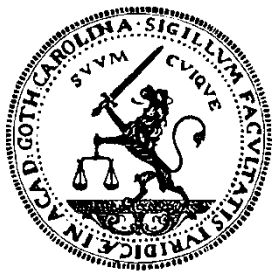

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End of a blockbuster?

Preventing evergreening of pharmaceutical patents under EU competition law

JAEM03 Master Thesis

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Contents

Summary

The pharmaceutical industry is dependent on the granting of patents. Patents make it possible for pharmaceutical companies to invest in the necessary R&D to bring new drugs to the market. This benefits consumers and the health care sector at large. The biggest pharmaceutical companies invest in R&D, and as a result are the major holders of pharmaceutical patents. While the big pharmaceutical companies contribute positively to the health of European citizens, the conduct of those companies may sometimes have a negative impact on competition. EU competition law can be used for this purpose to prevent competition on the internal market from being distorted. Evergreening is one type of anti-competitive conduct where originator companies use different strategies to extend expiring patent rights in order to maintain their market position and to keep generic competition off the market.

This thesis investigates abuse of dominant position by evergreening of pharmaceutical patents. The aim is to examine the effectiveness of EU competition rules to prevent evergreening practices by pharmaceutical companies on the internal market. This is carried out by first providing an analysis of the pharmaceutical sector in Europe and its special characteristics. This includes a definition of evergreening and a summary of the Pharmaceutical Sector Inquiry which was conducted by the European Commission in 2009. Thereafter, EU competition law in the pharmaceutical sector is investigated, with special focus on the assessment under Article 102 TFEU.

The findings of the thesis indicate that EU competition rules can be a suitable tool to deal with evergreening in the pharmaceutical industry. However, the efficiency of competition rules is limited because of the lack of precedent and guidance primarily from the Commission, CJEU and national competition authorities. One way to increase the effectiveness would therefore be if pharmaceutical companies were provided with clearer guidance regarding use of their patent rights. This could be implemented through guidelines issued by the Commission in relation to evergreening under Article 102 TFEU in combination with a notice on the definition on the relevant market in the pharmaceutical sector.

Sammanfattning

Läkemedelsindustrin är beroende av patent. Rätten till patent möjliggör de nödvändiga investeringar i forskning och utveckling som krävs för att utveckla nya läkemedel och få ut dessa på marknaden. Detta gynnar både konsumenter och samhället i stort. De största läkemedelsföretagen investerar i forskning och utveckling, och är därmed de primära innehavarna av läkemedelspatent. Samtidigt som de största läkemedelsföretagen bidrar positivt till hälsan hos europeiska invånare, så kan dessa företags uppförande ibland ha en negativ inverkan på konkurrensen. EU:s konkurrensregler kan användas i syfte att förhindra att konkurrensen på den inre marknaden snedvrids. Evergreening är en form av konkurrensbegränsande beteende som innebär att företagen som utvecklat originalläkemedlen använder olika strategier för att förlänga rätten till patent som håller på att löpa ut. Detta görs i syfte att behålla deras position på marknaden samt förhindra inträdandet av generiska läkemedel.

I denna uppsats undersöks missbruk av dominerande ställning genom evergreening av läkemedelspatent. Syftet är att granska effektiviteten av EU:s konkurrensregler för att förhindra att läkemedelsföretagen utövar evergreening på den inre marknaden. Detta genomförs genom att först analysera den Europeiska läkemedelsindustrin och dess speciella egenskaper. En definition av evergreening tillhandahålls samt en sammanfattning av branschutredningen av läkemedelssektorn som utfördes av Europeiska Kommissionen år 2009. Därefter undersöks EU:s konkurrensregler med särskilt fokus på bedömningen under Artikel 102 FEUF.

Resultaten av uppsatsen visar tecken på att EU:s konkurrensregler kan vara ett lämpligt verktyg för att hantera evergreening av läkemedelspatent. Emellertid är effektiviteten av konkurrensreglerna begränsad på grund av bristen på vägledning och prejudikat från Kommissionen, nationella konkurrensmyndigheter och EU-domstolen. Effektiviteten kan därmed öka om läkemedelsföretag förses med tydligare vägledning angående användningen av patent. Detta kan genomföras genom riktlinjer som utfärdas av Kommissionen angående evergreening under Artikel 102 FEUF, i kombination med ett tillkännagivande om definition av relevant marknad inom läkemedelssektorn.

Preface

I would like to express my gratitude to Ulf Maunsbach, Associate Professor in the Faculty of Law, for supervising my thesis and for valuable insights and guidance throughout the period of this research. I would also like to thank my father for his endless support and for always being by my side.

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Abbreviations

AG	Advocate General
ATC	Anatomical Therapeutic Chemical
CJEU	Court of Justice of the European Union
ECJ	European Court of Justice
EFPIA	European Federation of Pharmaceutical Industries and Associations
EMA	European Medicines Agency
EPC	European Patent Convention
EPO	European Patent Office
EPUE	European Patent with Unitary Effect
EU	European Union
GC	General Court
NCA	National Competition Authority
OJ	Official Journal of the European Union
OJ EPO	Official Journal of the EPO
PPI	Proton Pump Inhibitor
R&D	Research and Development
SPC	Supplementary Protection Certificate
SSNIP	Small but Significant Non-transitory Increase in Price
TEU	Treaty on European Union
TFEU	Treaty on the Functioning of the European Union
TRIPS	Agreement on Trade-Related Aspects of Intellectual Property Rights
UPC	Unified Patent Court
WHO	World Health Organization
WIPO	World Intellectual Property Organization
WTO	World Trade Organization

1 Introduction

1.1 Background

The pharmaceutical industry is a key asset to the European economy and one of Europe's top performing high-technology sectors.[1] Accordingly, the pharmaceutical industry plays an important role in economic growth and competitiveness within the European Union (EU). Investment in research and development (R&D) provides improvement in the sector leading to a high level of public health protection by being able to provide safer and cheaper medicines to consumers. In 2012, the pharmaceutical sector employed about 800,000 people on the internal market.[2]

Patent on pharmaceutical products gives the holder an exclusive right to the production of the drug, but only for a limited period of time. After the patent protection has expired competitors are free to copy, manufacture and sell generic imitations, which are often sold at a lower price than the original drug. The process of developing new pharmaceutical products is expensive. Companies who invest in R&D for new drugs also need to ensure that they can profit from the investment in the long run. A major factor for a pharmaceutical company's success is the revenue generated from the so-called blockbuster drugs. These are the top pharmaceuticals on the market generating at least 1 billion USD in sales at global level.[3] There are estimates that between 2016 and 2022, sales of blockbuster drugs worth 249 billion USD are at risk due to patents expiration.[4]

While having an important role in developing new drugs and investing in the health care industry, pharmaceutical companies may also engage in anti-competitive business practices such as charging high prices or restricting access to medicine in other ways. Companies that have invested time and money in order to develop a new pharmaceutical product, sometimes use methods to try to maintain their exclusive right after the patent protection

[1] European Federation of Pharmaceutical Industries and Associations (EFPIA), *The Pharmaceutical Industry in Figures - Key Data 2016*.
[2] European Commission, *Healthcare Industries*.
[3] European Commission, Pharmaceutical Sector Inquiry: Final Report, 8 July 2009, p. 6; Li, Jie Jack, *Blockbuster drugs: the rise and decline of the pharmaceutical industry*, New York: Oxford University Press, 2014, p. 1.
[4] EvaluatePharma, *World Preview 2016*, 9th Edition, p. 9.

has ended. In the special case of pharmaceutical patents, it is sometimes possible to circumvent the law in order to extend the period of protection. As a result, companies within the pharmaceutical industry have developed different methods of strategic patenting in order to maintain their exclusive right. This is commonly observed in the case of the highly profitable blockbuster drugs.

One of the strategies to maintain the market position created by a pharmaceutical patent is evergreening. Evergreening refers to a variety of methods used by pharmaceutical companies to extend their exclusive patent right which is about to expire. The reason companies choose to evergreen their patents is to maintain their profits on the pharmaceutical product in which they have invested. If the patent is not extended, the result will be a steep fall in revenue for the company that has developed the original product as generic competitors enter the market. The steep fall in profits that can be observed after a pharmaceutical patent has expired is referred to as the patent cliff, and is the phenomenon the proprietors try to avoid by evergreening their patents.

When evergreening occurs, EU competition law plays an important role in protecting public interests and the interest of smaller undertakings trying to enter the market. Within this area of law measures have been taken in order to actively limit the use, misuse and extension of pharmaceutical patents by the proprietors of the exclusive right. However, these measures have not been entirely successful since the phenomenon of evergreening still occurs in the pharmaceutical industry in Europe. EU competition law prohibits the abuse of a dominant position on the market under Article 102 of the Treaty on the Functioning of the European Union (TFEU).

One example of an attempt to evergreen pharmaceutical patents that failed occurred in the *AstraZeneca*-case.[5] The company AstraZeneca used different strategies to try to extend expiring patents on their best-selling drug Losec. The attempt was unsuccessful and the company was fined by the European Court of Justice (ECJ) for violation of EU competition rules. *AstraZeneca* was the first case where the prohibition on abuse of dominance prevented evergreening strategies by a pharmaceutical company.[6]

In regard to recent developments, competition law cases in the sector are expected to increase.[7] If evergreening constitutes an abuse of dominant

[5] Case C-457/10P *AstraZeneca v Commission.*

[6] Fagerlund, Niklas and Rasmussen, Søren Bo, "AstraZeneca: the first abuse case in the pharmaceutical sector" in *Competition Policy Newsletter*, Number 3 Autumn 2005, p. 54.

[7] See more in section 2.4; See also Nissen, Morten, van de Walle de Ghelcke, Geoffroy and Vilarasau, Melanie, "Competition Law in the Pharmaceutical Sector", in Shorthose, Sally

position then competition rules should be able to successfully prevent such conduct and thereby facilitate the entry of other market players. This is where legislation possibly is lacking. It is therefore of interest to examine evergreening in the light of EU competition law.

1.2 Purpose and research questions

The purpose of this thesis is to analyse evergreening in light of EU competition law. In particular, the thesis will discuss the use of Article 102 TFEU to prevent evergreening of patents in the case of a company holding a dominant position on the pharmaceutical market. EU competition rules will be examined on the backdrop of the theory of effective competition, meaning in terms of the benefits produced on European citizens.[8] The research questions central to the thesis will therefore be the following:

i. Can Article 102 TFEU be used to effectively prevent evergreening of pharmaceutical patents within the EU, especially in line with the theory of effective competition?
ii. Is it necessary to make changes to EU competition legislation in order to make the prevention of evergreening more effective?

1.3 Method and materials

In order to answer the research questions a legal dogmatic method and EU legal method will be used throughout the thesis. Additionally, a law and economics perspective will be applied to a certain extent. The legal dogmatic method aims to clarify and establish the meaning of applicable law. The method interprets the universally recognised legal sources. The legal sources are legislation, preparatory work, case law and legal doctrine.[9]

The EU legal method is applicable since the thesis takes an EU perspective. EU law is based on a hierarchy of norms and general principles. If there is a conflict between EU law and the law of a Member State, EU law prevails due to the principle of supremacy.[10] The EU legal method involves analysis

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(ed.), *Guide to EU Pharmaceutical Regulatory Law*, Alphen aan den Rijn: Kluwer, 2012, p. 541.

[8] See section 1.3.

[9] Kleineman, Jan, "Rättsdogmatisk metod" in Korling, Fredric and Zamboni, Mauro (eds.), *Juridisk Metodlära*, Lund: Studentlitteratur, 2013, p. 21.

[10] Hettne, Jörgen and Otken Eriksson, Ida (ed.), *EU-rättslig metod: teori och genomslag i svensk rättstillämpning*, Stockholm: Norstedts Juridik, 2011, p. 173; Craig, Paul and De Búrca, Gráinne, *EU Law: text, cases, and materials*, Oxford: Oxford University Press, 2015, p. 267; Case 6/64 *Costa v ENEL*.

of EU primary and secondary law.[11] Primary law in the EU consists mainly of the founding Treaties that are binding on the Member States. Secondary law includes directly applicable regulations as well as directives which are binding as to the result to be achieved.[12] Case law from the Court of Justice of the European Union (CJEU) will also be used. The status of case law depends on which instance the decision originates from, where the ECJ is the highest instance with highest precedential value followed by the General Court (GC). At the time of writing, there is only one judgement from the ECJ where a company has been penalised for evergreening patents as an abuse of dominant position. This is the case of *AstraZeneca* which will be the main case study, discussed in Chapter 3 below.[13]

The legal method of law and economics will also be used. The aim of this method is to examine and explain the economical implications of law.[14] The method will be used both in relation to economic aims of competition rules and economic implications of using patent strategies to extend an exclusive right. It will also be used in order to explain the economic results of evergreening and why proprietors of pharmaceutical patents sometimes use this strategy as a means to maintain their market share. Law and economics is also a way to support legal arguments on the basis that changes in legislation can lead to an increase in economic efficiency.[15] The economic characteristics of the pharmaceutical industry will be evaluated in chapter 2.

The two major areas of law that will be the focus of the thesis are patent law and competition law. The legal framework surrounding patent law is rather complex due to its incomplete degree of uniformity. Patent law is partially harmonised on an international level. The substantive law of patentability is governed by the European Patent Convention (EPC), while scope of the right, infringement and enforcement of European patents are mostly regulated by national laws. The EPC was first signed in 1973. The original convention was modernised and replaced in 2007 by the EPC 2000.[16] The EPC provides the autonomous legal system for the granting of European patents.[17] The EPC is an intergovernmental treaty distinct from the EU. The signatories to the EPC therefore extend beyond states that are members of

[11] Hettne supra, p. 40.
[12] Article 288 TFEU.
[13] Case C-457/10P *AstraZeneca v Commission.*
[14] Reidhav, David, Glader, Marcus and Dahlman, Christian, *Rättsekonomi - en introduktion*, Lund: Studentlitteratur, 2002, p. 8; Lehrberg, Bert, *Praktisk juridisk metod*, Uppsala: Iusté, 2016, p. 243.
[15] Lehrberg supra, p. 243.
[16] The provisions of EPC 2000 apply in this thesis unless reference is explicitly made to EPC 1973.
[17] Article 2(1) EPC; See further discussion under Chapter 2.2.

the EU.[18] Patent law in Europe is currently undergoing changes and plans are underway to introduce a unitary patent within Europe, which will be further discussed in the subsequent chapter. Case law stemming from the Boards of Appeal of the European Patent Office (EPO) will also be used in order to establish principles of patent law. Although not binding on the Member States, case law from the EPO still has precedential value.[19] EPO case law will be particularly useful when examining patentability in the pharmaceutical sector, since the EPO is the responsible body for the granting of European patents. A strong precedent creates an increased level of legal certainty, which is desirable. Case law from the EPO can give an understanding of how the law is working in practice. It can also give an idea of how prior decisions affect the outcome of later decisions.[20]

EU competition law is a fully harmonised area within EU law regulated in the Treaty, as well as in regulations and directives. The objectives of competition rules include economic efficiency, economic freedom and fair competition.[21] The theory of perfect competition is a model that illustrates economic efficiency where monopoly is at the other end of the spectrum. A perfectly competitive market has a large number of firms with small market shares and there are no barriers to entry or exit.[22] In a monopolistic market on the other hand, exists only one big firm. The pharmaceutical market in Europe is a far shot from a perfectly competitive market. The pharmaceutical market typically consists of a small number of large firms making considerable profits from blockbuster drugs. Competition rules can be a tool to protect small firms in order to allow the latter to enter the market and compete with the dominant firms. In the case of pharmaceutical companies, patent rights are the essential barrier that prevents other firms from entering the market.

