorisation, coordination and supervision arrangements.

Two regulations, adopted on a unitary patent in December 2012, sprung from the initiative of a group of Member States. The group utilised the enhanced cooperation procedure as provided in Article 20 of the *TFEU*. [129] The two regulations, *Unitary Patent Regulation*[130] and the *Council Regulation Implementing Enhanced Cooperation in the Area of the Creation of Unitary Patent Protection with Regard to the Applicable Translation Arrangements*[131], was drafted as a package together with a third instrument, the *UPC Agreement.*[132] Whilst the two regulations are legislative acts of the EU and, therefore, enjoy the privilege as a source of EU law, the *UPC Agreement* is an international agreement and separated from EU law as such. This renders the *UPC Agreement* only applicable if ratified, and only

[126] Namely, the *Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions*, Official Journal L 213 , 30/07/1998 p.13 – 21, and, *Council Regulation (EEC) No 1768/92 of 18 June 1992 concerning the creation of a supplementary protection certificate for medicinal products*, OJ L 182, 2.7.1992, p. 1–5.
[127] See Tritton, supra n 76, pp 278 ff.
[128] See Ibid.
[129] See Alfredo Ilardi, *The New European Patent* (Hart Publishing Ldt, 2015), p 29.
[130] Unitary Patent Regulation, supra n 24.
[131] *Council Regulation (EU) No 1260/2012 of 17 December 2012 implementing enhanced cooperation in the area of the creation of unitary patent protection with regard to the applicable translation arrangements*, OJ L 361, 31.12.2012, p. 89–92 ("Reg 1260/2012").
[132] See UPC Agreement, supra n 25.

to the Member States who ratifies it.[133] However, the regulations are co-dependent on the ratification of the *UPC Agreement* in order to enter into effect.[134] The unitary patent regime lies in the future, awaiting a number of ratifications of the *UPC Agreement,* before it will come into effect.[135]

The current system of EU patent law consists of parallel systems. An inventor can file for protection in a single Member State, making use of the national system and enjoy protection in that specific territory. The other option is to apply for an EPO patent, which will provide protection in selected states simultaneously. Nevertheless, the acquired protection will still be regarded as a bundle of national patents for each of the designated states.[136] The system is Europe wide and offers protection in selected European countries, including some non-EU Member States.[137] However, the risk of such a system is diversified precedence in the Member States, which leads to a legal uncertainty for all parties involved in disputes since a patent rarely is nation specific but enjoys protection in multiple countries.[138] For example, a patent deemed infringing a generic pharmaceutical in Germany might not be considered to infringe the same patent in Sweden. Such inconsistency renders high costs for litigation and a legal uncertainty hampering development.

The main reason to enforce the Unitary Patent System is the need for an effective adjudication and application on enforcement and infringements in the EU. The new system aims at enhancing legal efficiency and keeping costs low. Currently, undertakings have to litigate in all Member States where the disputed patent is registered in order for it to be enforced or revoked.[139] A Unitary Patent Court would assure Member States adjudication in one forum only for the patent claims with coherent interpretation of the regulations.[140] Furthermore, the *UPC Agreement* and the procedural rules for the court stipulates that questions shall be referred to the CJEU upon request, and such referrals shall follow the rules established for the CJEU.[141]

---

[133] See Ibid Article 2.
[134] See Unitary Patent Regulation, supra n 24, Article 18.2; Reg 1260/2012, supra n 131, Article 7.2.
[135] For current status of ratification see link: http://www.consilium.europa.eu/en/documents-publications/agreements-conventions/agreement/?aid=2013001.
[136] See Tritton, supra n 76, p 240.
[137] See Ibid pp 90 f.
[138] See Ibid p 240; Levin, supra n 116, pp 274 f.
[139] See Judgment in Roche Nederland and Others, C-539/03, ECR I-6535, and compare to Judgment in *GAT mot LuK*, C-4/03, ECR-6509. See also Levin, supra n 116, p 274.
[140] See Ilardi, supra n 128, pp 66 f.
[141] See UPC Agreement; supra n 25, Article 21 & 38; *Rule of Proceedings of the Unified Patent Court (18th draft of 19 October 2015)*, Rule 266.

3.2.2 Pharmaceutical patents

3.2.2.1 The pharmaceutical sector's use of patents

The intensity of patenting inventions is higher in the pharmaceutical sector compared to other areas of business.[142] The pharmaceutical sector includes businesses that are producing and selling chemical and biological medicinal products on the market. The sector consists of few very large companies and multiple small ones. However, middle-sized pharmaceutical companies are rare on the market.[143] Applications for patent protection are normally filed at an early stage of the research of the pharmaceutical products. The protection is essential for the pharmaceutical companies to be sure to have the exclusive right to the pharmaceutical and recapitalise their investments.[144]

Pharmaceutical products constitute in most cases individual markets, even if the pharmaceutical sector as such is a heterogenic sector, which is due to the lack of substitution between the products. The lack of substitutes might stem from either that the medicinal products treat different deceases or that the side effects caused by the medicinal products are different whilst treating the same decease.[145]

Generic pharmaceutical products are medicaments consisting of an already known biological API.[146] An indication is the symptom that the substance aims at treating. The indications can aim to treat a disease, specific symptoms or have mere preventive effects.[147] They are the counteroffer to the previously patent-protected pharmaceutical. The product to which the patent has expired is the reference medicinal product referred to by a generic when applying for market authorisation.[148] Generic pharmaceuticals are low-priced and normally tough competition for the original product to adjust to. The general thought, based on economic theory, is that the original product will decrease in price in order to adjust to the new competitor at the market. However, there are situations when both parties have benefitted from the market entry of a generic product. Consumer preferences are governing the market, and there have been cases when an original product has been able to increase its price after the entry of a generic producer. The consumers that value the original brand chose to pay a higher piece whilst the price-oriented consumers choses the generic pharmaceutical.[149]

The area of pharmaceutical patent is a unique field of patent law in many ways. The "for use" indications are generally known not to limit the patent to an actual specific use, but rather to indicate what products that might fit

[142] See Marianne Levin & Hanna Nilsson, *Läkemedel & Immaterialrätt* (Jure, 2008), pp 12 f.
[143] See Bengt Domeij, *Läkemedelspatent* (Norstedts Juridik, 1998), p 4.
[144] See Ibid pp 1 f.
[145] See Ibid pp 8 f.
[146] See Ibid p 8.
[147] See Ibid p 313.
[148] See below Chapter 3.2.2.2.
[149] See Domeij, supra n 140, pp 8 f.

the purpose. Subsequently, the novelty of a product does not rest in its use and a patent cannot be granted for an addition to the usage or purpose, but for pharmaceutical patents it is rather the opposite.[150] Pharmaceutical substances and compositions are exempted from the general rule of Article 54(4) and (5) *EPC* and second medical use patents are common. Such an exemption only extends to substances and compositions, and no analogies have been accepted by the EPO.[151]

3.2.2.2 Pharmaceutical products' market authorisation

A pharmaceutical product must be assessed and approved before entering the EU market.[152] A market authorisation is granted either by the competent national authority or by the European Medicines Agency ("EMA") according to Article 6 of *Directive 2001/83/EC on the Community code relating to medicinal products for human use*[153] ("*Medicinal product directive*").[154] Such limitation sets the frame within which the product is authorised to be utilised in and the conditions imposed on the product. The purpose of such a system is to guarantee the safety, efficiency and quality of the product.[155]

There are four different types of procedures to grant authorisation: the centralised procedure, the mutual recognition procedure ("MRP"), and the decentralized procedure and the national procedure.[156] Regulation (EC) No 726/2004 regulates the centralised procedure. The procedure is compulsory for pharmaceutical products containing a new API intended for AIDS, cancer, neurodegenerative disorder or diabetes.[157]

The MRP is the recognition of the pre-existing authorisation by one or more Members States of the pharmaceutical product.[158] The decentralised procedure is executed by application for authorisation in several Member States. One of the Member States is chosen as "Reference Member State" and the market authorisation is after a review granted in both the reference

---

[150] See Rainer Moufang, "Patentability of pharmaceutical inventions: the European perspective" in Josef Drexl & Nari Lee, *Pharmaceutical Invention, Competition and Patent Law* (Edward Elgar Publishing, 2013), p 65.
[151] T 227/91 of 15 December 1992, OJ EPO 1994, 491 – Second surgical use/CODMAN.
[152] See *Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (Text with EEA relevance)*, OJ L 136, 30.4.2004, p. 1–33 ("Regulation (EC) No 726/2004"), Tile IV.
[153] *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*, OJ L 311, 28.11.2001, p. 67–128 ("Medicinal product directive ").
[154] See Ibid Article 6.
[155] See Sally Shorthose, *Guide to EU Pharmaceutical Regulatory Law* (Sweet & Maxwell, 5th ed, 2014), p 119.
[156] See Ibid pp 122 f.
[157] See Regulation (EC) No 726/2004, supra n 152, Whereas 8 & Annex.
[158] See Shorthose, supra n 155, pp 122 f.

state and the other Member States.[159] The national procedure is carried out on a Member State level and is rather rarely used.[160] The procedures are applicable to most conventional pharmaceutical products.[161]

The application must fulfil certain requirements in order to be granted the authorisation. The *Medicinal product directive* sets the general requirements utilised both by the EMA and the national authorities when assessing applications. Article 8(3) *Medicinal product directive* requires that amongst others the following are submitted:[162]

- Description of the manufacturing method,
- Therapeutic indications,
- "A written confirmation that the manufacturer of the medicinal product has verified compliance of the manufacturer of the API with principles and guidelines of good manufacturing practice",
- Results of pharmaceutical, pre-clinical and clinical tests, and
- Summary of the product characteristics, the packaging including leaflet

The EMA and its Committee for Medicinal Products for Human Use is the granting and supervising authority of pharmaceutical products in the EU.[163] The Committee forms an opinion on the application that the EMA sends to the Commission. The file sent to the Commission contains the opinion and an assessment report. The report includes the details of the submitted application. The decision is valid in all Member States and results in that the products "may be marketed in all Member States."[164]

As mentioned above, an applicant can chose to apply to the EMA or the national authority. The most commonly used system for larger pharmaceutical companies is to apply to the EMA whilst smaller companies apply to the national authorities.[165] A market authorisation holder may withdraw the market authorisation to the pharmaceutical product by submission of written observations to the national competent authority.[166]

