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The Use and Abuse of Patents – Evergreening in the Pharmaceutical Sector

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Abstract: Evergreening of patents is common in the pharmaceutical sector. Lately, it has become increasingly difficult for originator companies to know how far they can go when using their patent rights without abusing their dominant position. This thesis makes an attempt to provide guidance for these companies. Evergreening is presented by giving the reader a theoretical background by looking at the essential components of evergreening, namely the pharmaceutical sector, patent law and competition law. This outline will be used as a base to analyse under what, if any, circumstances evergreening constitutes an infringement of Article 102 TFEU. The result of this study indicates that evergreening can lead to a foreclosure on the market and that such conduct will be liable under Article 102 depending on the circumstances in the specific case. As a concluding remark, the author gives her view on why pharmaceutical companies engage in evergreening and suggests that a reform of the patent system may be a way forward.

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Summary

This thesis identifies some of the uncertainties surrounding the application of Article 102 of the Treaty on the Functioning of the European Union (TFEU) to evergreening of pharmaceutical patens. The concept of evergreening refers to a multitude of strategies adopted by patent holders with the aim to extend the privileged position that the patentee holds due to this exclusive right. Evergreening is common in the pharmaceutical sector, considering the financial profits that a successful patented drug can generate. Recently, the pharmaceutical industry has undergone some significant changes with several lucrative blockbuster medicines having lost patent protection. Even though an increased amount of money is spent on research and development (R&D), the companies seem to have difficulties to launch new medicines. As a consequence, they become increasingly dependent on their existing patents and do their utmost to maximize profits from them. This may lead to evergreening.

The purpose with this thesis is to investigate the legality of evergreening by describing and analysing such behaviour in relation to Article 102. This thesis primarily put focus on one of these strategies: the launch of a second generation medicine. By launching a newly patented version of a product which is close to patent expiry, the risk of generic companies gaining a significant market share is decreased while the originator company maintains comparable sales numbers and avoids a decline in price. Depending on the measures taken around the launch of a second generation product, a pharmaceutical company may be liable under Article 102.

Evergreening involves three fields of regulation: pharmaceutical regulatory law, patent law and competition law which may seem difficult to reconcile since they pursuit different policy objectives. For example, the intersection between intellectual property law and competition law has been the subject of intense debate and when applied to the context of pharmaceutical patents, it becomes even more complex. In this thesis, it will be demonstrated that they may just be different means to the same goal. Nonetheless, it is shown that the relationship is complicated and that the application of competition rules to evergreening can lead to difficulties.

To decide how far a patent holder can go when it comes to evergreening, this thesis takes its stance in the recently decided *AstraZeneca*: the first case in which a pharmaceutical company was fined for an abuse of its dominant position in relation to evergreening in the EU. The result of this study indicates that evergreening may, depending on the circumstances in the specific case, constitute a violation of Article 102. The concluding chapter elaborates on the reasons to why pharmaceutical companies engage in evergreening and suggests that a reform of the patent system may be a way forward.

Sammanfattning

Denna uppsats behandlar några av de frågetecken som uppkommer vid tillämpningen av artikel 102 i Fördraget om Europeiska unionens funktionssätt i förhållande till evergreening av läkemedelspatent. Begreppet evergreening syftar till ett flertal olika patentstrategier som har för avsikt att förlänga den privilegierade position som en patenthavare åtnjuter när hans eller hennes produkt skyddas av ensamrätt. Med tanke på de vinster som ett framgångsrikt patenterat läkemedel kan ge generera är det inte konstigt att evergreening är vanligt inom läkemedelsbranschen. På senare tid har läkemedelsbranschen genomgått stora förändringar då flera lukrativa storsäljande läkemedel har förlorat patentskydd. Även om företagen investerar pengar på forskning och utveckling verkar de ha svårt att lansera nya läkemedel. Till följd av detta blir företagen allt mer beroende av sina befintliga patent och gör sitt yttersta för att maximera vinsterna från dem. Denna situation kan leda till evergreening.

Syftet med denna uppsats är att undersöka lagligheten i evergreening genom att beskriva och analysera dess förhållande till artikel 102. Uppsatsen fokuserar främst på en av dessa strategier: lanseringen av en andra generationens medicin. Genom att marknadsföra en ny patenterad version av ett läkemedel vars patentskydd är på väg att löpa ut minimeras risken för att generikaföretag vinner marknadsandelar samtidigt som patenthavaren behåller sina höga försäljningssiffror och undviker en prisnedgång. Beroende på de åtgärder som vidtas vid lanseringen av en andra generationens medicin kan läkemedelsbolaget missbruka sin dominanta ställning och vara ansvarigt under artikel 102.

Evergreening aktualiserar främst tre rättsområden: läkemedelsrätt, patenträtt och konkurrensrätt vilka kan tyckas svåra att förena på grund av de motstridiga syften som ligger bakom deras existens. Till exempel är förhållandet mellan immaterialrätt och konkurrensrätt sedan länge omdiskuterat, en debatt som intensifieras i läkemedelsbranschen. I denna uppsats kommer det visas att de båda disciplinerna endast är två olika verktyg som arbetar sida vida sida för att nå samma mål. Trots detta går det inte att bortse från att relationen dem emellan är komplicerad vilket gör en tillämpning av konkurrensreglerna på evergreening problematisk.

För att avgöra hur långt en patentinnehavare kan gå tar uppsatsen sin utgångspunkt i det nyligen avgjorda *AstraZeneca*: det första fallet där ett läkemedelsbolag bötfälldes för missbruk av dominerande ställning på grund av evergreening i EU. Denna uppsats kommer fram till att evergreening kan, beroende på omständigheterna i det specifika fallet, utgöra ett brott mot artikel 102. I det avslutande kapitlet görs en analys av varför läkemedelsbolag ”evergreenar” sina patent och det föreslås att en reform av patentsystemet kan vara en framtida lösning.

Preface

In Greek mythology, Sisyphus was sentenced by the mighty God Zeus to push a heavy stone up a high mountain. To complete his task, he had to use all his powers. Before Sisyphus could reach the top, however, the massive stone would always roll back down, forcing him to start all over again. Sisyphus became frustrated as he could not see an end to his work and felt like it would continue into eternity. In one version of the tale, Sisyphus continues the work for infinity. In another version, Sisyphus finds a way to escape his sentence. By deciding that the work was the most enjoyable thing one could do, Sisyphus did not feel like it was a punishment anymore.

I felt like Sisyphus several times during the work with this thesis. Nonetheless, some differences between my story and Sisyphus's story should be pointed out. He did body work; my thesis (mostly) comes from intellectual work. Zeus sentenced Sisyphus to do his hard work; I took on all the hard work myself. And last, although I never felt like writing my thesis was the most enjoyable thing I could do during my last semester in Lund, I managed to accomplish something that I am actually rather proud of.

There are also some similarities between me and Sisyphus. In times of despair, it felt like the work would continue into eternity. To finish it, I had to use all my powers. But by not giving up and deciding that the work would lead to something enjoyable (my law degree) it was not a punishment anymore. Thus, my story is similar to the second version but also differs in a significant way: I found a way to make my stone stay up that mountain. The result is presented in this paper.

I am deeply grateful to my friends and colleagues in Lund and at the Faculty of Law. Without your endless love, encouragement and support I could never have finished this. A special thanks to Filippa, for putting up imaginary deadlines, Mathilda, my partner in competition, and Malin, for proof-reading.

Also, I would like to thank my supervisor Hans Henrik Lidgard for valuable opinions and inputs to the discussions in this thesis.

Lund, it has been a pleasure. Five years of studies have come to an end. I say goodbye with sadness in my heart, but fully aware that the best is yet to come.

Lund, July 11, 2013

Abbreviations

CJEU	Court of Justice of the European Union
ECLR	European Competition Law Review
EFPIA	European Federation of Pharmaceutical Industries and Associations
EIPR	European Intellectual Property Review
EPC	European Patent Convention
EPO	European Patent Office
EU	European Union
GC	General Court of the European Union
IFPMA	International Federation of Pharmaceutical Manufacturers and Associations
IIC	International Review of Intellectual Property and Competition Law
IPR	Intellectual Property Rights
NCE	New chemical entities
OFT	UK Office of Fair Trading
ParC	Paris Convention for the Protection of Industrial Property
PL	The Swedish Law of Patents
R & D	Research and development
SPC	Supplementary Protection Certificate
TFEU	Treaty on the Functioning of the European Union
TRIPS	Trade Related Aspects of Intellectual Property Rights
US	The United States
WTO	World Trade Organization

1 Introduction

1.1 Background

In recent years, the pharmaceutical industry has undergone significant changes. A number of large pharmaceutical companies have lost patent protection for their lucrative blockbuster medicines and even though an increased amount of money is spent on research and development (R&D), the companies seem to have difficulties to innovate new medicines. As a consequence, they become increasingly dependent on their existing patents and do their utmost to maximize profits from them. This leads to different patent strategies, i.e. evergreening, which have the aim to extend the privileged position that a patentee holds during exclusivity. Such practices may be questioned from a competition law perspective.

The law of patents confers exclusive rights; Article 102 in the Treaty on the Functioning of the European Union (TFEU) prohibits the abuse of a dominant position. The intersection between intellectual property law and competition law has been debated. Competition law imposes obligations where the holder of an intellectual property right (IPR) has a position of dominance on the relevant market, the IPR probably being the reason to why the company is dominant. When applied to the context of pharmaceutical patents, the issue becomes even more complex. Evergreening constitutes of different well-thought out tactics to use this exclusive right to its utmost, behaviour which most definitely balance at the border between lawful and unlawful conduct.

In December 2012, the Court of Justice of the European Union (CJEU) in all essentials upheld the Commission's decision that the pharmaceutical company AstraZeneca had abused its dominant position by (mis) using both the patent system and regulatory procedures with the intent to delay or prevent market entry by generics. The judgment has attracted attention for a number of reasons. It was the first time that a pharmaceutical company was fined for an abuse of dominant position in relation to evergreening. Furthermore, it was one of the first occasions in which the CJEU tried the legality of strategic use of patent rights. The case is useful as a base when discussing the legality of different evergreening strategies in the pharmaceutical market.

Since long, dominant companies have been under the obligation not to abuse their position of dominance but lately, as the concept gradually has widened, conduct close to legitimate business behaviour has been under the scrutiny of the European Union (EU) authorities. Thus, it has become increasingly difficult for pharmaceutical companies, holding a patent right, to know how far they can go. This thesis investigates where to draw the line between the use and the abuse of pharmaceutical patents with a focus on

evergreening. Is evergreening just a legitimate way of using a legally obtained right, or is it an abuse of dominance within the meaning of Article 102?

1.2 Purpose

The purpose of this thesis is to investigate the legality of evergreening. Evergreening may involve a variety of strategies adopted by patent holders. This thesis will mainly focus on the launch of second generation products but will also examine other strategies with the purpose to extend the privileged position that the patentee holds during exclusivity. With an objective approach, this study aims to describe and analyse the development and current state of Article 102 in relation to potentially unlawful conduct of pharmaceutical originator companies when using their patent rights.

This thesis seeks to address the following research questions:

- *What concerns does evergreening give rise to under Article 102?*
- *How far can a patent holder go when it comes to evergreening?*

1.3 Method and material

This thesis investigates and analyses the applicable law in relation to evergreening by pharmaceutical companies by using a legal dogmatic method. A legal dogmatic method is a method where sources such as legislation, case law and doctrine are used to investigate the content of the applicable law. This method has been applied when describing the legal framework relevant to evergreening, i.e. chapter two, three and four. Primarily, this thesis looks at case-law, doctrine and official documents from the EU. In chapter two, three and four, a descriptive method has been applied.

In chapter five and six, the result of this thesis is presented and analysed. To some extent, chapter five provides the reader with new material on the application of Article 102. In these parts, a descriptive method has been applied. However, a more analytical approach has been used when discussing how this legal framework should be applied to evergreening and also when giving comments on how far a patent holder can go.

In 2008, the Commission launched a sector inquiry into the pharmaceutical industry with the aim to uncover originator companies' attempts to delay or prevent generic competition. The result was presented in the *Pharmaceutical Sector Inquiry Final Report* in 2009, in which several practices by originator companies were identified as potentially anti-competitive. This report has been used extensively to categorise and explain evergreening strategies in chapter five, although it is acknowledged that the report is neither a statement of the law or guidance on its application.

In addition to the traditional legal dogmatic method, a law and politics perspective has been applied. A law and politics perspective involves a more broad analysis of the reasons for the current development in case law and the interests that have been taken into account when reaching conclusions in these cases. Also, this method has been used in chapter five and six when making some tentative suggestions for a way forward.

Furthermore, a law and economics perspective has been used to some extent. A law and economics perspective is used to explain the economic effects of the law. The purpose with applying such a perspective is to analyse the effects of the law from an economic point of view. For example, this method has been used when explaining the reasons to why companies turn to evergreening.

In this thesis, evaluation of sources has been done continuously. In the more general descriptive parts, the main sources used are Whish and Bailey's *Competition Law* (2012) and Hans Henrik Lidgard's *Competition Classics* (2011). These standard books on the subject must be seen as independent and unbiased. In the more specific parts dealing with evergreening, a more critical approach has been deemed necessary due to the large number of articles and the small number of established doctrine.

1.4 Delimitations

Several limitations to this thesis need to be acknowledged. This thesis will focus on evergreening of patents by pharmaceutical companies. Hence, a limitation is made to the pharmaceutical sector. Given the latest developments in the sector, having in mind the Commission's Pharma Report and the CJEU's *AstraZeneca* case, such a limitation seems the most reasonable. Thus, the thesis will solely focus on the use and abuse of pharmaceutical patents, even though the same general principles should be applicable in other sectors of the economy.

The thesis focuses on the prohibition against abusive unilateral behaviour under Article 102. There are similar practices e.g. patent settlements[1] which may be unlawful under Article 101 TFEU. These practices are equally interesting from a competition law perspective but will not be dealt with in this thesis.

Furthermore, exploitative abuse of dominance falls outside the scope of this thesis. Exploitative abuse has a detrimental effect on consumers, for example by charging them excessive prices. Without ignoring the importance of preventing such behaviour, exclusionary conduct that excludes competitors from the market, and thereby prevents effective competition, is more relevant for the purpose of this thesis.

[1] Patent settlements have been identified as potentially anti-competitive in the Commission's Pharma Report, see paras 702 – 855.

Also, without ignoring the importance of the other prerequisites in Article 102, focus will be on the assessment of whether a dominant position exists and how to examine whether that position has been abused or not. This thesis will assume that the other prerequisites of Article 102 are fulfilled.

Also, evergreening may encompass strategies concerning the relationship between originator companies.[2] In this thesis, such strategies will not be dealt with. Instead, focus will be on the relationship between originator companies and generic companies.

