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Intellectual Property in pharmaceutical sector and Competition Policy within the European Union

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Abstract

This dissertation was written as part of the LLM in Transnational and European Commercial Law, Banking Law and Mediation/Arbitration at the International Hellenic University. Titled “Intellectual Property in pharmaceutical sector and Competition Policy within the European Union”, this dissertation provides an overview of the function and application of intellectual property law and competition law in the pharmaceutical sector as well as the interface of these fields of law. It describes the main characteristics of the pharmaceutical sector presenting the issues raised by the 2009 Pharmaceutical Sector Inquiry which influenced the development of the competition law policy within the sector. Considering that the development of a pharmaceutical product is a costly, time-consuming process and the pharmaceutical companies can recoup their investments during a particular period of time, this dissertation aims to shed light into the competitive relationship between the companies of the industry and their conducts that may restrict or block competition. This dissertation analyses case law and investigations initiated by the Competition Authorities regarding 'pay-for-delay' settlement agreements and patent strategies employed by pharmaceutical companies from an antitrust perspective aiming to contribute to the open discussion under what conditions these practices violate competition law.

I would like at this point to acknowledge the aid of my supervisor, Professor Pavlos Masouros whose guidance, assistance and encouragement was essential for the completion of this dissertation.

Keywords: intellectual property rights, competition, pharmaceutical industry, strategic patenting, competition authorities

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Introduction

The access to innovate, safe and affordable medicines is the key element of social welfare. After the covid pandemic the European Commission has adopted a new Pharmaceutical Strategy for Europe[1] based on the primary necessity for accessibility, availability and affordability of medicines enhancing at the same time the innovation and the competition in the pharmaceutical sector. The European Commission understanding the value of the pharmaceutical market and the crucial role of the pharmaceutical sector to people welfare carried out in 2008 the sector inquiry attempting to reveal market distortions and to give guidelines for better performance in the market to the ultimate benefit of consumers.

Fostering competition is often a key component of sustainable healthcare systems. Competition driven by the entry of generic medicines in the market allows patients access to treatments at a lower price and contributes to the sustainability of the healthcare systems. In addition, the competition by the generic medicines can lead to invention of new, more effective, and safer treatments for patients. Since the pharmaceutical industry is very active in research and development, promoting innovation is the most effective way for the companies of the sector to overcome the threat of competition. Intellectual property law shields innovation protecting the novel creation which becomes public granting exclusive rights to the inventor over the use of his/her creation for a certain period of time. However, market actors deviant conduct may affect the incentives to innovate to the detriment of fair competition and consumers prosperity. In the pharmaceutical industry, this is the case when companies engage strategies to extend the commercial life of their product and their profits to counter the impact of competition. These strategies and practices that can affect market competition are investigated by competition authorities and are subject to competition law scrutiny [2].

[1] https://ec.europa.eu/health/sites/default/files/human-use/docs/pharma-strategy_report_en.pdf

[2] European Commission, Report from the Commission to the Council and the European Parliament, Competition Enforcement in the Pharmaceutical Sector (2009-2017), 28.1.2019, p.5

This dissertation aims to provide an overview of the intellectual property rights that the pharmaceutical industry is using to protect its inventions, the practices that pharmaceutical companies employ that affect the competition in the market, the interaction between intellectual property law and competition law along with the implementation of the EU competition policy by the Competition Authorities.

In the first chapter, the characteristics of the pharmaceutical sector are analysed in order to be stressed the importance of the industry for the economy in Europe and its valuable contribution for accessible and affordable pharmaceutical products.
The second chapter focuses on intellectual property rights, incentives, and rewards which are available for the protection of pharmaceutical products along with EU competition policy in pharmaceutical sector.

Furthermore, the third Chapter is examined the conducts that the pharmaceutical companies engage to extend the lifetime of their products and the negative effects of these practices to competition with reference to the case law.
In the fourth chapter is demonstrated the legal basis on the intervention of the competition law in cases related to an abuse of a dominant undertaking and the arguments raised against this intervention.

Finally, in the closing chapter, having dissected the pharmaceutical companies' behavior in the previous chapters from a competition law perspective, the most important points are highlighted concluding with a forward-looking approach regarding the competition policy in the pharmaceutical sector.

1. Characteristics of Pharmaceutical Industry

Pharmaceutical industry is quite profitable. In 2019 the worth of the world pharmaceutical market was estimated at € 949,462 million ($ 1,062,923 million) at ex-factory prices[3]. The same year in Europe the total pharmaceutical market value at ex-factory prices was estimated at €228,200 million[4]. The importance of pharmaceutical market for the growth of Europe is illustrated in pharmaceutical exports which are amounted for the year 2019 to €435,300 million compared to the amount of €313,269 million of imports [5]. The pharmaceutical industry is one significant employer in Europe since approximately 765,000 people are working directly to the sector and about four times more people are employed indirectly – upstream and downstream[6] . In addition to that the pharmaceutical industry retains high intensity in Research and Development investing in Europe in 2019 € 37,500 million[7]. These figures demonstrate the importance of the sector for the European economy.

1.1. Demand and Supply structure of pharmaceutical sector

The structure of the of demand and supply in pharmaceutical market is different to other sectors since the final user cannot select the medicines him/herself and the costs of pharmaceuticals in majority are covered by health systems or insurances. On the supply chain the upstream market is consisted of the pharmaceutical companies which provide the wholesalers with pharmaceuticals and the last level of the chain constitutes of the patients who receive through pharmacies their medicines that are prescribed by medical doctors[8]. The demand side is influenced by the patients that pay a small amount of the prescribed medicines price, the medical doctors who decide which treatment and medicines the patients will consume, the pharmacies which after

[3] European Federation of Pharmaceutical Industries and Associations, (EFPIA, The Pharmaceutical Industry in Figures Key Data 2020, EFPIA Publication pg. 14
https://www.efpia.eu/media/554521/efpia_pharmafigures_2020_web.pdf
[4] Ibid
[5] Ibid
[6] Ibid
[7] Ibid
[8] European Commission (2009) Pharmaceutical sector inquiry final report, para. 45
http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/staff_working_paper_part1.pdf., para. 45

the entry of generics in the market and the prescription of active ingredients are on their disposal to provide the cheapest version of the medicine, the public health systems and the private insurance schemes that cover the medical costs[9].

It is notable that in 2018 the average spending for retail pharmaceuticals was EUR 381 per person in EU member states, however health spending varies broadly across member states influenced by multiple factors such as the availability of medicines, prices of pharmaceuticals, differences in health care systems and the entry of the generics to the market [10]. The member states define their social security policies and affect through their regulatory power various dimensions of the market delimiting the prices and determining the reimbursement scheme of pharmaceuticals[11].

On the supply side, the pharmaceutical companies do not sell their products directly to the consumers. There is a block of wholesalers that distributes the pharmaceuticals to the pharmacies and to hospitals which provide the medicines to the final users. Moreover, there is a distinction between the pharmaceutical companies: the originator companies which manufacture and supply originator medicines and companies that manufacture generic products. It is possible in the market a company to produce both original and generic products[12].

Originator companies invest in research to develop a novel chemical or biological substance, offering a new pharmaceutical in the market that is a new treatment and no other medicine provides the same or equivalent benefits[13]. The new compound is patent protected and the pharmaceutical company that is the patent owner has the absolute right to exploit the discovery until the provided protection come to an end[14]. When the protection expires the barriers to entry of generic products to the market

[9] European Commission (2019) Report from the Commission to the Council and the European Parliament, Competition Enforcement in the Pharmaceutical Sector (2009-2017), pg.16

[10] OECD, Pharmaceutical expenditure. https://www.oecd-ilibrary.org/sites/78878924-en/index.html?itemId=/content/component/78878924-en#

[11] European Commission (2019) Report from the Commission to the Council and the European Parliament, Competition Enforcement in the Pharmaceutical Sector (2009-2017), 28.1.2019, pg.17

[12] Ipid, pg.16

[13] European Commission (2009) Pharmaceutical sector inquiry final report, para. 53

[14] European Commission, Report from the Commission to the Council and the European Parliament, Competition Enforcement in the Pharmaceutical Sector (2009-2017), 28.1.2019, pg.20

disappear, consequently the originator and generic medicines become competitive products[15].

Manufactures of generic products supply a generic version of the originator medicine after the protection of the intellectual property rights on the product expires (loss of exclusivity). Their expenditures to research and development are low since they can use the same qualitative and quantitative composition of the active ingredient and the same formulation of the originator medicine[16]. The generic products are in competition with the originator products since they are homogenous and their penetration in the market is performed through their low price comparable to the originator products [17].

Member States demonstrates a critical role through their regulatory function regarding important aspects of pharmaceutical circulation. Public agencies are competent for managing pharmaceuticals marketing, pricing, procurement, and reimbursement. Main objectives of the government's regulations are relative to pharmaceuticals quality and efficacy, accessibility and affordability, innovation, and research[18].

1.2. Research and Development in Pharmaceuticals

The discovery of a new chemical compound is the first step in the development of a new drug. After a successful completion of the basic research which is held by the originator manufacturers or independent research institutions that sometimes are financing by public funds, the examination of the drug safety and effectiveness in various laboratory tests is the next step of the development process. After the "early phase" of the research which can last 4 to 6 years about 250 compounds from approximately 10.000 candidate molecules are taken for further development and testing. The further examination in pre-clinical stage is perform on animals and in test

[15] Jaume Puig-Junoy (2010) Impact of European Pharmaceutical Price Regulation on Generic Price Competition, Pharmacoeconomics, pg.650

[16] European Commission (2009) Pharmaceutical sector inquiry final report, para.99

[17] Jaume Puig-Junoy, (2010) Impact of European Pharmaceutical Price Regulation on Generic Price Competition, Pharmacoeconomics, pg.650

[18] European Commission (2019) Report from the Commission to the Council and the European Parliament, Competition Enforcement in the Pharmaceutical Sector (2009-2017), p.17

tubes. At the end of this phase only 10 compounds apply the criteria of the test and will continue with the phase of clinical trials on patients. The clinical trials are consisting of three phases which are carried out to test the safety and effectiveness of new drugs on humans examining the possibility of compounds side effects. Trials last about six to seven years. Most compounds during the process are either eliminated or left for later review. However, on average, there is one compound that can apply for market authorization and finally enter to the market[19].

