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„Anticompetitive Patent Practices in the Pharmaceutical Sector : Analysis of EU Competition and US Antitrust Law“

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LIST OF ABBREVIATIONS

EC	European Communities
EU	European Union
FDA	U.S. Food and Drug Administration
FTC	Federal Trade Commission
IP	Intellectual Property
TFEU	Treaty on the Functioning of the European Union
USPTO	United States Patent and Trademark Office

1. INTRODUCTION

Competition and antitrust law have set limitations on rights provided by patent law to balance competition and innovation. Pharmaceutical industry has a unique position in this field. With its unique interlay of patent rights and regulatory procedures, pharmaceutical companies have been sanctioned by competition and antitrust authorities on many occasions.

The exclusionary rights provided to holders of intellectual property may have anticompetitive effects. "Intellectual property law bestows on the owners of intellectual property certain rights to exclude others. These rights help the owners to profit from the use of their property. An intellectual property owner's rights to exclude are similar to the rights enjoyed by owners of other forms of private property. As with other forms of private property, certain types of conduct with respect to intellectual property may have anti-competitive effects against which the antitrust laws can and do protect. Intellectual property is thus neither particularly free from scrutiny under the antitrust laws, nor particularly suspect under them."[1]

Article 8.2 of TRIPS agreement provides for governments to apply appropriate measures in order to prevent abuse of intellectual property even though it does not specifically refer to competition law.[2]

Patents promote innovation as well as provide exclusionary rights to the patent holder. This issue has been in the centre of most competition cases relating to pharmaceutical patents due to the fact that patents have a special importance to originator companies and provide additional exclusivities to remain on the market as the sole player. Both patent and pharmaceutical regulatory framework provide originator pharmaceutical companies additional rights to market their products as a monopoly in exchange of sharing their assets of clinical trials and pharmaceutical research. This facilitates generic companies entering

[1] U.S. Department of Justice & Federal Trade Commission, `Antitrust Guidelines for the Licensing of Intellectual Property` (justice.gov, 2006) <https://www.justice.gov/sites/default/files/atr/legacy/2006/04/27/0558.pdf> accessed 18 December 2022.

[2] Agreement On Trade-Related Aspects Of Intellectual Property Rights.

the market thus reducing the prices of the medicines. By providing cheaper medicines for people the economic burden of healthcare on the government funds is reduced.[3]

The pharmaceutical sector has been one of the industries that competition authorities keep under close observation. Both the European Commission and the Federal Trade Commission has focused on the sector and the anti-competitive practices of pharmaceutical companies.

The Pharmaceutical Sector Inquiry Report underlines European Commission`s goals of "providing European patients with safe, effective and affordable medicines, while at the same time creating a business environment that stimulates research, boosts valuable innovation and supports the competitiveness of the industry"[4]. It also points to the importance of intellectual property rights for the pharmaceutical industry and the need to protect such rights to promote innovation.[5]

The inquiry`s main area of interest is "practices which companies may use to block or delay generic competition as well as to block or delay the development of competing originator products". The report focuses on a few areas of concern including patent filing strategies, patent litigation, patent settlements, other practices related to regulatory procedures, strategies for second generation products (e.g., product hopping) and also mentions that these practices might also be combined in some cases.[6]

Following the Sector Inquiry Report, the Commission later published another report in 2017 summarizing and reviewing the Competition Enforcement of the European Competition Authorities (national competition authorities and the European Commission) in the pharmaceutical sector and explains how the particularities of the industry have an impact on the enforcement of European competition law.[7]

[3] European Commission, `Executive Summary of the Pharmaceutical Sector Inquiry Report` COM(2009) 351 final.
[4] Ibid.
[5] Ibid.
[6] Ibid.
[7] European Commission, Directorate-General for Competition `Competition enforcement in the pharmaceutical sector (2009-2017) : European competition authorities working together for affordable and innovative medicines` Publications Office (2019).

The Federal Trade Commission has also conducted a study[8] to analyse the strategies that have the potential to prevent generic entry which are facilitated by the Hatch Waxman amendments to the Federal Food Drug and Cosmetic Act.