This thesis will exclusively investigate the European legal framework on a Union level. The reason to this limitation is the extensive harmonisation process that has taken place between EU law and national laws. Therefore, an investigation into national laws is deemed unnecessary for the purpose of the thesis.

Lastly, a comment should be made on the essay's selection of evergreening strategies. Evergreening strategies are numerous and an exhaustive enumeration of such strategies is not possible. In this essay, the author has chosen to investigate patent litigation, patent clusters and second generation products. The selection was partly due to that they were examined in the Commission's recently launched Pharma Report. They also share in common that they may be forbidden under Article 102 while other evergreening strategies, such as patent settlements, may be forbidden under Article 101, why it was considered an appropriate choice.

1.5 Terminology

In December 2009, the Treaty on the Functioning of the European Union entered into force. As a consequence, a combination of the old Article 82 and the new Article 102 is used in case law and doctrine. In this essay, reference is continuously made to the new Article 102. Furthermore, when making references to the Court of Justice of the European Union, formerly known as the ECJ, the new abbreviation CJEU will be used continuously.

The use of the term *evergreening* seems to vary in doctrine. In this thesis, evergreening is a general term, referring to all legal or illegal strategies that a company conducts in order to extend the benefits of their patent right. The same sort of conduct will also be referred to as *strategic patent planning*. By using these terms in the thesis, no negative connotation is intended, as conduct should be valued on the basis of the criteria in Article 102.

When using the term *second generation product,* the thesis refers to a product which results from innovation essentially based upon that of an existing product which has essentially the same mode of action. No negative

[2] For a detailed review of patent strategies in the relationship between originator companies, see the Pharma Report C3.

connotation is intended when using this term, since patentability should be valued by the patentability criteria in the applicable patent law.

The thesis distinguish between patents covering inventions consisting of new active substances, referred to as *primary patents,* and patents covering inventions which are the result of subsequent, incremental innovation, referred to as *secondary patents*.

For the purpose of this thesis, a *pharmaceutical company* is understood as a company that produces, markets and/or sell medicinal products. These entities are also referred to as *pharmaceutical undertakings*.

1.6 Disposition

This paper has been divided into six chapters. Following this introductory chapter, the second chapter will give the reader an overview of the thesis' subject matter by providing an outline of the pharmaceutical sector and its main features. Also, a comment on the relationship between IPR and competition law in the sector is made. In addition, this chapter contains an introduction to the concept of evergreening.

In chapter three, the law of patents is reviewed. First, a comment on the rationale of patents is made. The procedure and requirements when obtaining a patent needs to be identified in order to examine whether evergreening of such patents is abusive, why the regulatory framework is outlined. Also, a short comment on patenting in the pharmaceutical sector is made.

Chapter four describes the development and current state of Article 102. After a short introduction to the concept of abuse of dominant position, a rather extensive presentation of the objective of Article 102 is provided. The, the thesis presents how the actual assessment of whether an abuse exists or not is conducted. The aim with this chapter, in conjunction with chapter two and three, is to provide a base for the discussion and analysis in chapter five and six.

In chapter five, evergreening strategies are discussed. The chapter begins with a comprehensive presentation of the concept of evergreening, whereupon a discussion on the application of Article 102 to such conduct follows. This chapter aims at presenting three sorts of evergreening strategies as well as the potential anti-competitive effects they may have.

In the concluding chapter six, the result of this study is summarized and conclusions are drawn. In this part, the thesis seeks to analyse the evergreening strategies presented, with the aim to provide guidelines on their legality under competition law. The author will also make some general comments on the findings in the thesis and, if possible, some recommendations for further research.

2 Main Features of the Pharmaceutical Sector

2.1 Introduction

The pharmaceutical sector is influenced by elements from different legal disciplines including pharmaceutical regulatory law, competition law and intellectual property law. These areas of law have different policy objectives which needs to be united in order to create a favourable climate for innovation of new and better medicines.[3] The relationship between those will be outlined in this chapter.

When discussing evergreening of pharmaceutical patents, there are some important differences between the pharmaceutical sector and other sectors which are necessary to take into account. This section will highlight these differences by giving an overview of the pharmaceutical industry and its main features. In addition, an introduction to the concept of evergreening will be provided with an explanation to why there is an inherent tension between IPRs and competition law in the pharmaceutical sector.

2.2 Main features and market structure of the pharmaceutical sector

The pharmaceutical sector is an essential part of the European economy, its market for prescription and non-prescription medicine being worth over €138 billion ex-factory and €214 billion at retail prices in 2007.[4] In the same year, every European spent an average of €430 on medicine, making access to affordable and safe medicine essential to the health of Europe's citizens.[5] With the global pharmaceuticals market being worth $US 300 billion a year, a number expected to rise to $US 400 billion within three years,[6] it is not surprising that the industry attains a lot of attention.

The pharmaceutical sector is one of the world's most research-intensive industries. Because of high expenditures on R&D and clinical tests, combined with the fact that new products are easily imitated, patent protection is crucial.[7] As will be shown in this thesis, patent protection usually leads to a monopoly on the relevant market, giving the patent owner significant market power over supply and price. Therefore, the market is highly regulated to guarantee the safety and efficiency of the medicine that

[3] Priddis & Constantine (2011) p. 241.
[4] Executive Summary of the Pharma Report, p. 1.
[5] Ibid, p. 1.
[6] WTO., Trade, foreign policy, diplomacy and health: Pharmaceutical Industry, retrieved 2013-05-20, <http://www.who.int/trade/glossary/story073/en/>.
[7] Domeij (1998) p. 1.

is available for consumers on the market. Also, price levels are negotiated on a national level before the medicine is approved for marketing.[8]

The existence and scope of patent laws have varied over time and place. According to Boldrin and Levine, a modern pharmaceutical industry was developed faster in countries with weak patent laws. For example, in most European countries, only the process of producing a medicine but not the product could be patented for many years. Not until the late twentieth-century did most countries allow patents on the actual product. In the US, on the contrary, patents on pharmaceuticals have always been granted.[9] According to Boldrin and Levine, the European pharmaceutical industry has not been affected in a negative way. Instead, it was the European industry which was world leading for many years.[10] Still today, the global pharmaceutical market is geographically concentrated. The ten largest pharmaceutical companies are based in the developed world: six of them in the US and four of them in Europe.[11] The explanation is simple: a new pharmaceutical is expensive to develop and as a consequence, the initial price for it will be high. Only companies with the financial strength can afford the cost of innovation and only consumers in rich countries can afford to buy them.[12]

Recent developments in the pharmaceutical industry spurred the Commission to make an inquiry into the sector in 2008.[13] A decline in innovation had been noticed at the same time as several medicines were going off patent without being replaced by new bestsellers. The result of the inquiry was presented in a report in July 2009.[14] The report was limited to prescription medicine for human use in the 27 Member States of the EU. The report concludes that companies in the pharmaceutical sector apply defensive patenting strategies, which creates obstacles for generic competitors to enter the market. Moreover, it is suggested that when these measures have the object to delay or prevent generic entry, their compatibility with competition law may be questioned.

2.2.1 The undertakings

The structure of the global pharmaceutical market is unique: it consists of a small number of large companies, a large number of small companies and an almost non-existence of medium-sized companies.[15] Furthermore, it has a two-tier structure. The first tier is comprised of innovative pharmaceutical companies (hereafter "originators"), often large and multinational, holding

[8] Pharma Report, para 337.
[9] Boldrin & Levine (2008) p. 215.
[10] Ibid, p. 218.
[11] WTO., Trade, foreign policy, diplomacy and health: Pharmaceutical Industry, retrieved 2013-05-20, <http://www.who.int/trade/glossary/story073/en/>.
[12] Boldrin & Levine (2008) p. 213.
[13] The legal basis for a sector inquiry is Article 17 of Regulation 1/2003 on the application of the EC Treaty competition rules (Articles 101 and 102).
[14] Pharma Report.
[15] Taggart (1993) p. 4.

patents to best-selling prescription drugs. The second tier is comprised of generic companies, which produce generic versions of a medicine when the patent has expired.[16] In addition to this, a third tier is emerging: the biotechnology companies. These companies dedicate their efforts to innovation and usually lack the ability to produce or market pharmaceuticals to consumers. These companies usually partner with originator companies for the later steps in the development and most often in the actual marketing of the medicine.[17]

Between originators, competition is mainly in the innovative step. Their R&D activities aim at developing a new medicine or enhancing an already existing medicine in order to stay competitive.[18] Moreover, competition occurs between originators and generic companies. When a pharmaceutical product goes off patent, generic versions will appear on the market which are manufactured and marketed by generic companies. These companies generally compete on the merits of price of the medicine and therefore invest less or no money on R&D.[19]

Today, the division between originators and generic companies is not as rigid as it used to be. This is especially true in emerging markets like Eastern Europe, Asia and Latin America where consumers cannot afford the expensive brand-name drugs.[20] For example, in 2011, AstraZeneca acquired the Chinese company Guangdong BeiKang Pharmaceutical Company Ltd, a privately-owned generics manufacturing company.[21] Furthermore, Sanofi has acquired the generic companies Zentiva, Kendrick and Medley, all operating in emerging markets.[22]

2.2.2 The market

The pharmaceutical sector is subject to extensive regulation. Primarily, state intervention is justified by the need to ensure safety and efficiency of the medicine being sold. The government may also intervene to regulate price-levels and the channels in which pharmaceuticals are marketed and sold.[23] For example, pharmaceutical companies are limited when it comes to price-setting of their products. Usually, the state is the largest purchaser of pharmaceuticals which is why the decisions of their institutions have a direct impact on the economic incentives of pharmaceutical companies.[24]

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[16] Gunther & Breuvart (2005) p. 669.
[17] Domeij (1998) p. 7.
[18] Gunther & Breuvart (2005) p. 669.
[19] Priddis & Constantine (2011) p. 248.
[20] Singer, Natasha., "Drug Firms Apply Brand to Generics", *The New York Times*, 15 February 2010.
[21] AstraZeneca, "AstraZeneca to acquire generics company to broaden patient access to medicines in China", retrieved 2013-05-26 at <www.astrazeneca.com/Media/Press-releases/Article/20111208--astrazeneca-to-acquire-generics-company>
[22] Sanofi, "Generics", retrieved 2013-05-26 <en.sanofi.com/products/generics/generics.aspx>
[23] Priddis & Constantine (2011) p. 248.
[24] Ibid, p. 249.

Although price and reimbursement levels are a national competence, almost all Member States require that the price is determined before introduction on the market for prescription drugs funded under the social security system.[25] In addition, all measures must comply with Directive 89/105/EC.[26] Since the main consumers of pharmaceuticals are national health care systems, there is a great incentive to keep prices low in order to control budget costs and keep taxation low.[27]

Furthermore, pharmaceutical markets suffer from a significant market failure. The doctor who prescribes the medicine does not pay for it; the patient, or in some countries the social security system, which pays for the medicine does not choose it. Thus, the market suffers from a price disconnect where the consumer does not make the usual price/quality trade-off that constitutes a significant part of a competitive market.[28] As a consequence, doctors are only slightly sensitive to the price of medicines when prescribing them.[29] Pharmaceutical companies seem to be fully aware of this and therefore heavily promote their products directly to doctors.[30] The phenomena is referred to as detailing which entails promotional visits to prescribing doctors with the purpose to increase the prescription of the detailing company's medicine.[31]

2.2.3 The key role of innovation

Another defining feature of the pharmaceutical sector is that it is usually described as technology intensive and highly innovative.[32] The sector has one of the highest investments in R&D in the EU.[33] Originator companies spent an average of 17 % of their turnover on R&D in the years 2000-2007. In contrast, 23 % was spent on marketing and promotion activities during the same years.[34] Hence, marketing expenditure exceeds expenditure on R & D, an interesting aspect to keep in mind for chapter five and the analysis in chapter six.

In order to stay competitive and profitable, research-based pharmaceutical companies must develop new and improved substances.[35] But the pharmaceutical sector is risky business: R&D projects are often lengthy and uncertain with a low success rate. It has been estimated that only 1 in 5,000–10,000 compounds actually reach the market as a medicine. Also, the timeline for bringing a new medicine to the market is long; usually it takes

[25] Pharma Report, paras 337-395.
[26] Directive 89/105/EEC, pp. 8-11.
[27] Hunter (2001) p. 10.
[28] Shadowen et al. (2011) pp. 700-701.
[29] Case T 321/05, *Astra Zeneca,* para 34.
[30] Shadowen et al. (2010).
[31] OECD, "Competition and Regulation in the Pharmaceutical Industry", p. 7.
[32] Ibid.
[33] Executive Summary of the Pharma Report, p. 1.
[34] Ibid, p. 7 f.
[35] Gunther & Breuvart (2005) p. 670.

10-12 years from initial discovery to the actual launch on the market.[36] Since stakes are high, the business is dependent on profits from the products that actually reach the market in order to recoup their investments.[37]

Even small therapeutic improvements to an existing product can lead to increased profitability.[38] This is usually referred to as *incremental innovation,* a practice most originator companies engage in.[39] Incremental innovation means innovation of a product that results from subsequent, follow-up R & D, essentially based on an existing product which in essence have the same mode of action. The result is a second-generation product, also referred to as a "follow-on product".[40]

Today, some originators involve less in R&D than they used to. Instead, they rely on the acquisition of new compounds from the biotechnology companies. In 2007, around 35 % of the formulas pending for a marketing authorisation had been bought or in-licensed.[41] It seems like innovation has "moved down one level". Potentially, biotechnology companies could do even more innovation in the future while the large originator companies take care of putting the medicine on the market.

The profit imperative leads to some unwanted effects on the pharmaceutical market. There have been some accusations against the choice of where to invest R&D. As a result of the high costs for the innovation of a new medicine, the drugs chosen for development are the drugs that are most likely to provide a high return on the company's investment. This result in companies investing their money into research for drugs used in the developed world, while drugs sold in the developing world are not prioritized.[42]

2.3 The introduction of a new pharmaceutical on the market

The life cycle of a pharmaceutical can be divided into three phases: the pre-launch period, the marketing and sales period and a later period when the patent protection expires and generic entry is possible.[43] All steps of the product's commercialization are regulated: a myriad of rules for pharmaceutical companies to navigate in.

