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Patent Strategies in the Pharmaceutical Industry
Abuse of Dominant Position or a Necessary Feature of IP Law

Bachelor Thesis

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I hereby declare that I am the sole author
of this Bachelor Thesis and it has
not been presented to any other
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Definitions	1
1. Introduction	2
2. Patents and the Pharmaceutical Industry	5
2.1 Features of the Pharmaceutical Market in the EU	6
3. Patent Strategies in the Pharmaceutical Industry	10
3.1 Patent Clusters	12
3.2 Secondary Patents	13
3.3 Defensive Patenting	14
4. Relationship between Competition Law and Intellectual Property Rights	15
4.1 Article 102 TFEU- Abuse of Dominant Position	18
4.2 Application of Art. 102 and the Pharmaceutical Industry	18
5. Generics in the Pharmaceutical Industry.....	27
5.1 Generic Market Entry	29
5.2 Possible problems that Generics pose for Innovation	30
6. Case Law Strategic Patenting.....	33
6.1 Astra Zeneca v Commission.....	33
6.2 Boehringer Ingelheim v Commission	34
6.3 Servier v Commission	34
6.4 SmithKline Beecham v Generics (UK).....	35
7. Conclusion	36
8. Bibliography.....	40

Definitions

“Originators” - Large corporations in the pharmaceutical industry who make the investment in the research and development phase as well as manufacturing of the new drugs. Originators hold multiple patents to the active ingredients of the drugs and to the different processes they were made.

“Generics”- After the expiry of the originator’s patent protection, smaller manufacturing companies copy the drug and produce their own cheaper version of the originator’s drug. These manufacturers are called “generics”, they are able to manufacture relatively cheaply as they do not need to invest in the expensive research and development phase.

“Evergreening”, “Secondary Patents” or “life-Cycle Patents” - All describe the different ways patent owners (originators) try to extend the protection of their IP monopoly by acquiring patents that do not protect the active ingredient in the drug making it effective but instead protect different forms of that drug.

“Patent Clusters”-Patent thickets or clusters are used to defend against competitors designing around a single patent. Originators may file several patents around the original patent in order to prevent the generics “copying” the drugs and creating a group of overlapping IP rights that a company must hack its way through in order to actually commercialise new technology."

“Paraller Importers” - Wholesalers who buy batches of the drug distributing it unlicensed for sale less than the manufacturer’s (originator) official retail price.

“Exhaustion of patents” - Termination of a patent owner’s rights to control the use of the patented product or a process used for making the product.

1. Introduction

Defensive patent strategies are strategies conducted by the patent holders in order to protect their inventions from competitors or prolong the patent's validity. Defensive patenting strategies occur nearly in every industry when undertakings with dominant position are seeking to protect their market monopoly. Pharmaceutical industry among other industries has engaged in such strategies but due to the sensitive nature of the Pharma industry, the EU Commission launched a special inquiry to investigate the alleged anticompetitive nature of the Pharmaceutical industry. In its preliminary and final report back in 2008 and 2009 the Commission identified series of strategies mainly conducted by the originators in order to maintain protection and prolong the life-cycle of its patents. The Interim Report suggested that the common practice of filing so-called 'secondary' patents around the original patent could be anticompetitive, however this position was heavily criticised.¹ The report suggested that secondary patents are of lesser quality compared to primary patents, which protect the active ingredients in the original products.² In the final report of the pharmaceutical sector inquiry, the Commission concluded that merely filing several patents around the same invention is common practice known to all industries and therefore not necessarily problematic strategy as such, thus the concerns on competition should only arise when it has the direct intent to exclude competitors from the market.³

The Thesis will discuss a series of originator patent strategies pointed out by the Commission, which would fall under the scope of 102 TFEU⁴; The creation of "patent clusters" and the general practice of evergreening by filing numerous patents around the active ingredients of them same medicine.⁵ By filing several patents around the original compound, it is far more challenging for other companies seeking to enter the market to harvest the expired patent for their own use. Creation of patent clusters will make it more challenging for the generic companies to develop their own version of the original drug created by the originator companies

¹ David W. Hull, *Journal of European Competition Law & Practice*, *The Application of EU Competition Law in the Pharmaceutical Sector* (2010), Available: <https://doi.org/10.1093/jeclap/lpq043>

² *Ibid.*

³ *Ibid.*

⁴ Treaty on the Functioning of the European Union - Article 102, Abuse of Dominant Position <http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A12008E102>

⁵ Pharmaceutical Sector Inquiry - Preliminary Report (2008), *Fact Sheet on Originator-Generic Competition p.1*, http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/fact_sheet_2.pdf

without infringing any of the patents surrounding the original product.⁶ “Common tactic is to seek additional patent protection in respect of certain aspects or modifications of an already patented product. Examples of this approach, known as life-cycle management or evergreening”.⁷ Prolonging the life-cycle of the patents by using different types of patenting strategies can be considered as common practice within pharmaceutical industry, however the practice could be considered as a consequence resulting from the invention or it could be used for purely extending the life-cycle of the patent⁸ and therefore delay the market entry of the generics who compete with products based on the same original invention.⁹ Filing for patent clusters as well as secondary patents are practices conducted by the originators and mainly aimed at the generics in order to make their entry to the market more challenging. However the pharmaceutical sector inquiry report identified a series of defensive practices between the research-based pharmaceutical companies (originators) as further possible causes for a falling rate of innovation.¹⁰ Defensive patenting between the originators is aimed to block the market access of competing medicines rather than delay the copy of existing medicines. It supposes that an originator company files applications for new patents or maintains patents for innovations merely to eliminate competition without holding any incentive to engage in new research.¹¹

The aim of the thesis is to prove that patent strategies conducted by the originators against generics and other originators should not constitute as an abuse of the EU competition law and particularly Art. 102 of the Treaty on the Functioning of the European Union. The thesis will discuss whether defensive patenting in the pharmaceutical industry is anticompetitive or merely a necessary feature of Intellectual Property law, which in its nature is anticompetitive by granting a monopoly for the IP owner. The thesis will further analyse relevant case law, the patenting

⁶ Pharmaceutical Sector Inquiry - Preliminary Report (2008), *Fact Sheet on Originator-Generic Competition p.1*, http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/fact_sheet_2.pdf

⁷ Brian Whitehead, Stuart Jackson, Richard Kempner; Managing generic competition and patent strategies in the pharmaceutical industry. *Journal of Intellectual Property Law & Practice* (2008) 3 (4): 226-235
Available: <https://doi.org/10.1093/jiplp/jpn013>

⁸ Mike Hutchins, Extending the Monopoly - How Secondary patents can be used to delay or prevent generic competition upon expiry of the basic product patent, *Journal of Generic Medicines* (2003)
Available: <http://journals.sagepub.com/doi/pdf/10.1057/palgrave.jgm.4940018>

⁹ European Commission, Pharmaceutical Inquiry, Final Report, p.13, para 2

¹⁰ European Commission, Pharmaceutical Inquiry, Final Report, p. 17, para 5

¹¹ Stephen Mavroghenis, Article 82 EC and Strategic Patenting - Patent Thickets, Defensive Patents and Follow-on Patents, January (2009) p.4
Available: <http://webcache.googleusercontent.com/search?q=cache:-j09xHJoSrQJ:professorgeradin.blogs.com/files/article-82-and-strategic-patenting---conference-version-2-3.ppt+&cd=1&hl=en&ct=clnk&gl=ee&client=safari>

strategies which fall under Art. 102 of TFEU, as well as aims to display whether strategic patenting is harmful for the consumers by delaying generics market entry.

2. Patents and the Pharmaceutical Industry

Patents are granted following an invention which constitutes as an technological improvement and are in their nature innovative in regards what is previously known.¹² It grants exclusive rights for the patent holder in respect of intellectual property in order to protect and prevent others from harvesting and using the same innovation for the duration of the patent.¹³ The nature and conception of innovative patents portray why they are the most valuable assets of intellectual property and therefore hold the most value in regards of competition.¹⁴

Patents were created to provide effective protection for the new inventions and therefore enhance and develop innovation. Pharmaceutical industry in this regard is no exception compared to other industries. However, there are several unique features in the pharmaceutical industry which sets it apart from the other industries. Research and development phase in the Pharmaceutical industry can be particularly exhausting as it can include years of research and clinical trials. It can be argued that patents hold the key for the functioning of the pharmaceutical industry, which is characterised by long research development phases and long product life cycles. Patents grant the innovator companies an exclusive period to gain remuneration from particular drug innovation, which allows the originators to be rewarded for the risks and efforts taken during the research and development phase.¹⁵ The development phase is particularly risky as most research leads nowhere despite the vast investments and efforts by the originator companies.¹⁶ Despite growing criticism and discussion, no one has ever truly questioned the importance of the patent system for medicines, as it has made the improvements and advances in medical research possible.¹⁷ Therefore it can be argued that without a reliable patent monopoly, there is simply no incentive to invest.¹⁸ In addition to extensive research and development costs, the pharmaceutical

¹² W.Cornish, D.Llewelyn and T.Aplin, *Intellectual Property: Patents, Copyright, Trademarks and Allied Rights* (1981), Sweet & Maxwell Limited London, Seventh Edition , Chapter1, p.7

¹³ *Ibid*, Chapter 1, p.8

¹⁴ *Ibid*, Chapter 1, p.8

¹⁵ Dominik Schnichels, Satish Sule; *The Pharmaceutical Sector Inquiry and its Impact on Competition Law Enforcement. Journal of European Competition Law & Practice* 2010; 1 (2): 93-111. doi: 10.1093/jeclap/lpq001

¹⁶ Robin Jacob, a Judge of the Court of Appeal of England and Wales (2009), a Paper given on 29th November at the Presentation of the Directorate-General of Competition's Preliminary Report of the Pharma-sector inquiry, p.6

¹⁷ Robin Jacob, a Judge of the Court of Appeal of England and Wales (2009), a Paper given on 29th November at the Presentation of the Directorate-General of Competition's Preliminary Report of the Pharma-sector inquiry, p.4

¹⁸ *Ibid*, p.4

industry also has unique features relating to its innovations, it doesn't only produce products of merely monetary value. Medicines are used for health care and can have serious implications and consequences on public health. Therefore with longer R&D phase compared to other industries, even waiting for the approval of the product can take significant amount of time. The process of the discovery, production and distribution of invented drugs differentiates the pharmaceutical industry from any other industry.¹⁹ In comparison to other markets, the pharmaceutical market can be considered as highly fragmented one as individual products such as drugs that are used to treat rare diseases "orphan drugs" can hold very little market share compared to the drugs used for larger amounts in the national markets, thus the Pharmaceutical market comprises companies varying in size and some companies cover markets outside the European Union as well.²⁰

2.1 Features of the Pharmaceutical Market in the EU

Due to its sensitive nature, the pharmaceutical industry in the EU is highly regulated. The pharmaceutical sector holds great importance for the public as it provides access to innovative, safe and affordable medicines.²¹ The pharmaceutical industry is far more profitable than any other sector of the manufacturing industry.²² The EU Commission's final report on the Pharmaceutical sector inquiry further stated that "in 2007, the market for prescription and non-prescription medicines for human use in the EU was worth over € 138 billion ex-factory and € 214 billion at retail prices".²³ The pharmaceutical market thus accounted for close to 2 per cent of annual EU GDP.²⁴ The Pharmaceutical market consists of several actors including the originators who engage in the research and development, the companies who are considered as the multinational players in the industry leading the innovation, development and marketing of the new drugs. Their products are widely protected by several patents to ensure compensation for

¹⁹ Subseries I: Impact on manufacturing, Vol 2: Pharmaceutical Products, The pharmaceutical sector in the EU (1997), The Single Market Review, p.99

²⁰ Nicoletta Tuominen, *Patenting Strategies of the EU Pharmaceutical Industry Crossroad between Patent Law and Competition Policy* (2011), Research paper in law, College of Europe, p.3, para 2 Available: <http://aei.pitt.edu/44320/>

²¹ Dominik Schnichels, Satish Sule; The Pharmaceutical Sector Inquiry and its Impact on Competition Law Enforcement. *Journal of European Competition Law & Practice* 2010; 1 (2): 93-111. doi: 10.1093/jeclap/lpq001

²² Commission Communication, of 8 July 2008, Executive Summary of the Pharmaceutical Sector Inquiry Report, p. 1. Available at: http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/communication_en.pdf

²³ *Ibid.*

²⁴ Dominik Schnichels, Satish Sule; The Pharmaceutical Sector Inquiry and its Impact on Competition Law Enforcement. *Journal of European Competition Law & Practice* 2010; 1 (2): 93-111. doi: 10.1093/jeclap/lpq001

the research and development efforts as well as awarding for the risks taken, depending on the commercial success of the invented drug.²⁵ Generics, who are the manufacturers of the “generic drugs” meaning the drugs made based on the original product created by the originator, after the expiry of the originators patent can be considered as important players in the industry on the part of the public, as they can undercut the price of the medicines ones gaining an access to the market. Parallel importers are wholesalers who purchase batches of the originators products reselling it at varying prices across the EU, gaining considerable profits without the burden of manufacturing and the R&D costs. However, both of these groups represent a problem for the originators as parallel importers and generics are both competitors gaining profits without the long research and development period, clinical trials and not having to wait for the drug approval from the relevant authorities.