The new medicines are able to enter the market after a lengthy and costly research and development process. This process usually lasts 12-13 years until the drug is ready for use by patients[20]. The cost on research and development for a new pharmaceutical product are estimated between EUR 0.5 billion and EUR 2.2 billion (converted from USD)[21]. Beyond the costs for the discovery of new medicines, the pharmaceutical originator companies remain quite profitable. It is remarkable that the expenses in research and development are not the only priority of the sector since the costs for product marketing are quite excessive reaching 20-25% of their total turnover[22].

The time between the first patent of the medical invention that traditionally is the patent protecting the monocle, until the first marketing authorization of the medical product is defined as the development time. This period indicates the elapsed time between an invention taking place and the beginning of commercial benefits of this invention. According to a study written by Copenhagen Economics the average development time across EU countries has increased from 10 years to 15 years and

[19] European Commission (2019) Report from the Commission to the Council and the European Parliament, Competition Enforcement in the Pharmaceutical Sector (2009-2017), p.19

[20] European Federation of Pharmaceutical Industries and Associations, (EFPIA, The Pharmaceutical Industry in Figures Key Data 2020, EFPIA Publication pg. 6, EFPIA Publication. https://efpia.eu/media/554521/efpia_pharmafigures_2020_web.pdf

[21] Copenhagen Economics (2018) Study on the economic impact of supplementary protection certificates, pharmaceutical incentives and rewards in Europe, Final Report. Pg.10
The dataset covers 558 unique medicinal product names including all relevant information to allow the identification for each of them, which of the patents, incentives and rewards expires last and how many years of protection that implies. The dataset covers the period from 1996 to 2016 and 28 European countries, https://ec.europa.eu/health/sites/health/files/human-use/docs/pharmaceuticals_incentives_study_en.pdf

[22] European Commission (2009) Pharmaceutical sector inquiry final report., para. 927

50% of the products during the period 1996 to 2016 had a development time between 5 and 15 years[23].

On the other hand, the effective protection period is defined as the time during which a medical product launched to the market after granted marketing authorisation until the expiration of protection granted by patents, supplementary protection certificates, or regulatory incentives and rewards. The effective protection period indicates the time a product is on the market and is protected from generic competition via either IP rights or regulatory incentives and rewards. The Copenhagen Economics study demonstrates that since the 1990s the average effective protection period in the EU has decreased from 15 years to 13 years[24].

[23] Copenhagen Economics (2018) Study on the economic impact of supplementary protection certificates, pharmaceutical incentives and rewards in Europe, Final Report, pg.
[24] Ibid. pg. 10

2. Intellectual Property Rights and Competition Policy

2.1. Intellectual Property Rights, incentives, and rewards

Developing a new medicine and providing a new treatment for a disease is a costly process that demands large scale investments and considerable risk to be undertaken. The balance between the risk and the costs for the pharmaceutical production and the intensives to continue innovation is achieved with the contribution of intellectual property rights which provide protection to novel products. In European level, the pharmaceutical industry can protect the invention of new medicines using instruments of intellectual property law such as patents, supplementary protection certificates, data and market exclusivities providing to the holder the exclusive right for commercial exploitation of the product.

2.1.1. Patents

Patents provide to the originator companies the exclusive right to benefit of their invention's commercialization for up to 20 years from the patent application. A manufacturer is filing the patent application in an early stage of the development process to ensure that the current research will be available, and no other researcher is allowed to apply for the same invention. These early applications are referred to "primary patents" in contrast to the applications of the patents that will be filed during the development process and sometimes after the market entry. These "Secondary patents" can protect the production processes, dosage forms, alternative formulations, uses in new therapeutic classes, new combinations etc[25]. It is worth noting that from a patent law perspective each patent has to fulfil the patentability requirements as they are mentioned bellow. In the Final Report Sector Inquiry is stated that from nearly 40,000 cases that the Commission has analysed, 87% were sorted by the companies as referred to secondary patents, forming the ratio of primary to secondary patents within the pharmaceuticals 1:7[26]. According to this fact, for every primary patent protecting a pharmaceutical product, later other 7 patents applied for the same product.

[25] European Commission (2009) Pharmaceutical sector inquiry final report, para. 138
[26] Ibid. para. 427

The patent system in EU is not common in all Member States but is harmonized since all Member States are parties to the European Patent Convention along with the TRIPS Agreement. Patents can be registered in the European Patent Office or at national level in the local patent offices. Rights conferred by a European patent are the same as the rights conferred by a national patent in each contracting state in respect of which is granted[27]. However, the protection of the European Patent has to be validated by the national patent office[28].

According to article 52 of EPC an invention is patentable if is new, involve an inventive step and is susceptible of industrial application. The protection of the patent is 20 years from the date of filing the application[29]. Any infringement of the rights conferred by a patent are evaluated in accordance with national law. On the same basis, pursuant to article 28 of TRIPS Agreement, when a patent refers to a product, its proprietor grants the exclusive rights to restrict third parties from producing, exploiting, trading inside or outside a country that product for these purposes without proprietor's agreement. Alternatively, when a patent refers to a process, non-authorized third parties are avoided to use or trade that process or the product that is the conclusion of that process. However, the patent owner can transfer the conferred rights through succession, assignment, or licensing agreements.

The benefit to the public of the patent system is the availability of the detailed description of the invention while the benefit to the owner is the given right to prevent third parties from exploiting the invention for commercial purposes without authorisation in a limited period of 20 years.

When a European patent application is filed, after the formal examination of the application and the accompanied documents that are required for the application, a thorough research is taking place regarding the novelty of the patent and a meticulous examination ensuring that the patent protection is limited to what is actually

[27] European Patent Convention (art.64).
[28] EU official website, Patents your rights, https://europa.eu/youreurope/business/running-business/intellectual-property/patents/index_en.htm
[29] European Patent Convention (art.63).

patentable[30]. Patents applications are published on Espacenet [31] 18 months after the date of filing. If the criteria of the EPC are met the patent is granted however third parties have the possibility to opposed to the granted patent within 9 months of its publication and the applicant has the right to respond to that claim[32]. The decisions regarding the receiving, examining and opposition of a patent are subject to appeal. According to the European Patent Office (EPO), which conducted the research, 7.697 patents applications in pharmaceuticals were filed in 2019, rising by 4.4 percent respectively over 2018[33].

Under the provisions of (EU) No 1257/2012 Regulation the EU established a Unitary Patent within the Members States. The procedure obtaining a Unitary Patent would be based on the current European patent system. After a European patent is granted, the patentee will be able to request unitary effect by filing an application before EPO. According to the Regulation the EPO will confer a Unitary Patent upon submission of a single request that would apply uniformly to all Member States having signed the agreement. However, the Unitary Patent agreement has not been ratified in all countries, and the process has been delayed several times. Simultaneously, a Unified Patent Court will be formed to resolve infringement and other patent-related issues.

2.1.2. Supplementary Protection Certificates (SPCs)

Patents protection for new monocles last for 20 years. Since the patent is granted at an early stage of the medicine development and years before the final product enter the market, in 1992 the EU adopted the Regulation (EC) No 1768/1992 which introduced supplementary protection certificate for medicinal products. This Regulation with its amendments were codified on Regulation (EC) No 469/2009. In the recital (4) of the Regulation is illustrated that the elapsed period between the filing of patent application for a new medicinal product and authorisation for market entry of

[30] European Patent Convention (art. 69, 78, 83, 84, 85, 90-94 and Rule 42,43,47)
[31] Available at: https://worldwide.espacenet.com/
[32] European Patent Convention (art. 97,99,113)
[33] EPO, Patent Index 2019, available at: https://www.epo.org/about-us/annual-reports-statistics/statistics/2019/statistics/patent-applications.html

the product results in the restriction of the effective protection period of the patent which is insufficient to return the funds invested in research[34].

An SPC extends the patent protection period up to 5 years, depending on the duration of the research, development and testing processes. The duration of the protection granted by the certificate is defined such as the holder that obtain both a patent and a certificate should be able to enjoy an overall maximum of 15 years of exclusivity from the time the medicinal product first receives marketing authorisation in the Community[35].

The maximum protection of an SPC is 5 years and the combined protection period is 15 years. If the period between patent application and market authorization is less than 5 years, the prerequisite for the maximum protected period is not fulfilled, thus the SPC is not granted. If the time of the patent filing until to first authorisation to market entry is between 5 and 10 years, the inventor is covered for the 'loss' of protection period after market authorisation. If the period between patent filing and market authorisation is more than 10 years, the maximum SPC period of 5 years is conferred.

A certificate is granted if the product is protected by a basic patent and has received a valid market authorisation[36]. The basic patent according to the regulation is a patent which protects the active ingredients of the medicinal product. SPCs are granted nationally by the competent domestic authorities in each member state and the application has to be submitted within six months of the date on which the marked authorisation was conferred in that particular Member State[37].