While the theory of perfect competition is a model that is usually impossible to attain, the concept of effective competition has emerged as one of many competition theories.[23] Effective competition is recurrent in EU competition law and has been defined as "the degree of competition necessary to ensure

[18] Bently, Lionel and Sherman, Brad, *Intellectual property law*, Oxford: Oxford University Press, 2014, p. 381.
[19] Cf. case NJA 2000 s. 497 where the Swedish Supreme Court held that case law from the EPO shall be followed by Swedish courts in cases regarding national patents.
[20] Smyth, Darren, *EPO Bound again - more precedential than ever: Precedent 2*, IPKat, 2014-07-16.
[21] Jones, Alison and Sufrin, Brenda, *EU competition law: text cases and materials*, Oxford: Oxford University Press, 2016, pp. 26-50.
[22] Jones and Sufrin supra, p. 7.
[23] The term "workable" competition is sometimes used; See Jones and Sufrin supra pp. 24-25; Bernitz, Ulf, *Svensk och europeisk marknadsrätt 1: Konkurrensrätten och marknadsekonomins rättsliga grundvalar*, Stockholm: Norstedts Juridik, 2015, p. 48.

the attainment of the objectives of the Treaty".[24] Effective competition is outcome-based and concerns the benefits it produces on consumer welfare.[25] Whether the pharmaceutical market in Europe is characterised by effective competition or not is therefore dependent upon whether European citizens benefit from the outcome.[26] The theory is fitting when analysing the pharmaceutical market in Europe. This is because the sector could be affected by anti-competitive conduct, impairing access to medicines and thereby affecting the health of European citizens. In the light of effective competition and the public interest, it is therefore important to investigate the conduct of large firms taking advantage of their position on the pharmaceutical market in order to make profits.

A proprietor of a pharmaceutical patent is referred to as an originator company.[27] Originator companies develop novel drugs that are protected by patent when entering the market. Generic companies sell pharmaceutical products which are no longer protected by patent but is composed of the same active pharmaceutical ingredient as the originator product.[28] If generic companies are hindered from entering the market, prices on pharmaceutical products will be kept high since originator companies are free to set the price level.[29] As a result, restriction of access to medicine affects consumers. It is therefore important to control anti-competitive conduct within the pharmaceutical market by preventing the evergreening of patents as a means of barrier to entry. Consequently, it is within the public interest to prevent dominant companies from abusing their position on the pharmaceutical market with such conduct. It is against the backdrop of health and availability to medicines that this thesis has been written, thus keeping the public interest in mind.

Non-binding EU sources are also central to the thesis, including guidelines, communications and reports. Although the CJEU occasionally deals with cases of strategic patenting, it is rare that it explicitly refers to the phenomenon of evergreening. The concept and definition of evergreening is

[24] Case C-6/72 *Continental Can v Commission*, para. 225.
[25] Bishop, Simon and Walker, Mike, *The Economics of EC Competition Law*, London: Sweet & Maxwell, 2010, pp. 20-21.
[26] Cf. ibid.
[27] The term "originator company" is used frequently on the subject of pharmaceutical patents, see e.g. Pharmaceutical Sector Inquiry: Final Report, p. 9; Drexl, Josef, "Intellectual Property in Competition: How to promote dynamic competition as a goal" in *More Common Ground for International Competition Law?*, Cheltenham: Edward Elgar, 2011, pp. 224-228; Tuominen, Nicoleta, "An IP Perspective on defensive patenting strategies of the EU pharmaceutical industry" in *European Intellectual Property Review*, 2012; OECD, *Generic pharmaceuticals and competition*; Case T-472/13 *Lundbeck v Commission*, para. 764.
[28] Pharmaceutical Sector Inquiry: Final Report, pp. 7-8.
[29] Ibid., p. 8; Although cf. section 2.3.1.

therefore largely based on the European Commission's Pharmaceutical Sector Inquiry.[30] The sector inquiry is a report carried out by the Commission clarifying how the European pharmaceutical industry functions and has provided important remarks regarding anti-competitive conduct by some pharmaceutical undertakings. The sector inquiry will be further discussed in section 2.4.

Where legislation and case law is lacking, legal doctrine will be used to a large extent. This includes books and articles by prominent practitioners in the field of EU competition law and intellectual property law, as well as in the specific field of pharmaceutical patents. The primary authors on the overarching subjects of patent law and competition law include Annette Kur, Thomas Dreier, Jonathan D.C. Turner, Alison Jones, Brenda Sufrin, Lionel Bently and Brad Sherman. On the more narrow topic of pharmaceutical patents have works by Josef Drexl, Bengt Domeij and Marianne Levin, among others, been considered. The doctrine will be used in order to examine applicable law and as a basis for legal analysis.

1.4 Delimitations

This thesis will deal with EU law at the EU level. The relevant provisions will be based upon the EU competition legislation and the legislation applicable to the European patent system. The focus will be on evergreening of patents on pharmaceutical products. Pharmaceutical products concern prescription medicines for human use. Pharmaceutical companies may use other patent strategies besides evergreening, such as patent acquisitions, pay-for-delay settlements and refusal to give access to essential patents. These types of strategies are outside the scope of this thesis. Although evergreening of pharmaceutical patents is a global problem, the paper is delimited to the European market since the basis is EU law. Therefore will the pharmaceutical sector within Europe as well as the implications on the European market be prioritised.

The conduct of pharmaceutical companies that hold a dominant position on the relevant market is central to the thesis. Evergreening is typically the conduct of those companies which already hold a large market share in order to keep making profits. EU competition rules will thus be delimited to Article 102 TFEU which prohibits an abuse of a dominant position. It is not possible within the scope of this thesis to provide an exhaustive account for neither competition law nor patent law. Brief overviews of both systems will instead be presented to facilitate understanding.

[30] European Commission, Pharmaceutical Sector Inquiry: Final Report, 8 July 2009.

The research questions central to the thesis deal with the effectiveness of EU competition law, and whether changes to the competition legislation are necessary to prevent evergreening. It may be possible to deal with evergreening by imposing changes to the patent system. Although this possibility is mentioned in the thesis, it is not the aim of the thesis to conduct a deep analysis of patent law.

Companies may choose to use other intellectual property rights, such as trade marks and designs, to complement patent protection for their pharmaceutical product. The role of other intellectual property rights beside patents will not be part of the discussion. Issues relating to parallel imports of pharmaceutical products have additionally been left outside the scope of this paper.

1.5 Outline

This thesis is divided into five chapters. Chapter two will introduce the legal framework surrounding patent law in Europe. The second chapter also provides a discussion on the nature of pharmaceutical patents and the characteristics of the pharmaceutical industry within the EU. Chapter three takes focus on EU competition rules and explores abuse of dominant position in the pharmaceutical sector. Chapter four is where the research questions central to the thesis are answered. The final chapter provides concluding remarks.

2 Pharmaceutical patents

2.1 Introduction

This chapter will deal with patents granted in the pharmaceutical sector in Europe. Firstly, a brief overview of the European patent system will be provided in order to introduce the reader to the legal framework governing patents. The subsequent section describes the pharmaceutical industry in Europe. Special characteristics of the sector and patentability of pharmaceutical products will be examined in order to facilitate the understanding of the following parts of the thesis. The last section in this chapter will be dedicated to the definition and effects of evergreening.

2.2 Overview of the European patent system

The Paris Convention, adopted in 1883, was the first major agreement to ensure the protection of intellectual property rights in other countries. The Paris Convention applies to intellectual property in the widest sense and is still in force today. One of the most significant provisions established with the Paris Convention is the right of priority. The priority entails that, on the basis of a first application filed in one contracting state, the applicant may within a certain time apply for protection in any of the other contracting states. The applicant will have a right of priority over subsequent applications filed by others. The Paris Convention has played an important role in the further development of intellectual property rights. The EPC is a special agreement within the terms of the Paris Convention.[31] This means that principles of the Paris Convention, including the principle of priority, apply in the procedure for European patents.

In addition to the Paris Convention, the Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS) has had an important impact on intellectual property since it came into force in 1995. TRIPS is signed by all member states of the World Trade Organization (WTO) and establishes minimum standards for intellectual property on matters such as

[31] Article 19 Paris Convention for the Protection of Industrial Property of March 20, 1883.

procedure, remedies and criminal sanctions. TRIPS developed a global harmonisation of the patent term, consisting of minimum 20 years protection from the filing date.[32] The relevant provisions of TRIPS are implemented in the EPC since nearly all contracting states of the EPC are members of the WTO.[33]

Patent protection in Europe may be obtained either by applying directly at a national office or by applying at the EPO. The EPO grants European patents under the EPC based on one single application. The European patent is not a unitary right, but a bundle of national patents. The patent holder indicates which countries it seeks protection for in the application, subject to the contracting states to the EPC. In 2017, the EPC had 38 contracting states that are also members of the European Patent Organisation.[34] The EPC is concerned with the validity of European patents. National patents resulting from the granting procedure at the EPO are subject to national judicial procedures for matters such as infringement, enforcement, revocation and renewal.[35] It is also possible to file an international patent application at the World Intellectual Property Organization (WIPO), covering 151 countries worldwide. The patent granting procedure is then carried out at the relevant national or regional patent office, such as the EPO.[36]

A patent grants the owner exclusive rights for an invention for a limited period of time, which for European patents is maximum 20 years from its filing date.[37] A patent can be granted for any invention having technical character provided that it is new, involves an inventive step, and is susceptible to industrial application.[38] The invention must in addition provide a solution to a technical problem.[39] The conditions for patent protection are therefore novelty, inventive step and industrial application. An invention is considered new if it does not form part of the prior state of the art.[40] The prior art comprises everything made available to the public before the date of filing the European patent application.[41] The patent will not fulfil the condition of novelty if the invention has been disclosed to the

[32] Article 33 TRIPS; Before TRIPS the term of protection for patents varied between 7, 10, 17 or 20 years; cf. WTO, *Pharmaceuticals and the WTO TRIPS Agreement*, p. 3.
[33] EPO, *Guide for applicants: How to get a European patent*, A-III, 7.
[34] As of May 2017, the 38 members were Albania, Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Macedonia, Malta, Monaco, Netherlands, Norway, Poland, Portugal, Romania, San Marino, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey, and the United Kingdom.
[35] Bently and Sherman supra, p. 383.
[36] Patent Cooperation Treaty (1970).
[37] Article 63 EPC.
[38] Article 52(1) EPC.
[39] EPO, *Guidelines for examination in the European Patent Office*, G-I, 2(ii).
[40] Article 54(1) EPC.
[41] Article 54(2) EPC.

public before the patent is filed. The condition of novelty applies strictly.[42] An invention is considered having an inventive step if, having regard to the state of the art, it is not obvious to a person skilled in the art.[43] The condition of industrial application is fulfilled if the invention can be made or used in any kind of industry.[44] For pharmaceutical products, industrial applicability is usually fulfilled if the invention includes chemical compounds.[45]

The drafting of a patent application is a difficult process because they are all at once technical, commercial, and legal documents.[46] The application must fulfil certain requirements which administers the way the patent is drafted. In order to obtain a patent, the applicant must disclose the invention to the public in a manner which is sufficiently clear and complete for it to be carried out by a person skilled in the art.[47] The application must contain information about the uses of the invention and which steps should be taken in order to put it into effect.[48] The most important features of the application are the claims whose purpose is to describe the patent. The claims must therefore be clear and concise and be supported by the description.[49] Since there is a direct link between the breadth of the patent and its economic value, would the inventor naturally like to obtain as broad claims as possible. Unclear claims make it difficult for competitors to establish the scope of the patent and are a possible ground for rejection of the application.[50]

There has been a lengthy debate since the 1970s to harmonize the European patent system and create a patent with unitary effect in the Member States of the EU.[51] A new type of European patent with unitary effect (EPUE) is currently in the process of being validated. The new system will include a patent which can be registered with unitary effect in the participating

[42] The criteria of the patent not having been made publically available does not mean that the public must be aware of it; See e.g. EPO decision T 877/90 where the invention was made available to the public due to an oral presentation for a selected group of people who were not subject to a non-disclosure agreement.
[43] Article 56 EPC.
[44] Article 57 EPC.
[45] Domeij, Bengt, *Pharmaceutical Patents in Europe*, Stockholm: Norstedts Juridik, 2000, pp. 19-20.
[46] Bently and Sherman supra, p. 406.
[47] Article 83 EPC; A person skilled in the art is a fictional person who has the skill and knowledge relevant to the invention in question.
[48] EPO decision G 2/93, OJ EPO 1995, 275, Sufficiency of disclosure.
[49] Kur, Annette and Dreier, Thomas, *European Intellectual Property Law: text, cases and materials*, Cheltenham: Edward Elgar, 2013, p. 98.
[50] See EPO decision T 79/91 where overlapping claims placed an undue burden on others seeking to establish the extent of the patent; See also EPO decision T 246/91, which held that claims must be clear and concise in order to enable competitors to ascertain whether their planned use is likely to cause infringement.
[51] Kur and Dreier supra, p. 149; Bently and Sherman supra, p. 383.

Member States of the EU. The EPUE will be based on one single application granting uniform protection in 26 EU countries. Included in the new patent package will also be two regulations and the formation of a single Unified Patent Court (UPC). The UPC will have exclusive competence of European patents and EPUEs.[52] The UPC will have a complex task in finding a working relationship between the EPO, national patent offices, the CJEU, and national courts, whilst at the same time develop its own precedent.[53] It is likely that the UPC will become a central policymaker for future patents in Europe, and may be biased towards certain policy aims.[54] The agreement that establishes the UPC was signed by 25 EU Member States in 2013 and needs to be ratified by at least 13 states, including France, Germany and the United Kingdom, to enter into force.[55]

2.3 Characteristics of the pharmaceutical market

2.3.1 Key features

The pharmaceutical sector is essential for the health of European citizens. The sector differs from other sectors because it is characterised by a variety of stakeholders, involvement from the State and a high degree of regulation to achieve different goals.[56] These goals include protection of public health and protection of innovation.[57] The manufacturing industry is knowledge-based and driven by R&D. The sector relies heavily on the protection of intellectual property rights in order to protect and encourage continuous innovation. Patents are the primary protection for pharmaceutical products.