The objective of competition authorities of both jurisdictions (US and EU) is to ensure that consumers benefit from cheap accessible drugs. So, the main challenge is to balance competition and antitrust law and intellectual property law. Their goal is to ensure competition is not affected by patent law and other intellectual property rights. In addition, regulatory framework provides incentives to promote innovation for pharmaceutical companies to continue with their efforts of research and development of more advanced medicines. This system assigns originator and generic companies marketing authorisation and special exclusivities under special circumstances. Competition and antitrust law also oversee this system and evaluate any anticompetitive effects certain acts allowable under regulatory framework may have or any potential misuse of the regulatory system.

The challenge of balancing innovation and competition has been a struggle for a long time. Patent laws give a monopoly right to the originator company (the patent holder) for a limited period of time to keep generic companies from entering the market and thus restricting the competition. Furthermore, regulatory framework provides originator companies additional exclusivity rights. These rights are given to the originator companies as incentives to continue to do research and development.

On the other hand, competition law and antitrust law ensures that a healthy level of competition continues to exist in the market and consumers are not negatively affected by the lack of competition or disrupted competition.

Even though other types of conduct such as mergers and pricing are also areas of concern in the pharmaceutical industry for competition authorities, this work will focus on the conducts related to patents and patents rights as well as the regulatory framework governing pharmaceutical marketing authorizations relating to exclusivities such as patent exclusivities or data exclusivities. These regulatory frameworks are densely interrelated with patents and regulate the conditions when generics can enter the market, which is the essential point of time when competition starts and legalized monopoly of the originator

[8] Federal Trade Commission, `Generic Drug Entry Prior to Patent Expiration: An FTC Study` (2002).

company ends in the pharmaceutical market. Therein lies difficult role of competition law to oversee that these rights do not affect competition negatively.

The aim of this work is to examine the limits set by competition and antitrust laws on rights provided by patent law and other rights provided by regulatory framework of the pharmaceutical industry. The work will also examine patent related conducts and practices that are considered to be "anticompetitive" by European competition law (national courts and competition authorities, European Commission and European Court of Justice) and US antitrust law.

The aim of this work is also to analyse the competition and antitrust case law of higher Courts and authorities relating to pharmaceutical cases in both jurisdictions. The cases will be analysed by focusing on the points of law applied by competition authorities and courts, while analysing different types conduct and their anticompetitive nature within the legal framework pharmaceutical industry and how competition and antitrust law might in some cases limits rights provided by patent and pharmaceutical regulatory laws.

The work aims to cover practices under 3 main groups categorised depending on the conduct under scrutiny and its elements:

1. Patent System and Procedure
2. Regulatory framework and patents in the pharmaceuticals
3. Patent Enforcement

2. OVERVIEW OF THE PHARMACEUTICAL PATENT PRACTICES AND REGULATORY FRAMEWORK OF PHARMACEUTICALS

The regulatory procedures for medical products are detailed and complicated. Here, a simplified overview will be provided that applies in most cases. More detailed information will be provided with the case summaries as needed.

2.1 EU

The EU pharmaceutical market is "highly regulated and R&D driven" according to the European Commission.[9] Originator companies and generic companies are the two key suppliers of pharmaceuticals in the market.[10]

An originator company, after research and development efforts and conducting clinical trials applies for a marketing authorization[11]. European law provides data exclusivity to the originator company. During this time a generic company cannot rely to the clinical trial data of the originator company to apply for a marketing authorization application of the same active ingredient. This legal framework thereby provides the generic company the chance to market the generic version of the originator company`s product without conducting clinical trials. [12]

Having put in efforts in research and development, originator companies usually have patents covering different aspects of the pharmaceutical product, e.g. the active ingredient, formulation, indication or dosage regimens. EU law further provides additional exclusivity

[9] European Commission, `Executive Summary of the Pharmaceutical Sector Inquiry Report` COM(2009) 351 final.
[10] Ibid.
[11] Council Regulation (EC) 726/2004 of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency [2004] OJ L136/1; Council Directive 2004/27/EC of 31 March 2004 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use [2004] OJ L 136/34.
[12] Council Directive 2004/27/EC of 31 March 2004 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use [2004] OJ L 136/34, Article 10.

in terms of supplementary protection certificates, which extend the protection conferred to a patent.[13]

After a marketing authorization is granted, market exclusivity also comes into play. Following the expiry of the market exclusivity, a generic company may enter the market unless there are additional exclusivities or the patent term(s) has not yet expired, with additional protection term provided by SPC's if available.