The introduction of a pharmaceutical product to the market is made subject to the grant of a marketing authorisation, a process for which rules are

[36] Priddis & Constantine (2011) p. 243-244.
[37] Gunther & Breuvart (2005) p. 670.
[38] Domeij (1998) p. 7.
[39] Pharma Report, para 987.
[40] Ibid, para 990.
[41] Executive Summary of the Pharma Report, p. 8.
[42] WTO., Trade, foreign policy, diplomacy and health: Pharmaceutical Industry, retrieved 2013-05-20, <http://www.who.int/trade/glossary/story073/en/>.
[43] Pharma Report, para 128.

primarily laid down in Directive 2001/83/EC.[44] The application is filed with the competent authority in the Member State where the company wishes to market the pharmaceutical.[45] If a company wishes to introduce the pharmaceutical on several national markets, the Member State which first granted a marketing authorisation shall act as a reference state, simplifying the application.[46] To obtain a marketing authorisation, the results of extensive pre-clinical tests and clinical trials must be accounted for.[47] These tests can be both costly and lengthy and as a consequence, the time period that elapses between a patent being granted and the actual launch of the product to the market may be significant.[48] Once a medicine has been authorised and is placed on the market, its safety and efficiency is monitored through the EU system of pharmacoviligance.[49] The purpose of pharmacoviligance is to identify previously undetected adverse drug reactions and, if any, propose improvements of the medicine. [50]

Advertising is used extensively[51] and is subject to the same minimum rules as the advertising of other products. There are also special rules for advertising of pharmaceuticals in Directive 92/28/EEC. For example, advertising of prescription drugs is not permitted.[52] Furthermore, detailing i.e. promotion and marketing directed against prescribing doctors, needs to comply with certain rules in the Directive. For example, it must include detailed information of the product[53] and may not include gifts, pecuniary advantages or benefits in any kind.[54]

2.4 Generic entry

Generic versions of a pharmaceutical are allowed to enter the market on patent expiry of the original medicine. The entry of generics usually leads to a decrease in price and an increase in supply. Therefore, legislation is designed to simplify and encourage the entry for these companies by offering an abridged route to achieve a marketing authorisation. By using the originator medicine as a reference, the generic company saves time and is able to enter the market more rapidly.[55] Also, the generic company does not have to invest money in expensive R&D and does not have other costs related to innovation of medicines.

[44] Directive 2001/83/EC as amended by Directive 2010/84/EU.
[45] Ibid, Article 6.
[46] Ibid, Article 28.
[47] Ibid, Article 8 (3i).
[48] Pharma Report, para 142.
[49] Directive 2001/83/EC.
[50] Smillie (2012) p. 265.
[51] Ibid, p. 193.
[52] Directive 92/28/EEC, Article 3 (1).
[53] Ibid, Article 6 (1).
[54] Ibid, Article 9.
[55] Westin II 2011, p. 596.

Directive 2001/83/EC define a generic as

> "a medicinal product which has the same qualitative and quantitative composition in active substances and the same pharmaceutical form as the reference medicinal product, and whose bioequivalence with the reference medicinal product has been demonstrated by appropriate bioavailability studies."[56]

Before 2005, a generic company could only use the originator pharmaceutical as a reference, and thereby benefit from the abridged procedure, if the original product was still on the market. Today, a generic company can take advantage of a marketing authorisation up to eight years after a withdrawal of the original marketing authorisation.[57] Also, and most importantly, a generic company is not required to conduct pre-clinical tests and clinical trials to obtain a marketing authorisation. As long as the generic company can demonstrate that the product is bioequivalent with the reference product it will be approved.[58]

Bioequivalence can be demonstrated in two alternative ways. Either, the generic company relies on an existing marketing authorisation in line with the procedure explained above. The other possibility is to demonstrate that the active substances have been in well-established use in the EU for at least ten years, with recognised efficacy and an acceptable level of safety through published scientific documentation.[59] The latter is obviously more complex and time-consuming. In the case of *AstraZeneca*,[60] discussed in chapter four and five, this was of great significance.

2.4.1 The impact of generic competition

The factors that affect the impact of generic entry are numerous. The Pharma Report suggests that the turnover of the branded medicine before patent expiry may play a role. Countries that oblige pharmacies to substitute a medicine for a generic version if the generic is cheaper have earlier generic entry. Also, generic entry seems to be faster if the Member State does not enforce a certain price cap on the generic version.[61]

The impact of generic entry on the pharmaceutical market can be divided into two sections: the *extent* of entry and the *effect* of entry. The extent of generic entry was investigated in the Pharma Report in the years 2000 - 2007. The report found that half of the products faced generic competition within the first year of loss of protection. On an average, generic entry happened within seven months. For the best-selling medicines, average

[56] Directive 2001/83/EC, Article 10 (2b).
[57] Ibid, Article 10.
[58] Ibid, Article 10 (1).
[59] Ibid, Article 10 (a).
[60] Case C-457/10 P, *Astra Zeneca*.
[61] Executive Summary of the Pharma Report, p. 9.

generic entry happened within four months. In most cases, generic competition has the effect of lower prices. According to the Sector Inquiry, generic versions were sold at a price 25 % below the price of the original product before loss of exclusivity. In a year, the price was 40 % lower. The inquiry also found that the price of the previously patented product decreased. According to the Pharma Report, savings could have been even greater if generic entry would have occurred at an earlier stage.[62]

2.4.2 Generic substitution

Generic substitution is a popular political tool to increase the use of generics. By allowing or obliging pharmacies to exchange a prescribed medicine in cases when there is a cheaper generic version available,[63] government spending on reimbursed drugs can be decreased. Another purpose[64] of generic substitution is to change certain prescribing habits by doctors. However, generic substitution does not apply to generics of different dosages, different formulations or different delivery systems.[65]

In Sweden, mandatory generic substitution was introduced in 2002. The substitution is not carried out if the prescriber of the drug has objected the exchange or if the patient pays the price gap between the generic and original medicine.[66] In Sweden, generic substitution has led to lower prices on pharmaceuticals which no longer benefit from patent protection. In an article, published in *Läkartidningen* in 2007, the authors provide proof for this observation and in addition, argue that doctors have changed their prescription habits after the introduction of generic substitution.[67]

2.5 Intellectual property rights and competition law in the pharmaceutical sector

The relationship between IPRs and competition law has been a long-running debate. Considering the essential character of both disciplines; IPRs confer an exclusive right upon its owner whereas the primary goal with competition law is to keep competition on the market free, it has been suggested that they are inherently in conflict.[68]

To make the issue a bit clearer: by being granted an intellectual property right, e.g. a patent, the owner receives an exclusive right to exploit his or her patent for a limited period of time. This exclusive right includes the right to exclude others from exploiting the patent. Depending on the circumstances, e.g. availability of substitutes in the market, the patentee may hold a

[62] Executive Summary of the Pharma Report, p. 9.
[63] Domeij, Bengt (2013) p. 135.
[64] Ibid, p. 135.
[65] O'Donoghue & Padilla (2006) p. 531.
[66] See Lag (2002:160) om läkemedelsförmåner mm. 21 §.
[67] Lundin, Jacob, Engström, "Generikareformen pressade läkemedelspriserna" LäkarTidningen, vol 104, nr 9, 2007.
[68] Anderman (2011) p. 4.

monopoly, or at least dominance, on the market since he or she is the only one who can manufacture, sell and market the product. This inevitably leads to concerns from a competition law perspective since its main goal is to keep competition free.[69] One of these concerns is the unilateral conduct of a company in a dominant position, a position possibly attained through the possession of an exclusive right. In order to ensure that these companies do not misuse their exclusive right, Article 102 put certain restrictions on their freedom of action.

One could come to the conclusion that competition law and intellectual property law contradict one another. But this seems to be a simplistic and false conclusion. Instead, it seems to be generally accepted that intellectual property law and competition law are just two means to the same end.[70] The disciplines share the same objective of promoting consumer welfare and an efficient allocation of resources with the ultimate aim to bring new and better products to consumers at the lowest possible price.[71] As emphasized in the Commission's Guidelines on the application of Article 101[72] "innovation constitutes an essential and dynamic component of an open and effective market economy."

Intellectual property law strikes a balance between over- and under-protection of an innovator's innovation, whereas competition law works as a safety net that unfolds when that balance is called into question. But even though it can be concluded that intellectual property law and competition law are not inherently in conflict, the innate tension between the disciplines cannot be ignored. Therefore, the matter is rather to determine at what point the exercise of an IPR is so harmful that competition law should intervene.[73] Evergreening of pharmaceutical patents may be a scenario in which the balance between over- and under-protection is threatened. Following is an introduction to evergreening in the context of the pharmaceutical market.

2.6 Evergreening of pharmaceutical patents

Evergreening involves a variety of strategies adopted by patent holders when their valuable patent rights are about to expire. Such strategies aim at extending the privileged position that a patentee holds during exclusivity. Evergreening tactics are especially common in the pharmaceutical industry.[74] On patent expiry, originator companies are met with competition from generic companies which most often leads to a decline in price and demand for the branded product.[75] In order to meet this competition, originator companies adopt countermeasures to protect their market position. These tactics have been named several things: most often

[69] Whish & Bailey (2012) p. 769 ff.
[70] Jones & Sufrin (2011) p. 711, see also Pepperkorn (2003) pg. 527-528.
[71] Whish & Bailey (2012) pp. 769 -770.
[72] Commission Guidelines on Technology Transfer, para 7.
[73] Whish & Bailey (2009) p. 770.
[74] Shadowen et al. (2011) p. 698.
[75] Executive Summary of the Pharma Report, p. 9.

evergreening but also "life-cycle strategies" or "strategic patent planning."[76]

In its Pharma Report, the Commission refers to such methods as "life cycle management strategies". These different strategies work as "a tool-box" for originator companies with the goal of maximizing the return from their pharmaceutical products.[77] The report suggests a variety of such strategies as potentially anti-competitive, including patent clusters, patent litigation, life cycle strategies for follow-on products and interventions before national regulatory authorities.[78]

These strategies have two broad aims: to extend the time in which the pharmaceutical product enjoys market exclusivity and to maintain or expand the market share in the market in which the product acts. This might have a negative impact on generic competition, hindering its emergence to the market and also by having a detrimental effect on the supply and price of medicine, especially in developing countries.[79] Although ethical aspects of such strategies can be discussed, this thesis will focus on the legal uncertainties. Evergreening will be further investigated in chapter five.

[76] See for example Domeij (2013) p. 163.
[77] Pharma Report, para 466.
[78] Ibid, para 1557.
[79] Correa (2012) p. 749.

3 Patents on Pharmaceuticals

3.1 Introduction

Patents are the backbone of the research-based pharmaceutical sector, making the industry one of the main users of the patent system.[80] However, there used to be a universal principle, stating that patents could not be granted for medicines since it was seen as inappropriate to grant a single entity the exclusive right to a product that could mean the difference between life and death. Today, often justified by a more nuanced application of the patent law system, almost all countries allow patents on pharmaceutical products.[81]

The following chapter will mainly deal with two issues relating to pharmaceutical patents: the object behind patents and the regulatory framework applicable when obtaining a patent. Considering the scope of this thesis, it is not possible, neither necessary, to exhaustively deal with the substantive law of patents. Therefore, this section will focus on giving the reader an overview presentation to patent law which can be used as a reference point for the upcoming discussion and analysis.

3.2 General on patents

A patent is a form of intellectual property. The patent gives its owner the exclusive right, conferred by law, to exploit the innovation, in exchange for public disclosure of the patent.[82] A patent right means that the owner has the exclusive right to make, use and sell the patented product, including the right to prevent others from exploiting the product. In Europe, patent protection lasts for 20 years from the date of the filing the application.[83]

Applying for a patent is the first step in the process of introducing a new medicine on the market, ensuring that it is the inventor and not his or hers competitors who reap the rewards of the invention. In the pharmaceutical sector, an application for a patent is usually filed when the substance has been made and a pharmacological effect can be established.[84] The Pharma Report suggests that the time for applying may be as early as during the research stage of developing the medicine. For most originator companies, however, patenting continues throughout all stages of development and even after the first launch of the product.[85] At what point the most favourable time to apply for a patent occurs is a difficult question. The inventor has to

[80] Executive Summary of the Pharma Report, p. 9.
[81] Levin (2011) p. 272 ff.
[82] Korah (2007) p. 24.
[83] EPC Article 63, see also TRIPS Article 33.
[84] Domeij (1998) p. 1.
[85] Pharma Report, para 443.

consider the risk of competitors filing a patent application for the same substance before him or her and weigh it towards the financial benefits of waiting, considering the additional profits that every extra day of selling a medicine will bring.[86]

3.3 The rationale for patents

The most common argument in support of patent protection is the need to create incentives for innovation. Innovation is desirable since it stimulates economic growth and leads to greater efficiency. Innovative companies are incentivized to make the necessary investments in R&D by the promise of monopoly rights.[87] This argument can be illustrated by Abraham Lincoln's statement that patent law:

> "[...] secured to the inventor, for a limited time, the exclusive use of his invention; and thereby added the fuel of interest to the fire of genius, in the discovery and production of new and useful things."[88]

The exclusive right is a remedy for the financial risks that the companies in the research-based pharmaceutical industry take. It is clear that pharmaceuticals need to be covered by favourable rules, providing for sufficient protection, in order for costly and lengthy R&D to be facilitated.

Patents can also bring benefits to society as a whole. When the patent becomes public, as all patents do, the information in the application becomes available to anyone. By doing so, the technological and scientific knowledge available to the public is increased and may be used for the purpose of further research.[89] Hopefully, this information leads to further innovation and the development of new inventions. In this way, patents do not only foster innovation for the patent owner, but also more favourable conditions for competitors to innovate. Thereby, patents may ultimately improve competition.[90] Ultimately, innovation is also good for the consumer since increased competition will lead to lower prices, better products, wider choice and greater efficiency, as will be explained in chapter four.

However, the benefits of patents have been questioned. Although incentives are necessary for innovation to exist, concern has been expressed that too many and too broad patents are being granted and that patents might not actually lead to more innovation. For example, Boldrin and Levine are

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[86] Domeij (1998) p. 1.
[87] European Commission, <ec.europa.eu/internal_market/indprop/patent/>, retrieved 2013-05-14.
[88] Abraham Lincoln., Lecture on Discoveries and Inventions, p. 357.
[89] Pharma Report, para 255. A patent does not include a right to exclude others from using the invention for the purpose of further research. This is often referred to as the "research exemption" which is a well-established principle of patent law that should apply world-wide, or at least in the European countries. In the Swedish Patent Law, this provision is provided in 3 § 3 st. 3 p. PL. For further reading, see Domeij (1998) p. 457 ff.
[90] Pharma Report, para 255.

sceptical to patents. According to the authors, patents produce what they call "IP-inefficiency". The authors conclude that IPRs are an unnecessary evil, since there is no evidence that its desired purpose of increasing innovation is achieved.[91] Boldrin and Levine go as far as calling IPRs a "cancer" that needs to get cut off entirely.[92]

3.4 Regulatory framework

Modern patent laws are complex and comprise of complicated technical and legal aspects. As of today, there is no coherent EU patent that can be obtained for the entire EU. This is about to change. Since long, it has been under discussion in the EU whether to establish a unitary patent and a unitary patent court. In December 2012, 25 of the 27 Member States agreed to create a unitary patent with a unitary effect, the first to be granted in April 2014.[93] This "EU Patent Package" is predicted to reduce the cost of patent applications and lessen the administrative burden for patent authorities.[94]

Today, innovations can receive patent protection in three ways: (1) by a national patent, as granted by the competent national authority in each Member State, (2) by a European patent granted by the European Patent Office (EPO), (3) by using the Patent Cooperation Treaty (PCT) where the applicant designates one patent office as a reference office which then transmits the application to the other Member States that the applicant wishes to obtain a patent in.