Whereas the manufacturers of “generics”²⁶ can play a significant role in the European pharmaceutical markets, their market shares vary greatly between the Member States of the European Union.²⁷ In addition the generic companies have a completely different cost structure compared to the originators, who spent on average 17 per cent of their turnover from prescription medicines on R&D (of which 1.5 per cent went into basic research and 15.5 per cent into clinical trials/approval procedures) and 23 per cent was spent on advertising and marketing duties.²⁸ Whereas the generic companies spent most on manufacturing (51 per cent) and R&D (7 per cent).²⁹ This displays the problem related to the industry. Whereas there is no question that generic companies are vital in balancing and lowering the prices in the pharmaceutical industry, which has an positive impact on the public and consumers, providing necessary competition in the industry dominated by patent owner monopolies, it can alternatively impact the incentive to invest in new drug research and development. Originators engage in certain patent strategies in order to prevail their market monopoly and enhance the patents life-cycles. This can lead to

²⁵ Dominik Schnichels, Satish Sule; The Pharmaceutical Sector Inquiry and its Impact on Competition Law Enforcement. *Journal of European Competition Law & Practice* 2010; 1 (2): 93-111. doi: 10.1093/jeclap/lpq

²⁶ “Generics are usually produced by a manufacturer who is not the inventor of the original product, and are marketed when intellectual property protection rights are exhausted. “ European Federation of Pharmaceutical Industries and Associations: The Pharmaceutical Industry in Figures (2016), p. 17. Available: <http://www.efpia.eu/uploads/Modules/Documents/the-pharmaceutical-industry-in-figures-2016.pdf>

²⁷ Nicoletta Tuominen, *Patenting Strategies of the EU Pharmaceutical Industry Crossroad between Patent Law and Competition Policy* (2011), Research paper in law, College of Europe, p.4, para 1 Available: <http://aei.pitt.edu/44320/>

²⁸ Dominik Schnichels, Satish Sule; The Pharmaceutical Sector Inquiry and its Impact on Competition Law Enforcement. *Journal of European Competition Law & Practice* 2010; 1 (2): 93-111. doi: 10.1093/jeclap/lpq

²⁹ *Ibid.*

delays in generic entry to the market as patent clusters or secondary patents are aimed to protect the original compound of the drug, making it harder for the generics to “copy” the original drug without infringing the patent holders other intellectual property rights. Delays of the generic market entry can have a significant impact economically as the market prices of the generic drugs can be up to 25% lower compared to the prices of the original drugs before the expiry of the patents.³⁰ However, the pricing in the pharmaceutical sector is unique in its nature. Patients do not directly make decisions based on the products but the responsibility lies on the prescribing doctors or pharmacists.³¹ The costs of the drugs is usually never covered by the individual patients themselves, nor the health care professionals but the costs are covered by national health care or insurance companies.³² In addition the regulation of the drug prices are not solely decided by the pharmaceutical companies but are the result of negotiations between national health care administrations and pharmaceutical companies, with cases where countries have free pricing the prices are dependent on the reimbursement status.³³ Significant portion of the pharmaceutical industry’s customers consist of member state’s governments.³⁴ Therefore achieving a fully competitive market in the pharmaceutical industry is rather difficult as the prices are controlled by the authorities limiting the full competitiveness of the industry.³⁵ The Commissions sector inquiry back in 2007 took closer look to the pharmaceutical industry to investigate its anticompetitive features. The Commission was particularly concerned about the patent strategies conducted by the originators in order to delay or block the market entry of the generics. As discussed above the Pharma industry has several unique features compared to other industries, including its products, pricing, R&D and importance to the general public. However, whereas the Commission pointed out in its preliminary report in 2008 that patenting strategies conducted by the originators is a cause of concern down to its anticompetitive nature and possible negative

³⁰ Commission Communication, supra note 8, p. 9.

³¹ Dominik Schnichels, Satish Sule; The Pharmaceutical Sector Inquiry and its Impact on Competition Law Enforcement. *Journal of European Competition Law & Practice* 2010; 1 (2): 93-111. doi: 10.1093/jeclap/lpq

³² In line with the jurisprudence of the ECJ certain public health schemes cannot be considered to be undertakings in the sense of Art. 81 and 82 EC, see in particular ECJ, Judgment of 11 July 2006 in *Federación Española de Empresas de Tecnología Sanitaria (FENIN) v Commission*, Case C-205/03 P, 2006 ECR I 6295, para. 26; and ECJ, Judgment of 16 March 2004, *AOK Bundesverband and Others v Ichthyol-Gesellschaft Cordes, Hermani & Co. and Others*, Joined Cases C-264/01, C-306/01, C-354/01 and C-355/01, 2004 ECR I 2493, paras. 51ff.

³³ Dominik Schnichels, Satish Sule; The Pharmaceutical Sector Inquiry and its Impact on Competition Law Enforcement. *Journal of European Competition Law & Practice* 2010; 1 (2): 93-111. doi: 10.1093/jeclap/lpq

³⁴ *Ibid.*

³⁵ Russell Game Hunter, *The pharmaceutical Sector in the European Union: Intellectual Property Rights, Parallel Trade and Community Competition Law*, Juristförlaget, Stockholm, (2001) p.5

effects on the public. In 2009 final report the commission approached the issue with much more neutral and balanced tone, identifying the different strategies between the actors in the Pharma Industry.

3. Patent Strategies in the Pharmaceutical Industry

In 2007 the European Commission launched a sector Inquiry to the Pharmaceutical Industry to investigate whether the competition policy of the EU is infringed within the industry. The Commission identified several “tool-box” strategies conducted mainly by the originators in order to protect their inventions and prolong the life-cycle of their patents. These practices can delay the generic medicines entry to the market and lead to prolonged higher prices of medicines and consumers having less variety to choose from. The instruments consists of:³⁶ Strategic Patenting, Patent disputes and litigation, patent settlements, interventions before national regulatory authorities and life-cycle strategies and follow on products.³⁷ This paper will discuss strategies that fall under the scope of Art. 102 of TFEU abuse of dominant position as some of the strategies identified fall under the scope of Art. 101 TFEU. The strategies being included are the following; strategic patenting, the creation of “patent clusters” or “patent thickets”. Which consists of the filing of numerous additional patents to the same medicine.³⁸ Clusters of patents around the actual innovation in the drug makes it more challenging for the generic companies to identify and develop their own version of the drug, even though if the patents protecting the actual innovation has already expired.³⁹ Another strategy identified as a popular practice is secondary patenting, secondary patents do not protect the active ingredient within the drug but instead the dosage regimes, different physical forms and other formulations.⁴⁰ Therefore it is argued that secondary patents can be considered as weaker patents compared to the original ones.⁴¹ Whereas patent clusters and secondary patenting are strategies conducted by the originators against the generics, defensive patenting is a strategy against other originators. in the pharmaceutical industry. The Commission’s inspection concerning the pharmaceutical industry recognised originator research companies engaging in defensive patenting strategies that are not used for further development and innovative purposes but instead to block the development of

³⁶ Pharmaceutical Sector Inquiry - Preliminary Report (2008), *Fact Sheet on Originator-Generic Competition* p.1, http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/fact_sheet_2.pdf

³⁷ *Ibid.*

³⁸ *Ibid.*

³⁹ *Ibid.*

⁴⁰ *Ibid.*

⁴¹ Pharmaceutical Sector Inquiry - Preliminary Report (2008), *Fact Sheet on Originator-Generic Competition* p.2, http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/fact_sheet_2.pdf

the rival company's new product.⁴² The inquiry suggested that the purpose of the filing of the patents is not to develop the patents for further purposes or use them for the improvement of the drugs but rather eliminate competition from other large research based companies in the industry. The Commission argued that there is a rather clear indication by the presented data that patent strategies are pursued with the intention to specifically block competition in the industry and constitute as a possible abuse of the IP rights granted and dominant position, even though it is recognised that holding a dominant position or total monopoly itself does not constitute as an abuse of competition policies. Dominant position according to the EU law can be seen as a position of significant economic strength held by an undertaking, which enables the effective prevention of competition within the specific market and offers the dominant position holder the freedom to act independently from its consumers and competitors.⁴³ Although the Commission does recognise the patents as a key element in the pharmaceutical sector as they allow the innovator and research based companies to gain remuneration to cover their expensive research and investment efforts.⁴⁴

A patent grants its owner or the licensee an exclusive right to his innovation for the duration of 20 years in exchange for the research and efforts made in order to acquire and discover such invention.⁴⁵ However, it has become increasingly popular for the innovator companies to seek to prolong the duration of the patent protection that they were initially granted. In order to achieve the extended life-cycle of the patent, the companies engage in the strategic patenting practice of Evergreening, which can be described in the following way: "Evergreening refers to different ways wherein patent owners take undue advantage of the law and associated regulatory process to extend their IP monopoly particularly over highly lucrative blockbuster drugs by filing disguised/ artful patents on an already patent-protected invention shortly after expiry of the parent patent. These artful patents tend to protect delivery profiles, packaging, derivatives and

⁴² Pharmaceutical Sector Inquiry - Preliminary Report (2008), *Fact Sheet on Originator-Originator Competition* p.1, http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/3_Originator_Originator_competition.pdf

⁴³ Case-27/76, *United Brands Company and United Brands Continental BV* (1978) paragraph 65, and Case 85/76, *Hoffmann-La Roche & Co. AG v Commission of the European Communities*, (1979) paragraph 38.

⁴⁴ European Commission, *Pharmaceutical Sector Inquiry Preliminary Report* (DG Competition Staff Working Paper), of 28 November 2008, p. 5. Available at: http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/preliminary_report.pdf

⁴⁵ Nicoletta Tuominen, *Patenting Strategies of the EU Pharmaceutical Industry Crossroad between Patent Law and Competition Policy* (2011), Research paper in law, College of Europe, p.13, para 2 Available: <http://aei.pitt.edu/44320/>

isomeric forms, mechanism of action, dosing regimen, and dosing route, and dosing route, different methods of treatment, combinations, screening methods, biological targets and field of use for the same old molecule”⁴⁶

3.1 Patent Clusters

Patent clusters are considered as patents that are filed around the original molecule patent in order to protect it and make it more challenging for the competitors to obtain the compound for their own use after the expiry of the original primary patent.⁴⁷ The patents surrounding the original patent can differ from each other some being considered as stronger and some weaker than the others.⁴⁸ Patent clusters are also referred to as filing divisional patent applications to surround and provide the original product with protection in order to protect it from competitors. The strategy is usually conducted by the originator companies against the generic manufacturers in the pharmaceutical industry. Patent clusters or alternatively patent thickets have the purpose of enhancing the originator company’s intellectual property rights in order to protect the original patent, which raises uncertainty of the originator’s actual IP rights for the generics when trying to access the specific market.⁴⁹ Consequently this makes it much more difficult for the generics to determine whether any of the surrounding patents will be infringed in the process of obtaining the original compound.⁵⁰ Therefore the generics are left with the choice of waiting until all the surrounding patents have expired as well or to proceed and apply for marketing authorisation and therefore run the risk of court action taken by the originator companies.⁵¹ When patent clusters are built around new innovative technologies it can be referred to as similarly a blanket or floor strategy, where research is conducted on the purpose of methodically researching an entire technology area surrounding the ultimate research goal and then creating a patch of medium

⁴⁶ Inderjit Singh Bansal, Deeptymaya Sahu, Gautam Bakshi, Sukhjeet Singh, *Evergreening- a Controversial Issue in the Pharma Milieu*, July (2009) *Vol. 14 Journal of International Property Rights*, Panacea Biotec Ltd, Formulation & Research Facility, p. 299.