Market authorisation is granted for a generic pharmaceutical product by application to the authorities. The generic pharmaceutical product must meet the same quality requirements as the reference medicinal product, i.e. the prior patent protected product with which the generic product will compete. Furthermore, the generic product must be bioequivalent to the reference medicinal product. Bioequivalence is a comparison of the reference medicinal product and the generic product, assessing to what extent the API

[159] See Ibid p 123.
[160] See Ibid.
[161] See Levin, supra n 142, p 130.
[162] See Medicinal product directive, supra n 153, Article 8(3)(a-m).
[163] See Ibid Article 5 & 10; 55 & 57(1)(k).
[164] European Commission, *The Centralised Procedure.*
[165] See Shorthose, supra n 155, p 123.
[166] See Medicinal product directive, supra n 153, Article 22 a.

reaches its full effect. However, the generic product is allowed to differ from the reference medicinal product to some extent, for example in form, colour or size.[167]

3.2.2.3 First and Second Medical Use Patents

A pharmaceutical substance's description in a patent claim must be specified in order to be approved for registration. Such specification stems from the fact that the pharmaceutical product, and substance, must fulfil the requirement of industrial application.[168] An already patented substance can enjoy a second patent protection if it is the first time the substance is patented as a pharmaceutical substance. Such patent is called a first medical use patent.[169]

First medical use patents enjoy broad protection as held in EPO's early decision *Pyrrolidine Derivatives/HOFFMANN-LA ROCHE*.[170] The patent claims were disputed as they, allegedly, had been broadly defined. Hoffmann-La Roche had filed for a protection "for the use as an active therapeutic substance".[171] The Boards of Appeal made an analogy to chemical compounds and the principle of equal treatment that could not be interpreted from the wording of the *EPC*. It found that inventions, which were previously known but still patentable as a first medical use patent, were to be treated differently from other inventions. Based on the principle of equal treatment, the Boards of Appeals held that if a chemical compound could be granted absolute protection for use in therapy, so should the "inventor who for the first time makes a known compound available for therapy."[172] The Boards of Appeals found that the fact that Article 54(4) *EPC* does not provide the protection as broad as now stated, did not limit the scope. It was held that the usual practice relating to new compounds had to be followed even if it was a first medical use claim.[173]

First medical use patents focus on the use of the pharmaceutical. However, there are situations where a first medical use patent is discovered to treat other diseases than the ones indicated in the patent. Such discovery is not covered by the first medical use patent. However, it is possible to protect the new discovered area of treatment by the use of a second medical use patent.[174] A second medical use patent is a patent protecting the use of the

---

[167] See Levin, supra n 142, p 124.
[168] See Annette Kur & Thomas Dreier, *European Intellectual Property Law: Test, Cases & Materials* (Edward Elgar Publishing, 2013), p 110.
[169] See SOU 2006:70 *Oinskränkt produktskydd för patent på genteknikområdet*, p 139.
[170] See Decision of 12 January 1984, OJ EPO 1984, 164 – Pyrrolidine-Derivatives/HOFFMANN-LA ROCHE. T 128/82 OJ EPO 1984 ("T 128/82 Pyrrolidine-Derivatives") p 164. See also Domeij, supra n 143, p 316.
[171] See T 128/82 Pyrrolidine-Derivatives, supra n 170, [8].
[172] See Ibid [10].
[173] See G 2/08, OJ EPO 2010, 456 – Dosage regime/ABBOTT RESPIRATORY ("G 2/08 Dosage regime"), [5.8], [5.9.1] and [5.10.3] of the reasons. See also T 36/83, OJ EPO 1986, 295 – Thenoyl peroxide/ROUSSEL-UCLAF.
[174] See Kur & Dreier, supra n 168, p 110.

indication for a specific type of use. The novelty of the patent lies in the new use of the patent.[175]

The scope of protection for a second medical use patent is limited to the registered patent claims. Consequently, the patent claims must be specified and narrow in order for a second medical use patent not to infringe the first medical use patent, or other second medical use patents for that matter. The limitation in scope is "intended to match as closely as possible the scope of protection to the scope provided by a Swiss type claim."[176] This stems from the wording of Article 54(5) *EPC*. Article 54(5) *EPC* is expressly limited to the specific use in the patent claim, and seems to not leave room for expansion.[177]

Accordingly, second medical use "defines the use in a specific manner".[178] The Enlarged Board of Appeal accepted such type of claims early on, but is not accepting them any longer due to the amendment of the *EPC*.[179] The second medical use patent can be utilised on the same disease as the first medical use patent if done so with some modifications, as held by the Boards of Appeals in case law:[180]

> Article 54(5) EPC does not exclude a medicament that is already used in the treatment of an illness being patented for use in a different treatment by therapy of the same illness.
>
> Such patenting is also not excluded when a dosage regime is the only feature claimed that is not comprised in the state of the art.

In summary, first and second medical use patents have different scope of protection. There is no limitation as to how many second medical use patents that can be granted on the same substance. The wording of the patent claim is essential to the scope of protection. Nonetheless, the protection cannot be extended outside the specific use of the pharmaceutical patent in question.[181]

---

[175] See G 5/83, OJ EPO 1985 64, EISAI/Second medical indication ("G 5/83 EISAI"), p 22.
[176] See EPO, *Case law of the Boards of Appeals – 6.2.1 Introduction.*
[177] Article 54 EPC is worded:
(5) Paragraphs 2 and 3 shall also not exclude the patentability of any substance or composition referred to in paragraph 4 for any specific use in a method referred to in Article 53(c), provided that such use is not comprised in the state of the art.
[178] See T 1599/06 (Mycobacterium vaccinating agent/UNIVERSITY OF CALIFORNIA) of 13.9.2007, p. 19.
[179] See G 1/83, G 5/83, G 6/83 of 5 December 1984 , OJ EPO 1985, 60, 64, 67,
– Second medical indication/BAYER/EISAI/PHARMUKA. See also G-2/08 Dosage Regime, supra n 173.
[180] See G-2/08 Dosage Regime, supra n 173, p 2.
[181] See Domeij, *Pharmaceutical patents in Europe*, (Kluwer Law International/Norstedts Juridik, 2000), p 183.

3.2.2.4 Swiss type claims and EPC 2000 claims

Second medical use claims were up until the adoption of the *EPC 2000* designed as Swiss type claims.[182] *EPC 1973* did not approve of patent claims formed to protect an already known substance. The Swiss type claim was created to make it possible for pharmaceutical undertakings to protect the discovery that already known therapeutic substances could be used in the treatment of another disease. The Boards of Appeal held in G 5/83 *EISAI/Second medical indication* that the Swiss type claim had to be allowed in order to overcome the obligations stipulated in Article 54(5) *EPC 1973* and to ascertain legal certainty. Furthermore, the Board held that the German form claims were not to be approved since they aimed at the method of medical treatment.[183]

The structure of the Swiss type claim consists of pharmaceutical ingredient followed by a statement of purpose ("Use of a substance or composition X for the manufacture of a medicament for therapeutic application Z").[184]

The Enlarged Board of Appeal declared the invalidity of Swiss type claims in 2010. The Board held in Decision G 2/08 that Swiss type claims where to be disregarded and invalidated as a second medical use claim. However, due to legal certaintly, the pending applications before the EPO and applications submitted three months after the judgment's publication would not be affected by the new jurisprudence established by it.[185] Consequently, the application must have filing or priority date prior to 29 January 2011 in order to be approved containing a Swiss type claim.[186]

The rules of the EPO were amended by the *EPC 2000*. Some tend to say that the amendments lessened the complexity of the second medical use claims. The new convention approves of claims stated as "substance X for the treatment of Y", if X is a known substance, and "Substance X for use in the treatment of disease Y", if the claim involves an inventive step. EPO holds that the Swiss type claim is relating to the method of treatment, which is explicitly excluded from patentability under Article 53(c) EPC.[187] This type of claim only remedies the manufacturer or dealer, but cannot target the true infringer. Furthermore, its scope of protection only expands to the actual indication in the claim.[188]

---

[182] See EPC 1973; G 5/83 EISAI, supra n 175, [20 – 21] of the Reasons.
[183] See G 5/83 EISAI, supra n 175. See also Triton, supra n 76, p 152.
[184] See IP Kat, "No pain for Actavis – Warner-Lambert fail to stop launch of generic Pregabalin" 21 January 2015.
[185] See G 2/08 Dosage regime, supra n 173, [7.1.4].
[186] See EPO, *Notice from the European Patent Office dated 20 September 2010 concerning the non-acceptance of Swiss-type claims for second or further medical use following decision G 2/08 of the Enlarged Board of Appeal*, OJ EPO 2010, 514.
[187] See EPO, *Guidelines for examination - Second or further medical use of known pharmaceutical products*, G-IV-7.1.
[188] Triton, supra n 76, p 152; Domeij, supra n 143, p 325.

The difference between the claims is that the Swiss type claim grants a purpose-related process protection, whilst the EPC 2000 claim grants a purpose-related product protection.[189] It is not settled what the direct difference is. The relation between Swiss type claims and EPC 2000 claims remains highly disputed by scholars and practitioners. The definite scope of protection for the new type of claims remains uncertain since the issue still has not been settled. Not even the Boards of Appeals has been able to settle the issue. The Board held in T 1780/12 that the claims are kind of the same but different. It stated that a process protection confers less protection than a purpose-related product protection does, but that the new protection is equal to the old as provided by the Swiss type claims.[190] The Board recited the *travaux préparatoires* and stated that:[191]

> In contrast to previous Article 54(5), now Article 54(4) EPC, providing broad (generic) protection for use in a medical method for the inventor of such use for the first time, new Article 54(5) is expressly limited to a specific use. This limitation is intended to match as closely as possible the scope of protection to the scope provided by a 'Swiss type claim'.

The following study will refer to this definition of the scope of protection as provided by the EPC 2000, i.e. almost but not identical.