3.4.1 International agreements

The Paris Convention (ParC), signed in 1883, was one of the first international treaties for the protection of IPRs. One of the most important provisions is the right to priority.[95] The right to priority means that if an applicant is granted a patent in one of the convention states, the same applicant may, within a limited period of six or twelve months, apply for protection in other convention states, with a reference to the first patent.[96]

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[91] Boldrin & Levine (2008) p. 11.
[92] Ibid, p. 264.
[93] All Member States have signed the "EU Patent Package" except Spain and Italy. The international agreement creating a unified patent court will enter into force on 1 January 2014 or after 13 contracting states ratify it. For more information see <www.europarl.europa.eu/news/en/pressroom/content/20121210IPR04506/html/Parliament-approves-EU-unitary-patent-rules>.
[94] Speech by Commissioner Barnier, delivered on 11 December 2012, MEMO/12/97.
[95] See ParC Article 4 (A1): "Any person who has duly filed an application for a patent, or for the registration of a utility model, or of an industrial design, or of a trademark, in one of the countries of the Union, or his successor in title, shall enjoy, for the purpose of filing in the other countries, a right of priority during the periods hereinafter fixed."
[96] Muir et al. (1999) p. 1.

The PCT was established in 1970. PCT is a special agreement within the terms of Article 19 ParC.[97] The purpose of establishing the Treaty was to simplify the process of obtaining individual patents in more than one country by providing a unified procedure for filing patent applications.[98] Today, the PCT has 147 contracting states, Saudi-Arabia being the most recent.[99]

The Agreement on Trade Related Aspects of Intellectual Property Law (TRIPS) is an international treaty, signed in 1998, applicable to all countries which are members of the World Trade Organization (WTO). TRIPS requires its contracting states to comply with basic rules. For example, patent protection for 20 years is mandatory in all Member States.[100]

The European Patent Convention (EPC) was established in 1973, and contains rules on patents within Europe.[101] EPC is also a special agreement, created with support of Article 19 ParC.[102] Albeit Member States have their own national systems of laws, an extensive harmonisation has been achieved by the Convention and today, the Member States patent laws are to a large extent corresponding with the EPC.[103] After a substantive examination of the product's patentability, a European patent is granted by the competent authority EPO.[104] Once granted, the European patent turns into bundle of national patents and, according to Article 64, confers the same exclusive right as a national patent. Also, all national patents are subject to national laws and national enforcement.[105]

3.4.2 Requirements to obtain a pharmaceutical patent

A patent can cover a product (e.g. a molecule), a process (e.g. how this molecule is manufactured), or a medical indication (the effect the molecule has on the human body).[106] Article 52 EPC (1) dictates the criteria for patentability. A European patent will be granted if the invention is (1) novel, (2) contains an inventive step and (3) has industrial application. The patentability requirements are applied strictly objective and without any consideration of the applicant's intent to receive a patent.[107]

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[97] Muir et al. (1999) p. 2.
[98] Levin (2011) p. 47.
[99] http://www.wipo.int/pct/en/brief/index.html, retrieved 2013-05-28.
[100] TRIPS Article 33.
[101] The Convention on the Grant of European Patents of October 5, 1973. Amended by the act revising Article 63 EPC of 17 December 1991 and by decisions of the Administrative Council of the European Patent Organisation of 21 December 1978, 13 December 1994, 20 October 1995, 5 December 1996, 10 December 1998 and 27 October 2005.
[102] Muir et al. (1999) p. 2.
[103] See for example the Swedish Patent Law 1, 2 §§.
[104] EPC Article 4.
[105] Whish & Bailey (2011) p. 768.
[106] Levin (2011) p. 273.
[107] EPO Comments on the Pharma Report, p. 6.

When it comes to pharmaceuticals, the novelty requirement is the most important to consider. An invention is considered to be new if it does not form part of the state of the art.[108] This concept derives from the concept of the man skilled in the art. This imaginary person has an average knowledge in the particular area of technology and an invention is seen as new if it does not form part of the knowledge of this imaginary person.[109] If something is not part of the state of the art, then it is new and the novelty requirement is fulfilled. Moreover, the novelty requirement is absolute and global, meaning that everything which is or has been possible for a skilled man to find anywhere in the world belongs to the state of the art.[110]

3.5 The scope of a patent

The patent-holder is granted a monopoly over the product, meaning that others can be excluded from making, using, offering for sale, selling or importing that product.[111] How broad the scope of the patent should be has been intensively debated. This thesis limits itself to make a few comments on the issue. The patent claims determine the extent of protection, while the description and drawings are used to interpret the claims.[112] Hence, the scope of a particular patent is not determined in advance but instead, if infringement claims are brought against a competitor, the court will decide the extent of protection in that particular case. This is achieved by comparing the patent with the alleged infringement product.[113]

The Supplementary Protection Certificate[114] (SPC) gives the holder of a pharmaceutical patent the possibility to receive extended protection for a maximum of five years by Regulation 1768/92. A SPC confers the same rights upon its holder as were conferred by the basic patent, even though it should be noted that it is not a "new" patent.[115] This additional protection is motivated by the long time span that elapses between the patent application and the time when the product can be effectively marketed. As mentioned earlier, extensive regulatory obligations rest upon an applicant of marketing authorisation, obligations which may be significantly longer than in other sectors.[116] SPCs can be seen as a way to ensure that pharmaceutical companies can recoup their investment in R&D by extending the period of marketing exclusivity.[117] According to Article 19 of the SPC Regulation, the possibility to receive supplementary protection is only available to products that were marketed after 1 January 1985. According to the same provision,

[108] EPC Article 54 (1).
[109] Domeij (2000) p. 134.
[110] Ibid, p. 132.
[111] TRIPS Article 28 (1a).
[112] EPC Article 69.
[113] Domeij (1998) p. 481.
[114] Council Regulation 1768/92/EC. The original SPC has been amended several times, most recently by regulation No. EC/469/2009.
[115] Regulation EC/469/2009, Article 5.
[116] Pharma Report, para 293.
[117] Gunther & Breuvart (2005) s. 669.

an exception is made to Denmark and Germany, where the date is replaced by 1 January 1998 and Belgium and Italy, where the date is replaced by 1 January 1982.

3.6 A short comment on patenting in the pharmaceutical sector

As already outlined, patent protection is an essential component of the pharmaceutical sector. Since innovation of pharmaceuticals is a high-risk and high-cost business, and imitation on the contrary is a low-risk and low-cost business, solid protection against imitation must be provided in order for innovation to exist.[118] It may be argued, that if no protection were provided, the high cost for R&D would discourage companies from investing money in innovation, with the consequence that certain medicine would never reach the market.[119] Furthermore, it is important that protection can be rewarded at an early stage in the process of developing a new pharmaceutical. Besides creating incentives for the innovator, it is argued that early protection may have positive effects such as reducing duplicative research.[120] Thus, the function of a pharmaceutical patent is to provide a sufficient degree of protection to ensure that new drugs are being developed without making it too difficult for competitors to enter the market.

[118] Pharma Report, para 251.
[119] Hunter (2001) p. 8.
[120] Domeij (2000) p. 26.

4 Abuse of Dominant Position

4.1 Introduction

The landscape of EU competition law is constantly evolving. During the last decades, the boundaries of Article 102 have been widened and the number of confrontations between dominant companies and the enforcement authorities has been on the increase.[121] The pharmaceutical market has not been the main priority for the enforcement of competition policy in the EU. This is bound to change, which is obvious from the recent proceedings against AstraZeneca and the Pharma Report.

The purpose of this chapter is to describe the main features of the concept of abuse of dominant position, particularly in the context of IPRs, by reviewing the relevant legal framework and case law relating to the application of Article 102. In addition, the Commission's Guidance on Article [102] Enforcement Priorities[122] will be used as a point of reference, even though it is acknowledged that the Guidelines are not a statement of the law.

4.2 General on abuse of dominant position

To ensure a system of free competition on the market, controlling anti-competitive behaviour is crucial.[123] Article 102 liability is one of the stepping stones to attain this. The provision prohibits:

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

Article 102 gives examples of conduct that is abusive but the list is not exhaustive. Any practice, which fulfils the conditions of the provision, is considered abusive.[124] The criteria to be fulfilled is that: (1) it must be an undertaking, (2) that undertaking must hold a dominant position on a relevant market, (3) the relevant market where the dominant position is held must be a substantial part of the internal market, (4) the position must be abused in a way (5) and that abuse must substantially affect trade between Member States. These criteria have been the subject of intense interpretation by the EU Courts and the meaning and scope of Article 102 is still under development.[125]

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[121] Anderman (2011) p. 5.
[122] Commission Guidance on Abusive Exclusionary Conduct.
[123] O'Donoghue & Padilla (2006) p. 1.
[124] Joined Cases C-395 and 396/96 P, *Compagnie Maritime Belge and Others*, para 112. The principle was first established by the CJEU in Case 6-72, *Continental Can*, para 26.
[125] Lidgard (2011) p. 199.

4.3 The object of Article 102 TFEU

Before giving consideration to the development and current state of Article 102, it is necessary to consider its object. The main purpose of competition law is to create a competitive climate on the market. Ensuring a system of free and undistorted competition on the internal market is also one of the primary objectives of the EU.[126] The benefits of competition are many: lower prices, better products, wider choice and greater efficiency.[127] Greater efficiency means getting the maximum possible output from the given input of resources.[128] This is not only beneficial for the consumers but also for society that will be better off as a whole.

4.3.1 Competition as a promoter of innovation

Competition may also foster innovation. However, this is not self-evident and as earlier mentioned, the relationship between innovation and competition has been widely debated. In 2007, Baker published a paper in which he described two main approaches. One view, often associated with Kenneth Arrow, suggests that competition encourages innovation by spurring companies to find new products in order to satisfy consumer demand. A contrary view, often associated with Joseph Schumpeter, is that only dominant companies with significant market power have the financial strength to invest in R&D, and hence, monopoly is preferred over competition.[129] Baker agrees with Arrow and concludes that competition law should be embraced as essential for fostering innovation.[130] Today, the general view seems to be that competition fosters innovation and the challenge is rather to find the appropriate balance between competition enforcement on the one hand and incentives to innovate on the other.[131]

Article 3 (1b) TFEU states that the "[u]nion shall have the exclusive competence […] in the establishing of the competition rules necessary for the functioning of the internal market." Article 102 is one of those rules, operating as a tool to protect competition.[132] But free competition is a means to an end and not goal in itself. What purpose is the protection of competition intended to serve?

4.3.2 Protecting consumers by protecting competition

Competition law protects consumers by protecting competition and is ultimately pursued to the benefit of the consumer. One indication to this is the wording of the competition provisions: Article 101 (3) states that the provision's core objective is to protect competition to the benefit of

[126] Article 3 (1b) TFEU.
[127] Whish & Bailey (2011) p. 4.
[128] Osterud (2010) p. 29.
[129] Baker (2007) p. 575.
[130] Ibid, p. 602.
[131] See for example Communication from the Commission (2007).
[132] Case C-52/09, *Konkurrensverket v TeliaSonera Sverige AB,* paras 20- 21.

consumers.[133] Also, Article 102 (b) prohibits dominant undertakings to limit the production, markets or technical development to the prejudice of consumers. This view has been supported by the EU Courts. In *Continental Can*[134], the CJEU concluded that competition law does not only intervene against practices that cause a direct damage to consumers, but also against practices that has a detrimental effect on consumers through their impact on the competitive structure of the market i.e. a indirect effect. Hence, competition law is concerned with conduct that has a detrimental effect on consumers, irrespectively of whether that effect is direct or indirect.

Similarly, the Commission seems to view consumer welfare as the primary objective of competition law and Article 102. In the Commission's enforcement priorities, the essence of protecting the competitive process is emphasized: "What really matters is protecting an efficient competitive process and not simply protecting competitors."[135] Thus, even though steps to prevent dominant undertakings from excluding competitors have been taken and thereby protecting competitors, the primary focus has been to protect a competitive market as such. The primary purpose with Article 102 is consumer welfare, as outlined above, and not to protect weak competitors from going bankrupt.[136] Whish and Bailey make a comparison with other competitive activities to illustrate this. The authors suggest that as in any competition, whether in economics, in sports, or any other kind of competition, the most fitted competitor will win. This is an inevitable consequence of the competitive process, which should not be condemned but rather applauded.[137]

4.3.3 The wider perspective

Competition law plays an important role in the overriding goal of achieving market integration in the EU.[138] A unification of the internal market is of great significance; some have taken it so far as calling it "an obsession of the EU authorities."[139] The idea of an open single market is to encourage companies to expand their business over national borders by dismantling trader barriers between Member States in order to ensure the freedom of movement for goods, services, workers and capital.[140] In order to protect the free movement on the internal market, clear rules that ensure free

[133] Even though Article 102 does not contain an equivalent exception to Article 101 (3), it has been established that Article 101 and Article 102 serve to achieve the same goal. See Case 6/72, *Continental Can*.
[134] Case 6/72, *Continental Can,* para 26.
[135] Commission Guidance on Article 102 Enforcement Priorities, para 6.
[136] Opinion of Advocate General Jacobs, Case C-7/97, *Oscar Bronner,* para 58: "the primary purpose of [Article 102] is to prevent competition from distortion – and in particular to safeguard the interests of consumers – rather than to protect the position of particular competitors."
[137] Whish & Bailey (2011) p. 175.
[138] Whish & Bailey (2012) p. 23, see also Commission Guidance on Abusive Exclusionary Conduct, para 1.
[139] Whish & Bailey (2011) p. 24.
[140] Ibid, p. 23.

competition between companies needs to exist.[141] Thus, Article 102 is one of the tools used by the Commission when competition on the internal market is not working properly.

The object and meaning of Article 102 is constantly changing: it is an expression of the values and aims currently existing in society which is subject to change when the political agenda change.[142] Keep this in mind when we move on to explore Article 102 and the difficulties in finding a universal formula for its application.

4.4 Dominant position

Article 102 only applies to companies in a dominant position. Therefore, before moving on to the assessment of the actual abuse, the existence of a dominant position must be established.[143] Note that a dominant position is not in itself anti-competitive. On the contrary, a dominant company is still allowed to compete on the merits as any other company. Only if the company exploits this position, allowing its conduct to impair genuine undistorted competition, does it constitute a violation of Article 102.[144] The meaning of dominance was established by the CJEU in *United Brands*[145] to be:

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

A dominant position can be said to equal substantial market power, a terminology used by the Commission in its Guidance on Article [102] Enforcement Priorities.[146] The first step is to define the market in which this market power is exercised.