Available: <http://nopr.niscair.res.in/bitstream/123456789/5212/1/JIPR%2014%284%29%20299-306.pdf>

⁴⁷ Stephen Mavroghenis, Article 82 EC and Strategic Patenting - Patent Thickets, Defensive Patents and Follow-on Patents, January (2009) p.4

Available: <http://webcache.googleusercontent.com/search?q=cache:-j09xHJoSrQJ:professorgeradin.blogs.com/files/article-82-and-strategic-patenting---conference-version-2-3.ppt+&cd=1&hl=en&ct=clnk&gl=ee&client=safari>

⁴⁸ *ibid.* p.5

⁴⁹ *ibid.* p. 7

⁵⁰ *ibid.*

⁵¹ European Generic Association, Evergreening of Pharmaceutical Market Protection.

Available at: <http://www.egagenerics.com/gen-evergrn.htm>

scope of patents covering each are of the technology in order to extend the protection for the innovation.⁵² The research team creating the patent clusters can gain exclusivity as the published patent applications become prior art against others, therefore the research team can prevent themselves from being cut out of the technology of other patents.⁵³

3.2 Secondary Patents

Within the pharmaceutical industry it is estimated that 87 per cent of the originator companies use follow-on patenting practices.⁵⁴ Like patent thickets, secondary patenting is a strategy mostly conducted by the originator research companies against the generic manufacturers. Secondary patents can be also referred to as reformulations or second generation patents following the primary patents. Secondary patents or follow-on patents aim to extend the protection for the patent of the original compound by seeking new ways to reformulate them and therefore increase the life-cycle of the drug.⁵⁵ The Commission was particularly concerned about the quality of the secondary patents as they are not seen as “strong” and valuable as primary patents are considered to be. It was discovered that in several cases some originator companies tried to replace a patient’s medicine facing a loss of patent exclusivity to a second generation reformulation compound of the same drug in order to keep their product in use.⁵⁶ There are several methods used when engaging in secondary patenting including “seeking possible subsequent patents on derivatives of existing drug, altering the mixture of isomers, identifying compounds with the same molecular formula but different structural formulas or patenting methods of administration of an existing drug”.⁵⁷ The usual strategy in the pharmaceutical industry is to file many broad initial applications and later surround them with secondary applications.⁵⁸ It can be argued that the practice of secondary patenting is merely a product of innovation where the innovators seek to

⁵² Michael A. Gollin, *Driving Innovation- Intellectual Property Strategies for a Dynamic world* (2008), Cambridge University Press, New York, p.173, para 4

⁵³ *Ibid.*

⁵⁴ Mari Minn; *Strategic patenting decisions in the European pharmaceutical industry: the use of divisional applications and follow-on patenting practices*. *Journal of Intellectual Property Law & Practice* 2016; 11 (8): 619-627. <https://doi.org/10.1093/jiplp/jpw099>

⁵⁵ Mari Minn; *Strategic patenting decisions in the European pharmaceutical industry: the use of divisional applications and follow-on patenting practices*. *Journal of Intellectual Property Law & Practice* 2016; 11 (8): 619-627. <https://doi.org/10.1093/jiplp/jpw099>

⁵⁶ Pharmaceutical Sector Inquiry - Preliminary Report (2008), *Fact Sheet on Originator-Generic Competition* p.5, http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/fact_sheet_2.pdf

⁵⁷ Pratima Bhat, *Overview on Patent Evergreening*, MMS Holdings Incorporation, July (2012) Available: <http://www.mmsholdings.com/mms-blog/drug-patent-evergreening-an-overview/>

⁵⁸ M Hutchins, ‘Extending the Monopoly, *How Secondary Patents Can be Used to Delay or Prevent Generic Competition upon the Expiry of the Basic Product Patent*’ (2003) 1(1) *J Generic Medicines* 57–71.

protect their innovations but on the other hand secondary patents can be used purely to extend the market exclusivity period and consequently manage to create legal uncertainty among the competitors.⁵⁹

3.3 Defensive Patenting

As discussed previously, there are several existing strategies conducted by the originators against the generic manufacturers of the industry. What the Commission was initially concerned about was patenting strategies conducted for tactical reasons.⁶⁰ However the originators engage in so called defensive patenting strategies against the other originators with the purpose of blocking competition from competing products.⁶¹ Several defensive practices by the originators were identified in the pharmaceutical sector inquiry and this was considered as a contributing factor for the falling rate of innovation.⁶² The report suggested that originator companies file patent applications for further protection for innovations without any intention of further development and possible research.⁶³ This kind of practice with malicious intent against the competitors could possibly constitute as an abuse of competition law policy according to the Commission.

⁵⁹ *Ibid.*

⁶⁰ Paul England, European Intellectual Property Review, *Recent Developments in pharmaceutical secondary patents in the light of the Commission's inquiry in to the pharmaceutical sector*, (2011) Sweet & Maxwell and its Contributors, p.5, para 5

⁶¹ European Commission, Final Report, p. 17

⁶² *Ibid.*

⁶³ Stephen Mavroghenis, Article 82 EC and Strategic Patenting - Patent Thickers, Defensive Patents and Follow-on Patents, January (2009) p.8
Available: <http://webcache.googleusercontent.com/search?q=cache:-j09xHJoSrQJ:professorgeradin.blogs.com/files/article-82-and-strategic-patenting---conference-version-2-3.ppt+&cd=1&hl=en&ct=clnk&gl=ee&client=safari>

4. Relationship between Competition Law and Intellectual Property Rights

Competition law and the Intellectual Property Rights can be regarded as opposites considering their nature and initial purpose. The purpose of competition law is to regulate and effectively prevent abusive measures in the EU by limiting anticompetitive agreements and preventing abuse of dominant position within the market.⁶⁴ Whereas intellectual property serves the purpose of granting the inventor exclusive IP rights over the invention, therefore providing a possible monopoly in the market. In the European Union and under the EC law the balance between competition law and intellectual property rights (IPR) has been shaped by the structure of the EC Treaty and the interpretation it has been given by the Community Courts and the European Commission.⁶⁵ Generally, the rules provided in the Treaty do not interfere with the normal use of the intellectual property rights.⁶⁶ In the EU case of *Volvo*⁶⁷, the Court concluded that in order to detect abusive conduct “additional factor” was required with the attempt to eliminate competition of other manufactures in respect of the protected product since that corresponds to the substance of the professional right.⁶⁸ In the EU case of *Magill*⁶⁹, it was concluded that before the intellectual property rights can be considered as contrary to the Articles of the Treaty, “Exceptional” circumstances must be recognised and found in that case.⁷⁰ The emphasis in the EU law has been on the intellectual property rights rather than on competition law for the very reason as it is vital that those rights are protected to uphold innovation and the incentive to invest in it. The CJEU has regularly held that in case of IPR and competition law being in conflict, it is important that the IPRs override the competition rules.⁷¹ EU case law consequently has attempted to strike a balance between intellectual property rights and competition law. In cases

⁶⁴ Steven D. Anderman, *EC Competition Law and Intellectual Property Rights* (1998), Oxford University Press, Oxford, p.8

⁶⁵ *Ibid.*

⁶⁶ *Parke Davis v. Probel* (1968) ECR55; *Deutsche Grammophon* (1974) ECR 1147.

⁶⁷ *Volvo v. Veng (UK) Ltd.* (1988) ECR 299.

⁶⁸ Steven D. Anderman, *EC Competition Law and Intellectual Property Rights* (1998), Oxford University Press, Oxford, p.9

⁶⁹ *RTE v. Commission* (1995) ECR I-743

⁷⁰ Steven D. Anderman, *EC Competition Law and Intellectual Property Rights* (1998), Oxford University Press, Oxford, p.9

⁷¹ *Ibid.*

such as *Volvo v Erik Veng*⁷², *Magill*⁷³, *IMS Health*⁷⁴, and more recently *Microsoft*⁷⁵, the European Commission and the Court of Justice of the European Union sought to limit the scope of exercise of IP rights in order to ensure that competition in the internal market is not distorted and would function properly.⁷⁶ Therefore the result of setting up these particular standards regarding healthy competition was the creation of the notion “exceptional circumstances”⁷⁷ which stated that only in rare and exceptional circumstances could competition law intervene against the IP holders rights.⁷⁸

Therefore it can be argued that the general standard that the EU law has established through relevant case law seeks to prevail the rights of an IP holder and only in situations where the infringement of competition law is so obvious and has exceptional nature, only then it should surpass intellectual property rights. Companies holding a dominant position within the market may conduct their business efficiently and keep down the prices as well as maintaining or improving the quality of the product.⁷⁹ Therefore it can be argued that the existence of a dominant position may have positive impact on economy as the companies would be able to engage in more venturesome research and development policy compared to undertakings not holding a dominant position within the market.⁸⁰ Moreover, whilst the fact that an undertaking is in a dominant position cannot deprive it of its entitlement to protect its own commercial interests when they are attacked, and whilst such an undertaking must be allowed the right to take such reasonable steps as it deems appraise to protect those interests, such behaviour will not be allowed if its purpose is to purely strengthen that dominant position and thereby abuse it.⁸¹ This particular approach suggests that as long as the company seeks to protect its own commercial

⁷² *Volvo v. Veng (UK) Ltd.* (1988) ECR 299.

⁷³ *RTE v. Commission* (1995) ECR I-743

⁷⁴Case C-418/01 *IMS Health Inc. v Commission* [2004] ECR I-5039.

⁷⁵Case T-201/04 *Microsoft Corp. v Commission of the European Communities.*

⁷⁶Piotr Staniszewski; The interplay between IP rights and competition law in the context of standardization. *Journal of Intellectual Property Law & Practice* 2007; 2 (10): 666-681. doi: 10.1093/jiplp/jpm143

⁷⁷Paras 49 and 50, 53–56 of *Magill* (see note 2).

⁷⁸Piotr Staniszewski; The interplay between IP rights and competition law in the context of standardization. *Journal of Intellectual Property Law & Practice* 2007; 2 (10): 666-681. doi: 10.1093/jiplp/jpm143

⁷⁹Alan Dashwood, Michael Dougan, Barry Rodger, Eleanor Spaventa and Derrick Wyatt, *Wyatt and Dashwood’s European Union Law* (2011), Hart publishing, Portland Oregon, sixth edition, p.767, para 3

⁸⁰Alan Dashwood, Michael Dougan, Barry Rodger, Eleanor Spaventa and Derrick Wyatt, *Wyatt and Dashwood’s European Union Law* (2011), Hart publishing, Portland Oregon, sixth edition, p.767, para 4

⁸¹Case 27/76 *The United Brands Company v Commission* (1978) ECR 207, para 189, (1978) 1 CMLR 429

interests it does not necessarily constitute as an abuse of dominant position and Article 102 of TFEU. Ultimately, the companies within the pharmaceutical industry seek to protect their IP rights of their products by engaging in patenting strategies to prolong the life-cycle of the primary patents. Whether the originator companies have an intent of abusing their dominant market position when engaging in strategic patenting or simply an intent to protect their commercial interest is very hard, if not impossible to determine, however, the latter being more likely.

4.1 Article 102 TFEU- Abuse of Dominant Position

“Article 102 TFEU (formerly Article 82 EC, and hereinafter referred to as Article 102) prohibits abuses by dominant firms, individually or collectively”.⁸² Article 102 of the Treaty deals with the conduct of one or more economic operators consisting in the abuse of a position of economic strength which enables the operator concerned to hinder the maintenance of effective competition in the relevant market by allowing it to behave to an appreciable extent independently of its competitors, its customers and ultimately consumers.⁸³

4.2 Application of Art. 102 and the Pharmaceutical Industry

As discussed above, it is determined through the EU case law that simply holding a dominant position in the market does not in itself constitute as an abuse of the Art.102 of the TFEU. Many of the pharmaceutical companies hold a dominant position in the pharmaceutical industry in some regard; when possessing a patent for a particular drug it in itself grants a monopoly for the company. Patents exist in order to create an incentive for innovation, when companies such as pharmaceutical companies have spent significant amounts of resources and time for research and development activities and innovation in general, it is crucial that they will be compensated for their efforts in order to enhance innovation and provoke similar behaviour.