The cost of developing new pharmaceutical products is very high because of the need for thorough R&D before the product can enter on the market. This is necessary to guarantee the safety of the medicine and to avoid exposing consumers to unnecessary risks. The pharmaceutical sector in the EU has

[52] Agreement on a Unified Patent Court, OJ 2013/C175/01.
[53] Riis, Thomas, Petersen, Clement Salung and Schovsbo, Jens, "The Unified Patent Court: Pros and Cons of Specialization - Is There a Light at the End of the Tunnel (Vision)?" in *Intellectual Review of Intellectual Property and Competition Law*, 2015, p. 272.
[54] Ibid.
[55] There are hopes that the UPC will become operational at the end of 2017 despite the triggering of Article 50 TEU by the United Kingdom, see Battistelli, Benoît, *UPP: Parliament hearing shows continuing support*, EPO, 2017-03-27; See also Smyth, Darren, *The Unitary Patent and Unified Patent Court - where are we now?*, IPKat, 2017-03-30.
[56] Pharmaceutical Sector Inquiry: Final Report, para. 39.
[57] E.g. the marketing authorisation procedure and the SPC regulation, see sections 2.3.3 and 2.3.4.

one of the highest investments in R&D in Europe.[58] The granting of patent rights thus provides incentive for the investment in R&D and continuous pharmaceutical innovation in Europe.

The actors on the pharmaceutical market are divided into two main types on the supply side: originator companies and generic companies.[59] Originator companies are R&D-based and range from large multinational companies to small and medium sized enterprises focusing on specialised products. The large originator companies develop new prescription medicines and bring them to the market. They also engage in the marketing activities and promotion of their products. Originator companies are often the right-holders of the patents on blockbuster drugs, namely those pharmaceutical products which achieve annual revenues of more than 1 billion USD at the global level.[60] Generic companies manufacture and sell pharmaceutical products for which patents have expired. Generic products are corresponding copies of the originator drug containing the same active pharmaceutical ingredient. Generic drugs are usually sold at a much lower price than the original product. Generic producers appear to focus on the top-selling products which create the highest revenues in order to create a larger profit than those products with a smaller turnover.[61]

On the demand side, the pharmaceutical industry is distinct from other industries because the ultimate consumer (the patient) is not the decision maker.[62] Prescribing doctors decide which pharmaceutical product should be assigned to the patient. In some Member States, pharmacists also play a role in this decision. Doctors or pharmacists may therefore be influenced by marketing practices of originator pharmaceutical companies which encourage them to prescribe an originator medicine instead of a cheaper generic alternative.[63] Moreover, the costs of pharmaceutical products are generally covered or reimbursed by national health insurance schemes. Although pricing and reimbursement of medicines are dealt with on the national level, each Member State must ensure that health schemes comply with the requirements of Directive 89/105/EEC. The directive provides certain requirements designed to verify that national pricing and

[58] European Commission, Executive Summary of Pharmaceutical Sector Inquiry, p. 2.
[59] Pharmaceutical Sector Inquiry: Final Report, paras. 47-48.
[60] Ibid., p. 6.
[61] Levin Marianne and Nilsson, Emma (ed.), *Läkemedel och immaterialrätt*, Stockholm: Jure, 2008, p. 131; See further section 2.3.5.
[62] Pharmaceutical Sector Inquiry: Final Report, para. 119.
[63] Cf. Case CA98/2/2001 (UK OFT) *Napp Pharmaceuticals*, where a pharmaceutical company was found to have abused its dominant position by supplying sustained-release morphine products to hospitals at discount prices, knowing that doctors are strongly influenced by brands used in hospitals.

reimbursement decisions do not create obstacles to pharmaceutical trade on the internal market.[64]

The life cycle of a new pharmaceutical product can be divided into three main stages: (1) pre-launch period; (2) marketing and sales period; and (3) patent expiry leading to generic competition.[65] The initial discovery of a new medicine and its new active pharmaceutical substance occurs in the pre-launch period. This stage requires significant investment in R&D, clinical trials, and regulatory processes such as marketing authorisations. It is worth noting that this stage does not guarantee commercial success, and may result in a loss for the pharmaceutical company if the product fails to enter the second stage. If the product enters the second stage, it is during the marketing and sales period that an originator company must generate sufficient revenues to cover the expenses spent during the pre-launch period and to make profits.[66]

In the last stage, the patent on the originator product expires making generic competition possible. When originator companies face generic competition, sales generally decrease since there will be an alternative to the original product, often being significantly cheaper.[67] Generic competition therefore usually leads to a dramatic decline in profits and market share for the original product.[68] This is often referred to as the phenomenon of a patent cliff. The patent cliff results in that generic products become available at a cheaper price and thereby has positive implications on consumers who can benefit from pharmaceutical products at a lower cost.

2.3.2 Patentability

The pharmaceutical sector files an increasing amount of patent applications and is one of the main users of the patent system.[69] Pharmaceutical patents are patents granted for an invention in the pharmaceutical industry. Inventions in the pharmaceutical industry can be defined as drugs and medicines used to diagnose, cure, treat or prevent disease.[70] A patent may be granted for both products, such as medicine, and processes, such as a

[64] Article 1, Directive 89/105/EC of 21 December 1988 relating to the transparency of measures regulating the pricing of medicinal products for human use and their inclusion in the scope of national health insurance systems.
[65] Pharmaceutical Sector Inquiry: Final Report, para. 128.
[66] Ibid., para. 163.
[67] European Commission, *Pharmaceuticals & Health Services: Overview*.
[68] Li, supra p. 123; Hitchings, Andrew and Baker, Emma, "Making Medicines Evergreen" in *BMJ*, 2012;345e7941.
[69] Executive Summary of Pharmaceutical Sector Inquiry, para. 9.
[70] Cf. definition of "medicinal product" in Article 1(2) of 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.

method of producing the chemical ingredients for a medicine.[71] Patents may not be granted in respect of methods for treatment of the human body by surgery or therapy and for diagnostic methods practiced on the human body.[72] All prescription medicines contain at least one active pharmaceutical ingredient, which is what gives the drug its therapeutic effect.[73]

The requirements to obtain a pharmaceutical patent are the same as for all other types of patents. However, patent obtained on pharmaceuticals differ in the practical effects they produce.[74] It was previously the case that only the process of manufacturing pharmaceuticals could be patented and not the active ingredients itself. However, this practice has changed and it is now the norm that patent granted for pharmaceuticals include the exclusive right for the production of the substance.[75]

When filing a patent for a pharmaceutical product, the patentee needs to disclose the therapeutic effects in the claims in order to fulfil the requirement of industrial application. It may turn out however, that the pharmaceutical product in question produce different effects than anticipated when the product has been tested or used in practice. If this is the case, a separate patent may be obtained for the new-found use of the product provided that it fulfils the criteria of novelty and inventive step.[76] This is referred to as second medical use of the original (first medical use) patent, namely when a known pharmaceutical can be used for the treatment of a new disease.[77]

It has become established practice at the EPO to allow broad protection for patents relating to first medical use. In a landmark decision stemming from EPO case law, a patent application for a pharmaceutical was initially refused on the grounds that specific therapeutic use needed to be disclosed. The Board of Appeal had to consider whether the broad claim that chemical compounds were "therapeutically active", was permissible. The findings were that a patent for a first medical indication can be granted for the whole field of therapy, concluding the possibility for broad protection. Broad

[71] WTO, *TRIPS and Pharmaceutical Patents*, p. 2
[72] To be excluded from patentability, a treatment or diagnostic method must actually be carried out on the living human or animal body, Article 53(c) EPC; See also EPO, *Guidelines for Examination*, G-II, 4.2.1.
[73] Levin supra, p. 122.
[74] Kur and Dreier supra, p. 110.
[75] Ibid.
[76] Article 53(c) EPC; EPO Decision T 128/82 of 12 January 1984, OJ EPO 1982, 164.
[77] Article 54(4) EPC; EPO, *Guidelines for Examination*, G-VI, 7.1.; Domeij 2000, p. 181; Moufang, Rainer, "Patentability of pharmaceutical innovations: the European perspective" in Drexl, Josef and Lee, Nari (eds.), *Pharmaceutical Innovation, Competition and Patent Law: A Trilateral Perspective*, Cheltenham: Edward Elgar, 2013, p. 68.

patent protection for first medical use is now settled case law and has been repeatedly confirmed.[78]

2.3.3 Product safety and marketing authorisation

One fundamental aspect of the pharmaceutical market is that although a patent has been granted, it is not a guarantee that the product can enter the market. Pharmaceutical products need to undergo rigorous testing before entering the EU market in order to ensure consumer safety. Marketing authorisation can be granted either by the competent national authority or by the European Medicines Agency (EMA).[79] EMA is a decentralised agency for pharmaceutical products within the EU.[80] The EMA is responsible for the scientific evaluation, supervision and safety monitoring of medicinal products.[81] The EMA evaluates applications for European marketing authorisation for medicinal products and ensures that the products are safe, effective and of high quality. Companies submit one single marketing authorisation application to the EMA under a centralised procedure.[82] The EMA does not carry out clinical trials but relies on the results of those trials. The authorisation of clinical trials occurs at the EU Member State level.[83]

Patent protection needs to be applied before the invention has been disclosed to the public in order to maintain the novelty requirement.[84] It is possible that the invention will be considered disclosed to the public if it is put through clinical trials before the priority date.[85] Therefore, it is often the case that several years of the 20 year patent protection is spent during the preparatory procedures before the product can enter the market and be sold to consumers. Due to the need for R&D, lengthy trials and marketing

[78] See e.g. EPO decision T 36/83 of 14 May 1985, OJ EPO 1986, 295; EPO decision G 2/08 of 19 February 2010, OJ EPO, 456.
[79] Article 6, Directive 2001/83/EC.
[80] EU agencies are distinct bodies from the EU institutions. Decentralised agencies contribute to the implementation of EU policies.
[81] Regulation 726/2004 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.
[82] European Union, *European Medicines Agency*.
[83] Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use.
[84] Article 54(2) EPC.
[85] EPO decision T 7/07 where a pharmaceutical product used in a clinical trial before the priority date, was considered as made publically available and therefore did not meet the requirement of novelty in Article 54 EPC. See also EPO decision G 1/92.

authorisation, the time from discovery to market approval of a new pharmaceutical product reaches an average of up to 12 years.[86]

2.3.4 Supplementary Protection Certificates

As explained above, pharmaceutical products need to go through lengthy procedures before the medicine is available to consumers. The effective period of protection for a pharmaceutical patent is reduced by the time it takes to go through these procedures. To resolve this problem, a Supplementary Protection Certificate (SPC) was introduced, which grants an extension of the patent term to compensate for the time period where the proprietor has not been able to take full advantage of his rights. In particular, a SPC compensates a proprietor that has not been able to market the patented product because of delays in obtaining regulatory approval. An SPC comes into effect on expiry of the basic patent[87] and grants the holder of a pharmaceutical patent an additional protection of up to 5 years.[88] Furthermore, it is possible to extend the duration of an SPC with a single 6-month term under certain conditions for medicinal products on paediatric use.[89] Regulation 469/2009 governs the granting of SPCs.[90]

It is the national patent offices, not the EPO, that grant SPCs. Consequently, the SPC is a national right just like the patent. The requirements to obtain an SPC are that the product must be protected by a basic patent and that there is a valid marketing authorisation for that product in which the SPC is sought.[91] The SPC cannot last for longer than 15 years after the first marketing authorisation in the EU, if that would be earlier than the 5-year SPC duration. Strictly speaking, the SPC is not a "patent extension". It is a separate, usually narrower right that is subject to the same limitations and the same obligations as the basic patent.[92] A distinction is made in the SPC Regulation between "medicinal product" and "product". The latter term refers to the active substance of the pharmaceutical in the first term. The medicinal product is the category for which SPC protection is possible, but

[86] Levin supra, p. 125.
[87] A "basic patent" is defined as a patent which protects the active ingredient of a medicinal product, Article 1, Regulation 469/2009 of 6 May 2009 concerning the supplementary protection certificate for medicinal products.
[88] Article 13, Regulation 469/2009.
[89] Article 13(3), ibid.; Article 36, Regulation 1901/2006 of 12 December 2006 on medicinal products for paediatric use.
[90] Regulation 469/2009 of 6 May 2009 concerning the supplementary protection certificate for medicinal products.
[91] Article 3, Regulation 469/2009.
[92] Article 5, ibid.; Brazell, Lorna, "Supplementary Protection Certificates" in Shorthose, Sally, *Guide to EU Pharmaceutical Regulatory Law*, Alphen aan den Rijn: Kluwer, 2012, p. 153.

the protection only applies to the active substance of the pharmaceutical product.[93]

2.3.5 Generic products

Generic manufacturing is common practice within the pharmaceutical industry. Once patent protection has expired it is very easy for competitors to reproduce copies of pharmaceuticals since the invention has already been disclosed to the public. Generic companies manufacture and sell products which contain the same active pharmaceutical ingredient as an originator product. A generic pharmaceutical product is therefore chemically identical to the original product.[94] The copies are either sold under the name of the chemical ingredient or under a different brand name, which in both cases are examples of generic medicine.[95] Generic names are decided by the World Health Organization (WHO).[96]

The benefit for generic producers is that they do not need to invest the same amount of time and money in R&D and clinical trials since it has already been done by the originator company. Generic companies may still be subject to some R&D activities, although at a significantly lower cost than the originator company.[97]

Generic medicines are subject to the same strict regulations of quality, safety and efficacy as all other medicinal products entering the European market.[98] However, a generic drug manufacturer is not required to provide clinical test results if it can be demonstrated that the product in question is a generic version of a drug that already has been authorised for use on the market.[99] Generic producers are therefore not required to provide direct evidence of the safety and effectiveness of the product in question to obtain marketing authorisation.[100] The marketing authorisation does not need to be in force at the time of the application of the generic manufacturer. It is

[93] Article 1, Regulation 469/2009; Domeij 2000, p. 271.
[94] Levin supra, p. 124.
[95] For example, paracetamol is a chemical ingredient found in many products with different brand names, but is also sold without a brand name as a generic medicine, See WTO, *TRIPS and Pharmaceutical Patents*, p. 7.
[96] Läkemedelsverket, *Swedish Medical Products Agency*.
[97] Pharmaceutical Sector Inquiry: Final Report, para. 99.
[98] Ibid., para. 91.
[99] Article 8(3)(1)(i), Article 10, Directive 2001/83.
[100] Fackelmann, Christian R., "Clinical data, data exclusivity and private investment protection in Europe" in Drexl, Josef and Lee, Nari (eds.), *Pharmaceutical Innovation, Competition and Patent Law: A Trilateral Perspective*, Cheltenham: Edward Elgar, 2013, p. 151.

sufficient that the pharmaceutical product is or has been authorised in the Member State concerned.[101]

2.4 The Pharmaceutical Sector Inquiry

In 2008, the European Commission carried out a sector inquiry, aimed at investigating the causes of the apparently low levels of competition on the pharmaceutical market.[102] In particular, the Commission wanted to examine reasons for the delayed entry of generic medicine to the market and an apparent decline in innovation. Furthermore, the sector inquiry would allow the Commission to supply the information necessary to give effect to Article 102 TFEU.[103] The Commission began its sector inquiry in January 2008 by conducting inspections and dawn raids at several pharmaceutical companies. This was the first time dawn raids had been used for the purpose of a sector inquiry, which implied the rather aggressive standpoint taken by the Commission.[104] The final report was published in July 2009.