Regarding the patent protection for the product, the original company may have more than one patent protecting the product (first one so called basic patent covering the active ingredient), which are called secondary patents which may relate to formulation dose, dosage regimen, indication etc.

Regarding the timelines the data exclusivity and the market exclusivity have fixed time periods[14]. Patent protection is determined from the date of filing (20 years from the filing date + max 5 years if SPC is available) unless they are invalidated after being granted.

2.2 US

Like in EU, generic companies do not conduct clinical trials but use an abbreviated procedure. The generic company needs to wait for the expiry of exclusivities and patent terms.[15]

However, the regulatory framework in US differs from EU in many respects. The originator company submits patent information to FDA[16] and this information is published in a public database with other applicable exclusivities[17]. A generic company applying for market authorisation must file a patent certification referring to the originator´s application, and that the originator has not filed any patent information, patent(s) expired or will expire (reference date for market authorisation) or that the patent(s) is invalid or will not be

[13] Council Regulation (EC) 469/2009 concerning the supplementary protection certificate for medicinal products [2009] OJ L 152/1.
[14] [14] Council Directive 2004/27/EC of 31 March 2004 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use [2004] OJ L 136/34, Article 10.
[15] FDA's Approved Drug Products with Therapeutic Equivalence Evaluations (the Orange Book).
[16] 21 U.S.C. 355(b)(1) and (c)(2).
[17] Ibid.

infringed.[18] The last option is the so-called Paragraph IV certification which allows the generic company incentive to challenge the validity of the patents, since the first generic company to file a paragraph IV certification becomes a 180 day exclusivity to be the sole generic company on the market before other generic companies enter the market.[19]

The involvement of patents in the US pharmaceutical regulation proves the importance of patents in the pharmaceutical market dynamics for both originator and generics companies. Due to the regulatory framework and patents, originator companies having the position of "first" applicant, have power to manipulate the procedure via filing and requesting exclusivities and patents.

As in other industries, a generic company wishing to enter the market, has the option and opportunity to overcome the patent hurdles by litigation. Generic companies challenge validity of patents, or request for non-infringement declarations from courts.

[18] 21 U.S.C. 505(j)(2)(A)(vii).
[19] 21 U.S.C. 505(j)(5)(B)(iv).

3. MISUSE OF PATENT PROCEDURES AND PATENT SYSTEM

European Competition Law has some cases of misuse of the patent procedures in violation of Article 102 TFEU as abuse of dominant position. These include misuse of patent granting procedure via filing of divisional applications and providing misleading information to patent offices.

3.1 Divisional applications

In the Sector Inquiry[20] of 2009, the European Commission has identified divisional patent applications as a tool used by originator companies against generic companies. By filing divisional applications, prolonged and continued examination proceedings create "legal uncertainty" for generic companies.[21]

In 2009, European Patent Office limited the conditions and time limits for a divisional application.[22] A 24-month time limit was introduced for filing European divisional applications. However, this time limit was later repealed in 2013 and European divisional applications can now be filed as long as the earlier application is pending.[23]

3.1.1 Boehringer COPD

In one of the earlier cases, where the European Commission launched an antitrust investigation in the pharmaceutical industry based on concerns of "misuse of patent

[20] European Commission, `Executive Summary of the Pharmaceutical Sector Inquiry Report` COM(2009) 351 final.
[21] Ibid.
[22] Decision of the Administrative Council of the European Patent Organisation of 25 March 2009 amending the Implementing Regulations to the European Patent Convention (CA/D 2/09) <http://archive.epo.org/epo/pubs/oj009/05_09/05_2969.pdf>.
[23] Decision of the Administrative Council of the European Patent Organisation of 16 October 2013 amending Rules 36, 38 and 135 of the Implementing Regulations to the European Patent Convention (CA/D 15/13). <http://archive.epo.org/epo/pubs/oj013/11_13/11_5013.pdf>.