Patents are granted in order to promote innovation, which can be seen to serve the public’s interest. Patents can be considered to play an increasingly important role regarding innovation and economic performance.⁸⁴ Merely holding a patent over an invention and exercising the IP rights granted regarding the invention, does not make the patentee a monopolist nor is it considered as an abusive by principle.⁸⁵ When patent holders are granted adequate compensation for their efforts and strong enforcement of intellectual property rights the progress of the technology and industries and willingness to invest in innovation will be supported. Especially in the pharmaceutical industry due to its sensitive and ethical nature of creating medicines for human consumption and health care, preserving innovation is crucial and is considered to serve

⁸² Alan Dashwood, Michael Dougan, Barry Rodger, Eleanor Spaventa and Derrick Wyatt, Wyatt and Dashwood’s European Union Law (2011), Hart publishing, Portland Oregon, sixth edition, p.765, para 1

⁸³ Joined Cases C-395/96P and C-396/96P *Compagnie Maritime Belge Transports, Compagnie Martine Belge SA and Dafra Lines A/S v Commission* (2000) ECR I-1365, para 34; (2000) CMLR 1076

⁸⁴ OECD, Patents and Innovation: Trends and Policy Challenges, (2004), OECD Publications, 2 rue André-Pascal, 75775 Paris Cedex 16, France, p. 5 para 1

⁸⁵ Alison Jones, Brenda Sufrin, EC Competition Law, Oxford, Oxford University Press, 2007, p. 554.

the public interest and society. It has become increasingly important to seek definition when the practice of intellectual property rights can turn damaging for the consumers.⁸⁶ However, “over the past several decades, antitrust enforcers and the courts have come to recognise that intellectual property laws and antitrust laws share the same fundamental goals of enhancing consumer welfare and promoting innovation”.⁸⁷

In the Commission’s inquiry of the pharmaceutical sector several patenting strategies conducted by the originator companies were identified, in order to delay the market entry of generics or to block the development of drugs by the competing originators by engaging in defensive patenting strategies. The sector inquiry mainly focused on two issues: (1) Are there obstacles to market entry for generic companies caused by practices of originator companies? and (2) are there obstacles to market entry for originator companies caused by practices of competing originator companies?⁸⁸ As discussed earlier strategies related to the entry of generics included patent thickets and secondary patenting. Whereas originators engaged in defensive patenting strategies against other originators.

However the fact whether patenting strategies directly harm the consumers remains unclear from the inquiry.⁸⁹ Also according to the Commissions final report the delayed generic entry to the market due to originator’s patent strategies did not seem as significant as portrayed in the preliminary report. Originator industry representatives, which mainly consisted of representatives of law firms and patent attorneys argued that the Preliminary Report by the Commission did not provide any substantial evidence that the originator companies practices would hinder innovation, which would lead to a decline in innovation.⁹⁰ In addition they argued “that delays to generic entry cannot be attributed to the behaviour of originator companies but consider factors related to the regulatory framework to be most important delays”.⁹¹ The

⁸⁶ Richard Whish, David Bailey, *Competition Law*, Oxford, Oxford University Press (2008), p.758, p.759, sixth edition

⁸⁷ U.S Department of Justice and the Federal Trade Commission, *Antitrust Enforcement and Intellectual Property Rights: Promoting Innovation and Competition*, (2007) April, p.1 www.usdoj.gov/atr/public/hearings/ip/222655.pdf

⁸⁸ Pharmaceutical Sector Inquiry - Final Report (2009) p.16, para 1

⁸⁹ Nicoletta Tuominen, *Patenting Strategies of the EU Pharmaceutical Industry Crossroad between Patent Law and Competition Policy* (2011), Research paper in law, College of Europe, p.25, para 3 Available: <http://aei.pitt.edu/44320/>

⁹⁰ Pharmaceutical Sector Inquiry - Final Report (2009) p.18, para 1

⁹¹ Pharmaceutical Sector Inquiry - Final Report (2009) p.18, para 1

European Patent Office provided input on the functioning of the European patent system and drew attention to the line between intellectual property law and competition law as drawn by the CJEU previously.⁹² “In particular, it argued against a scrutiny of the intent of applicants in applying for patent rights for purposes of competition law”.⁹³

However, it can be argued that the Commission did not have a clear case regarding the supposedly malicious intent behind the patent applications as it remained unclear regarding the report. The scrutiny and general attitude towards the pharmaceutical industry specifically along with the inspection by the Commission can be perhaps explained by the delicate nature of the industry.⁹⁴ As the pharmaceutical industry develops and provides medicines for the human consumption it is possibly presumed to offer morally greater standards in comparison to other industries due to its nature.⁹⁵ However it should be emphasised that even though pharmaceutical companies produce medicines as their primary products, their investments to research and development can be considered as a positive effort for the public, without denying that all drug companies are commercial companies seeking to make the most profit.

“During the period 2000 and 2007 originator companies spent on average 17% of their turnover from prescription medicines on R&D worldwide, approximately 1.5% of turnover was spent on basic research – research to identify potential new medicines, the remaining part mostly on (pre-) clinical trials and tests”.⁹⁶ In 2004 the European Federation of Pharmaceutical Industries and Associations (EFPIA) stated that during the passed years the regulatory authorities had accepted extremely low number of new chemical entities.⁹⁷ There were several possible reasons for the diminishing numbers indicated by EFPIA within the report especially within the EU, “the need to generate increasing amounts of data before and after the approval of a new medicine, the

⁹² Pharmaceutical Sector Inquiry - Final Report (2009) p.18, para 2

⁹³ Pharmaceutical Sector Inquiry - Final Report (2009) p.18, para 2

⁹⁴ Dominik Schnichels, Satish Sule; The Pharmaceutical Sector Inquiry and its Impact on Competition Law Enforcement. *Journal of European Competition Law & Practice* 2010; 1 (2): 93-111. <https://doi.org/10.1093/jeclap/lpq001>

⁹⁵ *ibid.*

⁹⁶ Pharmaceutical Sector Inquiry - Preliminary Report, (2008), p.6, para 5

⁹⁷ EFPIA Position Paper on Barriers to Innovation in the Development of New Medicines in Europe and Possible Solutions to Address these Barriers, November (2004)
Available: <http://plg-group.com/wp-content/uploads/2014/03/Barriers-to-Innovation-in-the-Development-of-New-Medicines-i.pdf>

difficulty of conducting clinical research, the lack of predictability in the operating environment, the slow uptake of new medicines and lack of recognition of the value of incremental innovation, the public understanding and acceptance of science, and the need for support at early stage research”.⁹⁸ The Commission recognised that in order to produce a new medicine, it requires a significant amount of research and development, clinical trials and due to the technological development it has become more challenging to come up with new compounds and so called “bluckbuster” products.⁹⁹ It is therefore no surprise that originator companies, who are the multinational players and the ones taking the burden of the R&D, want to protect their IP rights for as long as possible as engaging constantly in new research includes high failure rates and risks. Investments, especially in research can be considered risky in very nature as most of the research efforts leads nowhere, therefore the ones who succeed must carry the burden of the risks taken for the ones who don’t.¹⁰⁰ In addition in the recent years the number of important drugs coming forward seems to be diminishing.¹⁰¹ Therefore it can be concluded that to enhance and promote innovation, adequate compensation for the efforts of the research based companies needs to be secured in order to prevail innovation. Whereas the time for the exclusivity of the patent is generally 20 years, the time of true monopoly is likely to be very limited and can last a lot shorter period of time.¹⁰² In reality a new drug is unlikely to get more than 10 or 11 years even with the supplementary protection system.¹⁰³ The short protection period may explain the popularity of the practice of evergreening, however it is most likely that the practice would be conducted regardless of the duration of the patent protection period.¹⁰⁴ Therefore it can be argued that flaws can be found in the protection system of the intellectual property rights or at least room for improvement. As stated previously, the EU case law has provided that unless exceptional circumstances are found, simply having a monopoly and the companies protecting their own commercial interests through the exercise of acquiring IP rights for themselves, that in itself does not constitute as an infringement of Art.102 of TFEU. Quite the contrary as strong

⁹⁸ Pharmaceutical Sector Inquiry - Final Report (2009) p.34, para 1

⁹⁹ *Ibid.* p.34, para 1

¹⁰⁰ Robin Jacob, a Judge of the Court of Appeal of England and Wales (2009), a Paper given on 29th November at the Presentation of the Directorate-General of Competition’s Preliminary Report of the Pharma-sector inquiry, p.4

¹⁰¹ *Ibid.*

¹⁰² Robin Jacob, a Judge of the Court of Appeal of England and Wales (2009), a Paper given on 29th November at the Presentation of the Directorate-General of Competition’s Preliminary Report of the Pharma-sector inquiry, p.4

¹⁰³ *Ibid.* supra note 7

¹⁰⁴ *Ibid.* Suppra note 7

enforcement of intellectual property rights have been found to enhance and promote innovation. The most important figure in the Preliminary Report states that the current research and development costs are found to be 17% of the turnover, that is considerably higher than in most if not all the other industries.¹⁰⁵ Whereas, the generic manufacturing companies have no or very low research and development costs and won't bear any of the risks similar to the ones with the originator companies.¹⁰⁶ However it should be recognised that within the internal market as well as globally the generic companies have proven to be an efficient way of cutting the prices of medicines, consequently the EU encourages generic entry to keep the healthcare expenditure costs under control which can be seen as serving the public interests as well.¹⁰⁷

Patents are considered to be a necessary incentive to be offered in return for the manufacturers to invest and commit to research and development investments.¹⁰⁸ The investment efforts made in regards to the invention including the risks taken within the research and development phase can be considered as prosperous when the invention has resulted in valuable patents.¹⁰⁹ The previous notion was developed in the Volvo¹¹⁰ case where the CJEU stated the following "It must also be emphasised that the right of the proprietor of a protected design to prevent third parties from manufacturing and selling or importing, without its consent, products incorporating the design constitutes the very subject-matter of his exclusive right . It follows that an obligation imposed upon the proprietor of a protected design to grant to third parties, even in return for a reasonable royalty, a licence for the supply of products incorporating the design would lead to the proprietor thereof being deprived of the substance of his exclusive right, and that a refusal to grant such a licence cannot in itself constitute an abuse of a dominant position".¹¹¹

¹⁰⁵ Robin Jacob, a Judge of the Court of Appeal of England and Wales (2009), a Paper given on 29th November at the Presentation of the Directorate-General of Competition's Preliminary Report of the Pharma-sector inquiry, p.3

¹⁰⁶ Robin Jacob, a Judge of the Court of Appeal of England and Wales (2009), a Paper given on 29th November at the Presentation of the Directorate-General of Competition's Preliminary Report of the Pharma-sector inquiry, p.5

¹⁰⁷ Pharmaceutical Sector Inquiry - Final Report (2009) p.62, para 1

¹⁰⁸ Valentine Korah, An Introductory Guide to EC Competition Law and Practice,(2007), Hart Publishing, Oxford, 9th Edition, p.364.

¹⁰⁹ Valentine Korah, An Introductory Guide to EC Competition Law and Practice (2007), Hart Publishing, Oxford 9th Edition p.364

¹¹⁰ Case 238/87, AB Volvo v Erik Veng Ltd. Abuse of a dominant position - Refusal by the proprietor for a registered design to grant a licence.October, (1988)

¹¹¹ Case 238/87, AB Volvo v Erik Veng Ltd. Abuse of a dominant position - Refusal by the proprietor for a registered design to grant a licence.October, (1988), para 8

This further supports the idea that in order for the exercise of Intellectual property rights to be effective and working properly, an undertaking in dominant position should have the ability to exercise his exclusive rights without the interference of competition law. While the possession of intellectual property rights does not automatically constitute the existence of a dominant position and of abuse¹¹², Art. 102 TFEU can be applied in “exceptional circumstances” in the interest of consumer welfare.¹¹³ Therefore it has to be determined whether strategic patenting conducted by the originators infringes the competition policy of the EU and whether it can have a negative affect on consumer welfare. It should be considered that, when depriving the R&D companies of their right to strong enforcement of their IP rights, that in itself can lead to a decline in innovation as investing in research becomes less profitable and lucrative compared to generic entry.