The findings of the report indicate that originator companies use different methods to extend the commercial life of their products. This finding reflects the delayed entry of generic medicines on the market as originator patent strategies create barriers to entry and uncertainty for generic companies. The different methods identified by the Commission include evergreening strategies to extend the duration of the patent protection for medicines.

The Commission held that filing numerous patents for the same medicine is common practice within the industry. Another way to maintain patent protection was identified by the Commission as lengthy litigation procedures started by originator companies against generic companies. There were indications that some originator companies attempted to influence wholesalers and put into question the quality of generic medicines as part of their marketing strategy. The sector inquiry suggests that an originator company may use combined strategies in order to delay generic entry. The Commission found that more strategies are invested in blockbuster drugs.

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[101] This was previously not the standard practice, see e.g. Case C-223/01 *AstraZeneca v Lægemiddelstyrelsen*, para. 48; cf. Case C-457/10P *AstraZeneca v Commission*, para. 140; See also Fackelmann supra, p. 154.

[102] European Commission, Pharmaceutical Sector Inquiry: Final Report, 8 July 2009.

[103] Article 17(1) of Regulation 1/2003 gives the Commission permission to carry out inquiries and investigations in a particular sector of the economy where competition may be restricted or distorted. Note that the sector inquiry included application of Article 101 TFEU, which is outside the scope of this paper.

[104] Nissen et al. supra, p. 565.

The Commission highlighted that delay of generic entry can be harmful not only to generic companies, but also to public health budgets and ultimately consumers. It is therefore the recommendation that public authorities in the pharmaceutical sector should aim at creating a competitive environment to improve the functioning of the market. A functioning competitive market should ensure European citizens safe and affordable medicine without unnecessary delays.

Unfortunately, the final report does not provide clear guidance as of when certain conduct within the sector should be considered abusive under EU competition law. Despite this lack of guidance, the Commission delivers a clear message that undertakings within the sector should expect a heightened level of scrutiny regarding anti-competitive conduct. This can be further observed in the fact that the Commission opened proceedings against several pharmaceutical companies on the same day the final report was published.[105]

2.5 Evergreening

2.5.1 Definition

Evergreening is defined as the conduct where different types of strategies are used by pharmaceutical companies to extend a pharmaceutical patent for longer than the initial 20 year limit, with the aim to block or delay the entry of generic competition on the market. The goal is to maintain profits generated from the patent for as long as possible. Evergreening is therefore often carried out by originator companies which already make considerable profits from patented pharmaceutical products. The more valuable a product is when exclusivity expires, the more likely it is that evergreening tactics are used.[106] Consequently, companies which hold patents on blockbuster drugs are more likely to engage in evergreening.[107]

Evergreening is not a legal term. Courts therefore do not use the term when dealing with cases of extension of patent rights. Evergreening can be recognised by the specific objective to shut out actual or potential competition from the market. The conduct of evergreening may sometimes

[105] European Commission, *Antitrust: Commission opens formal proceedings against Les Laboratories Servier and a number of generic pharmaceutical companies*, MEMO/09/322.
[106] Domeij, Bengt, "Anticompetitive marketing in the context of pharmaceutical switching in Europe", in Drexl, Josef and Lee, Nari (eds.), *Pharmaceutical Innovation, Competition and Patent Law: A Trilateral Perspective*, Cheltenham: Edward Elgar, 2013, p. 274.
[107] Some argue that patent holders of nearly all blockbuster drugs attempt evergreening; See e.g. Medicines for Europe, formerly European Generic Medicines Association, *Patent-related Barriers to Market Entry for Generic Medicines in the European Union*, May 2008, p. 13.

be referred to as patent "life-cycle management" or "strategic patent planning", depending on which perspective one takes.[108] Evergreening is possible because the strategies used are not limited by patent law. However, evergreening may be unlawful under EU competition rules as will be demonstrated in the following chapter.

2.5.2 Different types

There are different types of evergreening strategies. The ones included in this paper all refer to a misuse of the patent system in various ways. Evergreening strategies include so-called patent clusters, product switching to second-generation patents, defensive patenting and misuse of the regulatory framework.[109] Originator companies may use one or a combination of evergreening strategies to maintain their exclusive right and to block or delay generic competition.

Patent clusters are formed when originator companies hold a large number of patents in relation to a single medicine. This is usually done by filing multiple patent applications, which often have overlapping claims on new formulations, processes and forms.[110] This creates a web of patents, designed to provide multiple layers of protection. Clusters have the aim of increasing legal uncertainty for generic competitors regarding the originators patent rights.[111] This is because the generic producer will be unable to assess the scope of the originators patent portfolio. Consequently, generic producers will not know whether they can market a generic medicine since it will be unclear whether the new version will infringe upon one of the patents belonging to the originator company. This forces the generic producer to choose between either waiting for all the patents to expire or taking the risks of litigation and the associated costs.[112]

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[108] Pharmaceutical Sector Inquiry: Final Report, para. 864; Mireles, Mike, *Intellectual Property Challenges in the Bio-Pharmaceutical Field*, IPKat, 2016-05-04.

[109] It is possible that evergreening can be conducted in ways beyond what is mentioned in this chapter. For the purpose of this thesis, the selection of evergreening strategies have been chosen based on what is frequently acknowledged in doctrine; cf. e.g. Pharmaceutical Sector Inquiry: Final Report, paras. 467, 480, 930, 1007, 1117; Ullrich, Hanns, "Strategic patenting by the pharmaceutical industry: towards a concept of abusive practices of protection" in Drexl, Josef and Lee, Nari (eds.), *Pharmaceutical Innovation, Competition and Patent Law: A Trilateral Perspective*, Cheltenham: Edward Elgar, 2013, pp. 248-249; Matthews, Duncan and Gurgula, Olga, "Patent strategies and competition law in the pharmaceutical sector: implications for access to medicines" in *European Intellectual Property Review*, 2016, p. 661.

[110] Pharmaceutical Sector Inquiry: Final Report, para. 491.

[111] Tuominen supra, p. 546.

[112] Pharmaceutical Sector Inquiry: Final Report, para. 1315.

The Commission observed in it its sector inquiry one case where as many as 1,300 patent applications related to one single patent cluster.[113] However, the Commission highlighted that this does not necessarily mean that secondary patents are "weak" or of lower quality, since all applications are evaluated on the basis of the same patentability criteria. Presumably, this means that patents granted are for perfectly good inventions.[114] Others argue that the quality of patents sometimes is poor due to the volume and complexity of patent applications.[115]

Patents are generally filed with the intent of gaining the exclusive right to bring an innovation to the market and make commercial use of it. Defensive patenting occurs when originator companies maintain and use patents to block the development of a new, competing product rather than to protect its own invention.[116] Defensive patents are filed for inventions that the originator company has little or no interest of developing or bringing to the market. The main purpose is to block out competition by filing patents on combinations that are likely to pose a competitive threat.[117] This blocks market access and eliminates competition, which clearly can be argued to be anti-competitive conduct. Defensive patents may overlap with patent clusters.

Another evergreening strategy that may raise competition concerns is product switching to second-generation or follow-on patents. This entails originator companies trying to switch consumers from medicines facing patent expiration, to second-generation medicines. Second-generation medicines occur when a new patent is obtained by slightly changing an active ingredient and presenting an old medicine as a new product.[118] Another way to initiate product switching is to modify the means of administering a drug, for example by changing a tablet to a capsule.[119] To doctors and patients, this may seem as beneficial since they will get a new and improved version of the original medicine. Originator companies have the incentive to switch consumers from the first-generation drug to the second-generation drug when the patent on the first-generation is about to expire. In order to enforce this strategy, originator companies may use

[113] The figure covers applications across all EU member states, Pharmaceutical Sector Inquiry: Final Report, para. 488.
[114] Jacob, Robin, *Patents and Pharmaceuticals*, November 2008, p. 7
[115] Kur and Dreier supra, p. 85.
[116] Pharmaceutical Sector Inquiry: Final Report, para. 1117.
[117] Ibid., para. 1124.
[118] Ibid., para. 1018.
[119] Domeij 2013, p. 274.

additional methods, such as intensified marketing of the new drug while raising the price of the old drug.[120]

Other ways of evergreening patents include misuse of the regulatory framework or providing misleading information to state authorities. By providing misleading information, it could be possible to for example obtain extra SPC certificates which would otherwise not have been granted.[121] In order to invalidate the SPCs, generic competitors would have to start lengthy and costly litigation proceedings against the originator company. This could affect competition by delaying market entry and imposing unnecessary costs on generic companies.

2.5.3 Effects

Evergreening has been suggested to be the most effective strategy to counter generic competition.[122] Patent clusters, product switching and defensive patenting all involve applying for additional patents. Applying for patents is a lawful right granted by patent law to reward the innovator. Pharmaceutical companies may argue that since the strategies are in line with patent law, the conduct is therefore legal.[123] If the patents meet the requirements, the owner will have the right to exclude its competitors. Although lawful under patent legislation, such conduct could raise concerns as being anti-competitive under EU competition law.

Originator companies can maintain their position on the market by evergreening their patents. If they do not engage in evergreening, the medicine will become available to generic producers. The patent cliff occurs when there is a steep fall in revenue for the originator company following the introduction of generic competition on the market. Avoiding the patent cliff is therefore incentive for companies to partake in evergreening strategies. The presumption for the patent cliff is that the originator company makes large revenues to begin with, in other words it already maintains a large market share. The patent cliff is therefore a phenomenon that happens to undertakings which hold a dominant position on the relevant market, which is why an abuse of such a position triggers Article 102 TFEU.

Generic companies have strongly criticised evergreening, in particular when there are no improved therapeutic effects of the product in question.[124] They

[120] Matthews and Gurgula supra, p. 666.
[121] Case C-457/10P *AstraZeneca v Commission.*
[122] Quote of an originator company, Pharmaceutical Sector Inquiry: Final Report, para. 996.
[123] Matthews and Gurgula supra, p. 667.
[124] Pharmaceutical Sector Inquiry: Final Report, para. 994.

claim that the new products which show little or no benefits serve primarily to maintain the profits generated from the original product.[125] Evergreening can further be criticised because it does not create benefits in the public interest nor does it contribute to an improvement in the pharmaceutical sector. The purpose is for companies to maintain their exclusive right and thereby continue to make profits. No advantages are provided for patients using the pharmaceutical product when patents are evergreened. Instead, prices are kept high by keeping generic competition off the market. Evergreening is therefore merely creating an economic advantage for the company which evergreens their patent.

The Commission takes the view that legitimate business practices cannot become illegitimate simply by their cumulative application.[126] However, it must be taken into account that cumulative patent applications for evergreening purposes is essentially a misuse of the patent system. It can therefore be argued that evergreening should not be allowed, since it is exploiting the patent system in advantage of the personal interest and has negative effects on competition on the internal market. On the other hand, there is a difficulty in establishing whether evergreening strategies such as patent clusters have an anti-competitive objective. An originator company may argue that multiple patents for the same medicine are necessary. A strong patent protection is desirable and encourages companies to innovate. It may be difficult to establish early on whether a pharmaceutical company is applying for multiple patents with an intent to evergreen. This may be easier to demonstrate once the market has been affected.

Some representatives of originator companies deny the meaning of evergreening altogether. The main argument is that the term evergreening is derogatory and misinterpreted.[127] They mean that patent extensions or second-generation patents are not possible since patents by their very nature are new and inventive.[128] They further argue that a new patent in no way forms an extension to a previous patent, since the new medicine has its own legally unconnected patent life.[129] On this basis, evergreening would not contribute to anti-competitive behaviour since it does not prevent third parties from operating across the full scope of the earlier patent.[130]

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[125] Pharmaceutical Sector Inquiry: Final Report, para. 994.
[126] Ibid., para. 1065.
[127] Bergström, Richard, *The degree to which patenting, and in particular secondary patenting, protect pharmaceutical products during their lifecycle is often misconstrued*, EFPIA, 2012-11-28.
[128] Ganguli, Prabuddha, *Inside Views: Can Patents Ever Be "Ever-Greened"? The Answer...They are "Never-Greened"*, Intellectual Property Watch, 2016-05-20.
[129] Bergström supra.
[130] Ibid.

From the point of view of the originator company, this argument is understandable and may in some cases be justified. However, I disagree because even though an expired patent may in theory be free for use by a generic producer, in practice it will be difficult if the originator company has used evergreening strategies. Evergreening strategies create difficulties for generic competitors irrespective of whether the patent applications are valid or not. It is possible that many patents in a patent cluster were to be declared invalid if they were challenged. However, the existence of multiple patents creates uncertainty about which of those patents could be infringed upon. The generic producer will be unable to define the scope of the original patent and as a result, withhold production to avoid the risk of litigation.

Because of the time it takes from product discovery to market launch, there are arguments from originator companies and scholars, meaning that today's patent life of 20 years is insufficient and should be extended.[131] This is an argument for possible justification for evergreening. However, SPCs already exist to make up for the time where the owner has not been able to make full use of the exclusive right during the pre-launch period. Either way, it is likely that originator companies will always consider the extent of the patent period as too short while generic companies will think of it as too long.

A comparison can be made to some developing countries who have chosen to incorporate anti-evergreening provisions in their patent laws. The provisions adopt stricter standards on protection in respect of novelty and inventive step.[132] The objective is primarily health concerns and to lift obstacles preventing access to life-saving medicines. There may be a stronger incentive for developing countries to incorporate anti-evergreening provisions as part of their public health policy. However, it is an interesting comparison to make and it can be considered whether European standards should take inspiration from such provisions.

[131] Li supra p. 170.
[132] Yamane, Hiroko, *Interpreting TRIPS: globalisation of intellectual property rights and access to medicines*, Oxford: Hart, 2011, pp. 429-433.

3 Competition in the pharmaceutical sector

3.1 Introduction

This chapter deals with the competition law aspect of patents granted in the pharmaceutical sector. First, a brief overview of the relationship between patent law and EU competition rules will be provided in order to exemplify the potential impact of competition law on the use of patents. Thereafter, the focus will shift to the conditions and enforcement of Article 102 TFEU, which prohibits an abuse of dominant position. The following section is dedicated to market definition in the pharmaceutical sector. The chapter ends with a case study on *AstraZeneca*, the landmark judgement from the CJEU, regarding a violation of Article 102 TFEU resulting from an attempt to evergreen pharmaceutical patents.

3.2 The relationship between patent law and competition law

There is a close link between intellectual property rights and competition law. It is sometimes regarded that an inherent conflict exists between the two areas of law.[133] Intellectual property rights, such as patents, confer an exclusive right on the owner while a main objective of competition rules is to keep the market free. Patents therefore restrict some forms of competition, such as production and distribution, while enabling innovation and quality.[134] However, instead of viewing patent law and competition law as inherently conflicting, it may be more appropriate to highlight the need for a balance between the two. This balance must prevent abuses of patent rights without removing the reward provided by the patent system when it is

[133] Levin supra, pp. 131, 251.
[134] Turner, Jonathan D.C., *Intellectual Property and EU Competition Law*, Oxford: Oxford University Press, 2015, p. 3.

appropriately used.[135] Thus, competition law can be a useful tool to regulate potential abuses of patent rights.