To promote the research on medicinal products for paediatric use the Regulation (EC) No 1901/2006 introduced the possibility of a six-month extension to the duration of a SPC covering a marketed medicinal product if the inventor under certain conditions

[34] Regulation (EC) No 469/2009 art. (13), recital (4)
[35] Ibid art. (13), recital (9)
[36] Ibid art. (3)
[37] Ibid art. (9)

concludes studies agreed upon with the authorities in a Paediatric Investigation Plan (PIP), regardless of the outcome of the study[38].

2.1.3. Data Exclusivity and Market Protection

In the European Union, the pharmaceutical products before the market entry are obliged to obtain market authorization (MA) related to the efficacy and safety of a product. The European Medicines Authority (EMA) is the competent authority for the evaluation of applications for centralised marketing authorisations in the European Union[39]. This procedure enables pharmaceutical companies to file a single marketing authorisation application to EMA and to commercialize the medicine receiving access to the markets throughout the European Economic Area. On the other hand, pharmaceutical companies have the option to issue national authorisations through the national procedure before the competent national authority granting the right to market the impendent product within the national market. In addition, a national authorization can be recognized in other Member States via the mutual recognition procedure[40].

When a new medicine enters the market, the originator company that apply for the market authorization is obliged to submit to the relevant authorities the results of pharmaceutical tests, pre-clinical tests and clinical trials. In case, a generic manufacturer requests a market authorization for a generic version of an existing medicinal product, has the opportunity to submit a so-called abridge application with a reference to the data already produced by an originator company. The generic company has to prove that the generic medicinal product is essentially similar to the original product, having the same quantitative and qualitative composition, the same pharmaceutical form and being bioequivalent[41].

[38] Regulation (EC) No 1901/2006, art. (15)
[39] https://www.ema.europa.eu/en/human-regulatory/marketing-authorisation
[40] Directive (EC) No 83/2001 art. (28)
[41] This definition established by the ECJ in case C-368/96 was introduced in the Directive 2004/27/EC (Article 10(2)(b) of the Directive).

As a reward to the crucial investments made by originator companies to conclude the pre-clinical and clinical trial data, a period of 8 years of data protection is granted[42]. During these 8 years, the marketing-authorisation holder benefits from the exclusive rights to the results of preclinical tests and clinical trials on the medicine, therefore the generic manufacturers are restrained to use the data produced by the originator company and disclosed in the application for marketing authorisation. After 8 years, generic companies can request a marketing authorisation relying on the data produced by the originator company.

In parallel to the benefit of the eight-year period of data exclusivity, is provided a ten-year period of marketing protection[43]. During these 10 years, a generic medicinal product cannot be placed on the market even if has obtained a marketing authorisation since the data protection period elapsed earlier than the marketing protection. The marketing protection can be extended to a maximum of 11 years if, during the first eight years the marketing authorization holder receives an authorisation for a new therapeutic indication which considered to be a significant clinical benefit in comparison with existing therapies.

It is important to note that the protection of data and marketing exclusivity schemes are related directly to the final medicinal product, and the protection periods provided by them are independent of the protection provided by provisions on patents and SPCs, hence are applied in parallel with intellectual property protection[44]. Either Intellectual property provisions regarding patents and SPC or data and marketing exclusivity schemes protect originator products against generic competition, thus the "loss of exclusivity" takes place when all protected forms elapse [45].

According to the findings of Copenhagen Economics Study 39% of the medicinal products in study dataset were covered by data protection or market protection as the last measure of protection before loss of exclusivity. Data and market protection

[42] Regulation (EC) No 726/2004 art. (14)
[43] Ibid.
[44] European Commission (2009) Pharmaceutical sector inquiry final report, para. 322
[45] Ibid. para. 323

increases the duration of protection an average of 4.8 years while the average duration of protection for SPC is 3.5 years[46].

Beyond the above incentives, the Regulation (EC) No 141/2000 introduced the market exclusivity for orphan medicinal products which are intended for the diagnosis, prevention or treatment of life threatening or very serious conditions that affect no more than 5 in 10,000 people in the European Union. The incentive protects such medicinal products from competition from similar medicinal products targeting the same rare disease for 10 years[47].

2.1.4. Effective Protection Period

The effective protection period indicates the duration from a product receives a marketing authorization until the last form of protection expires[48]. It is the period where the pharmaceutical products are secure from generic competition, therefore the effective protection period is a useful indicator regarding the commercial impact of intellectual property rights and incentives schemes in pharmaceutical companies[49].

As reported by the Study of Copenhagen Economics, the effective protection period for the medicinal products has been decreased from an average of 15 years to 13 years during the period 1996 to 2016. The majority of medicinal products, 62% of them, are benefit of an effective protection period between 10 and 15 years, which is justified by the provisions of market protection, excluding the generic entry for a period of 10 years after the first market authorization of the product. Only 4% of the pharmaceutical products enjoy protection for less than 10 years period and 24% benefit of an effective protection period between 15 and 20 years. The 10% of the pharmaceutical products benefit more than 20 years of protection which can be explaining in virtue of the so-called secondary patents[50].

[46] Copenhagen Economics (2018) Study on the economic impact of supplementary protection certificates, pharmaceutical incentives and rewards in Europe, Final Report, p.11
[47] Regulation (EC) No 141/2000 art. (3) (8)
[48] Regulation (EC) No 469/2009 recital (9), article (13)
[49] Copenhagen Economics (2018) Study on the economic impact of supplementary protection certificates, pharmaceutical incentives and rewards in Europe, Final Report, p.11
[50] Ibid. p.12

2.2. Competition law policy within pharmaceutical sector

The aim of EU competition policy is to promote and preserve effective competition in the single market[51]. Antitrust rules protect effective competition and equal terms which are crucial for companies to provide a greater variety of products and services to consumers at competitive prices and conditions. Effective competition in pharmaceutical sector means that pharmaceutical companies compete on the basis of the qualities and prices of their products restraining from practices that impair their competitors' incentives to innovate.

The Commission acknowledging how important is the effective function of the pharmaceutical sector and how weaknesses such as the delay in the entry of generics to the market and the decline in innovation affect the competition in the sector, launched the sector inquire in order to examine these issues.

In the sector inquire, the Commission focused on product life cycle strategies that affect competition between originator and generic companies and competition amongst originator companies. It is worth mentioning that the Commission has followed up the inquiry with several competition law cases against specific companies and has continued monitoring the patent settlements between originator and generic companies. The most important cases will be discussed in the next chapter.

2.2.1. Applicable competition law

Competition Law ensures the proper functioning of the EU Single Market. The main antitrust rules are stated in articles 101 and 102 of the Treaty on the Functioning of the European Union but there is also secondary legislation such as Regulations 1/2003 which set rules for the Commission and the National competition authorities (NCAs) to enforce European competition law and Regulation 773/2004 relating to the conduct of proceedings by the Commission pursuant to Articles 101 and 102 TFEU. Moreover,

[51] European Parliamentary Research Service (Author: Marcin Szczepański) (2019) EU competition policy - Key to a fair single market PE 642.209 - Executive summary

Commission has adopted regulations[52] and guidelines[53] clarifying the applicability of antitrust rules.

Article 101 TFEU prohibits anti-competitive agreements between two or more independent market operators which have as their object or effect the restriction of competition. Article 102 TFEU prohibits abusive behavior of companies holding a dominant position on any given market[54]. The competition rules do not question the existence of intellectual rights and in the same manner the intellectual property rights are not excluded from the application of competition law[55]. Holders of intellectual property rights can be involved into agreements with a result the restriction of competition in breach of article 101 TFEU or being in a dominant position can employ practices constitute an abuse under the article 102 TFEU. These practices will be analysed in the following chapter.

2.2.2. Public Enforcement of Competition Law

The European competition authorities are consisting of the European Commission and the National competition authorities (NCAs). The European competition authorities work together supervising the implementation of competition law in the pharmaceutical market and enforcing antitrust rules in case of their violation.

The Commission and the NCAs are legally competent to enforce EU competition rules. Each competition authority can operate independently, initiates its own investigations, and imposes competition decisions under this parallel enforcement framework. In addition, the Commission and NCAs cooperate closely and together make up the European Competition Network (ECN)[56]. If certain conduct affects cross-border trade between Member States the NCAs, the national courts which are fully empowered to apply articles 101 and 102 TFEU, and the Commission share the competence to apply

[52] Regulation (EC) No 772/2004 on the application of Article 81(3) of the Treaty to categories of technology transfer agreements
[53] European Commission Guidelines on the applicability of Article 101 of the Treaty on the Functioning of the European Union to horizontal co-operation agreements
[54] Treaty on the Functioning of the European Union, articles (101), (102)
[55] European Commission (2009) Final Report Sector Inquiry, Annexes, para.13
[56] Regulation 1/2003 (articles 4, 5, 6)

antitrust rules. In case, certain contact does not affect cross border trade, the NCAs and the national courts apply their national competition law, which usually incorporates the European Union law[57]. When the Commission acts on its own initiative is directly responsible for its investigations[58]. The competition authorities are empowered to adopt decisions on commitment or impose fines when they find an infringement of articles 101 and 102 TFEU[59].

In the period 2009-2017 the NCAs and the Commission adopted 29 decisions finding an infringement or accepting binding commitments in cases related to pharmaceuticals[60]. Moreover, after the pharmaceutical sector inquiry the Commission has been conducting yearly monitoring the patent settlements between the pharmaceutical companies.

[57] Ibid
[58] Regulation 1/2003 (article 11)
[59] Regulation 1/2003 (article 5)
[60] European Commission (2009) Report from the Commission to the Council and the European Parliament, Competition Enforcement in the Pharmaceutical Sector (2009-2017), pg.9

3. Competition in Pharmaceutical industry

3.1. Competition between Originator and Generic Companies

The production of a new medicine is a costly procedure due to the high expenditures in research and development of the new product[61]. Thus, the originator companies attempt to recoup their investments during the effective protection period until the launch of the generic version of their medicines. The launch of generics results in the termination of the originator company monopoly considering that more sources of supply are accessible. Since the generic companies can grand market authorization proving that their product is equivalent to an originator product refraining from spending in pre-clinical tests and clinical trials, are able to provide cheaper versions of pharmaceutical products.