3.2.2.5 The Concept of Skinny Labelling

The pharmaceutical sector has been evolving and growing over the last decades. At the same time, there have been a significant increase of second medical use patents and the authorisation of generic products on the market.[192] A drastic intensification of competition has occurred by the generic products' entry.[193]

According to the *Medicinal product directive*, and as clarified above, a pharmaceutical product must be granted market authorisation in order to enter the market. A generic product must declare all necessary product information, e.g. a leaflet and list of contents.[194] However, a manufacturer can withhold certain indications from the product summary of the generic product, if such indications are patent protected.[195] Consequently, skinny labelling is, simplified, to withhold information on, e.g. the leaflet or packaging that would, that if specified would infringe a valid patent. Accordingly, information is deleted from the description in order to protect the valid second medical use patent and to produce a product able to

[189] See G 2/08 Dosage regime, supra n 173.
[190] T 1780/12 (Cancer treatment/BOARD OF REGENTS, THE UNIVERSITY OF TEXAS SYSTEM), OJ EPO 2014, 130 ("T 1780/12 Cancer treatment"), pp 22 f; Compare to EPO, *Basic Proposal - Explanatory notes - Article 54(4) and Article 54(5) EPC*, 21 November 2000, MR/18/00, p 4.
[191] See T 1780/12 Cancer treatment, supra n 188, p 23.
[192] See Domeij, supra n 143.
[193] See Domeij, supra n 140, pp 9 f.
[194] See e.g. Medicinal product directive, supra n 153, Article 10 & 11.
[195] See Ibid Article 11(2).

compete with the reference medicinal product.[196] However, due to substitution based on API by pharmacies in some Member States, the generic medicinal product might end up as a substitute to the patent protected pharmaceutical since the API remains named in the information to the skinny label generic product.[197]

EU law approves of generic medical product to enter the market, after the authorisation of a competent authority in a Member States.[198] Furthermore, Article 3(3) of the Regulation 726/2004 states that:[199]

> b) the summary of the product characteristics is in all relevant respects consistent with that of the medicinal product authorised by the Community except for those parts of the summary of product characteristics referring to indications or dosage forms which were still covered by patent law at the time when the generic medicine was marketed

The paragraph approves of the generic undertakings using skinny labelling in order to enter the market. Skinny labelling is essential for a generic pharmaceutical company, which otherwise would commit patent infringements of the valid second medical use patents. For example, a generic product of pregabalin can be dispensed for the treatment of epilepsy and generalised anxiety disorder ("GAD") since the protection has expired for these indications, but not for neuropathic pain for which the patent remains in force.[200] Consequently, skinny labelling guarantees that effective competition can prosper at the market of the reference medicinal product, whilst invention can make progress for other indications.

Conclusively, skinny labelling is an exemption to some of the basic principles of patent law, especially the principle of equivalence. The principle of equivalence is the core in establishing an infringement. The basic proposition is that if the two medicinal products are equal, infringement has occurred.[201] Article 3(3) Regulation 726/2004 stipulates a direct exemption to the general principle. This exemption is the basis for the use of skinny labelling and the safeguard for a potential market exposed to competition.

---

[196] See Ibid.
[197] See e.g. District Court Hamburg, decisions of 2 April 2015, docket numbers 327 O 67/15, 327 O 132/15, 327 O 140/15, 327 O 143/15 – Pregabalin ("District court Hamburg").
[198] See Levin & Hansson, supra n 142, p 131.
[199] See Regulation (EC) No 726/2004, Article 3 (3).
[200] See "What is the intention with skinny labels and second medical use patents?" by Christopher Hayes in *Journal of Generic Medicines* (2015) 11(3-4), pp166 ff.
[201] See Levin, supra n 116, pp 320 ff.

3.3 The Pregabalin Judgments

3.3.1 Background

Warner-Lambert Co. LLC ("Warner-Lambert"), part of the Pfizer group, has commenced proceedings in multiple countries in Europe challenging generic pregabalin products, claiming infringement in its second medical use patent.[202] Pregabalin is a pharmaceutical that treats epilepsy, GAD and neuropathic pain. Warner-Lambert's first pregabalin product on the market was Lyrica, patent as a first medical use patent in 1993 and expired 2013.[203] In 1997, a second medical use patent was granted for the use of pregabalin in a method to treat pain. The patent remains valid, and expires in 2017.[204]

The EMA granted Lyrica market authorisation for the first time in 2004. The authorisation extended to two indications: treatment of GAD and epilepsy.[205] By 2006, the market authorisation was extended to the treatment of neuropathic pain. The data exclusivity on the patent of Lyrica expired in July 2014, and due to Warner-Lambert letting the fees for the SPC laps, it was free for the generic companies to enter the market by use of skinny labelling. Subsequently, Warner-Lambert filed numerous claims all around Europe against the generic companies claiming that the generic pharmaceuticals infringed the second medical use patent.[206]

As mentioned, Warner-Lambert filed lawsuits against different generic companies around Europe, for example in Denmark, Italy, Spain and the United Kingdom. In Italy, the Italian Medicine Agency published a communiqué on the prescription and the dispensation practices of pregabalin, both aimed at the proscribing doctors and pharmacists.[207] In Spain, the regional health authorities have undertaken measures to protect the second medical use patent. For example, Murcia and Catalonia published statements stressing that pharmaceuticals had to be prescribed in accordance with the summary of product characteristics ("SmPC").[208] The following chapter will focus on the British, French and German judgments.

---

[202] See Patent EP no 6 641 330, *Pregabalin salts.*
[203] See Patent EP 0 934 061, I*sobutylgaba and its derivatives for the treatment of pain.*
[204] See Ibid. It is stated in the summary "The instant invention is a method of using certain analogs of glutamic acid and gamma-aminobutyric acid in pain therapy."
[205] See Centralised Market Authorisation EU/1/04/279/001-025.
[206] See Tribunal de Grande Instance de Paris, Ordonnance de Référé rendu le 26 octobre 2015 – Warner-Lambert Co LLC, Pfizer Ltd & SAS Pfizer PEE France v SAS Sandoz & Sandoz GmbH, N° RG 15/58725 ("Warner-Lambert v Sandoz"). See for an unofficial English translation of the judgment: https://docs.google.com/viewer?a=v&pid=sites&srcid=ZGVmYXVsdGRvbWFpbnxmcmVuY2hpcGRhbWFnZXN8Z3g6NzI2ZjFhZTEyOTNlNDE0MQ (Warner-Lambert v Sandoz), pp 2 ff.
[207] See Ibid pp 5 f.
[208] See Ibid p 6.

3.3.2 The United Kingdom

Actavis was the first generic pharmaceutical company to enter the British market with Lecaent, a generic pregabalin pharmaceutical, after the expiration of the patent.[209] Warner-Lambert brought action against Actavis, a dispute that gave rise to multiple judgments on preliminary injunctions and infringements, four in total at the present.[210]

In the United Kingdom, pharmaceuticals are prescribed and dispensed on the international non-proprietary name ("INN"), not indication. The prescription does not identify the product to be dispensed but the pharmaceutical substance. Consequently, a pharmacist may dispense Lecaent for the treatment of pain even if the SmPC does not contain the indication for it. Pharmacists are only obliged to dispense the branded product if specified in the prescription. However, pharmacists are strongly advised to prescribe on the INN, and the pharmacists will then dispense the cheapest pharmaceutical.[211] The pharmacist is compensated by the difference between the cost of the dispensed pharmaceutical and the NHS's reimbursement of the branded medicament under the Drug Tariff scheme.[212]

In a preliminary judgment, the first instance tried to define the test for the concept of "for". The judge held that "proof of subjective intent on the part of the manufacturer" was required in order to determine an infringement. The Court of Appeal eased the test stating that it was enough to establish that the manufacturer knew or could have "reasonably foreseen" that the product would be used in a patent infringing manner.[213]

In the most recent judgment, *Generics (UK) Ltd (t/a Mylan) v Warner-Lambert Co. LLC*,[214] the justice of the High Court of Justice, the Honourable Sir Justice Richard Arnold ("Arnold J"), hesitantly applied the test of the Court of Appeal. Doing so, Arnold J applied a narrow interpretation to the "intentional use" as stated by the Court of Appeal. Foreseeability was not enough, but it had to be shown that the generic product would be intentionally administered by, in this case, the prescribing doctor or the dispensing pharmacist in order to infringe the second medical use patent. As a finishing tribute, Sir Arnold J further held that it was not enough with the intent of the doctor and the pharmacist. The intention had to be tied to the manufacturer of the generic pharmaceutical in order to affect if deemed to be an infringement or not.

---

[209] See Warner-Lambert Company, LLC v Actavis Group Ptc EHF & Others [2015] EWCA Civ 556 the Court of Appeal [2015] EWCA Civ 556 ("Warner-Lambert v Actavis"), [6]; [8].
[210] See e.g. Warner-Lambert Company, LLC v Actavis Group Ptc EHF & Others [2015] EWHC 72 (Pat); and Generics (UK) Limited t/a Mylan v Warner-Lambert Company LLC [2015] EWHC 2548 (Pat) ("Generics v Warner-Lambert").
[211] See Warner-Lambert v Actavis, supra n 207, [11].
[212] See Ibid [12]; [13].
[213] See Ibid [114]; [122].
[214] See Generics v Warner-Lambert, supra n 210.

3.3.3 France

In the recent case, dated 13 October 2015, Warner-Lambert filed for a preliminary injunction against Sandoz, a multinational generic pharmaceutical manufacturer.[215] The dispute arose when market authorisation for a generic pharmaceutical to Lyrica was granted to Sandoz. The indication for pain treatment remained carved out with the product specified and authorised for the treatment of epilepsy and GAD.[216] Warner-Lambert filed a suit against Sandoz claiming an infringement of the second medical use patent.[217]

During the preparation for litigation, Sandoz published an announcement directed to the French pharmaceutical industry, mainly directed to pharmacists and proscribing doctors, informing them of the patent infringement of Warner-Lambert's patent they would commit if proscribing and dispensing Sandoz product for the treatment of pain instead of the patent protected product.[218] However, Warner-Lambert was not satisfied and persisted in their claim that the generic medicament had to be limited in supply to the market.[219]

The judge came to the finding that, in the light of the notice, there could not be a direct or indirect infringement. The court agreed with Sandoz stating that "a potential infringement should be assessed objectively, not subjectively".[220] Warner-Lambert had not denied the granted market authorisation due to the carve out by the EMA or that Sandoz sent the announcement to the industry.[221] Due to the information sent both by Pfizer, as a message to the health authorities to alert them of the rights under the valid patent, and by Sandoz, no direct infringement of Pfizer's right could have been conducted.[222]

The judge concluded that the national legislation governing prescription and substitution of pharmaceuticals could not automatically lead to an infringement of a patent right, especially not in the situation "where a second medical use patent has been granted for an API, offering it protection, when the previous indications for the same API are in the public domain."[223] The court furthermore pointed out that it could not be a responsibility of Sandoz to contact the health authorities to alert them of the rights stemming from the valid second medical use patent. It is up to the patent holder to alert the authorities of such rights. That is why the right

[215] See Warner-Lambert v Sandoz, supra n 206.
[216] See Ibid p 2.
[217] See Ibid pp 7 ff.
[218] See Ibid pp 12 f.
[219] See Ibid p 13.
[220] See Ibid p 21.
[221] See Ibid p 16.
[222] See Ibid p 20.
[223] See Ibid p 23.

holder is informed when a generic pharmaceutical is granted market authorisation.[224] Accordingly, Sandoz was not liable of any infringement.[225]

3.3.4 Germany

Germany has taken a different approach to the infringement issue in the dispute. Whilst the case law on direct infringement is well established, with the recognised principle of "sinnfällige Herrichtung" (i.e. "manifestly arranged"), the issue of indirect infringements remains disputed.