Case law from the CJEU has settled that EU competition policy cannot affect the *existence* of intellectual property rights, but can impose limits on the *exercise* of those rights.[136] EU competition rules apply when the use of a patent restricts competition in a way that is not justified for the specific subject matter.[137] The two main provisions of EU competition law are set out in Article 101 and Article 102 TFEU. Article 101 TFEU prohibits anti-competitive agreements between undertakings while Article 102 TFEU deals with the conduct of undertakings with substantial market power, prohibiting an abuse of a dominant position on the internal market.

Although the ownership of a patent grants a form of monopoly on the specific right, it does not automatically establish that the owner is dominant in a particular market.[138] The possession of an intellectual property right in itself cannot confer a dominant position on the relevant market, however the exclusive right can in some circumstances create a dominant position. The existence of patent rights may be especially important when a company has a strong patent position on the market while competitors do not have access to equivalent patents.[139] A patent right has in several cases from the CJEU contributed to the existence of a dominant position.[140]

Moreover, the fact that conduct is permitted under EU legislation is not an obstacle for that conduct to be regarded as an abuse of dominant position. Abuse of dominant position under Article 102 TFEU is unrelated to the compliance or non-compliance with other legislation.[141] Legal conduct under patent law may therefore breach EU competition law. More specifically, evergreening strategies may fall under the prohibition of an abuse of dominant position according to Article 102 TFEU.

[135] WIPO, *Competition and Patents*.
[136] Turner supra, p. 6; Levin supra, p. 251; See also Case C-24/67 *Parke, Davis v Probel*; Case C-457/10P *AstraZeneca v Commission*, para. 741.
[137] Case C-58/64 *Consten and Grundig v Commission*, para. 56; Case C-102/77 *Hoffmann-La Roche v Commission*, para. 16; Turner supra, p. 3.
[138] Nissen et al. supra, p. 553.
[139] Turner supra, p. 128.
[140] Case T-30/89 *Hilti v Commission*, para. 93, Case C-457/10P *AstraZeneca v Commission*, Case 24/67 *Parke, Davis v Probel*.
[141] C-457/10P *AstraZeneca v Commission*, para. 132.

3.3 Abuse of dominant position

3.3.1 Conditions of Article 102 TFEU

EU competition rules aim to promote effective competition and restrict certain conduct of undertakings which have negative impacts on the market. One negative impact on the market is if a dominant undertaking abuses its power for personal gain. Article 102 TFEU prohibits any abuse of one or more undertakings of a dominant position within the internal market or a substantial part of it, in so far as it may affect trade between member states. The conditions of Article 102 TFEU are therefore the following. Firstly, the entity in question must be an undertaking within the meaning of EU competition law. Secondly, the undertaking must hold a dominant position on the relevant market. Thirdly, the dominant undertaking must abuse that position. Lastly, the abusive conduct must affect trade between member states. A violation of Article 102 TFEU can be established when all of these conditions are fulfilled.

An undertaking within the meaning of EU competition law has been defined as every entity engaged in economic activity, regardless of the legal status of that entity and the way in which it is financed.[142] The ECJ has further clarified that the notion of economic activity consists in the offering of goods and services on the market.[143] The concept of an undertaking takes a functional approach, meaning that it focuses on the type of activity rather than the characteristics of the entity that performs it.[144] The legal personality of the entity is therefore insignificant.

Dominance is a position of economic strength on the relevant market that enables the undertaking to behave independently of its competitors, customers and ultimately, its consumers.[145] Market shares are a useful first indication of the market power of the undertaking on the relevant market.[146] Very high market shares are in themselves often evidence of a dominant position. A market share above 50% creates a presumption of dominance.[147] However, dominance may also be established at lower market shares. The assessment of dominance takes into account the competitive structure of the

[142] Case C-41/90 *Höfner and Elser v Macrotron*, para. 21.
[143] Case C-118/85 *Commission v Italy*, para. 7; Case C-35/96 *Commission v Italy*, para. 36; Case C-205/03P *FENIN v Commission*, para. 25.
[144] Case C-41/90 *Höfner and Elser v Macrotron*, para. 21; Case C-355/01 *AOK Bundesverband*, Opinion of AG Jacobs delivered on 22 May 2003, para. 25.
[145] Case C-27/76 *United Brands v Commission*, para. 65; Case C-85/76 *Hoffmann-La Roche v Commission*, paras. 38-39; Case C-457/10P *AstraZeneca v Commission*, para. 175.
[146] Case C-85/76 *Hoffmann-La Roche v Commission*, paras. 39-41.
[147] Case C-62/86 *AKZO Chemie v Commission*, para. 60.

market, barriers to entry, barriers to expansion and the market position of the dominant undertaking and its competitors.[148] Article 102 refers to "one or more undertakings", meaning that several undertakings may collectively hold a dominant position on the relevant market.

To hold a dominant position is in itself not prohibited. An undertaking which holds a dominant position on a market has a special responsibility not to abuse that position.[149] The notion of a special responsibility for dominant undertakings is a key element in Article 102 TFEU and imposes a duty on those undertakings to act in certain ways.[150] This makes it increasingly difficult for dominant undertakings to justify any abusive behaviour since they are responsible to behave in a way that does not distort competition on the market.

A distinction is commonly made between exploitative abuses and exclusionary abuses. Exploitative abuse is conduct where a dominant undertaking takes advantage of its market power to exploit its customers, for example by charging unfair prices or by limiting production. Exclusionary abuse refers to conduct which impedes effective competition by foreclosing actual or potential competitors from the market.[151] Evergreening is a type of exclusionary abuse since it aims at excluding potential competition from entering the market.[152]

The abuse of dominant position must appreciably affect trade between member states. Abuses in which a dominant undertaking engages in more than one member state are normally by their very nature capable of affecting trade between member states.[153] If an undertaking engages in exclusionary abuse in the whole of a single member state, then intra-state trade will also normally be affected. This is because the abuse will generally make it more difficult for competitors from other member states to enter the market.[154] If a dominant position is held in only part of a member state, it will be a question of whether that part is a "substantial part of the internal market".[155]

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[148] Guidance on the Commission's enforcement priorities in applying Article 82 of the EC Treaty to abusive exclusionary conduct by dominant undertakings, OJ C 45/7, para. 12.
[149] Case C-322/81 *Michelin v Commission*, para. 57; Case C-202/07P *France Télécom v Commission*, para. 105; Case C-52/09 *Konkurrensverket v TeliaSonera*, para. 24; Case C-457/10P *AstraZeneca v Commission*, para. 134.
[150] Jones and Sufrin supra, pp. 374-375.
[151] Ibid., p. 270.
[152] See further discussion in Chapter 4.
[153] Commission Guidelines on the Effect on Trade Concept contained in Articles 81 and 82 of the Treaty, OJ C101/81, paras. 73-76.
[154] Ibid., para. 93; See also Case 322/81 *Michelin v Commission*.
[155] Jones and Sufrin supra, p. 286.

3.3.2 Enforcement of Article 102 TFEU

The Commission has an important supervisory task in the enforcement of Article 102 TFEU. This task includes not only to investigate and penalise infringements, but also to pursue general competition policy to guide undertakings and national authorities.[156] The enforcement of Article 102 is governed by Regulation 1/2003, which gives both the Commission and national competition authorities (NCAs) enforcement powers in regard to EU competition rules.[157] The Commission and NCAs are obliged to cooperate in the enforcement of competition law, and may impose requirements on undertakings to put infringement under Article 102 to an end.[158] In this purpose, they can take any measure necessary and appropriate to end the infringement, and to prevent any similar infringement.[159] If there is a suspicion that competition is distorted on the internal market the Commission may, for example, make requests for information or make unannounced inspections at the premises of undertakings.[160] The results of such investigations can be published as a sector inquiry, which was the case in the Pharmaceutical Sector Inquiry discussed in the preceding chapter.[161]

A majority of Article 102 cases arise from complaints to the Commission or NCAs, often put forward by competitors.[162] Complaints therefore play an important role in finding breaches of Article 102. The Commission and NCAs may impose heavy fines on undertakings for abuse under Article 102. Decisions taken are subject to review by EU courts. The CJEU has unlimited jurisdiction to review decisions where the Commission has imposed a fine or periodic penalty, and may cancel, reduce or increase the fine imposed.[163]

Article 102 may also be enforced by a private action or by reference for a preliminary ruling since it is a directly effective provision under EU law. This entails that an entity affected by a breach of Article 102 may bring proceedings before a national court. National courts may make a reference to the ECJ for a preliminary ruling under Article 267 TFEU.

[156] Case C-189/02P *Dansk Rørindustri and Others v Commission*, para. 170.
[157] Regulation 1/2003 of 16 December 2002 on the implementation of the rules on competition laid down in Articles 81 and 82 of the Treaty.
[158] Articles 5, 7, Regulation 1/2003.
[159] Case T-83/91 *Tetra Pak v Commission*, para. 220; Turner supra p. 162.
[160] Articles 18, 20, Regulation 1/2003.
[161] Article 17(1) ibid.; See section 2.4.
[162] Jones and Sufrin supra, p. 273.
[163] Article 31, Regulation 1/2003; Article 261 TFEU.

3.3.3 Objective justification

There is no exemption provision under Article 102 TFEU. The EU courts have developed the concept of objective justification to defend conduct which otherwise might be abusive under Article 102. A dominant undertaking may claim that the conduct is either objectively necessary or by demonstrating that the conduct produces substantial effects which outweigh any anti-competitive effects.[164] This is however a difficult argument to make, once a dominant undertaking has abused its position.[165] It is the dominant undertaking who should provide all evidence necessary to demonstrate that the conduct in question is objectively justified.[166] The CJEU repeatedly refers to the concept of objective justification when analysing conduct under Article 102, and it has thus become an integral part of the assessment for abuse of dominance.[167]

Objectively necessary conduct could include the protection of legitimate public interest objectives, which would encompass the health and safety of consumers.[168] The Court has also accepted that objective justification on the ground of efficiency gains is possible if it is to the benefit of consumers. If the conduct has no advantages for the market or consumers, or if it goes beyond what is necessary in order to attain those advantages, then the conduct must still be regarded as an abuse.[169] Considering the conduct of evergreening, it is hard to see how a pharmaceutical company may argue that it is objectively necessary to maintain exclusive protection on a pharmaceutical product after patent expiry. This is essentially because entry of generic competition decreases the prices of medicine and thereby increases the access of that medicine to the consumer, both in terms of price and in terms of availability.

[164] Guidance on the Commission's enforcement priorities in applying Article 82 of the EC Treaty to abusive exclusionary conduct by dominant undertakings, OJ C45/7, paras. 28-30.
[165] Cf. Case T-228/97 *Irish Sugar v Commission*, para. 188, and Case T-201/04 *Microsoft v Commission*, para. 711, where the Court in both cases rejected the applicants' arguments of objective justification as a defence under the assessment of Article 102 TFEU.
[166] Guidance on the Commission's enforcement priorities in applying Article 82 of the EC Treaty to abusive exclusionary conduct by dominant undertakings, OJ C45/7, para. 31; Case C-209/10 *Post Danmark v Konkurrencerådet*, para. 42.
[167] See e.g. Case C-457/10P *AstraZeneca v Commission*, para. 134; Case C-209/10 *Post Danmark v Konkurrencerådet*, para. 41; Case C-95/04P *British Airways v Commission*, para. 69.
[168] Jones and Sufrin supra, p. 386.
[169] Case C-95/04P *British Airways v Commission*, para. 69.

3.4 Market definition

For competition rules to apply, it is necessary that the market is defined. The Commission's Notice on definition of the general market provides general guidelines on how the market should be defined in competition cases.[170] It does not however, give any specific guidance on how to apply the concept of market definition in sectors with distinctive features. Market definition in the pharmaceutical sector differs because of its special characteristics as described in the previous chapter.[171] The market definition is crucial and could influence the outcome of the case if it would be defined incorrectly. If the market is defined too narrowly, then the market share of the undertaking in question would increase. Likewise, a too broad market definition leads to a decrease in market share.[172] The broader the market, the less likely it is to find dominance. In order to define the relevant market, both the geographical market and product market have to be taken into account. Additionally, under application of Article 102 TFEU, it is necessary that the market definition follows the date of the abuse, that is the temporal market.[173]

The relevant geographic market comprises the area where the conditions of competition are sufficiently homogenous.[174] In the case of pharmaceuticals, the relevant geographic market is often national because of the differences in organisation of national health systems and reimbursement of prices.[175] It is also possible that the relevant geographic market comprises all states in which the owner has obtained the patent. The Commission defined the geographic market as all EU Member States in its Pharmaceutical Sector Inquiry.[176]

The relevant product market includes the products or services which are interchangeable with the product in question. The SSNIP-test is often used to define the product market, but is also used to define the geographic

[170] Commission Notice on the Definition of the Relevant Market for the Purposes of Community Competition Law, OJ C372/5.
[171] Section 2.3.
[172] See Case 6/72 *Continental Can v Commission*, where failure to define a correct market lead to annulment of a Commission's decision.
[173] Jones and Sufrin supra, p. 85; cf. Executive Summary of Pharmaceutical Sector Inquiry, p. 4.
[174] Case C-27/76 *United Brands v Commission*, para. 11; Commission Notice on the Definition of the Relevant Market for the Purposes of Community Competition Law, OJ C372/5, para. 8.
[175] Case C-457/10P *AstraZeneca v Commission*, para. 503; Directive 89/105/EC.
[176] Executive Summary of Pharmaceutical Sector Inquiry, p. 4.

market.[177] This is a test which determines whether a small but significant non-transitory increase in price would make consumers change from one product to another, interchangeable product.[178] If there are significant price differences between two products then it is possible that the products do not belong to the same product market.