The entry of the generics to the market has an impact on the prices of the originator products which are facing competition for a first time. In addition, the volume of products sold, and the market shares of the originator companies are affected. Consequently, the entry of generic decreases the turnover of the originator companies[62]. After the first entry of the generic version of a product, it is estimated that the price of the originator product drops 20-30 per cent. In case that more generic products enter the market, the price can decrease up to 90 per cent. Moreover, the originator companies are possible to confront even an 80 per cent market share loss. In expectation of the reducing revenue after the loss of exclusivity, originator companies may engage strategies intending to prolong the time of their market exclusivity without generic competition[63].

[61] Anderman S, Schmidt H. (2007) EC competition policy and IPRs. In: Anderman S, editor. The interface between intellectual property rights and competition policy. Cambridge: Cambridge University Press, pg.12

[62] European Commission (2009) Pharmaceutical sector inquiry final report, para. 465

[63] Ibid. para. 166

3.2. Strategic Patenting

Many originator companies adopt lifecycle management strategies with the purpose to extend the lifetime and the profitability of their products[64]. Patent filling strategies has been recognised by the Sector Inquiry as part of companies' toolbox which is used to preserve profits of pharmaceutical products through the extension of patent life discouraging the market entry of generic products[65].

The term "patent strategies" contains all the practices that a company may employ regarding enjoying the benefits of the patent system which are possible to have negative effects on market competition. A strategy entailed to preserve an originator's market position against generic entry is generally legitimate to the extent it resorts to measures correspond to "competition on the merits", which is defined as competition on product quality and the strategic use of the patent system. In contrast, a dominant company's conducts that diverge from competition on the merits and are capable of producing foreclosure effects will be subject to antitrust scrutiny[66]. The notion of competition on merits has been introduced by European Commission in relation with the application of art.82 of the EC Treaty implying that "*what really matters is protecting an effective competition process and not simply protecting competitors*[67]".

Originator companies until the protection period of the basic compound's patent elapsed, may obtain secondary patents in order to secure other aspects of the pharmaceutical product such as the process of manufacturing, formulation etc. It is possible under these conditions the secondary patents to extend the overall protection provided by the basic compound's patent for a particular pharmaceutical product which can explain the findings of Copenhagen Economics Study that 10% of the

[64] Roin BN (2009) Unpatentable drugs and the standards of patentability, Texas Law Review, 2009;87:503, pg.545, https://dash.harvard.edu/handle/1/10611775
[65] European Commission (2009) Pharmaceutical sector inquiry final report, para. 469
[66] European Commission, (2014), Case AT.39612 – Perindopril (Servier), n. 2766, Heineman, Blocking Patents and the Process of Innovation, p. 14
[67] European Commission (2009) Communication from the Commission — Guidance on the Commission's enforcement priorities in applying Article 82 of the EC Treaty to abusive exclusionary conduct by dominant undertakings, para.6

pharmaceutical products in its database benefit more than 20 years of protection[68]. This could be the case, when an originator company discloses in its patent application the manufacturing procedure which is sufficient to laboratory produce of the active compound but is unsuitable for massive commercial production. If the originator had protected by a secondary patent the manufacturing process for massive production of the active compound, it would hinder generic companies entering the market and reproducing the active compound in the same way since they would infringe this secondary patent[69]. The European Commission in the sector inquiry confirms a reduction of novel medicines introducing the market and indicates certain company practices that might lead to this outcome.

3.3. Patent clusters

Patent thickets or clusters are referred to describe numerous patent applications that originators file to surround the primary molecule patent securing the product in addition to the base patent. The aim of patent thickets is the creation a multiple layer of defense beyond of the molecule patent by other patents in respect of different dosage forms, formulations, or the production process. The incremental innovation of a pharmaceutical product can result in further patenting of its improvements regarding basic active agents or new medical uses[70]. However, originator companies engage conducts such as filing broad patent applications and multitudes applications for the same pharmaceutical product aiming not to secure their invention but to prevent the entry of generics in the market thus to avoid competition preserving their position[71]. It is worth mentioning that the patents around the basic patent are not always considered strong and the originator companies admitted that even though, they can delay generics through litigation procedures by applying interim injunctions[72].

[68] Copenhagen Economics (2018) Study on the economic impact of supplementary protection certificates, pharmaceutical incentives and rewards in Europe, Final Report, p.11
[69] Case CE-9531/11, para 3.70-3.71
[70] European Commission (2009) Pharmaceutical sector inquiry final report, para. 485
[71] Burdon M, Sloper K. (2003) The art of using secondary patents to improve protection. Journal of Medical Marketing 2003;3:226, pg. 227
[72] European Commission (2009) Pharmaceutical sector inquiry final report, para. 546

A large proportion of patent applications are filed late in a medicine's life cycle, especially for medicines with great economic success[73]. The European Commission after the investigation of the pharmaceutical industry, reports that the patents granted and pending applications related with blockbuster medicines are protected by up to nearly 100 product-specific patent families, which can lead to up to 1,300 patents and pending patent applications across Member States[74]. A generic company has to examine all granted patents and pending patents applications in those Member States in which it may seek to enter the market with a generic version of the original medicine. When patent clusters exist, the generic companies face legal uncertainty regarding the possibility to enter the market and in case that a generic medicine launch, opposition procedures and legal disputes against patent infringement follow this attempt. Consequently, patent thickets lead to generic delay or even deterrence since generic companies are obliged to wait until all the relevant patents expire or quit their entry plan[75].

3.3.1. Pfizer case (2011)

In 2011, the Italian competition authority imposed EUR 11 million sanctions on Pfizer for conducting a complex legal strategy which involved filing divisional patents and supplementary protection certificates with a result to extend the period of patent protection for its originator medicine Xalatan[76].

Pfizer challenge the decision and the Italian State Council at the final judgment of the case upheld the decision of the Italian competition authority. In its judgement the Italian State Council illustrated that this case is not related to the lawfulness or not of a behavior under intellectual property law but to the anticompetitive outcomes of conducts that are per-se compatible with the law.

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[73] Kapczynski A, Park C, Sampat B. (2012) Polymorphs and prodrugs and salts (oh my!): an empirical analysis of "secondary" pharmaceutical patents, PLOS ONE, https://doi.org/10.1371/journal.pone.0049470

[74] European Commission (2009) Pharmaceutical sector inquiry final report, para. 485

[75] Burdon M, Sloper K. The art of using secondary patents to improve protection. Journal of Medical Marketing2003;3:226. pg 227

[76] European Commission (2019) Report from the Commission to the Council and the European Parliament, Competition Enforcement in the Pharmaceutical Sector (2009-2017), pg.28

The court recognized that Pfizer's conduct was anti-competitive since the originator company's purpose to apply for divisional patents and an Italian SPC did not seem to be the protection of a new product, but the artificial extension of Xalatan's patent protection in Italy ,hence the delay of generic entry.

3.3.2. Teva case -Commission new investigation (2021)

In March 2021, the European Commission announced that formal investigations are initiating to evaluate whether the pharmaceutical company Teva has engaged anti-competitive conduct in relation to its blockbuster drug Copaxone, which is used in the treatment of multiple sclerosis with a result the delay of generic entry in the market.

In 2015, Teva's basic ingredient patent covering glatiramer acetate expired, consequently the entry of generic medicine in the market was possible. The Commission will assess whether, Teva conducts following the basic patent expiry, artificially extended the market exclusivity of Copaxone by strategically filing and withdrawing divisional patents, accompanying litigation as well as a communications campaign against competing products, contributed to delay entry of its generic competitor[77].

Divisional patents generate from a broader “parent” patent which is separated into one or more narrower patent applications and may increase uncertainty about patent rights[78]. Filing divisional patents multiply the barriers to the potential competitors, who have to challenge the validity of the patents in question which can result in a withdrawal of the divisional patent and then have to restart legal challenges for the further divisional patents that are granted.

This is the first time the Commission investigates a company’s conduct consisting of filing patent strategies. The launch of a formal investigation does not preclude an infringement but there is a chance for the Commission to analyse in depth the

[77] European Commission (2011), Press release, Antitrust: Commission opens formal investigation into possible anticompetitive conduct of Teva in relation to a blockbuster multiple sclerosis medicine, https://ec.europa.eu/commission/presscorner/detail/en/ip_21_1022

[78] European Commission (2009) Pharmaceutical sector inquiry final report, para. 509,528

possibility of an abuse of dominant position and infringement of Article 102 TFEU by a pharmaceutical company using the patent system with purpose the exclusion of generic competition[79].

3.4. Life cycle strategies for follow on products / evergreening

Incremental research leads to the improvement of existing pharmaceuticals with important benefits to the public health protection and patients, entails to the launch of second generation products. However, the introduction of follow on products in the market may sometimes be used as a measure for delaying the market entry of generics related to the first generation products[80]. In this way the originator companies reduce the risks of competition with generic version of the first generation product since they promote the improved follow on product[81]. According to the definition of the sector inquiry, follow on products are outcomes of research and development process based on the existing product and they are used for the same therapeutic purposes. These second generation products may involve new formulations, crystalline forms, particle sizes or medical uses, using the same International Nonproprietary Name as the first product or may involve combinations or parts of an existing INN consequently using a different INN[82].