4.4.1 Market definition

For the purposes of Article 102, market definition is a necessary preliminary step in finding an abuse because, before that abuse can be established, it must be demonstrated that the undertaking is holding a dominant position in a given market, which presupposes that the market is already defined.[147] Dominance is not related to the size of the undertaking under scrutiny: if the

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[141] Korah (2007) p. 13.
[142] Whish & Bailey (2011) p. 20.
[143] Such a position may be held by one undertaking (single dominance) or by two or more undertakings (collective dominance). This thesis will focus on single dominance. See the Commission Guidance on Abusive Exclusionary Conduct, para 4.
[144] Case C-322/81, *NV Nederlandsche Banden-Industrie Michelin*.
[145] Case 27/76, *United Brands Company*.
[146] Commission Guidance on Abusive Exclusionary Conduct, see paras 10 and 11.
[147] Relevant Market Notice, para 2.

relevant market is defined narrowly, even small firms become dominant. As follows, a wider definition of the market is better from an undertaking's point of view because it improves the company's chance of falling outside the scope of Article 102. The EU competition authorities are prone to define markets narrowly, creating single products markets, thereby making it easy to find a position of dominance for IP holders.[148] The market definition is divided into two separate subsections: the product market and the geographic market.

The definition of the relevant product market is a question of interchangeability or substitutability. The concept was introduced by the CJEU in *Continental Can*[149] where the CJEU concluded that products belong to the same product market if they are interchangeable from the consumers/buyers point of view. Two products are not substitutes if they are only to a limited extent interchangeable. Whether a product is interchangeable is dependent on the products characteristics, its price and its intended use.[150] Companies are also subject to supply substitutability and potential substitutability. Supply substitutability can be considered in special circumstances, for example if switching production to the relevant product does not incur significant additional costs or risks for the potential competing supplier.[151] Although potential competition is a competitive constraint, it is not considered when defining the relevant market but at the subsequent step: appraisal of dominance.[152]

When the product market has been established, the assessment continues to the geographic market. The relevant geographic market is a clearly defined area in which a product is marketed and the conditions of competition are sufficiently homogenous for the effect of the economic power of the undertaking concerned to be able to be evaluated.[153] When the relevant geographic market is determined, an evaluation into whether that market constitutes a substantial part of the internal market must be done. As of today, this prerequisite is usually met since it has been interpreted that a substantial part of the internal market can be a single Member States, or even just a part of that Member State.[154]

4.4.2 Appraisal of dominance

Having defined the relevant market, the analysis turns to whether the company is dominant on that market or not. First, *constraints imposed by actual competitors* are taken into account. Second, *constraints imposed by potential competitors* are considered. Last, *constraints imposed by consumers* (countervailing buyer power) are observed. These are the main

[148] Anderman (2011) p. 11.
[149] Case 6/72, *Continental Can*, para 32.
[150] Lidgard (2011) p. 204.
[151] Ibid, p. 209.
[152] Ibid.
[153] Case 27/76, *United Brands,* para 44.
[154] Lidgard (2011) p. 208.

factors that are used when examining the competitive structure of the market.[155]

The market share of the company is an indicator of constraints imposed by actual competitors. A large market share implies dominance; a small market share implies the opposite.[156] Only a very high or a very low market share can establish dominance. Clearly, monopoly amounts to a dominant position. A market share around 60-70 % is a clear proof of dominance.[157] A market share of 50 % or more constitutes a presumption for dominance.[158] More difficult to examine are market shares of around 25-60 %.[159] But market share alone cannot be determinative since they are only indicators and give no information about potential competition or buyer power, why other factors, as those described above, is taken into account. Let us look into the pharmaceutical market to see how this assessment can be done.

4.4.3 Dominant position in the pharmaceutical sector

Given the specific characteristics of the pharmaceutical sector, one could argue that special considerations should be taken when defining the relevant market. First, let us briefly repeat which those differences are. As pointed out in chapter two, governments usually regulate the price for prescription drugs, thereby setting the usual price mechanism out of play.[160] In the dual pricing policy case *GlaxoSmithKline*[161], the CJEU acknowledged that although the pharmaceutical sector is subject to the same competition rules as other sectors, the specific nature of the sector should be taken into account when making assessments under competition law. Furthermore, the Court stated that the sector to a significant extent is shielded from the free play of supply and demand, which may impact on the assessment.[162]

Another characteristic of the sector is that the demand-side is less price-sensitive than in other sectors, also described in chapter two, because it is the doctor who prescribes the medicine, but the consumer or health care system who pays for it.[163] From this, it is clear that the assessment has to be less focused on price and demand elasticity and more focused on factors specific to the sector.[164]

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[155] Whish & Bailey (2011) pp. 181-187.
[156] Lidgard (2011) p. 210.
[157] Ibid.
[158] Case C-62/86, *AKZO*, para 41.
[159] For a more extensive review of appraisal of dominance, see Whish and Bailey (2011) pp. 46-47.
[160] Westin I (2011) p. 58.
[161] Case C-501/06, *GlaxoSmithKline*.
[162] Ibid, para 104.
[163] Westin I (2011) p. 58.
[164] Ibid, p. 58.

The CJEU made a narrow market definition in *AstraZeneca*.[165] AstraZeneca's product Losec, a proton pump inhibitor (PPI) treating ulcers, was defined as a single product market, inevitably leading to dominance on that market for AstraZeneca. The defendant argued that PPIs should be part of the same product market as H2 blockers because the two products were substitutable. But the argument that H2 blockers put a competitive constraint on PPIs which, according to AstraZeneca's defence, is proved by the gradual nature of the increase of sales of PPIs, was rejected. Instead, the CJEU found that the PPI had replaced H2 blockers and had its own market.

According to Westin, too narrow market definitions, especially when it comes to innovative sectors may be counterproductive and stifle innovation. Westin suggests an alternative approach. According to his proposal, the medicine's therapeutic indication could be a starting point. From there, the relevant market can be further defined according to other factors such as the product's intended medical use.[166] Westin is backed up by Batchelor and Healy, who also express concerns about a narrow market definition in the pharmaceutical sector. The authors suggest that external factors as the regulatory environment, the ability of competitors to enter the market and the competitive role played by existing therapies should be taken into account when defining the market.[167]

4.5 Abuse of dominant position

When a dominant position has been established, the analysis turns to the assessment of whether that position has been abused. How can we distinguish legitimate from illegitimate behaviour? A risk associated with applying Article 102 too aggressively, and especially in relation to exclusionary conduct, is that competition is chilled rather than encouraged. Such a result would obviously be counterproductive: a law designed to promote competition should not have the effect of diminishing it.[168] Therefore, a careful application of Article 102 is called upon.

Article 102 (b) states that conduct consisting of "limiting production, markets or technical development to the prejudice of consumers" is an abuse. This is the more traditional sort of exclusionary abuse. But more subtle, non-price strategies aimed at excluding competitors may also be abusive, e.g. patent litigation, use and abuse of regulatory procedures and launch of second generation products.[169] Furthermore, since Article 102 does not provide a definition of "abuse", the meaning and scope has been developed through case law.

[165] Case 457/10, *AstraZeneca,* para 36-52.
[166] Westin I (2011) p. 58.
[167] Batchelor & Healy (2013) p. 171.
[168] Whish & Bailey (2011) p. 193.
[169] O'Donoghue & Padilla (2006) p. 519.

4.5.1 Developments of Article 102 in case law

The concept of exclusionary abuse has been defined in numerous cases by the EU Courts. In *Michelin I*,[170] the CJEU concluded that a dominant company has a special responsibility, meaning that a dominant company must not allow its conduct to impair genuine undistorted competition on the internal market.[171] This responsibility applies irrespective of the reasons to why the company has a dominant position. The scope of the special responsibility shall be considered in the light of the specific circumstances in each case which has been confirmed by the EU Courts several times, most recently in *AstraZeneca*.[172]

In *Continental Can*[173], the CJEU clarified that Article 102 aims at practices that may cause damage to consumers directly, but also to practices that are detrimental to consumers through their impact on the effective competitive structure. Thus, finding a directly negative impact on consumers is not necessary to find an infringement of Article 102, rather it is enough that the competitive structure is affected.

Hoffman-La Roche[174] dealt with the scope of the special responsibility. In the case, the CJEU defined abusive conduct as methods different from those governing normal competition, methods that have the effect of hindering the maintenance of the existing degree of competition on the market, or the growth of that competition.[175] Furthermore, the CJEU repeated its statement from *Continental Can,* arguing that:

> "Article 102 covers not only abuse which may directly prejudice consumers but also abuse which indirectly prejudices them by impairing the effective competitive structure as envisaged by (former) Article 3 (1) (g) of the Treaty."[176]

But what is *normal* competition? The Court dealt with the issue in *AKZO*[177], repeating its formulation from *Hoffman-La Roche*, but adding that a dominant company is prohibited to eliminate a competitor, and thereby strengthen its own position, by using means other than those that come within the scope of competition on the merits.[178] Thus, as long as the behaviour of a dominant firm is seen as competition on the merits, the behaviours lawfulness cannot be questioned from a competition law

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[170] Case 322/81, *Michelin I.*
[171] Ibid, *para* 57.
[172] Case C-457/10 P, *Astra Zeneca v Commission*, para 134, see also Case T-203/01, *Michelin II,* para 97; Case T-83/91 *Tetra Pak,* para 114; Case T-228/*97 Irish Sugar*, para 112.
[173] Case C-6/72, *Continental Can*.
[174] Case 85/76, *Hoffman-La Roche*.
[175] Ibid, para 6. See also Case C-52/07 *Kanal 5 and TV 4,* para 25 and Case C-52/09, *Telia Sonera,* para 27.
[176] Case 85/76, *Hoffman-La Roche,* para 125.
[177] Case 62/86, *AKZO*.
[178] Ibid, para 70.

perspective. Hence, the issue to discuss is the scope of competition on the merits. One may feel that the formulation is rather vague and gives no clear guidance on how to identify such conduct. But competition on the merits is a general definition which needs to be broad in order to catch a variety of conduct.[179]

Abuse of dominance is an objective concept. Therefore, an intention to exclude or weaken competition is not necessary for an abuse to be established and the conduct of a dominant company may be regarded as abusive in the absence of any intention to do harm. This has been emphasized by the EU Courts several times[180], while at the same time, in some rare cases, holding conduct as abusive only if it is part of a plan to hamper competition and eliminate competitors.[181]

It should also be added that in relation to IPRs, *CICRA v Renault* established that even though the mere possession of an exclusive right does not constitute an abuse, the exercise of that right may yet be prohibited under Article 102.[182] Therefore, the challenge is to decide at what point, if at all, the exercise of an IPR is abusive.

4.5.2 Objective justification

Once an abuse has been established, dominant companies may put forward arguments and evidence that justifies their conduct, thereby escaping the prohibition in Article 102. Østerud concludes that the concept of objective justification has been applied to conduct that furthers a legitimate purpose and is proportionate.[183] A valid justification can be economic justifications other than the elimination of a competitor, a formula that was used by the CJEU in *France Télécom SA*.[184]

The "objective justification principle" has been developed in case law since Article 102 lacks an equivalent to the exemption provision in Article 101 (3) TFEU.[185] The Commission has the burden of proof for the abuse and in a way, also for the objective justification. Even though it is the undertaking that is responsible to put forward evidence and arguments in support of its claim, in the end, it is the Commission who has the burden of proof to show the absence of such an objective justification.[186] The assessment under Article 102 should not be divided into two parts, one dealing with whether an abuse exists, and one following where the undertaking defends the abuse by showing objective justifications to the conduct. Rather, the objective

[179] Østerud (2010) p. 38.
[180] Case 85/76, *Hoffman La Roche,* para 91, see also C-82/01P *Aéroports de Paris*.
[181] Case C-62/86, *AKZO* para 63 et seq.
[182] Case 53/87, *CICRA v Renault*, para 18.
[183] Østerud (2010) p. 249.
[184] Case C-202/07P, *France Télécom SA*.
[185] Østerud (2010) p. 245.
[186] Anderman (2011) p. 24.

justification is an integral part of the assessment of abuse and only if there is an absence of objective justifications may an abuse be established.[187]

Irish Sugar[188] deals with an abuse of dominance on the retail sugar market, where the appellant, Irish Sugar plc, put forward its financial difficulties as an objective justification defence to its anti-competitive behaviour. The CJEU rejected Irish Sugar's defence, concluding that even though a dominant company has the freedom to protect their commercial interests, that conduct must, in order to be lawful, be based upon a criteria of economic efficiency and be consistent with the interests of consumers.[189] The CJEU also rejected the objective justification defence put forward in *Microsoft*.[190] According to Microsoft's argument, their refusal to supply was justified by objective considerations since the technology concerned was protected by an IPR which was secret and valuable and contained important innovations.[191]

The Commission touches upon the concept of objective justification in a Guidance paper were such claims are referred to as "objective necessity and efficiencies."[192] According to the Guidelines, an objective necessity must be based on factors external to the company itself and mentions health and safety reasons as two such factors. Although opening up for a more flexible application of abuse of dominant position, the approval of objective justifications have been limited by the Commission and the EU Courts.[193]

4.5.3 A more effects-based approach?

Whether the EU authorities have a *per se* approach or an effects-based approach to Article 102 has been under discussion. It has already been said that the Commission and the EU Courts have received some criticism against their application of Article 102. In particular, these comments have accused them for taking a too formalistic approach, considering some forms of abuses as prohibited *per se*. For example, in *Michelin II*[194], the Court seemed to consider all royalty-inducing discounts as an abuse irrespectively of whether it has an actual anti-competitive effect or not. Thus, in this case, no anti-competitive effect was necessary for an abuse to be established.[195]

Is this the general rule? Most would argue the opposite. For example, Whish and Bailey come to the conclusion that a trend against a more effects-based approach is clearly established.[196] According to them, for an abuse to exist under Article 102, it must be shown that the conduct has anti-competitive

[187] Case T-201/04, *Microsoft,* para 688.
[188] Case T-228/97, *Irish Sugar*.
[189] Ibid, para 189.
[190] Case T-201/04, *Microsoft*.
[191] Ibid, para 711.
[192] Commission Guidance on Abusive Exclusionary Conduct, paras 28-31.
[193] Ezrachi (2012) p. 172.
[194] Case 322/81, M*ichelin II*.
[195] Ezrachi (2012) p. 207.
[196] Whish & Bailey (2011) p. 201.

effects. Even though accepting that the EU Courts have tolerated *per se* rules under Article 102, for example in the above mentioned *Michelin II*, the authors conclude that the current state of Article 102 does require that an effect on the market has been showed.[197] They support their position with case law as well as the Commission's Guidelines. In *TeliaSonera*[198], for example, the potential anti-competitive effects had to be demonstrated before the conduct (margin squeeze) was condemned unlawful.[199]

Then, is it always necessary to show an anti-competitive effect for Article 102 to be applicable? In its Guidance paper, the Commission states that they will normally intervene if an alleged abuse is likely to lead to anti-competitive foreclosure, on the basis of cogent and convincing arguments.[200] A number of relevant factors are then enumerated which should be taken into account as well as the more specific factors that are set out later in the Guidance paper. Without going to deep into these factors, it can be concluded that the position of the Commission is that an assessment of abuse must take into account whether that conduct has anti-competitive effects or not. The legal position is obviously unclear, even though the above reasoning indicates that the Commission will require a potential or actual effect when enforcing Article 102.