However, price differences may not be a determinant for different product markets in pharmaceuticals, because of the nature of the industry.[179] Since the ultimate consumer (the patient) is not the decision maker (the doctor), there is usually limited price sensitivity on the decision maker.[180] Because of this limited price sensitivity, it may be more appropriate to carry out market definition in the pharmaceutical sector based on other factors than interchangeable products. The SSNIP-test may therefore not be suitable for the market definition.[181] Moreover, there is normally not a substitutable product for a medicine with a valid patent. Patented pharmaceutical products therefore hold a much stronger position on the market in comparison to other patented products.[182]

The preferred approach is instead to identify the therapeutic effects of the medicine, in other words its intended use. This is possible through an Anatomical Therapeutic Chemical (ATC) Classification system. The ATC system classifies pharmaceutical products into different groups depending on which therapeutic indication it possesses.[183] The Commission used this approach in *AstraZeneca* when defining the relevant market and the GC approved the Commission's approach.[184] Although the ATC system is useful, it should only be a preliminary step in assessing the relevant market in the pharmaceutical sector. One cannot solely rely on the ATC system but must also take into account the possibilities of competition and interchangeability with other products.[185]

In an early competition case, the Commission held that interchangeability of prescription drugs depends on their "functional substitutability" as viewed

[177] Small but significant and non-transitory increase in price, i.e. will the consumer stay with the product in question if its price increased by 5-10%?
[178] Jones and Sufrin supra, p. 306.
[179] Pricing and reimbursement of pharmaceutical products is regulated on the national level, see section 2.3.1.
[180] Westin, Jacob, "Defining relevant market in the pharmaceutical sector in the light of the Losec-case - just how different is the pharmaceutical market?" in *European Competition Law Review*, 2011, p. 57.
[181] Westin supra, p. 57.
[182] Levin supra, p. 245.
[183] WHO, *The Anatomical Therapeutic Chemical Classification System with Defined Daily Doses (ATC/DDD*).
[184] Case COMP/A.37.507/F3 *AstraZeneca*, para. 3; Case T-321/05 *AstraZeneca v Commission* paras. 61, 154-155; See section 3.5.2.
[185] Westin supra, p. 60.

by those supervising consumption.[186] This means that doctors prescribing the drug decide how interchangeable one medicine is for another in terms of treating a certain condition. This aspect disregards interchangeability of products depending on physical, chemical or technical properties. Nevertheless, definition of the relevant market in the pharmaceutical sector should reflect the market situation, and should take into account interchangeability and substitutability of the pharmaceutical product. The price, specific product characteristics, such as therapeutic indication and intended use, can be used in defining the relevant product market.[187]

3.5 The *AstraZeneca* case

3.5.1 Background

The first case on abuse in the pharmaceutical sector was *AstraZeneca* which confirmed that it can be a violation of Article 102 TFEU to engage in evergreening of pharmaceutical patents.[188] It was also the first case where European institutions had to assess the relevant market in the field of pharmaceutical products.[189] The case deals with a situation of purely transitory nature that is not likely to occur again in practice. The case is nevertheless significant because of the application of competition law to evergreening practices.

AstraZeneca AB and AstraZeneca plc are parts of a group, which invents, develops and markets pharmaceutical products (AstraZeneca). One of the main drugs marketed by AstraZeneca is Losec, a medicine for the treatment of stomach ulcers.[190] Losec obtained patent protection in 1979 and was during one period the world's best-selling prescription medicine.[191] In 1999, the Commission received a complaint from two generic companies alleging that AstraZeneca was abusing its dominant position on several national markets. The alleging conduct related to two abuses: the first relating to giving deliberately misleading information to national patent offices, and the second relating to withdrawal of marketing authorisations making generic authorisation more difficult.

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[186] Case COMP/M.737 *Ciba-Geigy/Sandoz*, para. 21.
[187] Westin supra, p. 60.
[188] Case C-457/10P *AstraZeneca v Commission*.
[189] Outside the area of merger control; Drexl, Josef, "AstraZeneca and the EU Sector Inquiry: When do Patent Filings Violate Competition Law?" in *Max Planck Institute for Intellectual Property and Competition Law Research Paper Series*, 2012, p. 2.
[190] The active pharmaceutical ingredient is omeprazole. Losec is the brand name under which AstraZeneca markets the medicine.
[191] European Commission, Press Release, IP/05/737, "Competition: Commission fines AstraZeneca €60 million for misusing patent system to delay market entry of competing generic drugs".

The Commission argued that the conduct by AstraZeneca was part of an overall strategy designed to keep generic competition off the market. In 2005, the Commission had initially imposed a EUR 60 million fine on AstraZeneca for two abuses of dominant position contrary to Article 102 TFEU.[192] On appeal, the GC upheld the decision at large in 2010.[193] However, the GC reduced the fine imposed to EUR 52.5 million because the Commission had not proved that deregistration of marketing authorisations in Denmark and Norway had produced anti-competitive effects. In December 2012, the ECJ upheld the judgement of the GC, imposing a EUR 52.5 million fine on AstraZeneca for two abuses of dominant position.

3.5.2 Market definition

The Commission carried out the market definition which was first upheld by the GC, then affirmed by the ECJ.[194] The product market was defined based on the therapeutic group to which the medicine belongs, namely through the ATC system.[195] The Commission had found that Losec was made up of only one category of products, namely "proton pump inhibitors" (PPIs). Losec became the first PPI on the European market.[196] The market definition according to the Commission did not include other categories of products to treat stomach ulcers, such as histamine receptor antagonists, or "H2 blockers".[197] The issue was therefore whether H2 blockers exerted such competitive restraints upon PPIs that they should be considered as being part of the same market.

The main argument put forward by AstraZeneca was that Losec was part of a larger product market than argued by the Commission. AstraZeneca essentially argued that Losec was an interchangeable product, where the product market was made up of both PPIs and H2 blockers. AstraZeneca further argued that insufficient account had been taken for therapeutic use and excessive attention was paid to price indicators between the two groups of products.[198]

The GC examined the competitive relationship between PPIs and H2 blockers. In its judgement, the GC took into account statements from medical experts from which it was apparent that PPIs and H2 blockers were used differently under the concerned time period. Although PPIs and H2

[192] Case COMP/A. 37.507/F3, *AstraZeneca*.
[193] Case T-321/05 *AstraZeneca v Commission*.
[194] ECJ, paras. 51, 59.
[195] Case COMP/A. 37.507/F3, *AstraZeneca*, para. 372.
[196] Ibid., paras. 36-37.
[197] H2 blockers block only one of the stimulants of the proton pump, which is different from how PPIs work, see GC, paras. 28-222.
[198] ECJ, para. 30.

blockers concerned the treatment of the same condition, it was concluded that PPIs were used to treat severe forms of stomach ulcers, while H2 blockers were generally prescribed to treat less serious forms.[199] Although the two types of products treated the same condition, they still had different therapeutic effects. The findings of the GC were therefore that PPIs and H2 blockers had different therapeutic uses and therefore belonged to two different product markets. The narrow market definition resulted in that AstraZeneca was dominant on the product market consisting of PPIs.

3.5.3 The first abuse: misuse of the regulatory framework

The first abuse related to that AstraZeneca deliberately misled several different national patent offices in order to obtain or maintain SPCs for Losec. The Commission found that AstraZeneca had submitted misleading information to national public authorities, which lead the authorities to incorrectly issue SPCs. AstraZeneca was in fact not entitled to the SPCs, or was only entitled to the SPCs for a shorter duration. This misuse of the patent system granted AstraZeneca an extension for the patent right which would not have been possible if the national authorities had not been misled. By misleading national authorities and thereby obtaining illegitimate SPCs, AstraZeneca maintained its market dominance by extending the patent term. The objective for the extension of the patent right was to keep generic manufacturers of Losec off the market.

In this case, the national patent offices were not obliged to check whether the information submitted by AstraZeneca regarding the SPCs was accurate. The national patent offices therefore relied upon the information provided by AstraZeneca and did not check whether the products fulfilled the specific requirement for SPCs.

AstraZeneca argued that the Commission had both erred in law in defining the abuse and had failed to provide sufficient facts for the abuse. AstraZeneca further argued that it should be a requirement of deliberate fraud or deceit in order to find an abuse in circumstances as those of the case. AstraZeneca submitted that they acted in good faith and should therefore not be penalised for abuse, especially in combination with the narrow market definition carried out by the Commission.[200]

The GC fully confirmed the Commission's decision in regard to the first abuse.[201] The GC noted that the misleading nature should be assessed on

[199] GC, paras. 69-72.
[200] GC, para. 387; ECJ, para. 71.
[201] GC, para. 355.

objective factors and that bad faith of the undertaking in dominant position was not required for the purposes of identifying an abuse.[202] The GC further observed that AstraZeneca did not correct the misleading information even though its internal documents showed that it was aware of the incorrect basis of the SPCs.[203] The GC held that the unlawful SPCs lead to a significant exclusionary effect and that they were liable to alter the structure of the market by negatively affecting competition. The GC confirmed that the conduct by AstraZeneca constituted a practice falling outside the scope of competition on the merits and therefore was an abuse of dominant position.[204]

ECJ upheld the judgement from the GC, holding that AstraZeneca had deliberately misled several national patent offices during a period of two years. This was done in the purpose of maintaining the market position for as long as possible.[205] The ECJ highlighted the special responsibility for dominant undertakings to not act in a way that distorts competition on the internal market.[206] The ECJ therefore held that the first conduct was an abuse of dominant position because AstraZeneca had tried to eliminate competitors and thereby strengthening its own position on the market.

3.5.4 The second abuse: withdrawal of marketing authorisations

The second abuse was due to the fact that AstraZeneca had sought to deregister Losec from marketing authorisations in Denmark, Norway and Sweden with the intent of blocking or delaying the marketing of generic products and parallel traders. At the time, generic products could only be marketed if there was an existing marketing authorisation for the corresponding product. The Commission had found that AstraZeneca hindered companies from marketing generic versions of Losec by deregistering its marketing authorisations.

The main argument by AstraZeneca was that the relevant EU regulation confers a right on the holder of a marketing authorisation to request the withdrawal of such an authorisation.[207] They maintained that the right to

[202] GC, para. 356.
[203] GC, paras. 508, 527, 530, 594.
[204] GC, paras. 355, 361; It is not the purpose of Article 102 TFEU to prevent an undertaking from acquiring, on its own merits, a dominant position. Nor is it the purpose to ensure that less efficient competitors remain on the market, see Case C-209/10 *Post Danmark v Konkurrencerådet*, para. 21.
[205] ECJ, para. 93.
[206] ECJ, paras. 98, 134.
[207] Article 14(d), Regulation 1768/92 of June 1992 concerning the creation of a supplementary protection certificate for medicinal products. The regulation has since then

withdraw a marketing authorisation, could not logically both be prohibited and at the same time be allowed.[208] AstraZeneca meant that a requirement on a dominant company to maintain in force a marketing authorisation it no longer needs, stretches too far the special responsibility of dominant undertakings.[209]

The GC held that even use of legally available procedures can be a breach of competition rules. Illegality under Article 102 TFEU is unrelated to compliance with other legal rules.[210] Even though it was legal to withdraw the marketing authorisations, it still constituted a breach of competition law because it hindered generic competition. The GC linked this with the special responsibility that dominant undertakings have to not behave in such a way that competition is distorted. Due to this special responsibility, dominant undertakings cannot use regulatory procedures in such a way to prevent or make more difficult the entry of competitors on the market.[211]

The GC found that the second abuse was designed to prevent generic manufacturers from entering the market. The GC observed that it was apparent that the purpose of deregistration of the marketing authorisations was solely to obstruct or delay the entry of generic products.[212] The fine imposed by the Commission was reduced by the GC because the Commission had failed to prove that the deregistration of marketing authorisations in Denmark and Norway had produced anti-competitive effects.

The ECJ upheld the judgement at large and stated that deregistration of marketing authorisation after the patent has expired was a breach of Article 102 TFEU. In order for the conduct to be a violation of Article 102, two conditions had to be fulfilled. Firstly, the conduct had to produce anti-competitive effects, and secondly, there were no objective justifications for the behaviour.[213] AstraZeneca did not provide any justification or reason for deregistering the Losec capsules. The ECJ held that the conduct was a serious violation of EU competition rules and therefore upheld the fine imposed by the GC.

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been replaced by Regulation 469/2009 of 6 May 2009 concerning the supplementary protection certificate for medicinal products.

[208] ECJ, para. 125.

[209] ECJ, para. 126.

[210] GC, para. 677.

[211] GC, paras. 672, 817; ECJ, para. 134.

[212] GC, paras. 675-676.

[213] ECJ, paras. 134, 140.

3.5.5 Aftermath

The judgement from the ECJ has gained a lot of attention. The CJEU was faced for the first time with an abuse of dominance in the pharmaceutical sector concerning evergreening. Some argue that the judgement makes a too wide application of competition law and the special responsibility of an undertaking.[214] One suggested solution would be if intellectual property law was incorporated with a prohibition on abuse of dominance.[215] This would open up for the possibility to assess evergreening cases on the basis of patent law, instead of through competition law.

One effect of the judgement was that, although the Court did not consider a dominant undertaking having a duty to protect its competitors, in effect it imposed an obligation on AstraZeneca to assist competitors to enter the market.[216] Since AstraZeneca was prohibited from withdrawing marketing authorisations to hinder the entry of competition, the marketing authorisations had to remain in force, thus assisting generic competition.

Following the *AstraZeneca*-case, the Commission opened proceedings against the originator company Boehringer for abuse of dominance.[217] The Commission alleged that the company had misused the patent system in order to exclude generic competition from the market. The case was closed in July 2011 when Boehringer agreed to stop the anti-competitive conduct.[218] There is unfortunately not much information on the case. It would nevertheless have been interesting to see the outcome of the case if it would have proceeded.

There is evidence that some NCAs have followed example and become more aware of competition issues within the industry following the *AstraZeneca* judgement. One example is an Italian case where the NCA imposed a 10.6 million EUR fine on Pfizer for abusing its dominant position by blocking generic entry.[219] Pfizer had adopted a complex strategy to prevent generic competition, including illegitimate SPCs and misuse of the national regulatory system. The Italian competition authority relied for the most part upon the judgement in *AstraZeneca* when assessing the abuse of

[214] Lidgard, Hans Henrik, "Mål C 457/10P, AstraZeneca" in *Europarättslig tidskrift*, 2013, p. 516.
[215] Ibid.
[216] Jones and Sufrin supra, p. 563.
[217] Case COMP/B2/39246 *Boehringer*.
[218] European Commission, Press Release, IP/11/842, "Antitrust: Commission welcomes improved market entry for lung disease treatments".
[219] Italian Competition Authority v Pfizer Italia and others, Italian Council of State, 2014.

dominance.[220] Another example from an NCA is a 2011 case from the UK Office of Fair Trading, where a fine of 10.1 million GBP was imposed on an originator pharmaceutical company for abusing its dominant position. The company had used evergreening strategies to maintain profits from expiring patents, such as promoting a second-generation product still under patent, making it harder for competitors to launch their own generic products.[221]

Following *AstraZeneca*, there have been changes in the EU legislation making it impossible to repeat the specific conduct in the case.[222] The first abuse regarding misuse of the regulatory system could only arise because of specific transition rules of the SPC regulation.[223] The second abuse was also transitory in nature. At the time when AstraZeneca deregistered the Losec capsules, there was some uncertainty as to the interpretation of the requirement of marketing authorisations. The situation made it seem that it was not possible for generic companies to rely on deregistered authorisations to obtain marketing authorisation. It was due to public health reasons that the law required marketing authorisations to still be in force.[224] This has now been replaced by Directive 2001/83/EC, no longer requiring marketing authorisations to be in force in order for generic companies to obtain authorisations.[225] After the amended changes, it suffices that the originator product has obtained marketing authorisation and that it is not required that it is still sold on the market.[226] The issue of obtaining illegitimate SPCs and withdrawing marketing authorisations as an abuse of dominant position are therefore situations unlikely to occur again in practice.