The principle of "manifestly arranged" stems from rulings by the Düsseldorf district court, and has been upheld by German Court of Appeal decisions.[226] The concept of "manifestly arranged" requires a close link between the purpose of use and the manner of the marketing of the product. For example, the marketing of generic pharmaceutical by meetings or flyers is not fulfilling the requirements of manifest arrangement.[227]

In April 2015, the District Court of Hamburg made a ruling in four preliminary injunction proceedings on pregabalin and indirect infringement of Warner-Lambert's second medical use patent. The companies had participated in a public procurement procedure for the API of pregabalin. In Germany, pharmaceutical products can be legally substitutable if both products are authorised in one identical indication. Substitution is strongly advised by the German public health insurances due to budget control reasons. After conducting procurements in accordance with EU public procurement law, the public health insurances may enter into rebate agreements with pharmaceutical companies. The exclusive agreement stemming from such procurement proceedings obliges the pharmacists to exchange the prescribed pharmaceutical product and dispense the product that won the tender, if it is not the product proscribed by the doctor.[228]

None of the generic companies had clarified that the generic pharmaceutical products were skinny labels and could not be dispensed for treatment of neuropathic pain, since protected by Warner-Lambert's second medical use patent. The Warner-Lambert proceeding against Aliud Pharma GmbH ("Aliud") will be utilised as an example.[229]

---

[224] See Ibid p 23.
[225] See Ibid pp 23 f.
[226] See 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 Court of Appeal - Cistus Incanus"); Düsseldorf District Court, docket number 4a O 145/12, 14 March 2013 – Chronic Hepatitis C ("Düsseldorf district court - Chronic Hepatitis C").
[227] Compare Düsseldorf Court of Appeal - Cistus Incanus, supra n 226, with Düsseldorf district court - Chronic Hepatitis C, supra n 226.
[228] See "Infringement of second medical use patents – important developments in Germany" by Anja Lunze for Tylor Wessing, September 2015.
[229] See District court Hamburg, supra n 197.

Aliud had entered into a discount agreement with the health insurance provider, "AOK PLUS – The Health Insurance Company for Saxony and Thuringia" ("AOK"), for its pregabalin product. The agreement was not expressively limited to the off-patent protected indication of epilepsy and GAD. Furthermore, Aliud entered into the agreement without informing AOK at any stage that the generic product did not extend to the use of neuropathic pain due to the valid second medical use patent.[230]

The district court of Hamburg held that Aliud had committed an indirect infringement of the second medical use patent by entering into the procurement procedure with a generic product without expressively stating that it was limited to the off-patented use to AOK. The fact that the patented indication had been carved out did not matter since the wording of the agreement did not mirror such a limitation.[231] By the wording of the agreement, the generic product was marketable and would be prescribed for the patented use. Consequently, Aliud had undertaken to offer and supply the generic pharmaceutical for the patent protected indication. The court further emphasised that Aliud had not informed AOK that their pharmaceutical was not to be dispensed for the treatment of neuropathic pain as such indication was protected by the second medical use patent.[232]

The Hamburg district court explicitly deviated from the rulings of the Düsseldorf courts. The Düsseldorf district court had held that the distinctive purpose-limited character of second medical use claims required that the substance would be "manifestly arranged" in order for it to infringe the patent.[233] The Hamburg court disagreed and stated that "manifestly arranged" was not a requirement, the mere fact that the substance had been offered or supplied was enough to constitute an indirect infringement.[234]

In conclusion, the Hamburg district court held that it is prohibited for a generic company to enter into a rebate agreement stemming from a procurement procedure without clearly informing the German public health insurances that it may not be dispensed for the indications, which are protected by the valid second medical use patent.[235]

[230] See Ibid p 6.
[231] See Ibid p 19.
[232] See Ibid p 20.
[233] See Ibid.
[234] See Ibid p 21.
[235] See Ibid.

4 Discussion

4.1 Introduction

The discussion will take its start in analysing the *AstraZeneca* judgement and Article 102 *TFEU* in a combined scrutiny of EU competition law, followed by a discussion on second medical use patents and generic pharmaceutical products. Such a discussion will to a start scrutinise the EPC 2000 claim and its effect on skinny labelling, and then proceed to discuss the pregabalin judgments. A general discussion will conclude the Chapter on the both areas of law and an analysis of the questions as posed above.

4.2 Competition law and the *AstraZeneca judgment*

The objective of EU competition law is to keep the internal market undistorted. The aim is to establish a strong single market that safeguards the consumers' rights. The objective of patent law is to protect the patent holder's rights and stimulate inventions. At the same time as Article 102 *TFEU* prohibits abuse of dominance, Article 36 *TFEU* safeguards the rights of a patent holder.

In order for Article 102 *TFEU* to apply, the pharmaceutical company must be deemed to be a dominant undertaking on the relevant market. The company must have the economic strength to prevent effective competition and be able to behave, to an appreciable extent, independently on the market. A pharmaceutical company whose previous product was patent protected must be assumed to be in a dominant position in the time-period close to the expiry of that patent. That company has been enjoying a monopoly position on the market prior to the expiry, which definitely affects the market structure on the future market. On that note, it is interesting to acknowledge the structure of the pharmaceutical market. The market is characterised by the non-existence of medium-sized companies, and a situation where multinational companies are competing against each other with small-sized companies trying to develop and grow in a hostile environment.

The products that are substitutable with the products of the dominant undertaking constitute the relevant market. On the same note, pharmaceuticals are normally substitutable on the API or a special ingredient. Such substitutability results in that the SSNIP test, if applied, would include all generic products in the relevant product market due to the lesser cost per product. However, it is this kind of interchange of products that the patent law is supposed to, and does, prevent. The main argument in most infringement disputes on pharmaceutical patents is that the medicinal

products are substitutable. Such an argument is very interesting in a competition law perspective, since it is the substitutability that defines the relevant product market. By such an argument posed by the claimant, the relevant market must be deemed as expanded from the normally narrow interpretation of pharmaceutical products market. Hence, such market should include both the market of the generic product and the market of the second medical use patented product.

The *AstraZeneca* judgment is the currently leading precedence on the intersection of competition law and patent law. The judgment touches upon multiple issues, such as the misuse of the exclusive rights stemming from patent law. In conclusion, the judgment establishes that an unlawful conduct under competition laws cannot be excused by the lawfulness of the conduct under another field of law. It affirms that EU competition law prevails over other fields of law, such as patent law, if such a law has been used in order to abuse a dominant position and foreclose the market.

Is the judgment too far reaching? The treaties that protect patent holders' rights and patent law are explicitly exempted from the realm of competition law according to Article 36 *TFEU*. However, Article 36 *TFEU* only exempts the intellectual property rights in the regard of quantitative restrictions. The act of a pharmaceutical company to prevent the market entry of a generic company to the market is not a quantitative restriction, but an abusive conduct aimed to distort competition. The wording of Article 36 *TFEU* cannot exempt an intellectual property right if conducted as an abusive act, and if in the fashion that renders Article 102 *TFEU* applicable. The Court states that an unlawful conduct under competition law could never be forgiven by the lawfulness under another law. This ultimately leads to that a lawful act can be unlawful by object.

AstraZeneca had abused the system of patent law by the withdrawal of the product from the Nordic market. The sole purpose according to the Court, and AstraZeneca could not prove otherwise, was to hinder or delay generic products of entering. It would be significantly harder and more time consuming than expected for the generic companies to establish themselves on the market, since AstraZeneca withdrew a reference medicinal product. The interesting aspect is that AstraZeneca had utilised its right to withdraw the market authorisation as stipulated in EU directives and in accordance with national law. AstraZeneca had abused legislative acts of the EU in order to foreclose the market for a little longer than allowed by the patent. In simple, the judgment holds that it is the intent of the use of the provisions, not the provisions themselves, which constitutes the abusive conduct.

Abuse of dominance is one of the most severe violations of EU competition law. Even if there is a theoretical possibility for the Court to exempt a conduct from the applicability of Article 102 TFEU, no party accused of infringement of the provision has up until this date been able to prove the abuse objectively justified before the CJEU. The burden of proof rests upon the alleged party. The efficiency gains stemming from such an abuse must

be great enough to overweight the loss of competition caused by the allowance. The relevant loss in question is the loss of the consumers; the loss of the competitors is irrelevant. The foreclosure of the market would lead to raised costs for the consumers, lesser variation in supply of products on the market and stagnation in improvements of the product. The concept of efficiency gains is interpreted strictly and narrowly. The requirement of proportionality, the necessity of the conduct to achieve the positive effect and that it still cannot eliminate effective competition renders it hard for a pharmaceutical company holding a patent to the market to successfully argue its case of objective justification before the CJEU. However, the fact that the Commission has won all cases against companies on objective justifications should be reason enough to reflect if the test should be modified in order to be more well-balanced.

Competition on the merits is the key issue. The mere fact that AstraZeneca was entitled to withdraw its marketing authorisation of Losec, and had legal support for such an action in the *Medicinal product directive*, did not mean that such an action was not deemed to be abusive. As held by the Court, AstraZeneca's strategy was rather clear, it meant to foreclose competitors from the market for as long as possible. It can be argued that the *AstraZeneca* judgment is an example of the greatness of competition law. If the other legal document is contravening the objective of Article 102 *TFEU*, they have to give way for the dominance of Article 102 *TFEU* and competition law. Competition law could punish the faulting company effectively, even if it faulted under another law by misrepresentation to governmental offices. This is true. Competition law is one of the most important areas of law within the EU and it is highly enforceable, in comparison to other fields of law. Its importance stems from that it is regarded as the guard of the internal market, which is the basic foundation of the EU as a whole. By the inclusion of Article 101 and 102 *TFEU* as primary law of the EU, competition law has been given a superior role. Primary law prevails all other norms, which is why it will be interesting to see how the balance of competition law and patent law will be conducted when the patent court and the regulation enters into force.