Also in some of the recent EU case law it is suggested that by merely making a patent application for “secondary patent” or for “patent clusters” a dominant company might be taking a step towards infringement of abuse of dominant position by simply taking court action.¹¹⁴ Article 345 TFEU (ex Article 295 EC) sets forth that the Treaty does not prejudice the system of property ownership within the Member States,¹¹⁵ Therefore the status of property ownership is protected by the constitutional law of the Member States and must be respected by the European law as well.¹¹⁶ This means that the EU law cannot provide any basis for interfering in the legal position of the inventor or his employer which is guaranteed as property ownership under the law of the individual Member State (e.g. Article 14 BCL).¹¹⁷ Therefore this guarantees them the fundamental allocation of the assets resulting from the creative achievement, set forth under private law rules and their freedom to dispose of them under their own responsibility,¹¹⁸ that

¹¹² Alison Jones, Brenda Sufrin, *EC Competition Law*, Oxford, Oxford University Press, 2007, supra note 130, p. 554.

¹¹³ Richard Whish, *Competition Law*, Oxford, Oxford University Press, 2008, supra note 116, p. 789.

¹¹⁴ Dominik Schnichels, Satish Sule; The Pharmaceutical Sector Inquiry and its Impact on Competition Law Enforcement. *Journal of European Competition Law & Practice* 2010; 1 (2): 93-111 <https://doi.org/10.1093/jeclap/lpq001>

¹¹⁵ Joseph Straus; Patent Application: Obstacle for Innovation and Abuse of Dominant Position under Article 102 TFEU?. *Journal of European Competition Law & Practice* 2010; 1 (3): 189-201. <https://doi.org/10.1093/jeclap/lpq011>

¹¹⁶ Clarified by the ECJ in case law; the prerequisite and modalities of the protection of intellectual property rights, in the absence of legal unification or legal approximation within the Community’, are determined ‘according to national law’ (cf. for example associated cases C-241/91P and C-242/91P, *Radiotelevis Eireann (RTE) and Independent Television Publications Ltd. (ITP) v Commission* [1995])

¹¹⁷ FCC, (2001) GRUR, 44—Clinical Trials.

¹¹⁸ *Ibid.*

includes the freedom to file a patent application. Therefore by merely filing a patent application, whether for secondary patents, patent considered as patent clusters or to engage in defensive patenting, regardless of the intent it should be considered that it is the exclusive right of the IP holder. Determining whether filing of the patent application has an intent to negatively affect competition is extremely difficult.

Applying for a patent does not yet constitute as an exploitation of an intellectual property right but is considered to form the first essential step—the *conditio sine qua non* - for establishing the specific subject of such right, without which, once the invention has been published, by whatever means, it is no longer possible to allocate the economic benefit arising from the exploitation of the invention in question to a specific inventor.¹¹⁹ The CJEU has repeatedly highlighted that the exclusivity effect of industrial property right does not in itself constitute as an evidence of a dominant market position on the part of their proprietors.¹²⁰ As stated by Ullrich and Heinemann, the question what truly matters is under what circumstances the owner of the right assumes the dominant position within the market and what is the significance of the ownership of those rights.¹²¹

However, when evaluating the significance of the rights acquired that constitute as a dominant position under the definition, the rules and criteria generally applicable for the determination of the exact market power needs the evaluation whether the undertaking can act to an appreciable extent independently of its clients, consumers and rivals.¹²² Therefore it can be argued that in order for a company becoming under suspicion of the abuse of dominant position, clear and strong indicators are needed to support such accusations.

¹¹⁹ Joseph Straus; Patent Application: Obstacle for Innovation and Abuse of Dominant Position under Article 102 TFEU?. *Journal of European Competition Law & Practice* 2010; 1 (3): 189-201. <https://doi.org/10.1093/jeclap/lpq011>

¹²⁰ Cf. the summary of the relevant decisions of the ECJ in H. Ullrich and A. Heinemann, in H. Ulrich Immenga and E.-J. Mestmäcker (eds.), *Wettbewerbsrecht der EG* (C.H. Beck Publisher, 2007) Part 2, GRUR note 250, p. 162.

¹²¹ Ullrich and Heinemann (n 25) 168.

¹²² Cf. ECJ, case 85/76—*Hoffmann La Roche & Co. AG v Commission* [1979] ECR, 461, paragraph 38 in fine. See also Ullrich and Heinemann (n 25), marginal note 43 (p. 168) with references to ECJ jurisprudence.

In the case of pharmaceutical industry with originators engaging in patenting strategies it is nearly impossible to determine whether the intent of filing for the patents is to eliminate possible competition or merely protect the patent owner's intellectual property, the latter not falling under the scope of Art.102 TFEU. Furthermore, according to Art. 52 of the EPC 2000¹²³, intent of possibly further developing and working on the patent does not constitute a condition for patentability, nor does lack of such intent give rise to an exception of patentability according to Art. 53 EPC.¹²⁴ When it comes to the specific practices conducted by the actors in the pharmaceutical industry it is difficult to determine when the practice of strategic patenting starts to fall under the definition of abuse by dominant position. However, Article 102 TFEU uses evaluation based on consumer welfare in order to determine whether the exercise or acquisition of Intellectual property rights is an abuse of dominant position.¹²⁵ Secondary patents similarly raise difficulties in determining whether the case falls under the scope of Article 102 TFEU.¹²⁶ The problem therefore, that the Commission faces is lack of competence in determining the value of patents to be able to recognise weak patents in order to override them and free the way for generic entry.¹²⁷

In accordance with the considerations discussed above, strategic patenting would merely appear to form part of normal conduct between competing companies, each trying to be the first to patent and thereafter to defend their positions.¹²⁸ Therefore it can be argued that there is no definitive evidence to show that the exercise of the patent owners rights (filing patents) would constitute as an abuse of dominant position nor is there substantial evidence that the patenting strategies directly harm the consumers and the competition within the pharmaceutical industry. The innovation of new drugs research and development rests usually on the originator research companies as they have the possible resources to invest in new drug research. Therefore it should

¹²³ European Patent Convention, Article 52 EPC 2000 - Patentable inventions
<https://www.epo.org/law-practice/legal-texts/html/epc/2016/e/ar52.html>

¹²⁴ European Patent Convention, Article 53 EPC 2000 - Exceptions to patentability
Available: <http://www.epo.org/law-practice/legal-texts/html/epc/2016/e/ar53.html>

¹²⁵ Lars Kjølbje , Partner, Howrey LLP, The Pharmaceutical Sector Inquiry and Strategic Patenting, What is the Commission's scope for action under Article 82 EC?, p.15
Available: <http://les-benelux.org/level2a/documents/L.Kjolbey.pdf>

¹²⁶ Nicoletta Tuominen, *Patenting Strategies of the EU Pharmaceutical Industry Crossroad between Patent Law and Competition Policy* (2011), Research paper in law, College of Europe, p.20, para 2 Available: <http://aei.pitt.edu/44320/>

¹²⁷ Lars Kjølbje , Partner, Howrey LLP, The Pharmaceutical Sector Inquiry and Strategic Patenting, What is the Commission's scope for action under Article 82 EC?, p.13
Available: <http://les-benelux.org/level2a/documents/L.Kjolbey.pdf>

¹²⁸ *ibid.* p.14

be seen as beneficial to ensure the protection of their intellectual property rights as in the end it serves a purpose for the public as well. The phenomenon of evergreening is not confined to the pharmaceutical field, nor is it new.¹²⁹ Every patent owner of a major invention is likely to come up with improvements and alleged improvements to the invention and by the time the main patent has expired there will be a thicket of patents intended to extend the monopoly.¹³⁰ When trying to investigate whether the patent is necessary in order to protect the medical invention it would end up being rather difficult and require a lot more resources. It is the nature of the patent system that some patents are stronger compared to the others, therefore they are of higher quality, however this is the way it should work and has always worked.¹³¹ There is nothing new about the practice of evergreening, nor is it confined exclusively to the pharmaceutical industry, unlike the inquiry implicated that there would be something corrupt going on and that it has only recently been discovered.¹³²

It can be argued that whether the patenting strategies has malicious intent in order to block competition in the market should be considered as irrelevant. The measures that would be needed to effectively tackle the practice would seriously harm and infringe the innovators rights to its own inventions and therefore open access to the intellectual property rights for others, which could in a consequence harm the innovators willingness to invest in the research of new medicines. Consequently, simply filing a patent application, whether the patent is primary or secondary patent, should not either be considered as an abuse of Art. 102 TFEU. Patent strategies can be considered as merely a way for the innovators to protect their property and receive the maximum remuneration for the vast amount of efforts and expenses that they have invested in the drug production, clinical trials and research. However, from the consumers perspective the lack of interest to invest in new medicines and research to treat new diseases and medical conditions can become more harmful in the long run than the higher prices in the market.

¹²⁹ Robin Jacob, a Judge of the Court of Appeal of England and Wales (2009), a Paper given on 29th November at the Presentation of the Directorate-General of Competition's Preliminary Report of the Pharma-sector inquiry, p.7 para 3

¹³⁰ *Ibid.*

¹³¹ *Ibid.*

¹³² *Ibid.*

5. Generics in the Pharmaceutical Industry

Whereas originator companies are the multinational players investing in research and development, clinical trials and production of new medicines, generics are the companies who “copy” the originators product after the expiry of the patent and manufacture their own product, lowering prices and providing variety of choices in the pharmaceutical market.¹³³ Many generic companies that are active in the European market are usually significantly smaller compared to the originator companies as many of them are SMEs.¹³⁴ They produce medicines for sale in their local markets and several generic companies have recently gained a global presence with a turnover exceeding € 1 billion per year with more generic companies set to join them in the near future.¹³⁵ Generic companies employed around 130,000 employees within the European Union in 2007, the work areas primarily consisting of development, production and sales.¹³⁶ The usual business model for generic companies is to develop an identical or equivalent medicine to an economically successful originator product and bring it to the market as soon as possible after the expiry of the originators patents.¹³⁷ The generics are able to access the market earlier in cases where the generic manufacturer are under the assumption that the IP protection of the research based company has expired and the patents are no longer protecting the original compound and due to the loss of patent protection generics wouldn't infringe the IP rights of the originators when trying to produce the medicine.¹³⁸ Most of the larger generic companies have significant and impressive range of products and are usually able to develop generic version of any medicine that has been previously protected by patents.¹³⁹ Although, in most of the cases the generic manufacturers will have their focus purely on the most value adding drugs that have the potential to produce most profits for the company.¹⁴⁰ The most successful products are often referred as the “bluckbuster” products and are the most valuable products for the originator companies. As the generic companies are able to offer more affordable versions of the pharmaceutical products, they are considered as important factors affecting the cost containment

¹³³ Pharmaceutical Sector Inquiry - Final Report (2009) p.35

¹³⁴ Pharmaceutical Sector Inquiry - Final Report (2009) p.35, para 2

¹³⁵ *ibid.*

¹³⁶ *Ibid.*

¹³⁷ Pharmaceutical Sector Inquiry - Final Report (2009) p.35, para 3

¹³⁸ *Ibid.*

¹³⁹ Some classes of medicines such as the cytostatic cancer or biosimilars require high levels of specialist and specific manufacturing capabilities that might be not easily available for the generic companies.