[220] European Commission, ECN Brief 01/2012, *Italy: The Competition Authority fines anti-competitive Practices aimed at delaying Market Entry for generic Medicines*, p. 41; For a discussion see Hull, David W., "The Application of EU Competition law in the Pharmaceutical Sector" in *Journal of European Competition Law and Practice*, 2015, pp. 64-65.
[221] Case CA98/02/2011 (UK OFT) *NHS v Reckitt Benckiser (Gaviscon)*.
[222] Press Release, IP/05/737, "Competition: Commission fines AstraZeneca €60 million for misusing patent system to delay market entry of competing generic drugs".
[223] Article 19, Regulation 1768/92; Drexl 2012, p 3.
[224] Opinion of AG Mazák delivered on 15 May 2012, para. 78; Case COMP/A. 37.507/F3, *AstraZeneca*, paras. 259-262; Drexl 2012, p. 3.
[225] Article 4(3), point 8(a)(iii), Directive 87/21/EEC of 22 December 1986 amending Directive 65/65/EEC on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products; This has also been clarified by a preliminary ruling regarding interpretation of Directive 65/65/EEC in Case C-223/01 *AstraZeneca v Lægemiddelstyrelsen*, para. 27; Cf. section 2.3.5.
[226] Case C-223/01 *AstraZeneca v Lægemiddelstyrelsen*, para. 27.

4 Evergreening and Article 102 TFEU

4.1 Introduction

This chapter will answer the research questions. First, the effectiveness of EU competition rules, especially Article 102 TFEU, to prevent evergreening of pharmaceutical patents will be considered from a *de lege lata* perspective. Thereafter, an attempt is made to recommend changes in the EU competition legislation, *de lege ferenda*, in order to explore ways to make EU competition rules more effective in preventing evergreening as an abuse of dominant position. The desired outcome of competition rules are viewed in light of the theory of effective competition.[227] Economic implications will also be discussed in order to further enlighten the perspective of law and economics.

4.2 Are EU competition rules effective to prevent evergreening?

It has been shown throughout this thesis that evergreening is a form of exclusionary abuse which can be subject to Article 102 TFEU. This is because pharmaceutical companies who engage in evergreening have an aim of foreclosing actual or potential competition in order to maintain their own position on the market. One consequence of evergreening is that generic competition is hindered or delayed, keeping prices of medicines at a higher level than it would be if generic products were available. The ECJ confirmed in *AstraZeneca* that companies can be heavily penalised under competition law for engaging in evergreening.

Competition rules are suitable for correcting abuse of dominance in relation to the exercise of patent rights. In the case of pharmaceutical patents, it is possible that the exclusive right gives a too strong protection. This is because the access to medicines is a matter of health of European citizens.

[227] I.e. the outcome shall benefit European citizens; See section 1.3.

All citizens are dependent upon medicine when they get sick. For pharmaceutical patents it may therefore be appropriate to closer evaluate whether additional protection such as SPCs should be reconsidered. Originator companies often argue that the patent protection is too short due to the lengthy time it takes to obtain regulatory approval such as marketing authorisations. However, if originator companies did not benefit from obtaining patents for their pharmaceutical products, it is likely that they would not continue to invest in R&D. Since originator companies continue to invest in R&D and continue to make big profits, it can be argued that the patent term of 20 years is sufficient despite that the effective patent period is reduced due to regulatory process.

Although competition law is a suitable tool to prevent evergreening, it is not always effective. This is essentially because of the lack of precedent and guidance from the CJEU and the Commission. The existing precedent mainly consists of the *AstraZeneca*-case. This is problematic for several reasons. Firstly, *AstraZeneca* only dealt with two types of evergreening strategies: misuse of the regulatory framework and withdrawal of marketing authorisations. Evergreening can be conducted in a variety of ways in addition to the mentioned strategies. Other evergreening strategies are still lacking from current precedent. Secondly, the abuse of withdrawing marketing authorisations as an evergreening strategy is no longer possible. Similarly, the specific abuse of the regulatory system was particular to the *AstraZeneca*-case. It is therefore unlikely that the evergreening conduct used in *AstraZeneca* will be prevailing in the future. Since the Court established in *AstraZeneca* that evergreening can be considered an abuse of dominant position, it is likely that other evergreening strategies not affected by the judgement also fall under Article 102 TFEU. Although there is evidence that some NCAs such as Italy have followed the judgement in *AstraZeneca*, there is still need for a stronger precedent, especially in relation to the variety of evergreening strategies that are available to pharmaceutical companies.

The Commission's sector inquiry consisted of a thorough investigation of the pharmaceutical sector in Europe. It identified that evergreening is a problem due to its anti-competitive effects. Unfortunately, the sector inquiry did not provide any concrete guidance for NCAs in order to assess anti-competitive conduct by pharmaceutical companies under Article 102 TFEU. This increases uncertainty for the NCAs to distinguish lawful from unlawful behaviour on the pharmaceutical market. It is important that guidance is provided so that NCAs effectively can enforce Article 102 TFEU against pharmaceutical companies engaging in evergreening.

There is a difficulty in defining the relevant market in the pharmaceutical sector, which is crucial for the application of Article 102 TFEU. Market definition in the pharmaceutical sector is complex and involves consideration of other factors compared to market definitions in other sectors. It is not clear exactly how market definition in the pharmaceutical sector should be assessed. A common SSNIP-test may not be sufficient for defining the product market because of the lack of price sensitivity in doctors and patients. Therefore, other factors have to be taken into account, for example through an ATC classification which groups pharmaceutical products after its intended use. Although the ATC system seems to be a preferred first step, it seems that it is not always adequate to define the market based solely on this system. Other factors regarding product interchangeability may instead be preferable. This could for example be to look at the functionality, in other words to compare medicines designed to treat a certain condition.

The ECJ did not comment on the market definition in the *AstraZeneca*-case. It is therefore still unclear how the market should be defined within the pharmaceutical industry. Both the GC and the ECJ accepted the market definition conducted by the Commission concerning the relevant product market for Losec. Even though the ECJ affirmed the market definition, it did not provide any guidance of a correct market definition in cases regarding pharmaceutical products. The Commission had defined the relevant product market primarily based on therapeutic substitutability in line with the ATC system. The Commission held that PPIs were superior to H2 blockers, and that the PPI Losec therefore constituted of its own product market separate from H2 blockers. Although the two types of products treated the same condition, the PPIs were considered as more efficient and therefore belonged to a separate product market. Before the discovery of PPIs, stomach ulcers were treated with different types of H2 blockers. The Commission's finding is interesting because it was the innovative, better product that managed to create a separate product market. This raises the question whether all new and innovative medicines that are more efficient than medicines currently on the market, automatically belong to a separate product market. By this logic, all new and innovative medicines could potentially be dominant in regard to the condition it treats.

The non-harmonised patent system and its complex, and sometimes confusing nature, complicates enforcement of Article 102 TFEU. Pharmaceutical companies are subject to a variety of legislation, ranging from price regulations to national patent laws. This intersection with competition law adds another dimension making it increasingly difficult to effectively enforce applicable rules. There is a difficulty in establishing

whether legal exercise of patent rights potentially could foreclose generic competition. It is furthermore difficult to establish whether a pharmaceutical company has an evergreening objective when, for example, applying for several new patents. The patent applications may very well be perfectly valid on their own, but from a competition law perspective they may have an evergreening objective, for example in the form of patent clusters.

Due to the volume and complexity of patent applications, it may be difficult for an authority like the EPO to examine whether a patent application overlaps with another patent application. It can be argued that there are "strong" and "weak" patents, where the weak patents could potentially be declared invalid if they were challenged before a national court. Such weak patents are typically part of a patent cluster, or patens filed with a defensive intent. In order to invalidate weak patents, they have to be challenged before a national court. This means that generic companies have to bear the cost of litigation, which can be an expensive and lengthy process. It can therefore not be considered as an effective remedy to rely on generic companies to initiate proceedings in order to invalidate weak patents. Generic companies should not bear the cost of preventing evergreening, thus making other solutions more favourable.

It can be concluded that competition rules are a suitable tool to prevent evergreening of patents granted in the pharmaceutical sector. The effectiveness of competition rules on evergreening is nevertheless limited due to the complexity of the industry. In theory, application of Article 102 TFEU to abusive conduct by pharmaceutical companies may appear as fitting. Due to the reasons described above, a correct analysis under Article 102 TFEU is difficult because of the specific market definition, strict regulations and other special characteristics of the sector.

It may be easier in practice to use the patent law framework to regulate evergreening. With the currently ongoing changes and the hope for a soon functional unitary patent, it will be of importance that the future UPC takes a stance regarding anti-competitive conduct in the pharmaceutical industry. The UPC will have room to make the necessary policy changes within the intersecting area of patent law and competition law. The UPC can use its position to set a benchmark for the practice in the EPO, national patent offices, the CJEU and national courts, which could have a big impact on ending future evergreening.

4.3 How can EU competition rules become more effective?

Since the developments with the sector inquiry and the *AstraZeneca*-case, it is likely that abuse cases in the pharmaceutical sector will increase in the future. The Commission plays an important role in spotting these abuses, but NCAs also have responsibility on the national level, and in cooperation with the Commission. In order to use competition law as a remedy against evergreening abuses, it is crucial that the right tools are available.

A balance must be struck between encouraging innovation and maintaining a competitive environment on the market. On the one hand, a strong patent protection is essential for the promotion of innovation and encouragement of R&D. When companies know that they can make profits by innovating, they will then continue to develop new medicines. New and improved medicines are crucial for a functioning health system. On the other hand, keeping a patent for longer than the law allows, is counter-productive in the light of the public interest. Not only does it hinder competition, but it also has a negative impact on the public health system. The originator company can keep prices of medicines at a high level and the consumers' access to medicine is thereby affected.

In order to underline the anti-competitive effects generated by evergreening, one possible solution could be to introduce a presumption of illegality in EU legislation. This could take form through an anti-evergreening provision under patent law, competition law or EU law in general. This provision would entail that when it has been established that an originator company has used evergreening practices, those practices are presumed to be incompatible with EU law. The provision would act as a justification to prevent evergreening on public health grounds. Such a provision would provide clarity and legal certainty for courts and NCAs to effectively prevent evergreening. Parallels can be drawn to some developing countries which have incorporated such provisions in their patent laws. If an anti-evergreening provision was introduced in the legislation concerning European patents, it would impose stricter standards on novelty and inventive step. This would decrease the possibility for originator companies to obtain patent clusters, defensive patents and second-generation patents. However, it can be questioned whether such strict provisions are necessary in order to prevent evergreening. It is possible that such provisions would function as a disincentive to innovate and thus become counter-productive.

I believe that both the Commission, national courts and NCAs should intervene to ensure that pharmaceutical companies do not use evergreening strategies to block competition. It is crucial that NCAs know when to act, and that they know what they should look for. If NCAs lack guidance, they will not be able to correctly enforce competition rules. The consequence could be that companies on the pharmaceutical market continue to evergreen their patents, especially if very few companies are actually punished for such conduct.

The Commission and NCAs are dependent upon complaints by competitors in order to start an investigation under Article 102 TFEU. It is therefore important that actors on the pharmaceutical market are aware of EU competition law, which may not always be the case. The Commission and NCAs could therefore be more active in spreading information regarding competition rules in order to encourage generic companies to act if they suspect that other pharmaceutical companies engage in evergreening.

Changes in the legislation as such may not be necessary in order to effectively prevent evergreening in the future. I think that it may be sufficient if the Commission issues guidelines to clarify that different ways of trying to extend patent life on the expense of generic competition, is abusive conduct under Article 102 TFEU. Ideally, such guidelines would help national courts and NCAs to identify abusive evergreening strategies and provide the right tools to end such conduct. These tools could include a provision of cooperation with the EPO in order to aid findings of, inter alia, patent clusters.

The market definition is a fundamental element of Article 102 TFEU, which is why further guidance in this area is needed. One possibility is that guidelines were to be issued in regard to the market definition in the pharmaceutical sector. The Commission has already issued a notice on the relevant market under Article 102 TFEU. The existing notice does not say anything about markets with specific characteristics. It may therefore be helpful if the Commission issued a notice on definition of the relevant market in the pharmaceutical sector. This would clarify whether the product market can be based solely upon the ATC system or whether other factors should be taken into account. It would provide concrete guidance and make the work of NCAs easier. If the market is incorrectly defined, it could make the difference whether an abuse has been committed or not.

Clear guidance in the form of guidelines, would not only help enforcement on the national level, but it would also send a clear signal to pharmaceutical companies who would be more likely to end evergreening in the fear of being penalised. New precedent and guidelines would create a benchmark

for pharmaceutical companies to follow and take into account when they enforce their business strategies. Not only would guidance stop current evergreening practices, but it would also prevent companies from partaking in such practices in the future. Although the guidelines are not binding on the Member States, it is likely that such documents would nevertheless have substantial weight in the future.

5 Concluding remarks

This thesis has investigated the effectiveness of Article 102 TFEU to prevent evergreening of patents granted within the pharmaceutical sector in Europe. It has been concluded that evergreening is a form of exclusionary abuse that can be prevented under EU competition law. There is room for improvement regarding the enforcement of Article 102 TFEU for this purpose. Difficulties arise due to a number of factors, including the conflict between patent law and competition law and because of the special features of the pharmaceutical industry.

EU competition law can be used to prevent evergreening of pharmaceutical patents. The European Commission and the CJEU has successfully used Article 102 TFEU to penalise companies which engage in such conduct. Precedent beyond the *AstraZeneca*-case is sparse, which brings uncertainties regarding the application of EU competition rules. Pharmaceutical companies which engage in evergreening should nevertheless be prepared for an increased scrutiny in this area. This was indicated by the Commission in its sector inquiry and through the following alleged infringements against pharmaceutical companies.

In regard to the questions stated in the introductory chapter, the effectiveness of EU competition rules on evergreening is limited and the efficiency of those rules can still be improved. It is suggested that guidelines are issued by the Commission regarding evergreening conduct in combination with a notice on the definition of the relevant market in the pharmaceutical sector. This would help NCAs and national courts to effectively assess evergreening under Article 102 TFEU. If Article 102 TFEU can effectively be enforced to prevent evergreening of pharmaceutical patents, it may be the end of the era of blockbuster drugs that continue to be marketed by the same originator company long after the initial patent should have expired. When pharmaceutical companies no longer can evergreen their patents, it might be the end of blockbuster drugs as we know it.

Bibliography

EU Legislation

Regulation 1768/92 of June 1992 concerning the creation of a supplementary protection certificate for medicinal products.

Regulation 1/2003 of 16 December 2002 on the implementation of the rules on competition laid down in Articles 81 and 82 of the Treaty.

Regulation 726/2004 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.

Regulation 1901/2006 of 12 December 2006 on medicinal products for paediatric use.

Regulation 469/2009 of 6 May 2009 concerning the supplementary protection certificate for medicinal products.

Directive 87/21/EEC of 22 December 1986 amending Directive 65/65/EEC on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products

Directive 89/105/EC of 21 December 1988 relating to the transparency of measures regulating the pricing of medicinal products for human use and their inclusion in the scope of national health insurance systems.

Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use.

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.