It is quite often originator companies before loss of exclusivity of the first generation product to launch a follow on product which is sometimes accompanied by the withdrawal of the initial product from the market. The new version of the medicine is promoted to persuade doctors to prescribe the advanced product therefore to shift the demand to the new product[83]. Generic companies enter the market offering bioequivalent medicines to the old version of the follow on product. If doctors and patients choose the follow on product which use different INN is possible that the

[79] European Commission (2011), Press release, Antitrust: Commission opens formal investigation into possible anticompetitive conduct of Teva in relation to a blockbuster multiple sclerosis medicine, https://ec.europa.eu/commission/presscorner/detail/en/ip_21_1022

[80] Bansal Inderjit Singh (2009) Evergreening – A Controversial Issue in Pharma Milieu, Journal of Intellectual Property Rights, 14(4):299-306

[81] European Commission (2009) Pharmaceutical sector inquiry final report, para. 988

[82] Ibid. para. 990

[83] Ibid. para. 989

pharmacist are not able anymore to substitute the medicine with a generic version since the generic medicine obtain a market authorization for the bioequivalent pharmaceutical which is the old version medicine using different INN from the prescribed.

3.4.1. AstraZeneca Case (2005)

The European Commission imposed a fine of €60 million on Anglo-Swedish group AstraZeneca for misusing the patent system and the procedures for marketing pharmaceuticals aiming to block or delay market entry for generic competitors of Losec medicine. The Commission has decided that AstraZeneca's conducts abused its dominant market position in breach of competition rules[84].

The abusive behavior of AstraZeneca constituted in two different types of conduct. On the one hand, the firm submitted misleading information before several patent offices in the European Economic Area regarding the date of the first market authorization of Losec medicine in order to extend patent protection through supplementary protection certificates (SPCs). On the other hand, switched the formulation of Losec from capsule to tablet and withdrew the market authorization of the previous form. At the time, a generic medicine could only access the market in a Member State if the market authorisation for the reference product was still in force[85].

The judgments of the General Court (in 2010) and the Court of Justice (in 2012) in AstraZeneca verified that misleading representations before public authorities and the misuse of the regulatory procedures as a part of an overall strategy, excluding manufacturers of generic products before the launch a follow-on product, can in certain circumstances constitute an abuse of a dominant position[86]. It is noteworthy to mention that regarding the second abuse of a dominant position, the Court held that

[84] European Commission (2005) Press release, Commission fines AstraZeneca €60 million for misusing patent system to delay market entry of competing generic drugs https://ec.europa.eu/commission/presscorner/detail/en/IP_05_737

[85] Heinemann Andreas (2018) Abusive Filing of IP Rights, SSRN: https://ssrn.com/abstract=3251209 or http://dx.doi.org/10.2139/ssrn.3251209 pg. 2

[86] European Commission (2019) Report from the Commission to the Council and the European Parliament, Competition Enforcement in the Pharmaceutical Sector (2009-2017), pg.27, Court of Justice (2012), AstraZeneca AB and AstraZeneca plc v European Commission, C-457/10 P, para. 68, 130

the deregistration of the marketing authorisations, without objective justification and after the expiry of the exclusive right granted by EU law, with the aim of preventing or hindering the entry of generic products and parallel imports, also is not compatible with the scope of competition on the merits[87].

3.4.2. Gaviscon case (2011)

The United Kingdom NCA fined Reckitt Benckiser GBP 10.2 million (approximately EUR 11.8 million) for abusing its dominant position by withdrawing and de-listing Gaviscon Original Liquid with a result the restriction of generic competition[88].

Before the expiration of Gaviscon Original Liquid which treat acid reflux (heartburn), gastro-oesophageal reflux disease (GORD) and dyspepsia, the company launched another version of the product Gaviscon Advance Liquid which was protected by different patent of the original product. After the patent for Gaviscon Original Liquid expired but before the generic name for the product was assigned, Gaviscon Original Liquid was withdrawn. Without a publication of a generic name, the most prescriptions would be issued for its alternative product, Gaviscon Advance Liquid which was patented protected and therefore without generic substitutes. Therefore, were not possible the original product to be substituted with its cheaper generic versions. However, Reckitt Benckiser admitted that its conduct was in violation of the United Kingdom and EU competition law and accepted to cooperate with the NCA[89].

3.4. Competition between Originator Companies

Originator companies are active in research and development with an effort to manufacture novel medicines and after to release them in the market. Originators usually compete against each other with purpose to invent, patent and launch first a

[87] Court of Justice (2012) AstraZeneca AB and AstraZeneca plc v European Commission, C-457/10 P, para. 130-134

[88] Office of Fair Trading (2011) Abuse of a dominant position by Reckitt Benckiser Healthcare (UK) Limited and Reckitt Benckiser Group plc , Decision No. CA98/02/2011

[89] European Commission (2019) Report from the Commission to the Council and the European Parliament, Competition Enforcement in the Pharmaceutical Sector (2009-2017), pg.28

new pharmaceutical product for a new treatment or when treatments already exist to increase their share to the market introducing a different treatment. In the sector inquiry the Commission investigated whether the behaviour of originator companies may affect the introduction of innovative medicines into the market[90].

Strategic patenting is practices employed by originator companies to prevent competition not only against generic companies but also against other originators. However, such practises that protect originators from competitive pressure and reduce their incentives to innovation, have negative impact on market competition.

3.5. Defensive patenting

Patents are granted as a reward for the investments into innovation and the introduction of novel products into the market. In addition, patent benefit society wealth since inventors have to disclose their inventions to the public fostering further innovation. Patented exclusive rights limit competition by imitation in order to encourage competition through substitution[91]. Without patent protection, there would be less incentives to develop, considering that anybody could take advantage the efforts of others.

However, not all granted patents are actively used. The European PatVal study illustrated that about 36% of European patents are not used for industrial or commercial purposes[92]. Some of the unused patents are "sleeping patents" related to inventions that their possibility to enter the market is unknown at the present. "Patents defending the freedom to operate" are unused patents that allow their holder to continue further research and improvement of its pharmaceutical product without intervention from competitors. "Blocking patents" are sleeping patents that

[90] European Commission (2009) Pharmaceutical sector inquiry final report, para. 1085
[91] Heinemann Andreas (2019) Blocking Patents and the Process of Innovation, New Developments in Competition Law and Economics pp 149-168, Springer, pg. 161
[92] European Commission (2012) *Towards enhanced patent valorisation for growth and jobs*. Commission Staff Working Document SWD (2012) 458 final. pg.5

block competitors from using an invention even though the patent holder does not use them or defends by them its alleys of research[93].

It is not problematic a patent not to be exploited by its holder because the product market is unclear. In addition, it is legitimate to file "defensive patents" maintaining the freedom to operate. In the latter case, the objective of patenting is to preserve the development of an invention so as to bring it to the market without research process being obstructed by competitors.

Once the patent application is published, the invention is referred to become public knowledge therefore the subject matter of the application would not be in the field of interest of other companies anymore. Companies may hinder the development of competing products by obtaining an exclusive right to the invention which at the same time become prior art [94].

Patent strategies are a legitimate way for protecting an invention against competitors when a novel product enter the market, however there is a limit to that practice[95]. In the Servier case, the European Commission make a distinction between patents strategies which constitute "measures representing competition on the merits" enhancing competition on product quality and the strategic use of IPRs and measures that "deviate from competition on the merits" which result in prevention or elimination of competitors access to the market[96]. While patents strategies in compliance with the notion of competition on merits are legitimate, patents strategies that deter competition and have an adverse impact on consumers welfare should be subject to antitrust scrutiny[97].

[93] Heinemann Andreas (2019) Blocking Patents and the Process of Innovation, New Developments in Competition Law and Economics pp 149-168, Springer, pg. 161
[94] European Commission (2009) Pharmaceutical sector inquiry final report, para. 1127
[95] Hull David W. and Clancy Michael J. (2017) The Application of EU Competition Law in the Pharmaceutical Sector, Journal of European Competition Law & Practice, 2017, Vol. 8, No. 3, pg.207
[96] Heinemann Andreas (2019) Blocking Patents and the Process of Innovation, New Developments in Competition Law and Economics pp 149-168, Springer, pg. 161
[97] European Commission (2014) Decision, PERINDOPRIL (SERVIER) Case AT.39612, para.2766

In the case of unused patents, the crucial criterion for the distinction between legitimate and abusive patent strategies is the intension of the non use. In cases of "sleeping patents" and "patents defending the freedom to operate", there is a legitimate interest in strategic patenting which is compatible with competition on merits. However, there is differentiation regarding blocking patents since the main purpose for their acquisition is the prevention of the competitors to introduce alternatives into the market[98]. In this sense blocking patents are in contrary with the scope of intellectual property rights. The aim of the exclusive rights obtaining by a patent is to allow originator companies to prevent third parties to use their invention but not to exclude competitors to develop alternatives. Consequently, there is an abuse of a dominant position when the main purpose of a patentee consists in blocking competitors[99].

3.5.1. Boehringer case

Boehringer is the second case after AstraZeneca that the European Commission in 2007 initiated investigation for potential misuse of the patent system[100]. A Spanish pharmaceutical company Almirall alleged that Boehringer Ingelheim filed unmeritous patents regarding the combinations of three broad categories of active substances treating COPD (lung diseases) with a new active substance that had been discovered by Almirall. The later expressed concerns that Boehringer's patent applications could block or considerably delay the market entry of its own innovative medicines. The Commission investigation related to the claimed misuse of the patent system aiming to exclude potential competition in violation of competition law. The Commission suggested both parties to find a mutually acceptable solution to their dispute, considering that a settlement is beneficial for the consumers. The Commission closed the investigation after the parties reached an agreement which removed the alleged blocking positions and allow the launch of Almirall's products[101].