¹⁴⁰ Pharmaceutical Sector Inquiry - Final Report (2009) p.35, para 5

measures of national health policies.¹⁴¹ In addition, originator and generic companies alike both agree that generic competition creates and maintains the incentive to invest for innovation as generic competition limits the duration when the originator companies can gain back remuneration for their investments in the research and development, therefore the originator companies are incentivised to constantly search for new medicines.¹⁴² However this view can be challenged. The Commission claimed that generic companies enhance competition between the generics and originators and therefore are able to enhance innovation within the industry as originators constantly search for new medicines in order to maintain their profits. However the generics are mainly interested of the “blockbuster” drugs, which are the most profitable and valuable medicines for the originator companies. By copying orphan drugs, which are drugs used to treat rare diseases and usually produced by the originator companies are not attractive to generics as they do not produce as much profit compared to the so called blockbuster drugs. Therefore generic companies have been able to market themselves as the providers of lower prices whereas in reality, generic companies are not actually in the favour of lower prices.¹⁴³ Like the research based originator companies, the generic companies are in the business for a profit.¹⁴⁴ Therefore when the prices are low, the profit will be consequently less as well, therefore it is more profitable for the generic companies to stay as close to the original prices set by the originators as possible.¹⁴⁵

The sector inquiry concluded that the generic companies do not enter the market with all existing product versions (formulations), but at least initially opt for those most commonly sold.¹⁴⁶ However several generic companies have stated that they are also engaging in the development of new formulations, dosage forms and methods of delivery (so-called "line extensions" of existing products).¹⁴⁷ However, these so called line extensions are usually produced for the goal of maximising generic's chances for profit and setting them apart from other generic

¹⁴¹Pharmaceutical Sector Inquiry - Final Report (2009) p.36, para 2

¹⁴² Pharmaceutical Sector Inquiry - Final Report (2009) p.36, para 2

¹⁴³ Robin Jacob, a Judge of the Court of Appeal of England and Wales (2009), a Paper given on 29th November at the Presentation of the Directorate-General of Competition's Preliminary Report of the Pharma-sector inquiry, p.5 para 4,5

¹⁴⁴ *Ibid.*

¹⁴⁵ *Ibid.*

¹⁴⁶ Pharmaceutical Sector Inquiry - Final Report (2009) p.36, para 3

¹⁴⁷ *ibid.*

manufacturers and originators alike by having differing product.¹⁴⁸ Therefore it can be concluded that the nature and purpose of the generic companies does not differ so significantly from the features and goals of the originator companies as both are in the business for profits. However it should be recognised that the generic companies do serve a purpose and are valuable by enhancing competition as well as regulating the prices within the pharmaceutical market.

5.1 Generic Market Entry

The expiry of the patent exclusivity period is the dreaded moment for any innovator company.¹⁴⁹ However after the generic entry has occurred what is the larger scale effect on the industry needs to be discussed, in particular to what extent are the prices of the original drugs affected. Despite the patent protection and exclusivity period many innovators of the original drugs do not remain as the sole owners of such drugs as even before the generic entry, other branded drugs also known as follow-on drugs can make an incursion.¹⁵⁰ After the expiry of the patent, when the market opens up to generic manufacturers as well, an aggressive price competition starts and the original brand loses some of its market shares quickly to the generics and it is worth noting that by then, the brand might have been competing with the follow-on drugs for a period of time already.¹⁵¹ However, the competition between the originators or the so called branded alternatives is usually more quality based rather than price centred.¹⁵² Therefore the issue whether the generic versions of the drugs possess the same quality compared to the original ones should be a question of concern. After the generic entry into the market the most direct effect seen almost immediately is the decrease on the average price of the pharmaceutical products.¹⁵³ Generally, the average price of the first generics to enter the market is around 25 % lower than that of the original brand, however over time and with increases in generic entry, generic drug prices stabilise at levels close to the long-term marginal cost of production and distribution, which is about 20 % of the original brand's price.¹⁵⁴ The average time for generic entry within

¹⁴⁸ *Ibid.*

¹⁴⁹ Elena Petrova, Innovation in the Pharmaceutical Industry: The process of Drug Discovery and Development, M. Ding et al. (eds.), *Innovation and Marketing in the Pharmaceutical Industry*, p.36 International Series in Quantitative Marketing 20, DOI: [10.1007/978-1-4614-7801-0_2](https://doi.org/10.1007/978-1-4614-7801-0_2),

¹⁵⁰ *Ibid.* p.32, para.2

¹⁵¹ *Ibid.*

¹⁵² *Ibid.*

¹⁵³ Pharmaceutical Sector Inquiry - Final Report (2009) p.70, para 4

¹⁵⁴ Pharmaceutical Sector Inquiry - Final Report (2009) p.36 para 2

the EU after the loss of exclusivity period by the originator is around thirteen months with high value (blockbuster) products taking less time for facing generic entry.¹⁵⁵ Generic companies appear to enter the pharmaceutical market with around 2 to 2.5 products or formulations, this appears to be less number of products active compared to the originator companies which are active with 3.5 to 4 products.¹⁵⁶ This can be explained by the fact that usually generics tend to focus on the commercially most successful drug products, leaving aside the ones which sell less, another reason for the difference can be explained with generics not being able to use formulations relating to the products that are still exclusive.¹⁵⁷ After the loss of exclusivity of the originator patents, the generics are able to harness some of the products for their own use, however there are usually several other formulations which are still exclusive for the originator or the licensees. It can be argued that early generic market access can serve a significant purpose by changing the market from one product dominance into one where competition serves the public more effectively and more supply sources are accessible.¹⁵⁸

5.2 Possible problems that Generics pose for Innovation

The very nature of the pharmaceutical industry sets it apart from all other industries as no other industry is expected to affect the health and life expectancy of people or how fast they are able to recover from their illnesses.¹⁵⁹ Consequently, no other industry exist that is under such an enormous pressure to innovate.¹⁶⁰ The fundamental role of the pharmaceutical industry can be considered to be to maintain and enhance human life and this is portrayed in the efforts invested within the research and development activities.¹⁶¹ The pharmaceutical research and development holds an impressive 19% share of all business spending on research and development worldwide, which can be seen as significant financial commitment for a single industry.¹⁶² However, most

¹⁵⁵ Pharmaceutical Sector Inquiry - Final Report (2009) p.70, para 4

¹⁵⁶ Pharmaceutical Sector Inquiry - Final Report (2009) p.77, para 1

¹⁵⁷ *Ibid.* para 2

¹⁵⁸ *Ibid.* para 2

¹⁵⁹ Elena Petrova, Innovation in the Pharmaceutical Industry: The process of Drug Discovery and Development, M. Ding et al. (eds.), *Innovation and Marketing in the Pharmaceutical Industry*, p.23, para 2 International Series in Quantitative Marketing 20, DOI: [10.1007/978-1-4614-7801-0_2](https://doi.org/10.1007/978-1-4614-7801-0_2),

¹⁶⁰ *Ibid.* p.23, para 3

¹⁶¹ Elena Petrova, Innovation in the Pharmaceutical Industry: The process of Drug Discovery and Development, M. Ding et al. (eds.), *Innovation and Marketing in the Pharmaceutical Industry*, International Series in Quantitative Marketing 20, DOI: [10.1007/978-1-4614-7801-0_2](https://doi.org/10.1007/978-1-4614-7801-0_2), p.21, para 1

¹⁶² *Ibid.*

new drugs that enter the market do not offer any significant gain over the products¹⁶³ which are already available in the market. ¹⁶⁴ The pharmaceutical industry has faced criticism over the issue of follow-on drugs (alternative formulations) that the drugs are a needless waste of resources as it can take hundreds of millions to develop such drugs without them bearing any significant meaning.¹⁶⁵ In Canada it was found that when the new generic drugs enter the market, that do not offer any significant new therapeutic value, they have been found not to compete with existing products in the same therapeutic class, unless there were at least 4 other or more competitors.¹⁶⁶ “Since price competition did not occur at the introduction of new drugs offering little or no therapeutic benefit over existing medications, it is unlikely that it existed in other situations”.¹⁶⁷ However, it was discovered that the prices of new medicines and drugs within the market were actually higher¹⁶⁸ than those of the most expensive competitors and the prices for the new products tended to rise over the subsequent years.¹⁶⁹ The results found from the Commission’s sector inquiry detected that it took on average more than seven months for the generic entry after the loss of exclusivity of the originator patents, however for the blockbuster medicines the average entry to the market was around four months.¹⁷⁰ Delays were considered to be important as the price when the generics entered the market was on average 25% lower than the price of the originator medicines after the loss of the patent exclusivity.¹⁷¹ Generic entry, according to the inquiry, seemed to play a crucial role in dropping the price within the market as two years later after the entry, price of the medicines were on average 40% less compared to the original originator price and the prices of the originators products appeared to drop as well.¹⁷² However, the entry of the generics seemed to shift the market share alike as the market share of the generic companies were 30% one year after the entry and 45% two years after the entry.¹⁷³

¹⁶³ Patented Medicine Prices Review Board (PMPRB). Annual report 2004. Ottawa: PMPRB; 2005.

A review of new drugs in 2004: floundering innovation and increased risk-taking. *adapted from Rev Prescrire* (2005);14:68-73.

¹⁶⁵ Joel Lexchin, Do manufacturers of brand-name drugs engage in price competition, Analysis of Introductory prices (2006), 4th of April, Available: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1421463/#r4-25>

¹⁶⁶ *ibid.*

¹⁶⁷ *Ibid.*

¹⁶⁸ Lu ZJ, Comanor WS. Strategic pricing of new pharmaceuticals. *Rev Econ Stat* 1998;80:108-18.

¹⁶⁹ Reekie WD. Price and quality competition in the United States drug industry. *J Ind Econ* 1978;26:223-37.

¹⁷⁰ Pharmaceutical Sector Inquiry - Final Report (2009) p.94, para 2

¹⁷¹ Pharmaceutical Sector Inquiry - Final Report (2009) p.92, para 3

¹⁷² *Ibid.*

¹⁷³ *Ibid.*

Whereas there is no denying of the positive affects of the generics to the market, it should be considered how the generic competition affects the actual innovation. Generics are able to drop the price significantly after the entry but as indicated before, the prices might steadily began to rise after some period of time. Patent strategies conducted by the originators seem to be a practice, specifically directed to delay the generic entry to the market. However, according to the Commission's inquiry findings the generic entry is on average around four to seven months after the expiry of the exclusivity period depending of the product in question. It remains debatable whether such a short period of time would harm directly the customers in the long term. The expected rate of remuneration plays a major role in the pharmaceutical industry's decision whether to invest in innovative activities.¹⁷⁴ There are several studies which have indicated that the gained return rates from the research and development investments made have declined significantly over the last two decades.¹⁷⁵

¹⁷⁴ Patent-Term Extension and the Pharmaceutical Industry (1981), US Gov. Printing Office, Washington, Chapter 3, p.27, para 1 Available: <http://ota.fas.org/reports/8119.pdf>

¹⁷⁵ Charles River Associates, Inc., "The Effects of Patent Term Restoration on the Pharmaceutical Industry," prepared for OTA, May 4, 1981, pp. 4-1 to 4-3.

6. Case Law Strategic Patenting

6.1 Astra Zeneca v Commission

The case concerned two strategies adopted by AstraZeneca¹⁷⁶ to protect its most successful blockbuster the anti-ulcer drug Losec, against the loss of profits due to the generic market competition and parallel trade.¹⁷⁷ AstraZeneca had applied for SPC (Supplementary Protection Certificate), which would grant it five extra years of patent protection in order to receive adequate compensation for the delays that can occur between filing of the patent and the grant of the marketing authorisation. However, the conduct that AstraZeneca was accused of was misleading the national patent offices about the date of the grant of the marketing authorisation in order to receive the Supplementary Protection Certificate.¹⁷⁸ In addition, AstraZeneca withdrew the original capsule form of Losac from the market in several member states and replaced it with a new form that could be dissolved in water, and as the new version was introduced the marketing authorisation of the original version was withdrawn.¹⁷⁹ Therefore it was much more challenging for the generics to enter the market effectively after the expiry of the original patent as they could not use the data on particular product. In its decision in 2005¹⁸⁰, the Commission held that AstraZeneca had a dominant position within the market and AstraZeneca had abused that position by engaging in regulatory and patenting strategies and the withdrawal of marketing authorisation was found to be abusive as well due to the fact that AstraZeneca's exclusive rights regarding to its data on clinical trials and tests had expired. AstraZeneca was imposed a fine of €60 million and the decision was appealed. The decision on AstraZeneca was significant as it redefined and specified the abusive conduct, previously it has been highlighted that exceptional circumstances are required in order for it to be possible for a pharmaceutical company to be hold a dominant position and abuse it indirectly. The decision confirmed that the restive effect is enough to constitute as an abuse, direct intent is not necessary needed.