European Commission

European Commission, *Executive Summary of Pharmaceutical Sector Inquiry*, accessed 2017-05-24 on: <http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/communication_en.pdf>

European Commission, *Healthcare Industries*, accessed 2017-05-24 on: <http://ec.europa.eu/growth/sectors/healthcare_en>

European Commission, *Pharmaceutical Sector Inquiry: Final Report*, 8 July 2009, accessed 2017-05-24 on: <http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/staff_working_paper_part1.pdf>

European Commission, *Pharmaceuticals & Health Services: Antitrust*, accessed 2017-05-24 on: <http://ec.europa.eu/competition/sectors/pharmaceuticals/antitrust_en.html>

European Commission, *Antitrust: Commission opens formal proceedings against Les Laboratories Servier and a number of generic pharmaceutical companies*, MEMO/09/322.

European Commission, ECN Brief 01/2012, *Italy: The Competition Authority fines anti-competitive Practices aimed at delaying Market Entry for generic Medicines*, accessed 2017-05-24 on: <http://ec.europa.eu/competition/ecn/brief/01_2012/it_medi.pdf>

Commission Notice on the Definition of the Relevant Market for the Purposes of Community Competition Law, OJ C372/5

Guidance on the Commission's enforcement priorities in applying Article 82 of the EC Treaty to abusive exclusionary conduct by dominant undertakings, OJ C45/7.

Commission Guidelines on the Effect on Trade Concept Contained in Articles 81 and 82 of the Treaty, OJ C101/81.

Press Release, IP/05/737, "Competition: Commission fines AstraZeneca €60 million for misusing patent system to delay market entry of competing generic drugs".

Press Release, IP/11/842, "Antitrust: Commission welcomes improved market entry for lung disease treatments".

Literature

Bently, Lionel and Sherman, Brad, *Intellectual property law*, Oxford: Oxford University Press, 2014.

Bernitz, Ulf, *Svensk och europeisk marknadsrätt 1: Konkurrensrätten och marknadsekonomins rättsliga grundvalar*, Stockholm: Norstedts Juridik, 2015.

Bishop, Simon and Walker, Mike, *The Economics of EC Competition Law*, London: Sweet & Maxwell, 2010.

Brazell, Lorna, "Supplementary Protection Certificates" in Shorthose, Sally, *Guide to EU Pharmaceutical Regulatory Law*, Alphen aan den Rijn: Kluwer, 2012.

Craig, Paul and De Búrca, Gráinne, *EU Law: text, cases, and materials*, Oxford: Oxford University Press, 2015.

Domeij, Bengt, "Anticompetitive marketing in the context of pharmaceutical switching in Europe" in Drexl, Josef and Lee, Nari (eds.), *Pharmaceutical Innovation, Competition and Patent Law: A Trilateral Perspective*, Cheltenham: Edward Elgar, 2013.

Domeij, Bengt, *Pharmaceutical Patents in Europe*, Stockholm: Norstedts Juridik, 2000.

Drexl, Josef, "Intellectual Property in Competition: How to promote dynamic competition as a goal" in Drexl, Josef, Grimes, Warren S., Jones, Clifford A., Peritz, Rudolph J.R. and Swaine, Edward T. (eds.), *More Common Ground for International Competition Law?*, Cheltenham: Edward Elgar, 2011.

Drexl, Josef, "AstraZeneca and the EU Sector Inquiry: When do Patent Filings Violate Competition Law?" in *Max Planck Institute for Intellectual Property and Competition Law Research Paper Series*, No 12-02, 2012.

Fackelmann, Christian R., "Clinical data, data exclusivity and private investment protection in Europe" in Drexl, Josef and Lee, Nari (eds.), *Pharmaceutical Innovation, Competition and Patent Law: A Trilateral Perspective*, Cheltenham: Edward Elgar, 2013.

Fagerlund, Niklas and Rasmussen, Søren Bo, "AstraZeneca: the first abuse case in the pharmaceutical sector" in *Competition Policy Newsletter*, Number 3 Autumn 2005, pp. 54-56.

Hettne, Jörgen and Otken Eriksson, Ida (ed.), *EU-rättslig metod: teori och genomslag i svensk rättstillämpning*, Stockholm: Norstedts Juridik, 2011.

Hitchings, Andrew and Baker, Emma, "Making Medicines Evergreen" in *BMJ*, 2012;345e7941, available at: <https://doi.org/10.1136/bmj.e7941>

Hull, David W., "The Application of EU Competition law in the Pharmaceutical Sector" in *Journal of European Competition Law and Practice*, 2015 6(1), pp. 61-70.

Jacob, Robin, *Patents and Pharmaceuticals*, November 2008, available at: <http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/jacob.pdf>

Jones, Alison and Sufrin, Brenda, *EU competition law: text cases and materials*, Oxford: Oxford University Press, 2016.

Kleineman, Jan, "Rättsdogmatisk metod" in Korling, Fredric and Zamboni, Mauro (eds.), *Juridisk Metodlära*, Lund: Studentlitteratur, 2013.

Kur, Annette and Dreier, Thomas, *European Intellectual Property Law: text, cases and materials*, Cheltenham: Edward Elgar, 2013.

Lehrberg, Bert, *Praktisk juridisk metod*, Uppsala: Iusté, 2016.

Levin, Marianne and Nilsson, Emma (ed.), *Läkemedel och immaterialrätt*, Stockholm: Jure, 2008.

Li, Jie Jack, *Blockbuster drugs: the rise and decline of the pharmaceutical industry*, New York: Oxford University Press, 2014.

Lidgard, Hans Henrik, "Mål C 457/10 P, AstraZeneca" in *Europarättslig tidskrift*, 2013 3(3), pp. 508-521.

Matthews, Duncan and Gurgula, Olga, "Patent strategies and competition law in the pharmaceutical sector: implications for access to medicines" in *European Intellectual Property Review*, 2016 38(11), pp. 661-667.

Moufang, Rainer, "Patentability of pharmaceutical innovations: the European perspective" in Drexl, Josef and Lee, Nari (eds.), *Pharmaceutical Innovation, Competition and Patent Law: A Trilateral Perspective*, Cheltenham: Edward Elgar, 2013.

Nissen, Morten, van de Walle de Ghelcke, Geoffroy and Vilarasau, Melanie, "Competition Law in the Pharmaceutical Sector" in Shorthose, Sally (ed.), *Guide to EU Pharmaceutical Regulatory Law*, Alphen aan den Rijn: Kluwer, 2012.

Reidhav, David, Glader, Marcus and Dahlman, Christian, *Rättsekonomi: en introduktion*, Lund: Studentlitteratur, 2005.

Riis, Thomas, Petersen, Clement Salung and Schovsbo, Jens, "The Unified Patent Court: Pros and Cons of Specialization - Is There a Light at the End of the Tunnel (Vision)?" in *Intellectual Review of Intellectual Property and Competition Law*, 2015 46(3), pp. 271-274.

Tuominen, Nicoleta, "An IP Perspective on defensive patenting strategies of the EU pharmaceutical industry" in *European Intellectual Property Review*, 2012 34(8), pp. 541-551.

Turner, Jonathan D.C., *Intellectual Property and EU Competition Law*, Oxford: Oxford University Press, 2015.

Ullrich, Hanns, "Strategic patenting by the pharmaceutical industry: towards a concept of abusive practices of protection" in Drexl, Josef and Lee, Nari (eds.), *Pharmaceutical Innovation, Competition and Patent Law: A Trilateral Perspective*, Cheltenham: Edward Elgar, 2013.

Westin, Jacob, "Defining relevant market in the pharmaceutical sector in the light of the Losec-case - just how different is the pharmaceutical market?" in *European Competition Law Review*, 2011 32(2) pp. 57-62.

Yamane, Hiroko, *Interpreting TRIPS: globalisation of intellectual property rights and access to medicines*, Oxford: Hart, 2011.

Websites

European Union, *European Medicines Agency*, accessed 2017-05-24 on: <https://europa.eu/european-union/about-eu/agencies/ema_en>

Läkemedelsverket, *Swedish Medical Products Agency*, accessed 2017-05-24 on: <https://lakemedelsverket.se/malgrupp/Allmanhet/Vad-ar-ett-lakemedel/>

OECD, *Generic pharmaceuticals and competition*, accessed 2017-05-24 on: <http://www.oecd.org/competition/generic-pharmaceuticals-competition.htm>

WIPO, *Competition and Patents*, accessed 2017-05-24 on: <http://www.wipo.int/patent-law/en/developments/competition.html>

WTO, *TRIPS and Pharmaceutical Patents*, accessed 2017-05-24 on: <https://www.wto.org/english/tratop_e/trips_e/tripsfactsheet_pharma_2006_e.pdf>

WTO, *Pharmaceuticals and the WTO TRIPS Agreement*, accessed 2017-05-24 on: <http://who.int/medicinedocs/pdf/whozip18e/whozip18e.pdf>

Blog posts

Battistelli, Benoît, *UPP: Parliament hearing shows continuing support*, EPO, 2017-03-27, accessed 2017-05-24 on: <http://blog.epo.org/unitary-patent-2/upp-parliament-hearing-shows-continuing-support/>

Bergström, Richard, *The degree to which patenting, and in particular secondary patenting, protect pharmaceutical products during their lifecycle is often misconstrued*, EFPIA, 2012-11-28, accessed 2017-05-24 on: <http://pharmaviews.eu/the-degree-to-which-patenting-and-in-particular-secondary-patenting-protect-pharmaceutical-products-during-their-lifecycle-is-often-misconstrued>

Ganguli, Prabuddha, *Inside Views: Can Patents Ever Be "Ever-Greened"? The Answer...They are "Never-Greened"*, Intellectual Property Watch, 2016-05-20, accessed 2017-05-24 on: <https://www.ip-watch.org/2016/05/20/can-patents-ever-be-ever-greened-the-answer-they-are-never-greened>

Mireles, Mike, *Intellectual Property Challenges in the Bio-Pharmaceutical Field*, IPKat, 2016-05-04, accessed 2017-05-24 on:

<http://ipkitten.blogspot.se/2016/05/intellectual-property-challenges-in-bio.html>

Smyth, Darren, *The Unitary Patent and Unified Patent Court - where are we now?*, IPKat, 2017-03-30, accessed 2017-05-24 on: <http://ipkitten.blogspot.se/2017/03/the-unitary-patent-and-unified-patent.html>

Smyth, Darren, *EPO Bound again - more precedential than ever: Precedent 2*, IPKat, 2014-07-16, accessed 2017-05-24 on: <http://ipkitten.blogspot.se/2014/07/epo-bound-again-more-precedental-than.html>

Other sources

Agreement on a Unified Patent Court, OJ 2013/C175/01.

European Federation of Pharmaceutical Industries and Associations (EFPIA), *The Pharmaceutical Industry in Figures - Key Data 2016*, accessed 2017-05-24 on: <http://www.efpia.eu/uploads/Modules/Documents/the-pharmaceutical-industry-in-figures-2016.pdf>

EvaluatePharma, *World Preview 2016 - Outlook to 2022*, 9th Edition September 2016, accessed 2017-05-24 on: <www.evaluate.com/PharmaWorldPreview2016>

Medicines for Europe, formerly European Generic Medicines Association, *Patent-related Barriers to Market Entry for Generic Medicines in the European Union*, May 2008.

EPO, *Guide for applicants: How to get a European patent*, May 2016, accessed 2017-05-24 on: <http://www.epo.org/applying/european/Guide-for-applicants/html/e/index.html>

EPO, *Guidelines for examination in the European Patent Office*, November 2016, accessed 2017-05-24 on: <https://www.epo.org/law-practice/legal-texts/guidelines.html>

WHO, *The Anatomical Therapeutic Chemical Classification System with Defined Daily Doses (ATC/DDD)*, accessed 2017-05-24 on: <http://www.who.int/classifications/atcddd/en/>

Table of Cases

European Court of Justice

C-6/64 *Costa v ENEL* [1964] EU:C:1964:66

C-58/64 *Consten and Grundig v Commission* [1966] EU:C:1966:41

C-24/67 *Parke, Davis v Probel* [1968] EU:C:1968:11

C-6/72 *Continental Can v Commission* [1973] EU:C:1973:22

C-27/76 *United Brands v Commission* [1978] EU:C:1978:22

C-85/76 *Hoffmann-La Roche v Commission* [1979] EU:C:1979:36

C-322/81 *Michelin v Commission* [1983] EU:C:1983:313

C-118/85 *Commission v Italy* [1987] EU:C:1987:283

C-62/86 *AKZO Chemie v Commission* [1991] EU:C:1991:286

C-41/90 *Höfner and Elser v Macrotron* [1991] EU:C:1991:161

C-35/96 *Commission v Italy* [1998] EU:C:1998:303

C-223/01 *AstraZeneca v Lægemiddelstyrelsen* [2003] EU:C:2003:546

C-189/02P *Dansk Rørindustri v Commission* [2005] EU:C:2005:408

C-205/03P *FENIN v Commission* [2006] EU:C:2006:453

C-95/04P *British Airways v Commission* [2007] EU:C:2007:166

C-202/07P *France Télécom v Commission* [2009] EU:C:2009:214

C-52/09 *Konkurrensverket v TeliaSonera* [2011] EU:C:2011:83

C-209/10 *Post Danmark v Konkurrencerådet* [2012] EU:C:2012:172

C-457/10P *AstraZeneca v Commission* [2012] EU:C:2012:770

General Court

T-30/89 *Hilti v Commission* [1991] EU:T:1991:70

T-83/91 *Tetra Pak v Commission* [1994] EU:T:1994:246

T-228/97 *Irish Sugar v Commission* [1999] EU:T:1999:246

T-201/04 *Microsoft v Commission* [2007] EU:T:2007:289

T-321/05 *AstraZeneca v Commission* [2010] EU:T:2010:266

T-472/13 *Lundbeck v Commission* [2016] EU:T:2016:449

Advocate General Opinions

Opinion of AG Mazák delivered on 15 May 2012 in Case C-457/10P *AstraZeneca*. EU:C:2012:293

Opinion of AG Jacobs delivered on 22 May 2003 in Joined Cases C-264/01, C-306/01, C-354/01 and C-355/01 *AOK Bundesverband.* EU:C:2003:304

European Commission

COMP/M.737 *Ciba-Geigy/Sandoz* [1996]

COMP/A.37.507/F3 *AstraZeneca* [2005]

COMP/B2/39246 *Boehringer* [2007]

European Patent Office

G 1/92 of 18 Dec 1992, OJ EPO 1993, 277 - Availability to the public

G 2/93 of 21 December 1994, OJ EPO 1995, 275 - Sufficiency of disclosure

G 2/08 of 19 February 2010, OJ EPO 2010, 456 - Second medical indication

T 128/82 of 12 January 1984, OJ EPO 1982, 164 - First medical indication

T 36/83 of 14 May 1985, OJ EPO 1986, 295 - First medical indication

T 877/90 of 28 July 1992 - Availability to the public

T 79/91 of 21 February 1992 - Clarity of claims

T 246/91 of 14 September 1993 - Clarity of claims

T 7/07 of 07 July 2011 - Novelty

Italy

Italian Competition Authority v Pfizer Italia and others, Italian Council of State, 2014

Sweden

NJA 2000 s. 497 Comviq v Europolitan

United Kingdom

CA98/02/2011 *NHS v Reckitt Benckiser (Gaviscon)*, UK OFT

CA98/2/2001 *Napp Pharmaceuticals*, 30 March 2001, UK OFT