[197] Whish & Bailey (2011) p. 199 ff.
[198] Case C-52/09, *Konkurrensverket v TeliaSonera*.
[199] Ibid, paras 60-77.
[200] Commission Guidance on Abusive Exclusionary Conduct, para 20.

5 Evergreening of Patents in the EU

5.1 Introduction

Evergreening is a new form of abuse that may fall within the scope of Article 102. The concept of evergreening was briefly presented in the second chapter of this thesis. In this chapter, we will take a closer look on its meaning and the application of Article 102 to such conduct. As a preliminary step to finding an abuse, a dominant position must be established. The present chapter assumes that such a position has been established and merely focuses on the assessment of abuse.

Initially, this chapter gives a general review of the concept of evergreening. The relation between such conduct and Article 102 will then be discussed, whereupon a case study of the recently decided *AstraZeneca* will be presented. Thereafter, three evergreening practices will be reviewed with focus on one of them, namely the launch of second generation products.

5.2 General on evergreening

Evergreening contains a multitude of strategies adopted by patent holders with the purpose to extend the privileged position they hold during exclusivity. Evergreening is not a formal legal concept but rather refers to numerous lawful or unlawful methods by which pharmaceutical companies aim to extend their patent rights. These methods can form a part of a company's strategy to become more competitive by limiting competition from generics or enhancing their bargaining position against other patentees.[201]

In the Pharma Report, the Commission identified several practices as potentially anti-competitive but without giving any guidance as to their legal significance. But just as the Commission itself points out, neither was it the purpose of the report.[202] Instead, the report provides a context and factual basis for dealing with potentially anti-competitive conduct. Note that the Commission does not explicitly use the term evergreening but refers to such conduct as "instruments of a tool-box, which is used to delay or prevent generic entry."[203] Examples of such practices are patent filing strategies[204], patent related litigation,[205] patent settlements[206] and life cycle strategies.[207]

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[201] WIPO, *2011 World Intellectual Property Report, The changing face of innovation*.
[202] Pharma Report, para 22.
[203] Ibid, para 466. Although the Pharma Report can be a useful starting point for further research, the purpose with this thesis is not to give a comprehensive review of the Report and its findings. Therefore, the patent strategies presented in this thesis are not corresponding or an exhaustive enumeration of the strategies reviewed in the Pharma Report.
[204] Pharma Report, paras 467-546.
[205] Ibid, paras 547-664.

The Report also provides a discussion on the effects of a using the strategies described cumulatively with a view to prolonging the life cycle of a pharmaceutical.[208] Furthermore, (mis) use of the regulatory framework has been seen as anti-competitive in *AstraZeneca*.[209]

An example of a definition of evergreening can be found in the Pharma Report, done by the European Consumer Association. Even though it may be influenced by the association's policy objectives, it is useful to understand the concept of evergreening. They define evergreening as:

> "[...] a specific tactic used by originators to extend patents by seeking to obtain as many patents as possible during the development of the product and the marketing phase, and to obtain a patent extension for new manufacturing processes, new coating and new uses of established products. […] Originators can also slightly change an active ingredient and present an old medicine as a new product and register a new patent."[210]

Why do pharmaceutical companies' evergreen their patents? When the exclusive period of protection ends, a pharmaceutical will most likely be exposed to rigorous competition from generic products.[211] To deal with this potential decline in revenue streams, the originator companies use different countermeasures to deal with the competition from generic companies. One of these tactics is evergreening. The object behind evergreening is to extend the privileged position that the patentee holds during the period of protection for the base patent.[212] In the Pharma Report, an originator company suggested that "[evergreening] represents the most effective strategic initiative to counter generic [versions of the first generation product]".[213]

Hence, evergreening may involve different kinds of conduct with a potentially anti-competitive object and/or effect. However, there has been some criticism against the use of the term evergreening. For example, the European Federation of Pharmaceutical Industries and Associations (EFPIA) is stating on their website that the concept of incremental innovation and evergreening is used in pejorative way. According to the EFPIA, evergreening implies that patenting of second generation products is seen as anti-competitive or as an inappropriate extension of exclusivity.[214] It is obvious that evergreening can be defined in various ways, and lead to

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[206] Pharma Report, paras 702-855.
[207] Ibid, paras 987-1049.
[208] Ibid, paras 1050-1081.
[209] Case C-457/10 P, *AstraZeneca*.
[210] Pharma Report, para 1018.
[211] The impact of generic entry has been discussed in chapter 2.3.
[212] Domeij (2013) p. 129.
[213] Pharma Report, para 996.
[214] EFPIA, <www.efpia.eu/blogs/degree-which-patenting-and-particular-secondary-patenting-protect-pharmaceutical-products>, retrieved 2013-05-19.

both positive and negative results. The thesis now turns to the application of Article 102 to such practices.

5.3 Article 102 and evergreening

Lately, new forms of abuse have been identified under Article 102. One of them is evergreening. Even though a notable amount of doctrine has been published on the concept of abuse of dominant position, the meaning and scope of Article 102 in relation to evergreening is uncertain. The application raise several questions and the result of such an assessment must most certainly balance at the border between lawful use and unlawful abuse. The assessment, as any assessment under Article 102, therefore requires a careful weighing of the conduct's object and effects as well as a consideration of the specific circumstances in each case. Evergreening does not fit under any of the enumerated examples in Article 102. But as outlined above, this list is not exhaustive and any behaviour that fulfils the criteria in Article 102 may be unlawful.[215] Therefore, as long as the particular evergreening practice fulfils the criteria of Article 102, it can also be forbidden.

Most pharmaceutical originator companies possess or have possessed patent protection to their pharmaceuticals. Patents, as all IPRs, are national rights, granted and enforced by national law. Therefore, community law cannot challenge the lawfulness of the right: Article 345 TFEU hinders that.[216] The defence from patentees when alleged of an abuse of Article 102 is that the patent right is just a lawful exercise of a right granted by law. EPO supports this view in a comment on the Pharma Report.[217] Although agreeing that some of the defensive patent strategies addressed in the report may not be in line with the policy objectives of the patent system, EPO suggests that the exercise of patent rights, including post-grant, should be lawful as long as the conduct remains in line with prevailing rules of competition law.[218] A company's efforts to make the most out of their by law granted patent right must at face be seen as a legitimate way of competing on the merits, even though, as pointed out before, patent laws are not immune against competition law.

Another aspect of the application of Article 102 to evergreening is that pharmaceutical product markets have been narrowly defined, for example in *AstraZeneca*[219], making it easier to become dominant. A patent gives the patentee an exclusive right to exploit the product which often, even though not always, leads to a monopoly on the market. At this point in the presentation, we know that the mere possession of a patent right does not

[215] Joined Cases C-395 and 396/96 P, *Compagnie Maritime Belge Transports SA and Others*.
[216] Article 345 TFEU "The Treaties shall in no way prejudice the rules in Member States governing the system of private ownership."
[217] EPO Comments on Pharma Report.
[218] Ibid, p. 6.
[219] Case C-457/10 P, *AstraZeneca,* paras 27-60.

automatically constitute a dominant position, although inescapably indicates a very strong position on the market. With the pharmaceutical market being highly innovative and characterised by these exclusive rights, almost all companies may be seen as dominant if the courts continue to define product markets narrowly.[220]

Also, classical abuses take place on the market. On the contrary, evergreening does not. Instead, evergreening usually takes place in a regulatory context which has an effect on the market.[221] As been described, the effect of evergreening may be to exclude or delay generic competition (an exclusionary abuse) but instead of creating economic barriers to market entry, as most of the classical abuses do, evergreening creates legal barriers.[222] Thus, the exclusion of competitors is not a result of a pricing policy or any other exclusive practice, but merely the use of regulatory framework. Still, the effect of the conduct will take place on the market, just as the classical abuses. This should not cause any problem when applying Article 102 to evergreening. Article 102 prohibits any conduct that has an effect on the market. It is settled case law that the abusive conduct can take place in market different from the one where the effects are caused.[223] It follows that the conduct can take place outside the market but still be abusive, as long as the conduct has effects on the market.[224]

Furthermore, the new abuses are most commonly based upon the existence of an intention to distort competition. But as mentioned above, abuse of dominant position under EU law is an objective concept why the application of Article 102 is independent of whether the pharmaceutical company has acted with the intention to delay or prevent generic entry or not. Consequently, even though intent may be common, it should not be a necessary condition for an abuse to exist. An intention to distort competition must be supplemented by some kind of objective behaviour that is seen as abusive. There are some good arguments for not relying on intent. Firstly, all companies seek to eliminate competitors in some way: that is what competition is about. Second, competition law is more about consumer welfare and less about catching the bad guys. Therefore, effect without intent should be unlawful while intent without effect should be lawful. Lastly, it is difficult to show intent by a company which leads to uncertainty and subjective evaluations.[225]

5.4 A case study - AstraZeneca

In December 2012, the CJEU delivered its decision in *AstraZeneca*.[226] The case has received a considerable amount of attention due to a couple of

[220] Case C-457/10 P, *AstraZeneca*.
[221] Siragusa (2012).
[222] Ibid, p. 181.
[223] Case C-310/93, *British Gypsum v Commission*.
[224] Siragusa (2012).
[225] Ibid, pp. 184-185.
[226] Case C-457/10 P, *AstraZeneca*.

reasons. The case was the first in which the CJEU ruled upon an abuse of dominance in the pharmaceutical sector in relation to evergreening. Moreover, *AstraZeneca* is one of few cases where the strategic use of the patent system has been considered an abuse.[227] Therefore, the findings by the Court are highly relevant to the possible outcome of this thesis.

The judgment was based upon the Commission's decision from 2005, first upheld by the General Court[228] (GC) and accordingly reconfirmed by the CJEU. In all instances, AstraZeneca was found guilty of abusing its dominant position on two grounds:

(1) Making misleading statements to patent offices and courts in several Member States to obtain an extension of patent protection through a SPC for its original Losec.
(2) Operating a strategy to minimize the impact of Losec going off patent by withdrawing its marketing authorisation for the original Losec in Denmark, Sweden and Denmark when launching Losec MUPS in those Member States.

One might add that Losec was AstraZeneca's bestseller, having annual sales reaching around €6 billion towards the end of the 1990s, making it one of the most successful products in the pharmaceutical history and obviously of great importance for AstraZeneca.[229]

The first abuse consisted in the misleading statements made to patent offices and courts in order to obtain a SPC. AstraZeneca argued that the GC took a "legally flawed approach to competition on the merits."[230] According to AstraZeneca's arguments concerning the first abuse, deliberate fraud or deceit should be a requirement to find an abuse of regulatory frameworks. To their defence, AstraZeneca claimed that they made an alternative interpretation of the SPC regulation, thus not misleading patent offices but instead, acted in good faith. A too strict application of Article 102 would, according to the argumentation by AstraZeneca, impede and delay the applications for patents, which in turn would have a bad impact on competition.[231]

In relation to the first abuse, the CJEU found that AstraZeneca's consistent and linear conduct, characterized by highly misleading representations and a manifest lack of transparency, falls outside the scope of competition on the merits.[232] The CJEU also made it clear that it cannot be inferred from the GC's reasoning, contrary to the opinion of AstraZeneca, that any patent application which is rejected on the grounds that it does not fulfil the

[227] Drexl (2012) p. 2.
[228] Case T-321/05, *AstraZeneca*.
[229] DG Competition Policy Newspaper (2005) p. 54.
[230] Case C-457/10 P, *AstraZeneca,* para 69.
[231] Ibid, para 71.
[232] Ibid, para 93.

patentability requirements, automatically infringes Article 102.[233] Furthermore, the CJEU made clear that *potential* anti-competitive effects are enough for a conduct to fall under the prohibition in Article 102. First, the Court emphasized that an abuse cannot be established in absence of current and certain anti-competitive effects on the market. However, such an effect does not necessarily have to be concrete and it is enough to show that the effect is potential.[234] To require deliberate fraud or deceit for Article 102 to be applicable is a misinterpretation of the law: Article 102 is an objective concept and good faith is irrelevant.[235]

The second abuse consisted of deregistration of marketing authorisations in Denmark, Norway and Sweden for the first generation medicine Losec, at the same time as the second generation medicine Losec MUPS was launched in those Member States. At the time, for a generic product to enjoy the benefit of an abridged procedure, a reference marketing authorisation had to exist in the Member State where the application was filed. Hence, the withdrawal of the marketing authorisation for Losec made it more costly and time-consuming for generic companies to launch generic versions of Losec.[236] AstraZeneca argued that the exercise by a legitimate right cannot constitute an abuse in the relevant case since the right to withdraw a marketing authorisation cannot be prohibited, and at the same time forbidden, by the EU.[237] Furthermore, AstraZeneca made an analogy with compulsory licensing cases, arguing that the withdrawal of an SPC can only be abusive in exceptional circumstances where there is an elimination of all effective competition. In the present case, the deregistration only rendered competition more difficult and according to AstraZeneca, it was not shown that it had a disproportionate effect on competition, which is necessary under the concept of compulsory licensing.[238]

First, the Court emphasized that a strategy may be legitimate even if it has the object to deal with generic competition and minimize the erosion of sales. Only when the conduct departs from practices coming within the scope of competition on the merits, which are detriment to consumers, will it be seen as an abuse of a dominant position within the meaning of Article 102.[239] Then, the Court concluded that the illegality of abusive behaviour under Article 102 is unrelated to its compliance or non-compliance with other legal rules.[240] In the present case, the conduct was designed to, *inter alia,* prevent generic competition, and not in any way based on the legitimate protection of an investment, which was within the scope of competition on the merits. The absence of grounds relating to the defence of a legitimate interest of an undertaking engaged in competition on the merits

[233] Case C-457/10 P, *AstraZeneca,* para 99.
[234] Ibid, para 112.
[235] Ibid, para 94.
[236] Ibid, para 130.
[237] Ibid, paras 125 & 127.
[238] Ibid, paras 142-143.
[239] Ibid, para 129.
[240] Ibid, para 132.