¹⁷⁶ Case-457/10 P - AstraZeneca v Commission, Available: <http://curia.europa.eu/juris/liste.jsf?num=C-457/10>

¹⁷⁷ David W. Hull; The Application of EU Competition Law in the Pharmaceutical Sector. *Journal of European Competition Law & Practice* 2012; 3 (5): 473-480. doi: 10.1093/jeclap/lps044

¹⁷⁸ *Ibid.*

¹⁷⁹ *Ibid.*

¹⁸⁰ Case COMP/A. 37.507/F3 AstraZeneca, Commission Decision 2005, Available at: http://ec.europa.eu/competition/antitrust/cases/dec_docs/37507/37507_193_6.pdf

6.2 Boehringer Ingelheim v Commission

A German pharmaceutical company Boehringer Ingelheim¹⁸¹ was accused of engaging in abusive conduct in violation of Article 102 against a Spanish pharmaceutical company, Ammirall. The alleged abuse was about making numerous filings for patents covering new treatments for a certain lung disease.¹⁸² Ammirall had appealed to the Commission about Boehringer Ingelheim's patent applications relating to fixed-dose combination products used to treat the particular illness, that they were without proper grounds and in case they would be granted, they would have the potential to delay or even block the generic market entry of Ammirall's own product.¹⁸³ After the Commission's intervention the case was settled between the two parties enabling Ammirall to enter the market. However, the intervention by the Commission can be considered as troubling as unlike many other instances involving the use of IP strategies this particular case was considered as fairly common dispute concerning the validity of a patent.¹⁸⁴ The Commission intervening with a regular IP case raised concerns as it can be questioned whether the Commission is qualified in technical means to decide whether a patent is valid or not.¹⁸⁵

6.3 Servier v Commission

The case of Servier¹⁸⁶ considered secondary patenting, the Commission imposed a fine on French pharmaceutical company for holding patents on drugs, where the basic molecule patent had already expired. The patents can be described as secondary patents as they did not protect the original molecule but rather protected the different formulations, dosages and matters related to the manufacturing process.¹⁸⁷ Generic manufacturers in the hope of being able to enter the market challenged the validity of these patents. The foundation for the decision in Servier was set back in the earlier decision of *Lundbeck*.¹⁸⁸ As the violation of Article 101 TFEU was found in the case of *Lundbeck*, the Commission found that in the case of Servier, an abuse of its

¹⁸¹ Case T-125/96 *Boehringer v Council and Commission*, Available: <http://curia.europa.eu/juris/liste.jsf?num=T-125/96&language=en>

¹⁸² European Commission Press Release, IP/11/842 (6 July 2011)

¹⁸³ David W. Hull; The Application of EU Competition Law in the Pharmaceutical Sector. *Journal of European Competition Law & Practice* 2012; 3 (5): 473-480. doi: 10.1093/jeclap/lps044

¹⁸⁴ *ibid.*

¹⁸⁵ *Ibid.*

¹⁸⁶ Case AT.39612, *Servier*; Decision of 9 July 2014

¹⁸⁷ David W. Hull, Michael J. Clancy; The Application of EU Competition Law in the Pharmaceutical Sector. *Journal of European Competition Law & Practice* 2017; 8 (3): 205-218. doi: 10.1093/jeclap/lpx004

¹⁸⁸ Case T-472/13, *Lundbeck v Commission*, Available: <http://curia.europa.eu/juris/liste.jsf?num=T-472/13>

dominant position and the violation of Article 102 was found in addition. This was the first case where the Commission applied Article 102 to late life cycle (secondary patents) management strategies since its decision of AstraZeneca.¹⁸⁹ The strategy meant to protect the dominant market position against the generics is “*generally legitimate to the extent it resorts to measures representing competition on the merits, which it described as competition on product quality and the strategic use of IPRs and the patent system.*”¹⁹⁰ In the case of Servier, it was established that the company did not acquire the patents for the purpose of developing or enhancing them but merely in order to acquire technology through patents that would pose a threat to the company from a potential competitor. The granting of a high number of patents than necessary, creates foundation for the opportunity to create patent clusters and thickets, which can become unnecessary drag on innovation.¹⁹¹

6.4 SmithKline Beecham v Generics (UK)

SmithKline Beecham¹⁹² pharmaceutical company’s patent for the drug paroxetine had expired in 1999 and was therefore manufactured and distributed in the UK by several generic companies. In 2001 SmithKline Beecham filed against Generics (UK) Ltd. for patent infringement. Initially Generics denied the infringement and alleged that the patent was invalid. The Generics tried to prove that the patent lacked novelty and did not possess an innovative nature. However the case was decided in the favour of SmithKline Beecham as the judge decided that the patent did not lack novelty, as it wasn't obvious to the public as a skilled person would need to carry out the development procedure. The case was settled and the court stated that Generics knew about the risks of running litigation and infringing the patent rights of the original owner. The case can be considered to display willingness on the national courts to prevail the rights of an IP owner.

¹⁸⁹ *Ibid.*

¹⁹⁰ *Servier*, para. 2766.

¹⁹¹ C Shapiro, ‘Navigating the Patent Thicket: Cross-Licenses, Patent Pools and Standard-Setting’ (2000) *Innovation Policy and the Economy* 119, 120.

¹⁹² *SmithKline Beecham Plc. v Generics (UK) Ltd.* [2003] EWCA Civ 1109, Case No: A3/2003/1441;1451 Available: <http://www.bailii.org/ew/cases/EWCA/Civ/2003/1109.html>

7. Conclusion

Determining whether strategic patenting infringes the competition policy of the European Union can turn out to be rather difficult and should be evaluated on individual case basis. Intellectual property law and competition law can be considered as the opposites by their very nature and purpose. Intellectual property law seeks to grant the owner of the patent exclusive rights over the invention, which can ultimately position the owner in a place of monopoly within the specific industry. Whereas competition law seeks to restrict and prevent abuses of dominant position or restrictive agreements between undertakings in order to ensure the proper functioning of the internal market and competition law within the union. The law of intellectual property confers exclusive rights as Article 102 prohibits¹⁹³ the abuse of a dominant position, therefore the question that arises is whether Article 102 can be applied in such a way as to limit the exclusive rights given by intellectual property law.¹⁹⁴ The Court of Justice of the European Union has made clear that mere ownership of intellectual property rights cannot be attacked under Article 102.¹⁹⁵ However, through the relevant EU case law such as *AstraZeneca*¹⁹⁶ and *Volvo*¹⁹⁷ it has been established that under exceptional circumstances competition law can override intellectual property rights when serious abuses are detected. The CJEU has also established that direct intent or attempt to affect competition negatively is not necessarily needed in order for it to be considered as abuse, the mere effect is considered as enough. In sum, it should be considered that the case law of the European Courts thus far provides no basis for subsuming the filing of a patent application and the original acquisition of a patent as an abuse of dominant market position under 102 TFEU.¹⁹⁸

¹⁹³ Richard Wish, David Bailey, *Competition law* (2012), Oxford University Press, Great Calendon Street, Oxford, Seventh Edition, Chapter 19, p.796, para. 4

¹⁹⁴ For further discussion: Govaere, *Use and Abuse of Intellectual Property Rights in EC Law* (1996), Sweet and Maxwell p.5; Coates, Kyølbye and Peepkorn in Faull and Nikpay *EC Law of Competition* Oxford University Press, (2007), paras 10.209–10.255; Tritton *Intellectual Property in Europe* (2008) Sweet & Maxwell, 3rd edition, ch 11; Anderman and Schmidt *EU Competition Law and Intellectual Property Rights: e Regulation of Innovation* (2011), Oxford University Press, 2nd Edition, chs 3–11; Kjølbye ‘Article 82 EC as Remedy to Patent System Imperfections: Fighting Fire with Fire?’ (2009) 32(2)

¹⁹⁵ Article 345 TFEU provides that the TFEU and TEU “shall in no way prejudice the rules in Member States governing the system of property ownership”

¹⁹⁶ Case-457/10 P - *AstraZeneca v Commission*, Available: <http://curia.europa.eu/juris/liste.jsf?num=C-457/10>

¹⁹⁷ Case 238/87- *AB Volvo v Erik Veng (UK) Ltd.*, Available: <http://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:61987CJ0238&from=IT>

¹⁹⁸ Joseph Straus; Patent Application: Obstacle for Innovation and Abuse of Dominant Position under Article 102 TFEU?. *Journal of European Competition Law & Practice* 2010; 1 (3): 189-201. <https://doi.org/10.1093/jeclap/lpq011>

However as demonstrated previously, intervening the IP owner's rights in such an extensive manner could potentially instead of enhancing competition actually harm it by limiting the freedom to exercise ones right to intellectual property. In order to enhance and promote innovation, the most important factor is to guarantee that the incentive to invest exist and is appealing to the innovators. The main issue is structured around the question whether IP law should prevail over competition law and should competition authorities have jurisdiction in deciding whether patenting strategies have infringed the competition policy or where a patent is considered invalid? Trying to find a balance between the two issues is challenging as the IP holder shouldn't be punished for applying for a patent or for exercising the rights of an IP owner. Although the advantages of the generic entry for the regulation of price levels cannot be ignored, the positive affect of the generics for the pharmaceutical industry as a whole can be seen perhaps slightly exaggerated. The firs priority should be in ensuring that the innovation and incentive to invest in research and development prevails. In addition to the commercially successful drugs, drugs for the rare diseases are needed as well and the responsibility of producing them has usually rested on the originators. Therefore guaranteeing support for the actual research and development based originator companies should be prioritised as generics are more willing to manufacture and produce cheaper versions of the so called blockbuster drugs, understandably, as they possess the possibility to produce most profits. It would be concerning and even dangerous to have a rule that applying for or seeking to enforce a patent of doubtful validity would be considered as an infringement of competition law, if becoming a reality, most companies from all industries would be considered guilty on that regard as courts are the basis for places deciding the validity of rights, therefore punishing an IP holder for taking court action would be considered as an infringement of Article 6 of the European Convention on Human Rights.¹⁹⁹

The Commissions pharmaceutical sector inquiry perhaps portrays more sinister picture of the industry, than it was originally intended. It is understandable that due to its highly sensitive nature, the pharmaceutical industry is under constant observation and scrutiny, which is rightfully needed as the innovations produced are used for health care purposes of the public. However whether the pharmaceutical inquiry has taken into account the fact that originators as

¹⁹⁹ Robin Jacob, a Judge of the Court of Appeal of England and Wales (2009), a Paper given on 29th November at the Presentation of the Directorate-General of Competition's Preliminary Report of the Pharma-sector inquiry, p.10 para 2

well as generics are both commercial medical companies seeking maximum profits, remains unclear.²⁰⁰ The application of competition law has a complex nature and should be applied in manner that respects the intellectual property rights and encourages investment in research and development.²⁰¹ Whether using patenting strategies is an infringement of competition law or not should remain as a matter of intellectual property law solely. Trying to enforce IP rights successfully and therefore guarantee the rights of an innovator will prove out to be a difficult task when IP rights are already by their nature very much anticompetitive. Perhaps, the best way to avoid decrease in innovation would be the enforcement of strong IP rights, without the intervention of competition law authorities. Therefore it can be argued, that even if weak patents are granted the ideal solution would be the quick revocation of those patents as it would be very problematic if pharmaceutical originator companies would lose their trust in ensuring that their research and investment efforts will be returned by granting exclusive rights to the innovation for certain period of time, this could eventually lead to decrease in incentive to invest. It can be concluded that the patenting system as a whole has benefitted the mankind enormously.²⁰² Therefore any changes to the current system should be considered with caution.²⁰³ The European Union along with the Parliament as well as all the Member States have come to an agreement of the necessity of a creation of Unitary patent in order to enhance cooperation, harmonisation and unison regarding the effective enforcement of IP rights.²⁰⁴ “With the introduction of the unitary patent and the UPC, the European Union tries to lower the barriers to obtaining a patent in Europe by introducing a patent that has equal effect in all participating Member States”.²⁰⁵ Both Regulations are aimed to foster scientific and technological advances and the functioning of the internal market.²⁰⁶ The United Kingdom has confirmed it will be part

²⁰⁰ Russell Game Hunter, *The pharmaceutical Sector in the European Union: Intellectual Property Rights, Paraller Trade and Community Competition Law*, Juristförlaget, Stockholm, (2001) p.11.