[98] Andreas Heinemann, Blocking Patents and the Process of Innovation, New Developments in Competition Law and Economics pp 149-168 (15 March 2019) p. 162-163
[99] Ibid.
[100] European Commission (2007) Press Release in case COMP/B2/39246 – Boehringer
[101] European Commission (2011) Press Release IP/11/842 in case COMP/B2/39246 – Boehringer

It is worth mentioning that the obtained patent by Boehringer for one of the combination products was revoked by UK High Court of Justice and by EPO because of obviousness (lack of inventive step) and insufficiency. However, since Boehringer had also filed divisional patent application based on the main patent, which were unused, the patent dispute was extended despite the annulled of the basic patent[102].

The Boehringer case did not answer the crucial question whether a "misuse of the patent system" consisted of filing patent applications aiming to deter or block competitors of the market, can constitute from a competition law perspective, an abuse of a dominant position. However, this case revealed the concerns of the European Commission regarding blocking patenting and entailed in the pharmaceutical sector inquiry in early 2008 followed by the final report in 2009 and the monitoring of patent settlements regarding to pay-for-delay agreements.

3.6. Patent Settlement agreements

Patent settlements are agreements between a patent owner and a third party with the aim to resolve actual or potential patent related disputes, opposition proceedings or litigation proceedings where no final decision has been reached. A patent settlement can be concluded at any time of the dispute even during court proceedings. The object of the patent disputes concerns the validity or the infringement of a patent and generally is a legitimate way for ending private disagreements[103].

The primary motivation for parties to settle patent disputes is to avoid significant expenses and the uncertainty of a litigation outcome regarding the strength of their case. Generally, settlements are a legitimate way of resolving patent disputes. However, in some cases when settlements involve a restriction on generic companies' market entry and a value transfer from the originator company to a generic company, an infringement of competition law is possible[104].

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[102] Ibid.

[103] Shapiro Carl (2003) Antitrust limits to patent settlements RAND Journal of Economics Vol. 34, No. 2, pg. 391–411, pg.394

[104] European Commission (2009) Pharmaceutical sector inquiry final report, para.708

The most decisive factor in respect of originator considerations to settle an agreement is the probability of winning or losing the case. At the same time their decision is influenced by the market size and the income to be protected especially when the product is a "blockbuster", the litigation costs, the uncertainty involved in patent litigation, and the expected duration of litigation. In addition, the possibility of obtaining interim injunctions is critical for the originator assessment in relation to a settlement agreement since the grant of interim injunctions prolong the exclusivity of the originator products in the market[105].

On the other side, generic companies concern mostly about the litigation costs, while are quite important criteria the uncertainty involved in patent litigation, the strength of the case, the country where the litigation takes place, and the expected duration of litigation[106].

The Commission in the sector inquiry distinguished settlement agreements regarding their ability to provide a limitation to the entry of the concerned generic product in the market related to the settlement. In respect of the agreements which limit generic entry, a further classification is available related to the existence of value transfer from the originator company to the generic companies[107]. Agreements that involve limitation to market entry and transfer value are also known as "pay for delay agreements" and attract competition law scrutiny since they violate the article 101 TFEU.

In "pay for delay agreements", the generic companies' entry is usually limited by an explicit clause confirming the validity of the originator company's patent(s) while declaring that will refrain from entering the market until the patent(s) have expired. According to Commission considerations if a settlement agreement concludes in granting of a license for specific patent rights or distributing of a pharmaceutical

[105] European Commission, Final Report Sector Inquiry (July 8, 2009), para. 720
[106] Ibid. para.721
[107] Ibid. pg.269

product, is deemed as an agreement limiting the market entry, since the market entry of the generic company is controlled by the originator company[108].

A pay-for-delay arrangement may benefit both parties, the originator companies which increase their revenue enjoying longer market exclusivity, and the generic companies which receive parts of the originator earnings from extended exclusivity[109]. However, patients and healthcare systems bear the cost of pay-for-delay agreements due to the price of the pharmaceuticals products which are not affected by the competition of an independent generic entry. Considering the reduction of pharmaceuticals price after an independent generic entry, even slight delays can have negative effects on competition[110].

Since pharmaceutical sector inquiry, which was concluded in 2009, the Commission has been conducting yearly monitoring the patent settlements. The last report for the year 2016 was published in March 2018[111]. After the publication of the Final Report European Commission has investigated numerous cases regarding pay for delay agreements and has raised sanctioning decisions when an infringement of competition law found.

In the following section of this paper, case law in reference to patent settlement agreements is illustrated focusing on Court Decisions and Commission's recent enforcement of EU antitrust rules in the pharmaceutical sector.

3.6.1. Lundbeck case (2013)

In 2013 the Commission imposed a sanction of EUR 93.8 million on a Danish originator company Lundbeck and EUR 52.2 million in total on four generic companies, namely, Merck KGa, Alpharma, Arrow, and Ranbaxy for coming to agreements that delayed the

[108] Ibid. para. 769
[109] Van der Woude M. (2009) 'Patent Settlements and Reverse Payments Under EU Law', 5(2) CPI 183 pg.186.
[110] European Commission (2019) Report from the Commission to the Council and the European Parliament, Competition Enforcement in the Pharmaceutical Sector (2009-2017), pg.25
[111] European Commission (2018) 8th Report on the Monitoring of Patent Settlements (period: January-December 2016)

market entry of a generic version of antidepressant medicine containing the active ingredient citalopram which was developed by Lundbeck[112].

According to the Commission findings, when the agreements were concluded, the patent of citalopram compound and its data protection had expired. Moreover, some patents regarding the original production processes had expired but Lundbeck still obtained exclusive rights to new ways of producing citalopram. Therefore, any originator company could enter the market using either the original production processes or any production process that was not covered by a patent or a valid patent. All agreements were settled within the framework of a patent dispute, before any litigation (except for the settlement with Alpharma) or a court ruling, even by issuing of interim measures.

The Commission established that settlements concluded by Lundbeck with 4 generic companies had as their object the restriction of competition, relying its rationale on the following findings: (i) Lundbeck and the generic companies were at least potential competitors when the agreements were concluded ; (ii) the agreement involved a value transfer from Lundbeck to the generic companies in respect of the profit the generic undertakings expected from marketing a generic citalopram aiming to affect generic incentives to independently enter the market; (ii) agreements contain generic undertakings commitment to refrain for the duration of the agreement from entering the market (iv) generic commitments regarding desisting market entry could not be enforced by Lundbeck through the patent process since they went beyond the scope of the rights obtaining by patent; (v) settlements did not oblige Lundbeck to abstain from infringement proceedings against generic companies if the latter entered the market with a generic version of citalopram after the expiration of the agreements.

The judgments of the General Court (in 2016) and the Court of Justice (in 2021) dismissed the actions brought by Lundbeck and the generic undertakings and confirmed the fines that Commission imposed on them[113].

[112] European Commission (2013) Decision in *Lundbeck* (Case AT.39226) OJ C368/13.

3.6.2. Perindopril case (2014)

In 2014, the Commission has fined EUR 427.7 million in total on the French pharmaceutical company Servier and five producers of generic medicines (Niche/Unichem, Matrix/Mylan, Teva, Krka and Lupin) for concluding a series of settlements with purpose to refrain from competition and prevent generic entry to market in favor of Servier's bestselling medicine for blood pressure, perindopril[114].

Servier had implemented a strategy for delaying generic entry which involved acquiring a competing technology and successively conducting patent settlement agreements. According to the Commission findings Servier employed a strategy to extent the exclusivity rights over perindopril applying for several processes and crystalline form patents. In addition, Servier acquired from Azad a competing technology which produced perindopril and conducted litigation proceedings with generic companies that intended to enter the market which entailed to five patent settlement agreements.

The Commission used the same criteria applied in the Lundbeck case, and according to its examination of each patent settlement agreement concluded that the content, objectives, and legal and economic aspects of the patent settlement agreements between Servier and the generic companies had as their object the restriction of competition resulting an infringement of article 101 of TFEU. The Commission decision established that Servier abused its dominant position by conducting a strategy including a technology acquisition and five patent settlement agreements aiming to deter competition regarding its branded medicine of perindopril that constitutes a single and continuous infringement of Article 102 of TFEU.

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[113] General Court (2016) Judgement *H. Lundbeck A/S and Lundbeck Ltd v European Commission*, T-472/13, C-591/16 P

[114] European Commission (2014) Summary of Commission Decision Perindopril (Servier) ,Case AT.39612

On 12 December 2018, the General Court upheld the Commission's findings in respect of the violation of Article 101 (with the exception of the Krka agreement) but rejected the Commission's market definition, hence annulled partial the decision in relation to the infringement of Article 102 TFEU and reduced the total fines to EUR 315 million[115]. Servier appeal the judgment of the General Court to the Court of Justice.

3.6.3. Teva and Cephalon case (2020)

In 2020, the Commission imposed a fine of €60.5 million on pharmaceutical companies Teva and Cephalon for entering into agreement with the purpose to delay the market entry of a cheaper generic version of modafinil, Cephalon's medicine for sleep disorders and most selling product, after several years of expiration of Cephalon's main patents[116].

In 2005 the Cephalon's primary patent protecting modafinil had expired while Teva was the main generic competitor of Cephalon in Europe. According to the Commission findings, Cephalon has obtained several secondary patents on modafinil that their strength was doubtful while Teva started proceedings against their validity. However, the parties concluded a settlement agreement containing non-compete and non-challenge commitments in return for a transfer of significant value.

Through the settlement agreement, Cephalon granted to Teva a non-exclusive license to market generic modafinil, nonetheless this licensing agreement was never enacted because of the companies' merger. The Commission decision demonstrated that this arrangement prolonged the delay of Teva's independent entry to the market and decreased the price competition between the two companies, preventing at the same time the entry of potential generic competitors[117].