4.3 The balance of second medical use patents and skinny labelling

4.3.1 The EPC 2000 claim and a skinny label

Patent law is the law of inventions, the law that protects development and prevents stagnation. Pharmaceutical patents form a different genre than other areas of technology in which inventions usually are patented. It is a unique field of patents that need, due to development and new discoveries, specially designed provisions ensuring its protection and custom made regulations that encourag new ground breaking discoveries.

The Swiss type claim stems from the need of legal certainty and guidance of the EPO. The main problem with this type of claim was that the patent holder only could bring action against a manufacturer or dealer, but was ineffective if the infringer would be any other actor on the market.

The majority of claims brought to court by lawsuits are still Swiss type claims, even if the Boards of Appeals officially does not approve of such claims after the G 2/08 ruling. There is an uncertainty on how the case law on Swiss type claims shall be assessed in the light of the new form of claims. All pregabalin judgments referred to and analysed below are Swiss type claim judgments. The Boards of Appeals held in the T 1780/12 ruling that the scope of protection was similar but not identical. In the light of competition law, the variance between the two may make a whole of a difference in the analysis of the effect on competition and the internal market.

Skinny labelling is in its basics a very simple solution to a complicated problem that arose by the approval of second medical use patents. A generic product, launched with a skinny label, is not by object infringing a patent. The carve out of the relevant patent protected indication from the label guarantees competition on the market of the reference medicinal product, and that the patent of the second medical use product remains honoured.

The scope of the new type of second medical use patent claims directly effect the generic product. If the claims are given a broader protection, the scope within which the generic product is operating will be narrowed in order for the generic not to commit a patent infringement. In a situation where the scope of the second medical use patent is deemed to be broader, the generic product could easily be accused of patent infringement if actions of caution are not undertaken. This would result in more lawsuits and inevitably more infringements. On the other hand, if the EPC 2000 claim would be deemed to be slightly narrower compared to the Swiss type claim, the generic would have a better protection against actions of patent infringements from of the second medical use patent holder. The question that needs to be settled is who the object to protect should be. Is it the patent holder or the generic company? This is a balance between the right to intellectual property weight against the right to conduct business, and will be discussed in the following subchapters below.

The two different types of patent claims are interrelated and their affection for one and another is immense. The scope of protection does not only affect the two concepts but also the effect that competition law might have on the issue. Consequently, the triangular complexity of problem is why it is of utter importance to define the scope of the now existing EPC 2000 claim. The issue has higher importance than most might understand. It is a discussion of legal certainty and the right to property, a basic fundamental human right.

A balance must be struck between the claims stemming from the second medical use patent right and the generic products' right after the carve out of the relevant indication. It can be argued that the mere carve out of the protected indication from the label should be enough to safeguard the generic company from any lawsuits based on infringement of the patent. It can be argued that such an action by the generic company effectively states that it does not intend to infringe the second medical use patent. However, with the new wording in place of patent claims worded as "substance X for the treatment of Y", and the uncertainty how to interpret the new wording has lead to an ambiguity that is most disturbing considering the legal certainty for all parties involved. Furthermore, the current situation is marked by the fact that one action might be considered lawful in one Member State but infringing patent rights in another. *Europe 2020* articulates strive for development and a scare for stagnation. The legal uncertainty causes such stagnation and hamper the internal market.

4.3.2 The Pregabalin judgments

The three studied judgments from Germany, France and the United Kingdom are interesting on their own, but even more so if scrutinised and discussed in a comparison. The national courts of the three jurisdictions all reached different results when tackling the complex of the issue of skinny labelling and second medical use patents, and awards the responsibility to different actors.

The *Generic v Warner-Lambert* judgment from the United Kingdom is the most discussed adjudication of the three by scholars and practitioners. In the end, the case examined the requirements of the test to establish direct infringements in second medical use patent. Pharmaceuticals are dispensed on the API in United Kingdom, and enrolled in a reimbursement scheme. The Court of First Instance set the criteria low, and required only that subjective intent had to be shown. The High Court of Justice refused such a narrow interpretation and widened the scope to "intentional use".

The High Court of Justice decided to interpret the test as stipulated by the Court of Appeal more narrowly, and consequently required more of the patent holder to prove an infringement in the second medical use patent. The test comprises the foreseeability, on the part of the manufacturer, that the product will be used in a manner that infringes the patent. However, Arnold J added that foreseeability was not enough; it had to be shown that the pharmaceutical was intentionally administered and that such administration could be tied to the manufacturer. Arnold J found there to be no foreseeability or intentional administration that could constitute an infringement. The stand taken by Arnold J is a well-balanced stand that safeguards legal certainty and protects competition on the merits. Interestingly, Arnold J states in clear wording that Pfizer is liable for groundless threats of patent infringement proceedings.

The French court had a slightly different take on the case it adjudicated. The court ruled on both the direct and indirect infringement by Sandoz in Warner-Lamberts second medical use patent, since the facts of the case were different in comparison to the two other cases. Sandoz decided to publish statements advising no dispensation or prescription of its generic product for the use of pain. This was the tipping point for the French court. It is clear that it made a difference by the statements all through the judgment. The court further stated that the national law of substitution and prescription practices could not automatically lead to a patent infringement, *especially* not when it concerned the problematic situation of the reference medicinal product being in the public domain, but a still valid second medical use patent. By such a statement the French court, even if unknowingly, acknowledges the importance of competition law and a functioning of the market. The court further underlined that messages had been sent by both Sandoz and Pfizer (as the head of the corporate group that Warmer-Lambert belongs to), but that it was up to the patent-holder to inform the governmental offices and health authorities of the patent infringement that a dispensation of the generic product would constitute. The French court, subsequently, burdened the patent holder with the responsibility of informing relevant disposers of the potential infringement.

The judgment by the German court is the least covered, but might be the most interesting. The Hamburg district court explicitly deviated from the previously established case law and refrained from the test of whether or not the dispensation had been "manifestly arranged". The mere fact that the substance had been offered and supplied to the market was enough to constitute an infringement according to the Hamburg court. Actions were brought against Aliude and a number of other generic companies by Warner-Lambert, due to the award of procurement contracts to the generic companies for pregabalin. The main issue was that the generic companies had not declared that their products could not be dispensed for the patent protected indication. The Germany system approved of substitution on a substance level, and substitution was advised by health authorities and insurance companies in order to keep the costs low.

Authorities purchase pharmaceutical products through public procurement procedures. EU directives, as described above, regulate these procedures rather intensively and afford the aggrieved party effective remedies. Such a system is the most effective way to keep costs low and safeguard competition. In the German pregabalin judgment, a procurement procedure and the award of the contract to a generic company was the starting point of the dispute. The conclusion is actually understandable and logic. By entering into a contract with no limitation on dispensation of the product, knowing that it was most likely to be substituted with a patented product, it is hard to not find Aliud's behaviour offensive, almost as offensive as an abuse of dominance. The interesting aspect of the dispute is Warner-Lambert's strategy to not attack the procurement procedure but rather the generic company's infringement of the second medical use patent by the mere participation in procurement procedure.

The Hamburg court held that the mere offer and supply to the market was enough for an infringement. However, according to public procurement law, a procurement offer must be disregarded if it does not fulfil the selection criteria in the procurement. In order for the generic company to win the procurement procedure the criteria must have been, conclusively, set and met in a manner that the award of contract to the generic company did not directly infringe the second medical use patent. For example, if the criteria required that the product comprised of the API of pregabalin, the generic company could enter the tender and be awarded the contract. On the other hand, the generic product would have been disqualified if the criteria required the product to be dispensable for all indications of the API. In conclusion, the criteria cannot have been specified enough to preclude products infringing the second medical use patent. But was the procurement procedure intended to cover only products for pain treatment or actually all the indications that pregabalin covers? To refuse a generic company's entry to a procurement procedure on the mere ground of the existence of a second medical use patent would be disproportionate, render the procedure non-transparent and discriminatory. Furthermore, it would safeguard a monopoly for second medical use patent holder on the market for the API acquired. If that would be the judgment, all generic products would be refused by their nature as generic products from all tender procedures. The public procurement procedure is an important source of income for the pharmaceutical companies, and a direct exclusion form such procedures would render their business more or less ineffective.

The reason for the publishing of information on the Italian health authorities' website, or the active actions taken by some regions in Spain against the prescription of generic pregabalin is not publically known. Consequently, such announcements by the authorities in mentioned countries cannot be used as a ground to require the generic company to inform all relevant authorities of a potential infringement of the second medical use patent if dispensed for the use as protected by such. The general rule in patent law is that it is for the patent holder to enforce its patent when infringed by another party. It would be odd if this general rule would be literally reversed in regard to second medical use patents. An owner of a second medical use patent has been granted a protection by exemption from the basic principle of patent law, namely, novelty. Such an exemption from the general rule must be interpreted narrowly. To burden the generic company of informing all authorities of the patent protected second medical use patent's existence seems disproportionate. A generic company cannot be expected to assume that neither the authorities has informed themselves of the structure of the market within which they are active, nor that the patent owner safeguards its patent rights. It is a backwards argument that the Hamburg court is advocating. At the same time, the Hamburg court refuses the concept of "manifestly arranged" and states that the mere supply and offer to the market is an infringement of the patent holder's right. Such an argument is unbalanced and directly contravenes all that competition law stand for.

The French court managed to balance the conflict between the two areas of law in a more proficient manner. The court pointed out that the matter had to be assessed objectively. Warner-Lambert had not objected to the market authorisation of the generic product. However, this argument might fall out a bit strange, since Sandoz had launched its product with a skinny label. The contest of the market authorisation by Warner-Lambert would consequently both trespass its' rights given under patent law and infringe competition law by abuse of dominance. The French court faulted in not acknowledging the complexity of this problem, but stood correct in the assessment of Sandoz announcement to the industry. Warner-Lambert was informed of what kind of information that Sandoz had sent to the relevant authorities and parties within the sector, and could have contested it at any point. By burdening the patent holder with the responsibility to inform authorities and pharmacists, a more proficient balance is found, especially in comparison to the judgment by the Hamburg court. However, it must be remembered that the generic company had sent out messages by own free will during the proceedings in order to inform relevant third parties of the potential infringement a dispensation to treat pain of the product might result in. Arguably, Sandoz actively strived to minimise the damage caused to Warner-Lambert. It remains uncertain how the French court would assess the dispute if such a message would not have been sent to affected parties. However, it could be assumed, when assessing the formulations in the judgment, that the language would not be as tough as the Hamburg court's.