makes that conduct unlawful under Article 102.[241] Thus, since it was the lack of an objective justification that made the conduct abusive, the existence of an objective justification would have turned the conduct lawful, even if it had the effect of preventing generic competition. The CJEU pointed out that the central element of the abuse was withdrawal of the marketing authorisation for the original Losec. AstraZeneca claimed that the GC exceeded its jurisdiction when defining the second abuse as a combination of the launch of Losec MUPS and the deregistration of Losec. The CJEU argued against this by claiming that AstraZeneca made a misinterpretation of the judgment by the GC. Instead, as the CJEU points out, it was the deregistration alone which produced the anti-competitive effects.[242] Lastly, the CJEU rejects the "compulsory license argument" stating that the present situation is in no way comparable to such a situation, most importantly because the deregistration of an marketing authorisation in no way compares to the possession of an IPR.[243]

A considerable amount of literature has been published on the GC's judgment, while comments on the findings in the CJEU have been limited.[244] Batchelor and Healy provide a short comment on the CJEU's findings in an article from 2013.[245] In their analysis, the authors come to the conclusion that a simple mistake in the communication with a patent office is probably not enough for an infringement of Article 102 to be established, while large scale intentional misleading falls within the prohibition.[246] In relation to the second abuse, the authors conclude that the judgment may not be as far reaching as the first abuse since the Court leaves the door open for legitimate reasons or objective justifications for the regulatory conduct which could exempt the undertaking from Article 102 liability. Potentially, one such act could be to avoid pharmacoviligance, which the Court seemed to be ready to accept.[247] Furthermore, the authors disapprove the CJEU judgment in that it does not give any clear guidelines as to when a conduct is abusive, but rather just not confirms the strict test set up by the General Court.[248]

To some extent, comments made in relation to the GC's judgment may be useful. For example, Westin published a paper in 2009 in which the strict legal test for abuse in *AstraZeneca* was criticized.[249] Lidgard is also critical to the judgment by the GC.[250] He argues that a too strict enforcement of the competition rules will have negative consequences for the pharmaceutical

[241] Case C-457/10 P, *AstraZeneca*, para 131.
[242] Ibid, para 140.
[243] Ibid, para 148.
[244] The author makes the conclusion that analyses of the judgment have not yet been published due to the short time span but, considering the importance of the case for the pharmaceutical sector, most definitely can be expected in the future.
[245] Batchelor & Healy (2013).
[246] Ibid, p. 173.
[247] Ibid, p. 172.
[248] Ibid, p. 172.
[249] Westin II (2009).
[250] Lidgard (2010).

sector. Originator companies, e.g. AstraZeneca, have been forced to make cuts in their budgets and as a consequence, research centers in Lund and Great Britain have been shut down. Clearly, this has a direct effect on future innovation. Contrary to the opinion of the Commission, Lidgard argues that generic competition is not beneficial for competition if it is promoted to the expense of originators.[251] Moreover, Lidgard questions the conclusion made by the GC in relation to under which circumstances a misleading statement to a patent office is seen as abusive. According to Lidgard, it is not an accurate balance between the interests of originators and generic companies if every incorrect statement made to the patent office is seen as abusive. It is the patent offices which has the competence to do such assessments and not the Courts, and if it turns out that the patent office have made a mistake, the remedy can be found in civil litigation. Lastly, Lidgard comes to the conclusion that the Court is taking liberties when using competition law as a remedy and complement to other legal rules. Lidgard questions whether this is in compliance with the policy objective to promote innovation in the EU.[252] Moreover, Murphy published a paper where he commented on the 2005 decision by the Commission.[253] In the paper, he expresses strong concerns about the decision. Murphy points out that the Commission's approach is radical and introduces a form of compulsory licensing through the back door since pharmaceutical companies are under the obligation to actively maintain rights i.e. marketing authorisations. According to the author, this extension of the special responsibility goes way beyond existing case law.[254]

5.5 A selection evergreening strategies

5.5.1 Patent litigation

Normally, litigation brought by or against a patent holder is perfectly legitimate and part of the fundamental right to justice.[255] Nonetheless, legal proceedings may have a chilling effect on competition and is therefore, under certain circumstances, within the scope of Article 102. Such patent litigation is usually referred to as *vexatious litigation*.[256] Vexatious litigation occurs when a party brings legal action against its adversary with an anti-competitive intent. It may also be described as an abuse of the justice system. Under exceptional circumstances, vexatious litigation may constitute an abuse of dominant position under Article 102.[257]

Patent litigation is discussed in the Pharma Report.[258] In the report, the Commission observes that legal proceedings, carried out by an originator

[251] Lidgard (2010), p. 784.
[252] Ibid, p. 787.
[253] Murphy III (2009).
[254] Ibid, p. 323.
[255] European Convention on Human Rights, Article 6, protects the right to a fair trial.
[256] See for example Siragusa (2012).
[257] O'Donoghue & Padilla (2006) pp. 526-529.
[258] Ibid, paras 547-664.

company, may be an effective barrier to entry for generic companies. Between 2000 and 2007, 54 % of all litigation (698 in total) was initiated by an originator company. 46 % was initiated by a generic company.[259] The report identifies this as a evidence that litigation might be used by originator companies as a way of protecting their patent rights when they become aware of the planned entry of a generic competitor.[260] The report deals with another aspect of vexatious litigation. It may not be necessary, for generic entry to be delayed or prevented, that legal proceedings are actually initiated. If there has been a contact between an originator company and a generic company, the generic company may be threatened by costly legal proceedings, why the risk of grant of interim measures and eventually damages may be enough. As a consequence, the generic company may be deterred from entering the market.[261]

ITT Promedia[262] deals with anti-competitive litigation. According to the judgment, two cumulative conditions must be established in order to identify situations in which litigation amounts to an abuse. First, it is necessary that the action cannot reasonably be considered as an attempt to establish the rights of the undertaking concerned and therefore only serves to harass the opposite party. Second, the action must be a part of a plan with the aim to eliminate competition.[263] Both criteria must be fulfilled to establish an abuse.[264] When making this assessment, the *intention* of the action is decisive. Only if the action is intended to enforce what the company, at the moment, could reasonably consider its right, will the conduct be seen as anti-competitive.[265] However, it is only in *wholly exceptional circumstances* that litigation can be seen as an abuse of dominant position, motivated by the fact that it is a key component of the right to access to justice.[266]

In *AstraZeneca*, the CJEU entirely left out a discussion on whether AstraZeneca had adopted anti-competitive litigation strategies, even though AstraZeneca initiated legal proceedings against several generic companies on false grounds. Lidgard draws attention to this in an article from 2010, concluding that it would have been interesting if the CJEU had made an assessment of whether this kind of litigation was within the scope of Article 102. According to Lidgard, if a company takes advantage of a patent which they have obtained on false grounds, then it should be seen as unlawful under Article 102, while a fraud of the patent office when obtaining the patent should lead to an invalidation of the patent.[267]

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[259] Ibid, para 564.
[260] Ibid, para 566.
[261] Ibid, para 553.
[262] Case T-111/96, *ITT Promedia NV* .
[263] Ibid, para 30.
[264] Ibid, para 56.
[265] Case T-111/96, *ITT Promedia NV,* para 73.
[266] Ibid, para 60.
[267] Lidgard (2010) pp. 587-586.

5.5.2 Patent clusters

A *patent cluster* can be described as a strategy where a multitude of patent applications are filed, relating to the same product but different features of it, with the result of creating several layers of defence against competition.[268] Such strategies can also be referred to as *patent thickets*.[269]

In the Pharma Report, patent clusters are intermingled with divisional patents under the headline "patent strategies". Patent strategies include strategies on the timing and the scope of filing the application as well as the manners in which patents are applied for.[270] The report suggests that patent strategies, and thereby patent clusters, are used to delay or prevent generic entry in order to secure future profits. According to the Pharma Report, as many as 36 of 43 of the originators asked, use patenting strategies as a general policy.[271] The purpose is to keep generic competition off the market, an argument supported by remarks by originators in the report.[272] There has been some criticism against the Commission's approach to patent clusters in the Report. For example, Batchelor argues that regulating patent portfolios through competition law is "fraught with dangers." To Batchelor, competition law should not second-guess the assessment made by a competent patent office since it is impossible, especially for the judiciary, to decide when an undertaking has too many or too weak patents.[273]

The Commission opened proceedings against the German pharmaceutical company Boehringer Ingelheim in 2007 for alleged misuse of the patent system with the consequence of excluding potential competitors.[274] The proceedings were closed when Boehringer settled with Almirall in 2011[275], why it is unclear how the Commission or the EU Courts would have examined the situation.

5.5.3 Second generation products and switching strategies

The launch of a second generation product may be a scenario in which a company tries to evergreen a patent. By replacing a product close to patent expiry with a newly patented product, essentially based on the first product but improved or changed in some way, the company seeks to extend the privileged position that they enjoy during exclusivity with another 20 years. Obviously, the patent holder has done some hard work: in order to receive patent protection the product needs to fulfil the patentability requirements, but the improvements may be marginal.

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[268] Siragusa (2012).
[269] Shapiro (2001).
[270] Pharma Report, para 467.
[271] Ibid, para 487.
[272] Ibid, para 503.
[273] Batchelor (2009) p. 213.
[274] COMP/B2/39246.
[275] COMP /11/842.

In order to avoid exposure to competition stemming from generic versions of the first generation product, the second generation product is launched together with intensive efforts to switch a substantial part of the patients to the new medicine.[276] By doing so, the originator will make it more difficult for generic companies to access the market. If the introduction of the second generation medicine is combined with other measures, for example marketing and promotion efforts, the situation for generic companies may become even more distressing.[277] Is this course of conduct just a legitimate way for originator companies to compete on the merits, or does it constitute a breach of Article 102?

There are well-founded arguments in support of not intervening against the launch of second generation products. Incremental innovation is further innovation of an existing product which is the way in which second generation products are invented. Such innovation may lead to significant improvements of the original product. As an example, new therapeutic indications may be discovered. Also, improvements may be done within the same therapeutic indication and expand the number of medicines within that therapeutic class.[278] Other advantages may involve an increased number of available dosage options and the discovery of new psychological interactions.[279] It is clear that incremental innovation may have pro-competitive consequences since innovation is good for competition, and one of the primary objects of competition law is to increase innovation. Hence, the innovation as such is fully legitimate and part of the normal competitive process as long as it does not depart from behaviour that constitutes competition on the merits.[280] It is not the incremental innovation itself that give rise to competition concerns but rather the combination with other activities to facilitate the switch, e.g. the withdrawal of marketing authorisations of the first generation product, marketing and promotion efforts or litigation. These measures may be unlawful steps in curbing generic competition which will be discussed in the following sections.

5.5.3.1 The Commission's approach to second generation products

In the Commission's Pharma Report, the launch of second generation products was identified as an instrument for originators to deal with generic competition.[281] This may render the market entry of generic versions more difficult since most patients are switched to the second generation product for which generic substitution is not allowed.[282] If successful, the switch will considerably decrease the risk of generic companies gaining a significant

[276] Westin II (2011) p. 597.
[277] Domeij (2013) p. 129.
[278] Pharma Report, para 987.
[279] IFPMA website, retrieved 2013-05-16.
[280] Case C-457/10 P, *AstraZeneca,* para 129.
[281] Pharma Report, paras 987-1049.
[282] Ibid, para 989.

share of the market while allowing the originator to maintain comparable sales numbers and avoid a cut in price.[283]

In its Report, the Commission found that in relation to 40 % of the products that lost patent protection, originator companies tried to switch patients to a second generation product. Preferably, the launch took place before the loss of exclusivity in order to facilitate the switch: on an average one year and five months before patent expiry of the original product.[284] The reason for facilitating this pre patent-expiry switch is that once generic versions are on the market, switching patients will become more difficult.[285]

5.5.3.2 Switching strategies

A switching strategy is a strategy in which an originator company, by using different measures, switch patients from a product facing patent expiry (the first generation product) to a new, recently patented product (the second generation product).[286] This may be a scenario where a company finds it difficult to switch patients from a first to a second generation product. The switch can then be supported by substantial market efforts to change the prescribing habits of doctors.[287] Domeij argues that there may be situations when switching strategies are anti-competitive and within the scope of Article 102.[288]

5.5.3.3 The significance of the withdrawal of a marketing authorisation

Is there a duty to keep a first generation product on the market, and by doing so also keeping the marketing authorisation, when launching a second generation product? In the case of *AstraZeneca*[289], the CJEU found AstraZeneca guilty of abusing its dominant position by withdrawing its marketing authorisations in some markets for Losec when Losec MUPS was launched. AstraZeneca argued that they had no commercial interest in selling original Losec and therefore had an objective justification for withdrawing its marketing authorisation. AstraZeneca emphasized that the existence of a marketing authorisation imposes stringent pharmacovigilance obligations on its holder, and that maintaining such duties would stretch too far from the special responsibility of companies in a dominant position. By arguing this, AstraZeneca challenged the interpretation made by the GC of the concept of competition on the merits.[290]

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[283] Ibid, para 1024.
[284] Ibid, para 1031.
[285] Ibid, para 1025.
[286] Domeij (2013) p. 129.
[287] Pharma Report, para 1033.
[288] Domeij (2013).
[289] Case C-457/10 P, *AstraZeneca*.
[290] Case C-457/10 P, *AstraZeneca AB*, paras 125-127.

After a revision of directive 2001/83/EC, a generic version is no longer dependent on an existing marketing authorisation because the reference can be made to a product which is or has been authorised.[291]

5.5.3.4 Significance of promotion and marketing activities

How far can a patent holder go when it comes to marketing activities? In order to switch consumers from a first generation to a second generation product, extensive marketing and promotion efforts are necessary.[292] The Pharma Report discusses the significance of marketing and promotion of a second generation product. It is suggested that the purpose with such measures is to show the advantages of the second generation product and thereby facilitate a switch of the doctor's prescription behaviour to the new product.[293] These efforts are mainly directed towards doctors since it is them who prescribe the medicine i.e. detailing. Furthermore, originators reported a decrease in marketing costs for the products that were about to lose exclusivity. Instead, marketing costs are invested in the originator's second generation product. Interesting to note is that the switch often took place in the year before loss of exclusivity of the original product.[294] This shows how marketing activities are intentionally used to encourage a switch from the second generation medicine, moving doctors away from prescribing the original medicine. This may have the consequence of less generic medicine being sold.