The Commission concluded that the settlement agreement infringed the Article 101 TFEU as a restriction by object and for six EU Member States also constituted a

[115] General Court (2018) Judgement Servier and Others v Commission, CASE T-691/14
[116] European Commission (2020) Press Release IP/20/2220 in case (AT.39686-Cephalon)
[117] European Commission (2020) Decision, Cephalon (Case AT.39686) C (2020) 8153

restriction of competition by effect under Article 101 TFEU. On 22 March 2021, Teva and Cephalon appealed the European Commission's decision fining them for breaching Article 101 of the TFEU before the General Court[118].

[118] European Commission (2020) Decision, Cephalon (Case AT.39686) C (2020) 8153

4. The scope of application of article 102 of TFEU

While there is no doubt on the application of competition law and particularly of the article 101 TFEU in cases of patent settlements agreements, a subject that generates a lot of discussion is whether strategic patenting by dominant pharmaceutical companies should constitute an abuse under art.102 TFEU.

The article 102 of TFEU prohibits the abuse by an undertaking of a dominant position which may affect the trade between Member States. It is compatible with the provision of article 102, an undertaking to be in a dominant position when its conduct is deemed as action based on competition on merits[119]. Exclusionary conducts by a dominant undertaking which is harmful for the consumers that can not be benefit from lower prices, better quality in products or services and alternative choices, as a result of competition, are subject to competition law scrutiny[120]. Effective competition enhances market activities, innovation, and consumers welfare. The only compatible way within the scope of article 102 for a dominant undertaking to engage competition against its rival is within the limits of competition on merits which protects an effective competition process and not only competitors[121]. An exclusionary conduct by a dominant that impair competitors to entry the market in detriment of consumers welfare with an adverse impact in price levels, products quality and supply options violates article 102 of TFEU.

The ECJ determines the notion of abuse as an objective concept concerning a dominant undertaking's conduct which affect the degree of competition in the market by employing practices that differs from those governing normal competition in

[119] European Commission (2009) Communication from the Commission -Guidance on the Commission's enforcement priorities in applying Article 82 of the EC Treaty to abusive exclusionary conduct by dominant undertakings (2009/C 45/02), para 1
[120] Ibid. para 5
[121] Ibid.

products or services resulting in the decline of the existing level of competition in the market and the progress that provides [122].

4.1. Should the strategic patenting constitute an abuse under art. 102 of TFEU?

Considering the scope of application of article 102 in relation to the strategic patenting a crucial question is raised: could the strategic patenting constitute an abusive conduct of a dominant undertaking?

The use of a strategy concerning the life-cycle management of a pharmaceutical product is not in itself an abuse incompatible with article of 102 TFEU. The General Court in the decision of Astra Zeneca case, illustrated that the abusive contact is related with the notion of competition on the merits [123]. Whereas the use of a patent can not constitute an infringement of Article 102 TFEU, it is the strategic use of the patent system that affects competition by foreclosing competitors and leads to harmful effects to consumer welfare. These practices entail to the decrease of the competitor´s incentive to innovate. In the case of patent clustering or evergreening these conducts create legal uncertainty and possible allegations for patents infringements discouraging the competition of generic companies. Moreover, in cases of blocking patents the competitor's incentives to innovate are affecting by the incapacity to market a product that is protected by a patent which its subject matter remains unexploited. Beyond the inefficiency of the incentives to innovation, the absence of competition results in the maintenance of high lever prices with detrimental effects in the consumers welfare and the sustainability of healthcare systems.

Consequently, it is a necessity to react in cases referred to patents that granted inappropriately [124] and as Commission mentioned in the case of Astra Zeneca "*the*

[122] General Court (1979), Judgement, Hoffmann-La Roche & Co. AG v Commission of the European Communities Case C- 85/76, ECR 461, para 91.
[123] General Court (2010), Judgement, AstraZeneca AB and AstraZeneca plc v Commission, Case T-321/05
[124] Scheffeman, D., (2003) "20 Years of Raising Rivals' Costs:History, Assessment, and Future" (2003) 12 Geo. MASON L. Rev. 371, pg.382

acquisition of intellectual property rights may be an abuse in itself since other undertakings are expected to respect the exclusive right associated with it[125]".

According to the "existence-exercise" doctrine, which has been followed in Perindopril case[126], the intervention of competition law should be occurred only at the stage when the intellectual property rights are exercised and not at the stage of their acquisition[127]. However, in the AstraZeneca case, the Court rejected the argument based on the aspect that an intellectual property right abuse must be related to the exercise of this right pointing that the mere existence of such a right may restrain competition. In the General Court's decision is noted that the obtaining of an exclusive right restricts the competitors who have to abide by the regulations and respect holder's exclusive right[128]. The decision continues noting that it is not necessary to exercise the intellectual property right in legal proceedings in order article 102 TFEU to be applicable otherwise the application of competition law would be depended on the infringement of a dominant's exclusive right by competitors[129]. The findings of the Pharma Sector Inquiry Report confirmed that both generic companies and originator companies usually respect the patents granted by their competitors and restrain from bringing legal proceedings against their validity thereby avoid entering the market.

The Astrazeneca case illustrates that the filing of an intellectual property right could affect the competition therefore constitutes potential abuse according to article 102 TFEU. This conclusion overcomes the argument based on the "existence-exercise" doctrine allowing the application of article 102 even in cases related to the acquisition of an intellectual property right. The Commission supports this view and in 2021 initiates investigation against Teva in order to examine company's conduct consisting of filing patent strategies.

[125] General Court (2010), Judgement, AstraZeneca AB and AstraZeneca plc v Commission, Case T-321/05, para 350
[126] General Court (2014) , Judgement, Perindopril (Servier) Case AT.39612 , para. 2766.
[127] Gurgula Olga (2020) Strategic Patenting by Pharmaceutical Companies – Should Competition Law Intervene? (2020) p.1080 doi: 10.1007/s40319-020-00985-0
[128] General Court (2010), Judgement, AstraZeneca AB and AstraZeneca plc v Commission, Case T-321/05, para.362
[129] Ibid.

Another argument against the application of article 102 in the strategic patenting states that this practice is lawful because patent law contains its own rules regarding filing, examination, registration, and revocation of intellectual property rights so this internal regulation is applicable rather than the external rules of the competition law. However, these two fields of law give guidelines in different perspectives of the same matter, and both have to be respected[130]. Moreover, in the Astra Zeneca case the Court noted that "the illegality of an abusive conduct under Article (102 TFEU) is unrelated to its compliance or non-compliance with other legal rules", therefore in the most cases which a dominant violates the article 102 TFEU, the conduct is compliant with other fields of law than competition law[131]. The decision stresses that the lawful obtaining of an intellectual property right does not exclude the holder from his liability against competition law[132]. The fact that that strategic patenting is lawful under intellectual property right law does not mean that it should be shielded from competition law scrutiny[133].

This principle is also referred in the article 8 (2) of the TRIPs Agreement pursuant to which "appropriate measures, provided that they are consistent with the provisions of this Agreement, may be needed to prevent the abuse of intellectual property rights by right holders"[134].

The application of competition law to strategic patenting seems reasonable since the mechanisms of the patent system could not identify any possible anticompetitive incentives of the patentee based on the submitted application. The findings of the Pharma Sector Inquiry Report proved that information referred to applicants' motives is often available in companies' internal documentation that could only be discovered

[130] Heinemann Andreas (2018) Abusive Filing of IP Rights, pg. 5
SSRN: https://ssrn.com/abstract=3251209 or http://dx.doi.org/10.2139/ssrn.3251209
[131] General Court (2010), Judgement, AstraZeneca AB and AstraZeneca plc v Commission, Case T-321/05, para. 677.
[132] Josef Drexl (2012), AstraZeneca and the EU Sector Inquiry: When Do Patent Filings Violate Competition Law? Max Planck Institute for Intellectual Property and Competition Law Research Paper No. 12-02, SSRN, pg.21 https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2009276
[133] Ullrich H. (2013) Strategic patenting by the pharmaceutical industry: towards a concept of abusive practices of protection. In: Drexl J, Lee N, editors. Pharmaceutical innovation, competition and patent law. A trilateral perspective, Edward Elgar Publishing, pg. 265-266
[134] TRIPS Agreement art. 8 (2).

by an official investigation of the competent competition authority. In addition, when the patentability criteria are met; the invention is novel involves an inventive step and is susceptible of industrial application, the patent is granted without any further examination of the patent office. In this respect the existing intellectual property rights legislation is not capable to control these practices. Moreover, any improvement of the existing legislation[135] probably will not bring a solution considering that in some jurisdictions the patentability requirements could not be strengthen as their purpose is to promote innovation. Any differentiation in the existing scheme may result in discouraging new inventions to be patented or being preferred other intellectual property rights such trade secrets which avoid disclosure[136].

Another element that has to be taken into account is the absence of discretion of the patent office to examine the potential use of a patent[137]. As it mentioned above if the patentability requirements are fulfilled the patent is granted. Therefore, the patent system does not facilitate the proper mechanisms to confront practices of strategic patenting in the same way that the competition law does.