The pregabalin disputes arising all around in Europe is just one example of disputes between second medical use patent holders and generic companies. In the end, it is a discussion on the balance of two fundamental human rights: the right to business and the right to property. The two principles are fundamental values of the Union and with *Europe 2020* as an underlying document the balancing of the two might be more complicated than a simple application of the *AstraZeneca* judgment to the problem.

The French court came to a well-balanced and well-thought decision. It managed to reach a balance between both the judgment from the United Kingdom and the German court. As mentioned, it is uncertain how the verdicts would have been worded if Sandoz did not publish the information, but the court did apply an objective test to the situation where both the right holders and the generic companies interest was weighted against each other.

4.4 The balance of patent protection, generic companies' sale and EU competition law

The *Paris Convention* arose from the strive to harmonise the patent laws around the world, in order to stimulate invention by better and a more aligned patent protection. The existence of multiple different systems was argued inefficient and confusing. More than a 100 years later, EU still has not been able to align its patent law or harmonised it even if the attempt to do so has been on-going for decades.

The lack of a EU system will potentially be remedied when the Unitary Patent Regulation comes into force. The questions remain though: when will it come into force, and will its appearance and existence in EU law clarify the hierarchy between competition law and patent law? Can the Treaty provisions protecting patent rights limit the scope of competition law, if there is an actual EU regulation in place to govern such right? Up until the enforcement of the Unitary Patent Regulation, the competition law will always prevail due to its succession over national patent law provisions.

The pregabalin judgments are proof enough to show that the same type of claim can be adjudicated differently depending on which Member State that settled the dispute. This is a clear hindrance of free movement and the harmonisation of the internal market. Patent law is the foundation for invention, but can also constitute a hindrance to competition if abused. The possibility for a generic product to be launched on the market is a reasonable balance to the allowance of a second medical use patent to be allowed.

Article 118(1) *TFEU* prescribes that the EU shall provide a uniform protection for intellectual property rights. The EU has obviously failed with respect to patent law. It is apparent from the case law from different Member States that they are handling and adjudicating differently on the same subject matter. Article 118 *TFEU* does not provide any rights to the patent holder, merely an obligation on the EU. The sole, and essential, effect a proper utilisation of Article 118 *TFEU* would have is legal certainty: legal certainty for the patent holder, generic companies and the authorities implementing the rules. Competition law and patent law will always affect each other and tend to restrict each other's scope. That is why it is of utter importance to establish the scope of both fields. However, there will always be a grey zone in the intersection of the two. Such a grey zone must be diminished, due to legal certainty and protection of the right holders.

The EU pharmaceutical sector is characterised of small businesses versus big corporate groups. One could say that it is an imbalanced market where the market domination of both multinational pharmaceutical originators and generic companies might constitute a problem for the smaller innovative companies to grow. The market is characterised by a non-existence of

medium-sized companies, since the smaller companies are acquired when they earn an all too great market-share. It is a complex market to scrutinize. On the one hand, inventions should enjoy a strong protection in order to provide a chance for the inventing companies to recapitalise their investments. On the other hand, by providing such protection the multinational corporations and can exploit the system by treats of patent infringement proceedings. Also, a third factor to keep in mind is that competition law never will protect the competitor. This cannot be emphasised enough. Competition law only strives to ensure that consumer harm is minimised.

Consumer harm is minimised by the safeguard of an open and free market where competitors can compete on the merits. Monopolies force an increase in price and a limited variation in supply of products, which it is deemed as harm to consumers. Besides, the safety regulations surrounding pharmaceuticals could be considered as barriers to the market, but are a necessity to ensure consumer safety. One could argue that patent law and regulations on pharmaceuticals in simple protect the aims of the EU, and to some extent balance such aims with competition law. Inventors are stimulated to innovate by the patent protection, and consumers are safeguarded by the market authorisation. At the same time, competitors are allowed market entry at the date of the expiry of the patent and afforded a market authorisation by simplified procedure by allusion to the reference medicinal product. Such a balance between the two interests must be considered as proportionate. The Unified Patent Court will hopefully be able to establish guiding case law, balancing the values of the EU in a sensible manner so that neither patent law or competition law is concerned and disregarded in its importance. This will be a difficult task for the Unified Patent Court, forcing the court to take an active stand in the discussion and try to clarify the hierarchy of the two areas of law.

Everything will not be settled by the Unitary Patent Regulation or the Unified Patent Court and their entry into effect. However, both these instruments will be instruments of EU law. They will provide a harmonising effect in a now shattered system of multiple national legislations, and unify EU to a more effective system. The judgments adjudicated in the court will be ruled in accordance with EU law and questions will be referred to the CJEU for review if required by a party. Furthermore, the court will be bound by the precedent of the CJEU, and consequently have to take the realm of EU law into consideration when delivering their judgments.

The Unified Patent Court cannot only regard the principles of patent law and competition law when conducting such a test of norm hierarchy. It must take into account the policy documents of the EU, such as *Europe 2020*, and accredit the *CFREU*. How far do the generic companies' rights to conduct business stretch and how far-reaching are the second medical use patents?

The right to launch products with a skinny label is a direct articulation of the right to conduct business. Consequently, when debating the existence of

skinny labelling and second medical use patents it all falls back to the general principles of competition law, and on the fundamental human rights. Competition law and patent law coexist in the realm of EU law, and even more so after the establishing of the Unitary Patent Regulation.

The factual situation in the pregabalin judgments, where the second medical use patent holder is the originator of the reference medicinal product, is a typical situation in disputes on second medical use patent infringements. Ultimately, by the threat of infringement proceedings or an actual lawsuit against the generic company, the originator tries to prolong and extend its second medical use patent to establish a monopoly in whole or in part on the API. Second medical use patents are the exemption to general rules in patent law, it is an expansion of novelty that is only accepted due to the unique character of pharmaceutical patents and the importance such patents play for development. The EPO has decided to take an ambiguous stand and settled the EPC 2000 claim to be similar but not identical in scope compared to the Swiss type claims. Such ambiguity is the main problem in deciding the actual rights of the patent holders but also of the generic companies.

The EPO held in the G 2/08 decision that second medical use patents could be granted on the same illness as the first medical use patent if utilised in a different type of treatment, and that the mere change of the dosage regime could be enough to establish new state of art. This allows the inventor to patent discoveries that are close to similar to the first medical patent or other already existing second medical use patents. Consequently, the EPO has granted the concept of second medical use a broad definition by the establishing of the new EPC 2000 claims. One could argue that such a broad interpretation should lead to a narrow scope of the actual patent, in order not to intrude other patented indications.

All authorities and institutions around the EU must actively discourage the misuse and abuse of patent law. It is not acceptable that a Member State allows such a conduct, which could be argued prohibited by analogy to the *AstraZeneca* judgment even if the judgment only rules on the facts of the case. As explained above, most second medical use patent holders are the right holders of the reference medicinal product as well. Such a link between the two products established a natural interest of the owner in the markets of the two products, especially when the two are substitutable with each other. The substitutability of the patented product and the generic product has been emphasised by the patent holders in their suits against the generic companies as establishing infringement. However, by making such a claim, patent holders indirectly violates competition law and abuses their dominant position on the market.

The patent holder utilises its dominance, as provided by the patent, to force a generic company to exit the market for a product to which the patent holder does not have an exclusive right. Such dominance, in relation to second medical use patents, normally expresses itself in aggressive infringement proceedings. The aggressive litigation style is problematic,

since the patent holder, arguably, is merely protecting its right to the patented product whilst it actually creates a monopoly on the API in the long run. The problem gets especially complicated when the patent holder questions the right of the generic company to enter a procurement procedure. Simply put, it is the procurement procedure that infringes the second medical use patent if the criteria are asking for an API, without specification or limitation regarding valid patents, not the participating tenderer. It could be argued that Warner-Lambert should, instead of commencing infringement proceedings against the generic companies, claim nullification of the award of contract to the generic company and damages due to patent infringement by the government. Such a claim would have been aligned with competition law.

Competition law has been established as a supreme field of EU law, and any abusive conduct can be challenged by the Commission and adjudicated by the Court. It is disturbing that the Hamburg court disregards, not only, this regime of law that is indirectly applicable, but also the issue of competition on the merits. This is especially noteworthy in contrast to Arnold J's explicit statement that such claims were groundless threats. The generic companies have launched their products after the grant of market authorisation by the authorities, by carving out the patented indication from their labels. Such carve out does not constitute any potential harm to the consumer, as it also provides an efficient competition on the market.

Then again, a property owner's right to its property is a fundamental human right, as drafted into *CFREU* and further pointed out in the treaties. Invention is held to be one of the most important values to safeguard in order to stimulate investments in EU. The development of the Unitary Patent Regulation further enhances this. Are the general principles as stated in preambles of regulations and Treaties establishing patent rights as claims valuable enough to protect against the realm of competition law? If the *AstraZeneca* judgment is followed literally the answer is no. However, the Court was rather obvious in pointing out that it mainly made fact-based statements and did not establish any general principles as such. However, it is hard to overlook the fact that they rather harshly enforced competition law as the superior law of the laws of the EU.

5 Conclusion

Europe 2020 is a political document setting up the goals, which forms the policy-making and the aim of the EU in general. It is clear from this document that there need to be a balancing of rights, the right to business and the right to property.

The EPC 2000 claim has intensified the discussion on second medical use patents and their enforceability, at the same time as patent litigations on second medical use patents has emerged all around Europe. The scope, similar but not identical to the Swiss type claim, remains disputed. Its scope is interconnected with the generic companies possibility to act on the relevant market of the reference medicinal product. The right to conduct business is countered against the right to property. Equilibrium must be found between the two in order for the EU to prosper. Both areas of law are of great importance of the EU, even if competition law shall be considered to set the outer framework. A framework to which second medical use patent holder need to adapt.

There must be a balance between competition law and patent law. The problem is that most national courts do not acknowledge that there is a potential conflict between the two fields of law, or that the two might directly affect each other. The intersection of competition and patent law might be one of the most important norm conflicts within EU law and it is important that the courts realise their connection.