²⁰¹ Blanca Rodriguez Galindo, Prohibition of the abuse of a dominant position, Directorate- General for Competition, European Commission, The international symposium on antimonopoly Enforcement (2007), p.9, para 2 Available: http://ec.europa.eu/competition/speeches/text/sp2007_18_en.pdf

²⁰² Robin Jacob, a Judge of the Court of Appeal of England and Wales (2009), a Paper given on 29th November at the Presentation of the Directorate-General of Competition’s Preliminary Report of the Pharma-sector inquiry, p.10 para 5

²⁰³ *Ibid.*

²⁰⁴ Ullrich Hanns, *Enhanced Cooperation in the Area of Unitary Patent Protection and European Integration*, January (2013), ERA Publications, p.591 Available:DOI 10.1007/s12027-013-0275-2

²⁰⁵ Wieger Weijland, *The Implications of the Unitary Patent and the Unified Patent Court to High-tech Start-up Patenting in Europe*, (2013) p.43 para.3 Available: <http://arno.uvt.nl/show.cgi?fid=130932>

²⁰⁶ Recital 4 Regulation 1257/2012 on the creation of unitary patent protection

of the unitary patent system, despite its departure from the European Union.²⁰⁷ Perhaps the unitary patent along with the unified patent court will be able to offer clarity on the complex relationship between competition and Intellectual Property law as both are necessary for the benefit of the society working efficiently as separate legal entities.

²⁰⁷ Intellectual Property Office, UK unitary patent, Available: <https://www.gov.uk/government/news/uk-signals-green-light-to-unified-patent-court-agreement>

8. Bibliography

Academic Sources

Books:

W.Cornish, D.Llewelyn and T.Aplin, *Intellectual Property: Patents, Copyright, Trademarks and Allied Rights* (1981), Sweet & Maxwell Limited London, Seventh Edition

Russell Game Hunter, *The pharmaceutical Sector in the European Union: Intellectual Property Rights, Paraller Trade and Community Competition Law*

Michael A.Gollin, *Driving Innovation- Intellectual Property Strategies for a Dynamic world* (2008), Cambridge University Press, New York

Steven D. Anderman, *EC Competition Law and Intellectual Property Rights* (1998), Oxford University Press, Oxford

Alan Dashwood, Michael Dougan, Barry Rodger, Eleanor Spaventa and Derrick Wyatt, *Wyatt and Dashwood's European Union Law* (2011), Hart publishing, Portland Oregon, sixth edition

Alison Jones, Brenda Sufrin, *EC Competition Law*, Oxford, Oxford University Press, 2007, p. 554

Valentine Korah, *An Introductory Guide to EC Competition Law and Practice*, Oxford, Hart Publishing, 2007, p. 364.

Inge Govaere, *The Use and Abuse of Intellectual Property Rights in E.C. Law*, Sweet & Maxwell, London, 1996, p. 113.

Elena Petrova, *Innovation in the Pharmaceutical Industry: The process of Drug Discovery and Development*, M. Ding et al. (eds.), *Innovation and Marketing in the Pharmaceutical Industry*, p. 36 *International Series in Quantitative Marketing* 20, DOI: [10.1007/978-1-4614-7801-0_2](https://doi.org/10.1007/978-1-4614-7801-0_2)

Lu ZJ, Comanor WS. Strategic pricing of new pharmaceuticals. *Rev Econ Stat* 1998;80:108-18.

Reekie WD. Price and quality competition in the United States drug industry. *J Ind Econ* 1978;26:223-37.

C Shapiro, 'Navigating the Patent Thicket: Cross-Licenses, Patent Pools and Standard-Setting' (2000) *Innovation Policy and the Economy* 119, 120.

Journals & Reports

Pharmaceutical Sector Inquiry - Preliminary Report (2008), *Fact Sheet on Originator-Generic Competition*

Available: http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/fact_sheet_2.pdf

European Commission, Pharmaceutical Inquiry(2009), *Final Report*

Available at: http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/staff_working_paper_part1.pdf

Stephen Mavroghenis, Article 82 EC and Strategic Patenting -Patent Thickets, Defensive Patents and Follow-on Patents

Available at: <http://webcache.googleusercontent.com/search?q=cache:-j09xHJoSrQJ:professorgeradin.blogs.com/files/article-82-and-strategic-patenting---conference-version-2-3.ppt+&cd=1&hl=en&ct=clnk&gl=ee&client=safari>

Dominik Schnichels, Satish Sule; The Pharmaceutical Sector Inquiry and its Impact on Competition Law Enforcement. *Journal of European Competition Law & Practice* 2010; 1 (2): 93-111. <https://doi.org/10.1093/jeclap/lpq001>

Robin Jacob, a Judge of the Court of Appeal of England and Wales (2009), *a Paper given on 29th November at the Presentation of the Directorate-General of Competition's Preliminary Report of the Pharma-sector inquiry*

Subseries I: Impact on manufacturing, Vol 2: Pharmaceutical Products, The pharmaceutical sector in the EU (1997), The Single Market Review

Nicoletta Tuominen, *Patenting Strategies of the EU Pharmaceutical Industry Crossroad between Patent Law and Competition Policy* (2011), Research paper in law, College of Europe Available: <http://aei.pitt.edu/44320/>

Commission Communication, of 8 July 2008, Executive Summary of the Pharmaceutical Sector Inquiry Report Available at: http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/communication_en.pdf

European Commission, Pharmaceutical Sector Inquiry Preliminary Report (DG Competition Staff Working Paper), of 28 November 2008, p. 5. Available at: http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/preliminary_report.pdf

European Generic Association, Evergreening of Pharmaceutical Market Protection. Available at: <http://www.egagenerics.com/gen-evergrn.htm> FIKSAA

Mari Minn; *Strategic patenting decisions in the European pharmaceutical industry: the use of divisional applications and follow-on patenting practices*. *Journal of Intellectual Property Law & Practice* 2016; 11 (8): 619-627. <https://doi.org/10.1093/jiplp/jpw099>

Piotr Staniszewski; The interplay between IP rights and competition law in the context of standardization. *Journal of Intellectual Property Law & Practice* 2007; 2 (10): 666-681. <https://doi.org/10.1093/jiplp/jpm143>

Joseph Straus; Patent Application: Obstacle for Innovation and Abuse of Dominant Position under Article 102 TFEU?. *Journal of European Competition Law & Practice* 2010; 1 (3): 189-201. <https://doi.org/10.1093/jeclap/lpq011>

Paul England, *European Intellectual Property Review, Recent Developments in pharmaceutical secondary patents in the light of the Commission's inquiry in to the pharmaceutical sector*, (2011) Sweet & Maxwell and its Contributors

Inderjit Singh Bansal, Deeptymaya Sahu, Gautam Bakshi, Sukhjeet Singh, “Evergreening – A Controversial Issue in the Pharma Milieu”, (2009) Vol. 14 Journal of International Property Rights, p. 299.

Available: <http://nopr.niscair.res.in/bitstream/123456789/5212/1/JIPR%2014%284%29%20299-306.pdf>

David W. Hull; The Application of EU Competition Law in the Pharmaceutical Sector. *Journal of European Competition Law & Practice* 2010; 1 (5): 429-437. <https://doi.org/10.1093/jeclap/lpq043>

Michele Giannino; Beware of competition law! Relying on patents to extend protection for medicines may be anticompetitive. *Journal of Intellectual Property Law & Practice* 2012; 7 (6): 391-392. doi: <https://doi.org/10.1093/jiplp/jps065>

Ullrich Hanns, ‘Enhanced Cooperation in the Area of Unitary Patent Protection and European Integration’, ERA Forum, May (2013), Volume 13 p. Available at: <http://link.springer.com/article/10.1007/s12027-013-%200275-2#>>

Blanca Rodriguez Galindo, *Prohibition of the abuse of a dominant position, Directorate-General for Competition, European Commission, The international symposium on antimonopoly Enforcement* (2007), p.9, para 2 Available: http://ec.europa.eu/competition/speeches/text/sp2007_18_en.pdf

Mike Hutchins, Extending the Monopoly - How Secondary patents can be used to delay or prevent generic competition upon expiry of the basic product patent, *Journal of Generic Medicines* (2003)

Available: <http://journals.sagepub.com/doi/pdf/10.1057/palgrave.jgm.4940018>

Brian Whitehead, Stuart Jackson, Richard Kempner; Managing generic competition and patent strategies in the pharmaceutical industry. *Journal of Intellectual Property Law & Practice* (2008) 3 (4): 226-235

Available: <https://doi.org/10.1093/jiplp/jpn013>

Wieger Weijland, *The Implications of the Unitary Patent and the Unified Patent Court to High-tech Start-up Patenting in Europe*, (2013) <http://arno.uvt.nl/show.cgi?fid=130932>

EU Case Law:

Case T-472/13, *Lundbeck v Commission*, Available: <http://curia.europa.eu/juris/liste.jsf?num=T-472/13>

Parke Davis v. Probel (1968) ECR55; *Deutsche Grammophon* (1974) ECR 1147.

Volvo v. Veng (UK) Ltd. (1988) ECR 299

Case-457/10 P - *AstraZeneca v Commission*, Available: <http://curia.europa.eu/juris/liste.jsf?num=C-457/10>

RTE v. Commission (1995) ECR I-743

Case C-418/01 *IMS Health Inc. v Commission* [2004] ECR I-5039.

Case T-201/04 *Microsoft Corp. v Commission of the European Communities*.

Case T-125/96 *Boehringer v Council and Commission*, Available: <http://curia.europa.eu/juris/liste.jsf?num=T-125/96&language=en>

SmithKline Beecham Plc. v Generics (UK) ltd.[2003] EWCA Civ 1109, Case No: A3/2003/1441;1451

Available: <http://www.bailii.org/ew/cases/EWCA/Civ/2003/1109.html>

Case AT.39612, *Servier*, Decision of 9 July 2014

Legislation:

Treaty on the Functioning of the European Union, Article 102 Abuse of Dominant Position

Available: <http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:12012E/TXT&from=EN>

Other Sources:

Joan Costa-i-Font, Nebile Varol and Alistair McGuire, *Does pharmaceutical price regulation affect the adoption of generic competition? Evidence from the OECD 1999-2008*

Available: <http://eprints.lse.ac.uk/>

[37537/1Does_pharmaceutical_price_regulation_affect_the_adoption_of_generic_competition_Evidence_from_the_OECD_1999-2008\(lsero\).pdf](http://eprints.lse.ac.uk/37537/1Does_pharmaceutical_price_regulation_affect_the_adoption_of_generic_competition_Evidence_from_the_OECD_1999-2008(lsero).pdf)

<https://www.bloomberg.com/news/articles/2014-12-03/indian-labs-deleted-drug-test-results-documents-show>

Factors Affecting Innovation in Pharmaceutical Industry, Chapter 3

<https://www.princeton.edu/~ota/disk3/1981/8119/811905.PDF>

Do manufacturers of brand-name drugs engage in price competition? An analysis of introductory prices

Available: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1421463/>

European Federation of Pharmaceutical Industries and Associations: The Pharmaceutical Industry in Figures (2016), p. 17.

Available: <http://www.efpia.eu/uploads/Modules/Documents/the-pharmaceutical-industry-in-figures-2016.pdf>

EFPIA Position Paper on Barriers to Innovation in the Development of New Medicines in Europe and Possible Solutions to Address these Barriers, November (2004)

Available: <http://plg-group.com/wp-content/uploads/2014/03/Barriers-to-Innovation-in-the-Development-of-New-Medicines-i.pdf>

Joel Lexchin, Do manufacturers of brand-name drugs engage in price competition, Analysis of Introductory prices (2006), 4th of April, Available: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1421463/#r4-25>

A review of new drugs in 2004: floundering innovation and increased risk-taking. *adapted from Rev Prescrire* (2005);14:68-73.

Patented Medicine Prices Review Board (PMPRB). Annual report 2004. Ottawa: PMPRB; 2005.

Available: http://www.pmprb-cepmb.gc.ca/CMFiles/Publications/Annual%20Reports/2014/2014_Annual_Report_Final_EN.pdf

Patent-Term Extension and the Pharmaceutical Industry (1981), US Gov. Printing Office, Washington, Chapter 3, p.27, para 1 Available: <http://ota.fas.org/reports/8119.pdf>