It is worth mentioning that the European Parliament's recent resolution on a pharmaceutical strategy in Europe raised concerns regarding the strategic patenting acknowledging the existence of "*so-called 'me-too' pharmaceuticals, that only offer minor improvements at a significantly higher cost; whereas it would be beneficial for patients if the framework for the pharmaceutical industry in Europe were to better incentivise real breakthrough innovations*". Furthermore, the resolution calls on the Commission to prevent fair competition when the time of exclusivity of intellectual property rights expires ensuring accessibility to biosimilar medicines removing all

[135] Inderjit Singh Bansal (2009) Evergreening – A Controversial Issue in Pharma Milieu p.306

[136] Gurgula Olga (2020) Strategic Patenting by Pharmaceutical Companies – Should Competition Law Intervene? (2020) pg.1081, doi: 10.1007/s40319-020-00985-0

[137] Drexl Josef (2012), AstraZeneca and the EU Sector Inquiry: When Do Patent Filings Violate Competition Law? Max Planck Institute for Intellectual Property and Competition Law Research Paper No. 12-02, SSRN, pg.21

barriers to access to competition, by excluding evergreening practices that unreasonably delay access to medicines[138].

[138] European Parliament (2021) A Pharmaceutical Strategy for Europe, European Parliament resolution of 24 November 2021 on a pharmaceutical strategy for Europe (2021/2013(INI)) P9 TA(2021)0470

Conclusions

Intellectual property rights are granted as a reward for the investments into innovation and the introduction of novel products into the market. During the effective period, the protection is granted to the holder in order to recover the expenses invested in the research and the development of the invention. At the same time the disclosure of the invention to the public promotes the further improvement of the existing achievements in benefit of society wealth. The protection of patents and the others intellectual property rights are crucial for the pharmaceutical industry since the development of a pharmaceutical product usually lasts 12-13 years and the costs of the process are excessive. These factors lead some companies to employ strategies in an effort to prolong the effective period of their best-selling medicines in order to increase their profits. Some of their strategies contain filling of secondary patents creating a multi-layer protection around the profitable product or concluding agreements with purpose to restrict competitors entering to the market.

These conducts are incompatible with the rationale of the patent system since incentives to innovate are reduced while competition is affected resulting in the maintenance of high lever prices with detrimental effects in the consumers welfare and the sustainability of healthcare systems. The European Commission understanding the crucial role of the pharmaceutical sector to people welfare carried out in 2008 the sector inquiry attempting to reveal market distortions which affect competition and discourage breakthrough innovation.

Considering that these strategies and practices hinder market competition should be subject to competition law scrutiny and investigated by competition authorities. Beyond the arguments that competition law is not applicable to cases related to the existence of intellectual property rights, taking into account the negatives effects, competition authorities should scrutinize not only agreements that set barriers to competitors entering the market but also conducts of dominants undertakings related to strategic patenting. The European Commission confirms this aspect initiating several investigation proceedings in cases related to strategic patenting. Moreover, the

European Parliament acknowledging the problem of strategic patenting in cases of evergreening which discourage innovation maintaining high prices for pharmaceuticals, calls the Commission to preserve healthy competition ensuring accessibility to generic medicines in the market.

Bibliography

1. Anderman S, Schmidt H. (2007) EC competition policy and IPRs. In: Anderman S, editor. The interface between intellectual property rights and competition policy. Cambridge: Cambridge University Press

2. Bansal Inderjit Singh (2009) Evergreening – A Controversial Issue in Pharma Milieu, Journal of Intellectual Property Rights, 14(4):299-306

3. Burdon M, Sloper K. (2003) The art of using secondary patents to improve protection. *Journal of Medical Marketing,* 2003;3:226.

4. Commission on Intellectual Property Rights (2002) Integrating intellectual property rights and development policy.
http://www.iprcommission.org/papers/pdfs/final_report/CIPRfullfinal.pdf.

5. Copenhagen Economics (2018) Study on the economic impact of supplementary protection certificates, pharmaceutical incentives and rewards in Europe, Final Report
https://ec.europa.eu/health/sites/health/files/human-use/docs/pharmaceuticals_incentives_study_en.pdf

6. Correa CM (2015) Guidelines for pharmaceutical patent examination: examining pharmaceutical patents from a public health perspective. UNDP.
http://www.undp.org/content/dam/undp/library/HIV-AIDS/UNDP_patents_final_web_2.pdf.

7. Drexl Josef (2012), AstraZeneca and the EU Sector Inquiry: When Do Patent Filings Violate Competition Law? Max Planck Institute for Intellectual Property and Competition Law Research Paper No. 12-02, SSRN
https://papers.ssrn.com/sol3/papers.cfm?abstract_id=200927611. DiMasi JA,

8. European Commission (2009) Communication from the Commission -Guidance on the Commission's enforcement priorities in applying Article 82 of the EC Treaty to abusive exclusionary conduct by dominant undertakings, (2009/C 45/02)

9. European Commission (2014) Guidelines on the application of Article 101 Treaty on the Functioning of the EU to technology transfer agreements. 2014/C 89/03

10. European Commission (2013) Decision in Lundbeck (Case AT.39226) OJ C368/13

11. European Commission (2020) Decision, Cephalon (Case AT.39686) C (2020) 8153

12. European Commission (2009) Executive summary of the pharmaceutical sector inquiry report

13. European Commission (2009) Pharmaceutical sector inquiry final report http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/staff_working_paper_part1.pdf.

14. European Commission (2019) Report from the Commission to the Council and the European Parliament, Competition Enforcement in the Pharmaceutical Sector (2009-2017)

15. European Commission (2005) Press release, Commission fines AstraZeneca €60 million for misusing patent system to delay market entry of competing generic drugs

16. European Commission (2011), Press release, Antitrust: Commission opens formal investigation into possible anticompetitive conduct of Teva in relation to a blockbuster multiple sclerosis medicine

17. European Commission (2007) Press Release in case COMP/B2/39246 – Boehringer

18. European Commission (2011) Press Release IP/11/842 in case COMP/B2/39246 – Boehringer

19. European Commission (2020) Press Release IP/20/2220 in case (AT.39686-Cephalon)

20. European Commission (2018) 8th Report on the Monitoring of Patent Settlements (period: January-December 2016)

21. European Commission (2014) Summary of Commission Decision Perindopril (Servier), Case AT.39612

22. European Parliament (2021) A Pharmaceutical Strategy for Europe, European Parliament resolution of 24 November 2021 on a pharmaceutical strategy for Europe (2021/2013(INI)) P9 TA(2021)0470

23. European Parliamentary Research Service (Author: Marcin Szczepański) (2019) EU competition policy -Key to a fair single market PE 642.209 - Executive summary

24. European Federation of Pharmaceutical Industries and Associations, (EFPIA, The Pharmaceutical Industry in Figures Key Data 2020, EFPIA Publication EFPIA Publication https://efpia.eu/media/554521/efpia_pharmafigures_2020_web.pdf

25. European Union official website, Patents your rights, https://europa.eu/youreurope/business/running-business/intellectual-property/patents/index_en.htm

26. European Patent Office https://www.epo.org/about-us/annual-reports-statistics/statistics/2019/statistics/patent-applications.html https://worldwide.espacenet.com/

27. Hull David W. and Clancy Michael J. (2017) The Application of EU Competition Law in the Pharmaceutical Sector, Journal of European Competition Law & Practice, 2017, Vol. 8, No. 3

28. General Court (2016) Judgement H. Lundbeck A/S and Lundbeck Ltd v European Commission, T-472/13, C-591/16 P

29. General Court (1979), Judgement, Hoffmann-La Roche & Co. AG v Commission of the European Communities Case C- 85/76, ECR 461

30. General Court (2010), Judgement, AstraZeneca AB and AstraZeneca plc v Commission, Case T-321/05

31. General Court (2018), Judgement Servier and Others v Commission CASE T-691/14

32. General Court (2014), Judgement, Perindopril (Servier) Case AT.39612

33. Heinemann Andreas (2018) Abusive Filing of IP Rights, SSRN: https://ssrn.com/abstract=3251209 or http://dx.doi.org/10.2139/ssrn.3251209

34. Heinemann Andreas (2019) Blocking Patents and the Process of Innovation, New Developments in Competition Law and Economics pp 149-168, Springer,

35. Jaume Puig-Junoy (2010) Impact of European Pharmaceutical Price Regulation on Generic Price Competition, Pharmacoeconomics, https://doi.org/10.2165/11535360-000000000-00000

36. Kapczynski A, Park C, Sampat B. (2012) Polymorphs and prodrugs and salts (oh my!): an empirical analysis of “secondary” pharmaceutical patents, PLOS ONE, https://doi.org/10.1371/journal.pone.0049470

37. Gurgula Olga (2020) Strategic Patenting by Pharmaceutical Companies – Should Competition Law Intervene? (2020) pg.1081, doi: 10.1007/s40319-020-00985-0 https://d-nb.info/1224525116/34

38. Office of Fair Trading (2011) Abuse of a dominant position by Reckitt Benckiser Healthcare (UK) Limited and Reckitt Benckiser Group plc , Decision No. CA98/02/2011

39. Roin BN. Unpatentable drugs and the standards of patentability. *Tex Law Rev.* 2009;87:503, https://dash.harvard.edu/handle/1/10611775

40. Shapiro Carl (2003) Antitrust limits to patent settlements RAND Journal of Economics Vol. 34, No. 2, pg. 391–411

41. Ullrich H. Strategic patenting by the pharmaceutical industry: towards a concept of abusive practices of protection. In: Drexl J, Lee N, editors. *Pharmaceutical innovation, competition and patent law. A trilateral perspective,* Edward Elgar Publishing, 2013. pg. 265–266.

42. Van der Woude M. (2009) 'Patent Settlements and Reverse Payments Under EU Law', 5(2) CPI, pg.183

Legislation

1. Directive (EC) No 83/2001

2. Directive (EC) No 27/2004

3. European Patent Convention

4. Regulation (EC) No 1768/1992

5. Regulation (EC) No 469/2009

6. Regulation (EC) No 1901/2006

7. Regulation (EC) No 726/2004

8. Regulation (EC) No 141/2000

9. Treaty on the Functioning of the European Union

10. TRIPs Agreement