Competition law has been given superior status within the EU norm hierarchy. The internal market is the Holy Grail of EU and competition law is its faithful guard. Intellectual property right is the only field of conflicting law that has been exempted from the reach of competition law by the stipulation of Article 36 *TFEU*. On the one hand, competition law is a fundamental component of the functioning of the internal market; on the other hand, patent law is a vital component to build an innovative Union that stimulates investments. The two fields of law must be able to coexist in order for the EU to functioning and be competitive on the global arena.

Invention would be hampered if the patent protection of a second medical use product were to be expanded to broadly. Exemptions are normally to be applied with a narrow and literal interpretation and to expand the second medical use patent protection to broadly cannot be accepted. Such an expansion would jeopardise competition on the merits, make way for a potential monopoly, stagnate the market and harm consumers, competition and invention. That is why competition law must be the supreme field of law. Competition law creates dynamic marketplaces; it safeguards competition on the merits and forces the companies competing on the market to be effective and innovative in order to be able to compete.

Skinny labelling is the equilibrium of competition law and patent law. The values of the EU are balanced by the acceptance of skinny labelling, and competition law ensured. One could argue that skinny labelling actually stimulates invention and development. By letting a generic product enter the market of a previously patent protected indication and expose the product to competition, the right owner to the product will have to adjust and be more creative in its take on the market in order to be effective enough to compete. This normally takes the expression in further research and studies on the API in order to find a new indication to apply for a patent on. Skinny labelling provides the legal certainty necessary in an elsewise uncertain system of law. Consequently, the generic companies forces the pharmaceutical companies that are focused on invention to further develop the sector and continuously strive to find new treatments for diseases. Ultimately, there cannot be any objective justifications for a pharmaceutical company holding a second medical use patent to foreclose a skinny label product from the market. The generic manufacturers provide qualitative medicinal products to the common public, reduced price and competition on the merits. No efficiency gains can stem from a foreclosure of such a market, since such an action could never be proportional, the consumer would not be given any surplus from such an action, and all effective competition would be eliminated not only from one but also from two markets.

Consequently, it is of importance to safeguard the concept of skinny labelling against attempts to invalidate it or minimise its applicability. To attack skinny label generic products by claiming infringement in the second medical use product violates not only competition law but also patent law regulations. The sole result is that the generic product would be refused access to the market of the reference medicinal product. The products are substitutable in most Member States, since they are based on the same API, but that does not lead to an automatic infringement of the valid patent by the generic company. Then again, it should be the responsibility of the patent holder to enforce its patent by informing relevant authorities. Authorities and pharmacists dispense pharmaceutical products, and consequently, the ones that need to be informed of the patent holders exclusive rights to the patented indication. However, such an exclusive right to one market cannot entitle the patent holder to foreclose the market for competitors to the reference medicinal product. To misuse the second medical use patent to the extent of foreclosing other markets cannot be deemed as something other than an abuse of dominance. How far do the generic companies' rights to conduct business stretch and how far-reaching are the second medical use patents? The simple and naïve answer to such question would be that the patents right stretches as far as to the limit when it would abuse its dominant position and distort competition on the merits.

It all comes down to legal certainty. Legal certainty is the cynosure. The certainty of a right holder that the right is enforceable. The certainty of a generic company that it will not be fined due to patent infringement after a grant of market authorisation. The certainty that companies compete on the

merits or elsewise are fined. All these certainties work perfectly in parallel systems but reality is not parallel; the reality is an intersection where they all three meet and a balance must be struck.

Only the future knows when the Unified Patent Court and the Unitary Patent Regulation will enter into effect, and only the future knows what effect a harmonising patent regulation will have on the adjudication in the Member States. One certain fact is that the CJEU is the superior court in the EU, also will be superior to the Unified Patent Court. It is unlikely that it will be long after the establishing of the court that the first case on skinny labelling will be presented before CJEU, this because skinny labelling is essential to the pharmaceutical industry in the EU and to the functioning of the internal market. Competition law is the framework within which patent law has to find its way of existence. What is clear is that the CJEU was not established to protect the competitors, and this will never change. The CJEU was established to safeguard the law of the EU and assure that it is implemented and enforced correctly. With the judgment of *AstraZeneca* at hand, it is hard to see how the CJEU would come to another conclusion other than that an attempt to hinder a generic pharmaceutical product, authorised by use of skinny labelling, to enter the market by use of its patent right is an abuse of its dominant position on the market.

6 Bibliography

ARTICLES/BOOKS/REPORTS

Bailey, David and Vivien Rose (eds), *Bellamy and Child: European Union Law of Competition* (Oxford University Press, 5th ed., 2014)

Bovis, Christoffer, *EU Public Procurement Law* (Elgar European Law, 2nd ed., 2012)

Craig, Paul and Gráinne De Burca, G., *EU Law: Text, cases and materials* (Oxford University Press, 2011)

Dahlman, Christian, *Rätt och rättfärdigande* (Studentlitteratur, 2011)

Domeij, Bengt, *Läkemedelspatent* (Norstedts Juridik, 1998)

Domeij, Bengt, *Pharmaceutical patents in Europe*, (Kluwer Law International/Nordstedts Juridik, 2000)

European Federation of Pharmaceutical Industries and Associations, *The Pharmaceutical Industry in Figures – Key data 2013*

Faull, Jonathan and Ali Nikpay (eds.), *Faull and Nikpay: The EU Law of Competition* (Oxford University Press, 3rd ed., 2014)

Groussot, Xavier, Gunnar Tor Petursson and Justin Pierce, 'Weak Right, Strong Court - The Freedom to Conduct Business and the EU Charter of Fundamental Rights' (2014) 01 *Lund University Legal Research Paper Series* (Online: http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2428181)

Hayes, Christopher, ”What is the intention with skinny labels and second medical use patents?” (2015) 11(3-4) *Journal of Generic Medicines: The Business Journal for the Generic Medicines Sector*

Hettner, Jörgen and Ida Otken-Eriksson, *EU-rättslig metod – teori och genomslag i svensk rättstillämpning* (Norstedts Juridik, 2nd ed., 2011)

Ilardi, Alfredo, *The New European Patent* (Hart Publishing Ldt, 2015)

IP Kat, ”No pain for Actavis – Warner-Lambert fail to stop launch of generic Pregabalin” 21 January 2015 (Online: http://ipkitten.blogspot.se/2015/01/no-pain-for-actavis-warner-lambert-fail.html)

Jones, Alison and Brenda Sufrin, *EU Competition Law; Text, cases and*

materials (Oxford University Press, 4th ed., 2014)

Korling, Fredric and Mauro Zamboni, *Juridisk metodlära* (Studentlitteratur, 2013)

Kur, Annette and Thomas Dreier, *European Intellectual Property Law: Test, Cases and Materials* (Edward Elgar Publishing, 2013)

Lehrberg, Bengt, *Praktisk juridisk metod* (Iusté, 7th ed., 2014)

Levin, Marianne and Hanna Nilsson, *Läkemedel and Immaterialrätt* (Jure, 2008)

Levin, Marianne, *Lärobok i immaterialrätt* (Norstedts Juridik, 10th ed., 2011)

Lunze, Anja, ”Infringement of second medical use patents – important developments in Germany” for Tylor Wessing LLP, September 2015 (Online: http://united-kingdom.taylorwessing.com/synapse/ti-infringe2ndmed-ger-sep15.html)

Martens, Marc and Nicolas Carbonelle, “White paper: Public procurement of medicinal products - Common legislation but diverging implementation approaches throughout the EU” for Bird & Bird LLP (Online: http://www.twobirds.com/~/media/pdfs/white-papers/public-procurement-of-medicinal-products.pdf)

Mario Monti, "A New Strategy for the Single Market", Report to the President of the European Commission, 9 May 2010

Moufang, Rainer, “Patentability of pharmaceutical inventions: the European perspective” in Josef Drexl and Nari Lee, *Pharmaceutical Invention, Competition and Patent Law* (Edward Elgar Publishing, 2013)

Peczenik, Aleksander, Juridikens teori och metod: en introduktion till allmän rättslära (Fritze, 1995)

Shorthose, Sally, *Guide to EU Pharmaceutical Regulatory Law* (Sweet and Maxwell, 5th ed., 2014)

Thomson and Reuters, “The History of Pantent” (Online: http://ip-science.thomsonreuters.com/support/patents/patinf/patentfaqs/history/)

Tritton, Guy, *Tritton on intellectual property in Europe* (Sweet and Maxwell, 2014)

Turner, Jonathan D.C., *Intellectual property and EU competition law* (Oxford University Press, 2010)

WIPO, *Contracting parties to the Paris Convention* (Online: http://www.wipo.int/treaties/en/ShowResults.jsp?lang=en&treaty_id=2)

CASE LAW

Court of Justice of the European Union

Judgment in *AKZO v Commission*, C-62/86, ECLI:EU:C:1991:286

Judgment in *Albany International BV v Stichting Bedrijfspensioenfonds Textielindustrie*, C-67/96, ECLI:EU:C:1999:430

Judgment in *Bronner v Mediaprint*, C-7/97, ECLI:EU:C:1998:569

Judgment in *Consten and Grundig v Commission*, C-56/64, ECLI:EU:C:1966:41

Judgment in *Daiichi Sankyo and Sanofi-Aventis Deutschland*, C-414/11, ECLI:EU:C:2013:520

Judgment in *EcoSwiss China Time Ltd v Benetton International NV*, C-126/97, ECLI:EU:C:1999:269

Judgment in *EMI v CBS*, Case 51/75, ECLI:EU:C:1976:85

Judgment in *Europemballage and Continental Can v Commission*, Case 6/72, ECLI:EU:C:1973:22

Judgment in *FENIN v Commission*, C-205/03 P, ECLI:EU:C:2006:453

Judgment in *Firma Ambulanz Glöckner v Landkreis Südwestpfalz*, C-475/99, ECLI:EU:C:2001:577

Judgment in *France Télécom SA v Commission*, C-202/07 P, ECLI:EU:C:2009:214

Judgment in *GAT*, C-4/03, ECLI:EU:C:2006:457

Judgment in *Giersch and Others*, C-20/12, ECLI:EU:C:2013:411

Judgment in *Hoffmann-La Roche v Centrafarm*, 102/77, ECLI:EU:C:1978:108

Judgment in *Hoffmann-La Roche v Commission*, C-85/76, ECLI:EU:C:1979:36

Judgment in *Höfner and Elser v Macrotron GmbH*, C-41/90,

ECLI:EU:C:1991:161

Judgment in *IMS Health v NDC Health*, C-418/01, ECLI:EU:C:2004:257

Judgment in *L'Oréal v De Nieuwe AMCK*, Case 31/80, ECLI:EU:C:1985:494

Judgment in *Monsanto v Cefetra*, C-428/08, ECLI:EU:C:2010:402

Judgment in *Parke, Davis and Co. v Probel, Reese, Beintema-Interpharm and Centrafarm*, Case 24/67, ECLI:EU:C:1968:11