Another questionable marketing strategy is negative marketing of the first generation product before patent expiry. This may have the same consequences as the above mentioned scenario.[295] In reality, such negative comparisons are actually directed against generic competitors that are about to enter the market. Since it is the first generation product that a generic potentially will be substituted for, non or negative marketing of the original product will actually affect the generic product.[296]

Furthermore, Domeij highlights a rather sad consequence of switching strategies. Pharmaceutical companies are tempted to put their R&D efforts towards incremental innovation based on their existing products, instead of putting their money into more ground-breaking innovation.[297] In conclusion, Domeij argues that some marketing activities of a second generation medicine can be an abuse of dominant position.[298]

In *Renckitt Benckiser*[299], a case decided in the United Kingdom, a pharmaceutical company admitted infringement of Article 102 for

[291] See revised Article 10 (1) of Directive 2001/83/EC.
[292] Domeij (2013) p. 136.
[293] Pharma Report, para 1037.
[294] Ibid, para 1037-1039.
[295] Domeij (2013) p. 129 ff.
[296] Ibid, pp. 137-138.
[297] Ibid, p. 138.
[298] Domeij (2013) p. 143.
[299] OFT case CA,98/02/2011, OFT decision of April 12, 2011.

withdrawing and delisting the hearth-burn medicine Gaviscon Original Liquid when launching the upgraded version Gaviscon Advance Liquid. The patent on Gaviscon Original had expired before any generic version was launched on the market. Also, the second generation product Gaviscon Advance Liquid, had already been introduced to the market. The OFT discussed the relevance of intent. With reference to the GC's decision in *AstraZeneca*, it was found that while intent does not constitute a necessary condition for Article 102 to be applicable, it could be useful to confirm the abusive nature of the conduct.[300]

[300] Ibid, paras 3.45-3.48.

6 Analysis and Concluding Remarks

6.1 A comment on the descriptive parts

The present study was designed to analyse the legality of evergreening of pharmaceutical patents from a competition law perspective. By reviewing the components necessary to make this analysis, namely the pharmaceutical sector, patent law and competition law, it is the author's anticipation that the reader has gained an understanding of the competing policy objectives that needs to be taken into account when discussing whether a certain conduct constitutes an abuse or not. The result of this study indicates that up to today, one cannot fully determine when evergreening is legal and when it is an abuse of a dominant position. The complexity of such an assessment, in combination with the absence of case law, leads to the conclusion that the legal position is unclear. Nonetheless, some comments and suggestions can be made which may be useful when making an attempt to draw the line between lawful use and unlawful abuse. Before moving to this part of the thesis, a few general comments shall be made concerning the findings in the descriptive chapters.

The second chapter dealt with the pharmaceutical industry. Noteworthy is the changing nature of the sector. This was one of the reasons for the Pharma Report in 2009, which suggested that innovation of new pharmaceuticals is on the decline. It is evident that less bestsellers like Losec or Viagra are launched on the market but it is not obvious that innovation has gone down throughout the entire sector. As apparent from this study, biotechnology companies are on the rise. It may be the case that innovation has just moved down a step from the large originators to the small biotechnology companies. Furthermore, incremental innovation seems to be more common. Thus, innovation may still be happening but in other ways than before.

The second chapter also highlighted the need for patent protection in the pharmaceutical sector. One of the sector's defining features is the presence of patents which has to be balanced off against the need to protect the competitive process on the market. These two disciplines are not in conflict. On the opposite, they work in tandem to achieve the same object of promoting consumer welfare and an efficient allocation of resources. What they do is that they seek to meet this object in contrasting ways. Therefore, the aim should be to protect competition from being distorted without strangling the incentives to innovate. In a way, competition law circumscribes intellectual property law and intervenes only when an exclusive right is used to an extent that the law did not intend. Even though it has been concluded that they have share the same aim, the means to that aim are sometimes conflicting which inevitably leads to tensions.

In chapter three, some interesting aspects of the patent law system were discussed. Patents are crucial for the pharmaceutical sector. The most common argument in support of strong patent protection is the need to create incentives to innovate by rewarding the innovator with a patent. The most interesting finding was that patent law itself, usually praised for its ability to stimulate innovation, can be counterproductive and actually impede innovation. Hence, the challenge is to find a balance between over- and under-protection which may be a difficult task for the legislator.

Chapter four dealt with abuse of dominant position. By studying case law on exclusionary abuse, it can be concluded that an undertaking, seen as dominant under Article 102, have a special responsibility to act in a way that does not impair genuine undistorted competition. An abuse within the meaning of Article 102 is established if the conduct departs from normal competition. Normal competition comprises of competition on the merits and, as follows, behaviour outside the scope of competition on the merits is unlawful. Therefore, the important thing to consider is at what point, if at all, a particular behaviour falls outside the scope of competition on the merits. An interesting finding is the EU Courts tendency to define the relevant market narrowly for pharmaceutical products. In the future, this may have the consequence of many originators being dominant which will activate their special responsibility under Article 102.

When tying chapter two, three and four together it seems like the challenge is to balance the policy objectives behind three legal areas: pharmaceutical regulatory law, the patent system and competition law, against each other. The ultimate level is reached when there is incentives to innovate without competition being distorted which eventually leads to greater access to effective and affordable medicine.

6.2 What concerns does evergreening give rise to under Article 102?

The first research question concerned the legality of evergreening in relation to Article 102. By studying case law, it can be concluded that evergreening can be an abuse of dominant position under Article 102, and thus an unlawful practice, even though evergreening practices most definitely balance at the border between lawful conduct and unlawful abuse. There is no single universal formulation to decide when evergreening becomes unlawful, instead the specific circumstances in each individual case will decide where to draw the line. When making this assessment, some factors needs to be taken into account such as the intention of the strategy and if the conduct has a potential or an actual effect on the market. In addition, the Pharma Report provides a useful starting point even if the report does not give any legal certainty or provide any clear guidance on how far a patent holder can go.

A small case study of *AstraZeneca* was provided. The judgment in the GC has met some criticism for setting the bar too low for when a misleading statement to a patent office can be seen as an abuse, while the CJEU's judgment has not yet been commented in academia. The author makes the conclusion that the CJEU was somewhat more cautious when ruling on how far the special responsibility of a dominant company extends and opens up for a more flexible application of Article 102. However, more case law is needed in order for a more certain and accurate statement of the legality of evergreening.

In this essay, three sorts of evergreening practices were presented, namely patent litigation, patent clusters and second generation products. The study was successful as it was able to identify these practices and their anti-competitive effects. First, *patent litigation* was presented. In this section, it was concluded that while the right to bring litigation is fundamental, there are situations in which litigation is anti-competitive and within the scope of Article 102. In order for the action to be abusive, two cumulative criteria need to be fulfilled. First, it is necessary that the action cannot reasonably be considered as an attempt to establish the rights of the undertaking concerned and therefore only serves to harass the opposite party. Second, the action must be a part of a plan whose goal is to eliminate competition. The decisive component that distinguishes anti-competitive litigation from legitimate litigation seems to be intent. In the case referred to in chapter five, *ITT Promedia*, adequate proof of an anti-competitive intent could be found.

Also, *patent clusters* were discussed. From the review in chapter five, it may be assumed that multiple patents, or even just a multitude of pending patent applications, may discourage generic companies from entering the market. Batchelor's critical view on this was presented. He argues that regulating patent portfolios through competition law is "fraught with dangers" and not a task for the Commission. To some extent, this is a valid argument: patent offices are the competent authority to deal with patents. But competition law works as a check on the patent system and intervenes when a patent is abused, why the validity of this argument may be questioned.

Last, *second generation products* were discussed. It can be concluded that incremental innovation as such is fully legitimate and part of the normal competitive process. Furthermore, the launch of a second generation product is lawful and cannot be questioned from a competition law perspective. However, it seems like the measures taken around such a launch can be abusive. One such measure is the promotion and marketing efforts taken by originators around the launch of a second generation product. In chapter two, it was demonstrated that marketing expenditure exceeds expenditure on R&D in the pharmaceutical sector. Hence, a large amount of money is spent on the promotion of pharmaceutical products. Usually these measures are directed directly against doctors with the purpose to facilitate a switch of the doctor's prescription behaviour from the original product to the second generation product. This kind of marketing can be focused on the benefits of the second generation product but also focus on negative marketing of the

original product, both with the aim to prevent generic substitution. In the thesis, this was demonstrated by the fact that the switch often took place in the year before loss of exclusivity of the original product. This shows how the originator company intentionally uses marketing activities to delay or prevent generic entry, which is an indicator of an anti-competitive intent.

Up to today, there is no precedent which condemns marketing of second generation products as forbidden under Article 102, even though it may be concluded that the launch of a second generation product in combination with extensive marketing and promotion efforts raise concerns about its anti-competitive effects. However, it must be questioned whether Article 102 reasonably extends to marketing activities. Any company who wants to make money will do their utmost to make their product known and marketing and promotion efforts could conceivably be within the scope of competition on the merits. But can medicine be compared to any other product? One could argue that the price-disconnect on the pharmaceutical market calls upon a more stringent assessment of marketing and promotion activities when launching a second generation product on the market. If an anti-competitive intent to delay or prevent generic entry can be established, in combination with an actual or a potential effect on the market, it is the author's opinion that it may constitute an abuse under Article 102. The pharmaceutical market cannot, and should not, be compared to markets for other products, for example cars.

6.3 How far can a patent holder go?

The second research question raised the question how far a patent holder can go before he or she infringes competition law. This issue is complex and initially it should be noted that each and every case has its own characteristics to be considered, making it impossible to give a general formulation as to when a patentee has gone too far. Therefore, only a few general assumptions can be made.

The result of this study indicates that the standard for abuse is conduct outside the scope of competition on the merits. But if the alleged undertaking brings arguments and evidence of an objective justification, for example a legitimate business rationale, its behaviour will not be seen as abusive. It is clear from *AstraZeneca* that the burden from pharmacovigilance obligations was not enough for the company's conduct to be lawful. But it may be the case that AstraZeneca failed to show any pro-competitive justifications. In the future, the concept of objective justification may be a safe haven for dominant pharmaceutical companies. For example, the Commission's dedication to a more effects-based approach to competition law enforcement is an indicator of such a scenario. Furthermore, even though not laid down in law, the Courts have opened up a possibility for undertakings in a dominant position, found guilty of abusing their position, to bring forth arguments and evidence that justifies their conduct. Possible justifications are probably economic arguments, for

example the need to recoup investments in R&D but also more general justifications such as the need to protect the company's patent portfolio.

AstraZeneca confirmed that the replacing of a product with a second generation product is not capable of being abusive in itself, though in combination with additional strategies, for example the withdrawal of a marketing authorisation, it may constitute an abuse. In this thesis, such additional strategies have been referred to as switching strategies. This could be illustrated as a "product switching plus." The switch becomes abusive when another element is added which has the intention to hinder competition. This may well be the difference between use and abuse when launching a second generation product. Even though Article 102 does not demand any subjective criteria to be applicable, intention matters when making the assessment of whether a certain conduct is a use or an abuse.

Does Article 102 provide for an adequate medicine to remedy anti-competitive conduct in the pharmaceutical sector? It may be questioned whether the EU authorities have gone too far in their enforcement of the competition rules. Competition law can provide for an adequate remedy in cases evergreening when the abuse is clearly anti-competitive and criteria of Article 102 are fulfilled. However, it is evident that competition law neither can nor should step in to correct imperfections in the patent system. Pharmaceutical patents are complex and their legality should not be reviewed by the CJEU.

6.4 Concluding remarks

As a concluding remark, I would like to give my view on why pharmaceutical companies engage in evergreening and suggest a way forward. The patent system gives a reward for those who innovate by granting a patent. A patent brings along many benefits, especially the exclusive right to exploit the patent, thereby bringing in high profits. In the case study of *AstraZeneca,* it has been showed that a pharmaceutical product may have annual sales reaching around 6€ billion if successful. But innovation in the pharmaceutical industry has declined, with several successful medicines going off patent without being replaced by new bestsellers. The reason for the situation is not obvious and the explanations are probably many. One potential explanation is that medicine for a lot of diseases already has already been invented. The counterargument is obvious: the world is still waiting for a cure against HIV/AIDS and there are countless other diseases, especially in the developing world, that need medicines. Another potential explanation can be the favourable rules that exist for generic companies, making it unprofitable to be a research-based originator company. This may have encouraged originators to make the most out of the patents they already possess by using different patent strategies i.e. evergreening.

The launch of a second generation product may be one such strategy. By investing money into incremental innovation, with the possibility to receive patent protection for another 20 years, an incentive to make smaller improvements to existing products exists. As concluded above, it is not the incremental innovation itself that is unlawful. Neither is it the filing of an application to the patent office that is unlawful, as long as the application is not characterised by highly misleading representations and a manifest lack of transparency, as confirmed by *AstraZeneca*. Rather, it is the measures taken around the launch of the second generation product that is suspicious from a competition law perspective.

Under what circumstances such measures are unlawful under Article 102 has already been discussed. But even if they are lawful from a competition law perspective, it may not be in the interest of society at large. Instead of investing money on new, revolutionary medicine which could save lives, money is invested in incremental innovation which only finds smaller improvements. The author is not denying that such innovation is beneficial. As outlined in this thesis, such innovation may lead to significant improvements of the original product e.g. new therapeutic indications may be discovered, improvements may be done within the same therapeutic indication and the number of medicines within that therapeutic class may expand. But how do we really need pharmaceuticals against everything? And from a more ethical perspective, would it not be better if we found a medicine that could cure millions of people in Africa, instead of a new version of an existing medicine that can be dissolved in water instead of swallowed as a tablet? To be really cynical, some of this research is actually useless and for the wealth of the society it would be better if this innovation were put into real and important research.

Therefore, the author suggests that a reform of the patent system may be a way forward. In this thesis, it has been shown that by raising the bar for patentability, a smaller amount of patents covering minor improvements will be granted. This will reduce the incentives to invest money on incremental innovation focused on minor improvements. Instead, by creating a favourable environment for innovation of medicine for neglected medicine, money will be invested into R&D that society needs. Incremental innovation will still occur: small improvements, for example by introducing a medicine that used to be in tablet form as one dispersible in water, will make the product more competitive and win new market shares without a new patent.

The establishment of a “unitary patent” may have an effect on evergreening. On the one hand, it may encourage some of the unlawful evergreening strategies, but on the other, it may also prevent some of them. First, it is most probable that a unitary patent will make it easier to obtain patent protection for a product. Even though there are ways to obtain a “European patent“ today, this will turn into a bundle of national patents once granted. A simplified patent process where one unitary patent is granted is beneficial for originators, which may affect the generic industry in a pejorative way.

But a unitary patent may also prevent some of the anti-competitive effects of evergreening. In addition to the unitary patent, a unitary patent Court is going to be established. A unitary court could potentially deal with some of the anti-competitive litigation. Furthermore, a judgment in favour of a generic manufacturer is valid for the entire EU, making separate patent processes in each Member State unnecessary. This could reduce litigation costs and potentially provide for a more rapid access to justice.

Another way forward could be the launch of new guidance paper from the Commission, similar to the Guidance on Abusive Exclusionary Conduct, but including the new forms of abuse and *inter alia* evergreening. Even though, as with the present guidelines, this would not constitute a statement of the law, such guidance would provide direction for pharmaceutical companies when using their patent rights.

Patents will be used to their utmost extent, as they have always been, and therefore the law must declare clear rules on when lawful use becomes an unlawful abuse. At this point, Article 102 does not do that. Clearer rules, more case law and and a little common sense is called upon.

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