Judgment in *Pavlov v Stichtting Pensioenfonds Medische Specialisten*, Joined Cases C-180/98, C-181/98, C-182/98, C-183/98, C-184/98, ECLI:EU:C:2000:151

Judgment in *Post Danmark II*, C-23/14, 6 October 2015, ECLI:EU:C:2015:651

Judgment in *Post Danmark*, C-209/10, ECLI:EU:C:2012:172

Judgment in *Roche Nederland and Others*, C-539/03, ECLI:EU:C:2006:458

Judgment in *Roquette Frères*, C-94/99, ECLI:EU:C:2000:677

Judgment in *RTE and ITP v Commission*, Joined cases C-241, 242/91 P, ECLI:EU:C:1995:98

Judgment in *TeliaSonera Sverige*, C-52/09, ECLI:EU:C:2011:83

Judgment in *Tomra v Commission*, C-549/10 P, ECLI:EU:C:2012:221

Judgment in *United Brands v Commission*, Case 27/76, ECLI:EU:C:1978:22

Judgments in *British Airways v Commission*, C-95/04 P, ECLI:EU:C:2007:166

General Court

Judgment in *AstraZeneca v Commission*, T-321/05, ECLI:EU:T:2010:266

Judgment in *CEAHR v Commission*, Case T-427/08, ECLI:EU:T:2010:517

Judgment in *Clearstream v Commission*, T-301/04, ECLI:EU:T:2009:317

Judgment in *Hilti* v *Commission,* T-30/89, ECLI:EU:T:1991:70

Judgment in *IMS Health v Commission*, T-184/01, ECLI:EU:T:2005:95

Judgment in *SELEX v Commission*, T-155/04, ECLI:EU:T:2006:387

Judgment in *Tetra Pak International v Commission (Tetra Pak II)*, T-83/91, ECLI:EU:T:1994:246

Commission Decision

Case COMP D3/38.044 – NDC Health v IMS Health: Interim measures, 3 July 2001, OJ 2002 L 59

Case COMP/A 37.507/F3 – AstraZeneca, 15 June 2015, OJ L 332, 30.11.2006, p. 24–25

Opinion by Advocate General

Opinion by Advocate General Kokott in Judgment *European Commission v Kingdome of the Netherlands*, C-368/10, e.r.

Opinion of Advocate General Kirschner in Judgment *Tetra Pak Rausing SA v Commission*, T-51/89, ECR II-309

Boards of Appeal of the European Patent Office

G 1/83, G 5/83, G 6/83 of 5 December 1984, OJ EPO 1985, 60, 64, 67 – Second medical indication/BAYER/EISAI/PHARMUKA

G 2/08 of 19 February 2010, OJ EPO 2010, 456 – Dosage regime/ABBOTT RESPIRATORY

G 5/83 of 5 December 1984, OJ EPO 1985, 64 – EISAI/Second medical indication

T 1599/06 (Mycobacterium vaccinating agent/UNIVERSITY OF CALIFORNIA) of 13.9.2007

T 1780/12 (Cancer treatment/BOARD OF REGENTS, THE UNIVERSITY OF TEXAS SYSTEM) of 30.1.2014, OJ EPO 2014, 130

T 227/91 of 15 December 1992, OJ EPO 1994, 491 – Second surgical use/CODMAN

T 36/83, OJ EPO 1986, 295 – Thenoyl peroxide/ROUSSEL-UCLAF

France

Tribunal de Grande Instance de Paris, Ordonnance de Référé rendu le 26 octobre 2015 – Warner-Lambert Co LLC, Pfizer Ltd and SAS Pfizer PEE France v SAS Sandoz and Sandoz GmbH, N° RG 15/58725. English translation: https://docs.google.com/viewer?a=vandpid=sitesandsrcid=ZGVmYXVsdGRvbWFpbnxmcmVuY2hpcGRhbWFnZXN8Z3g6NzI2ZjFhZTEyOTNlNDE0MQ (Warner-Lambert v Sandoz)

Germany

District Court Hamburg, decisions of 2 April 2015, docket numbers 327 O 67/15, 327 O 132/15, 327 O 140/15, 327 O 143/15 – Pregabalin

Düsseldorf Court of Appeal, docket number 2 U 54/11, 31 January 2013 – Cistus Incanus

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

Düsseldorf District Court, docket number 4a O 145/12, 14 March 2013 – Chronic Hepatitis C

Great Britain

Generics (UK) Limited t/a Mylan v Warner-Lambert Company LLC [2015] EWHC 2548 (Pat)

Warner-Lambert Company, LLC v Actavis Group Ptc EHF and Others [2015] EWCA Civ 556 the Court of Appeal [2015] EWCA Civ 556

Warner-Lambert Company, LLC v Actavis Group Ptc EHF and Others [2015] EWHC 72 (Pat) (Online: http://www.bailii.org/ew/cases/EWHC/Patents/2015/72.html)

INTERNATIONAL TREATIES

Agreement on a Unified Patent Court, OJ C 175, 20.6.2013, p. 1–40

Charter of Fundamental Rights of the European Union, OJ C 326, 26.10.2012, p. 391–407

Consolidated version of the Treaty on European Union, OJ C 326, 26.10.2012, p. 13–390

C*onsolidated version of the Treaty on the Functioning of the European Union*, OJ C 326, 26.10.2012, p. 47–390

Convention on the Grant of European Patents, 1973, 1065 U.N.T.S. 199, 5 October 1973, entry into force 7 October 1977

Council of the European Union, *Agreement on a Unified Patent Court,* Document 16351/12 of 11 January 2013 (OR.en) PI 148 Cour 77

European Patent Convention, 15th edition September 2013

Paris Convention for the Protection of Industrial Property, as last revised at Stockholm, 21 UST 1583, 828 UNTS 305

Patent Cooperation Treaty, June 19 1970, 28 U.S.T. 7645, 1160 U.N.T.S. 231 reprinted in 9 I.L.M. 978 (1970)

Rule of Proceedings of the Unified Patent Court (18th draft of 19 October 2015)

LEGISLATIVE ACTS

European Union

Commission Notice - Guidelines on the effect on trade concept contained in Articles 81 and 82 of the Treaty (Text with EEA relevance), OJ C 101, 27.4.2004, p. 81–96

Commission Notice on the definition of relevant market for the purposes of Community competition law, OJ C 372, 9.12.1997

Communication from the Commission — Guidance on the Commission's enforcement priorities in applying Article 82 of the EC Treaty to abusive exclusionary conduct by dominant undertakings (Text with EEA relevance), OJ C 45, 24.2.2009, p. 7–20

Council Regulation (EC) No 1/2003 of 16 December 2002 on the implementation of the rules on competition laid down in Articles 81 and

82 of the Treaty (Text with EEA relevance), OJ L 1, 4.1.2003, p. 1–25

Council Regulation (EEC) No 1768/92 of 18 June 1992 concerning the creation of a supplementary protection certificate for medicinal products, OJ L 182, 2.7.1992, p. 1–5

Council Regulation (EU) No 1260/2012 of 17 December 2012 implementing enhanced cooperation in the area of the creation of unitary patent protection with regard to the applicable translation arrangements, OJ L 361, 31.12.2012, p. 89–92

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, OJ L 311, 28.11.2001, p. 67–128

Directive 2007/66/EC of the European Parliament and of the Council of 11 December 2007 amending Council Directives 89/665/EEC and 92/13/EEC with regard to improving the effectiveness of review procedures concerning the award of public contracts, OJ L 335, 20.12.2007, p. 31–46

Directive 2014/23/EU of 26 February 2014 on the award of concession contracts, OJ L 94, 28.3.2014, p. 1–64

Directive 2014/24/EU of the European Parliament and of the Council of 26 February 2014 on public procurement and repealing Directive 2004/18/EC, OJ L 94, 28.3.2014, p. 65–242

Directive 2014/25/EU of the European Parliament and of the Council of 26 February 2014 on procurement by entities operating in the water, energy, transport and postal services sectors and repealing Directive 2004/17/EC, OJ L 94, 28.3.2014, p. 243–374

Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions, Official Journal L 213 , 30/07/1998 p.13 – 21

Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (Text with EEA relevance), OJ L 136, 30.4.2004, p. 1–33

Regulation (EU) No 1257/2012 of the European Parliament and of the Council of 17 December 2012 implementing enhanced cooperation in the area of the creation of unitary patent protection, OJ L 361, 31.12.2012, p. 1–8

Swedish preparatory works

SOU 2006:70 *Oinskränkt produktskydd för patent på genteknikområdet*

SOU 2014:25 "*Nya regler om upphandling*"

OTHER

Patents and Market Authorisation

Centralised Market Authorisation EU/1/04/279/001-025.

Patent EP 0 934 061, I*sobutylgaba and its derivatives for the treatment of pain*

Patent EP no 6 641 330, *Pregabalin salts*

Europen Patent Office

EPO, *Basic Proposal - Explanatory notes - Article 54(4) and Article 54(5) EPC*, 21 November 2000, MR/18/00

EPO, *Case law of the Boards of Appeals – 6.2.1 Introduction* (Online: http://www.epo.org/law-practice/legal-texts/html/caselaw/2013/e/clr_i_c_6_2_1.htm)

EPO, *Guidelines for examination - Second or further medical use of known pharmaceutical products*

EPO, *Notice from the European Patent Office dated 20 September 2010 concerning the non-acceptance of Swiss-type claims for second or further medical use following decision G 2/08 of the Enlarged Board of Appeal*, OJ EPO 2010, 514

European Union

EUROPE 2020: A strategy for smart, sustainable and inclusive growth, COM(2010) 2020 final, 3 March 2010

European Commission, The Centralised Procedure (Online: http://ec.europa.eu/health/authorisation-procedures-centralised_en.htm)

Council of the European Union, Signatories to the *Agreement on a Unified Patent Court* (Online: http://www.consilium.europa.eu/en/documents-publications/agreements-conventions/agreement/?aid=2013001)

Osram/Airam, Eleventh Report on Competition Policy (1981)