system" is the case of Boehringer[24]. The Commission initiated proceedings regarding the patent applications Boehringer has filed with concerns of "misuse of the patent system in order to exclude potential competition in the area of chronic obstructive pulmonary disease (COPD) drugs"[25] in response to allegations raised by the Spanish pharmaceutical company Almirall.[26]

Boehringer had filed patent applications covering combinations of an active substance (discovered by Almirall) with other three broad categories of active substances. Almirall alleged that Boehringer filed unmeritous patents in the COPD field which might block Almirall`s own products.[27]

Based on allegations raised by Almirall Commission`s goal was to determine if "Boehringer had filed patent applications and had obtained patents by providing misleading information to the EPO".[28] However, the investigation was closed after parties entered into a license agreement, and Boehringer agreed to remove the blocking position in Europe.[29]

3.1.2 Teva Copaxone

After the Boehringer investigation[30], the European Commission initiated another investigation in 2021 based on the concern of "misuse of the patent system by divisional applications" in Teva Capoxone[31] case. Alleged abuse of dominant position included two practices, first being "the misuse of patent procedures and/or patent litigation concerning divisional patent families"[32] and the second one concerning disparagement campaigns.[33]

[24] COMP/B2/39246 – Boehringer.
[25] Ibid.
[26] Ibid.
[27] European Commission, "Press release Antitrust: Commission welcomes improved market entry for lung disease treatments" (6 July 2011) <https://ec.europa.eu/commission/presscorner/detail/en/IP_11_840> accessed 15 December 2022.
[28] Ibid.
[29] Ibid.
[30] COMP/B2/39246 – Boehringer.
[31] AT.40588 – Teva Copaxone.
[32] Ibid.
[33] Ibid.

On December 2021, the Commission published a Press Release that it sent Teva Statement of Objections. According to the Press Release, the Commission preliminary view is that Teva has abused its dominant position by artificially "extending basic patent protection by filing and withdrawing secondary patent applications, thereby forcing its competitors to file new lengthy legal challenges each time".[34]

The Commission´s investigation is ongoing and there are no other details yet available on the Commission`s interpretation of the case and the conduct under investigation. A similar phrase of "artificially extending" patent protection was used in Pfizer Xalatan case as well.

3.1.3 Pfizer Xalatan Consiglio di Stato Judgement 693/2014

Another follow-up decision after *Astrazeneca v. Commission*[35] is the decision of the Italian Competition Authority[36] regarding Pfizer`s conduct regarding to filing of Xalatan product related patent applications and corresponding SPC filings. Pharmacia (later to be acquired by Pfizer 2003) marketed its Xalatan product in Europe from 1997 and filed SPC applications based on the main patent covering Xalatan`s active ingredient latanoprost, however failed to acquire a SPC in Italy due to the missed the deadline for the application. Later in 2002, Pharmacia filed a divisional patent application[37] which was then issued and a corresponding SPC granted in Italy. The Italian Competition Authority decided that Pfizer has abused its dominant position by applying for a divisional patent and corresponding SPC, thus "artificially extending" and the duration of patent protection and exploiting the state of legal uncertainty in order to delay generic entry.[38] In its reasoning the Italian Competition Authority argued on the timing of the filing of the divisional application (5 years later than marketing of the product) and the scope of the patent application having already been covered by the parent patent application with granted SPC`s in other countries.

[34] AT.40588 – Teva Copaxone.
[35] Ibid.
[36] Decision of the Autorità Garante della Concorrenza e del Mercato (AGCM) 23194 of 11 January 2012 - A431: Ratiopharm/Pfizer (Bollettino 2/2012).
[37] EP1225168A2.
[38] Decision of the Autorità Garante della Concorrenza e del Mercato (AGCM) 23194 of 11 January 2012 - A431: Ratiopharm/Pfizer (Bollettino 2/2012).

This decision was later revoked by the court of first instance[39] however, upheld by the higher court of Council of State in appeal[40]. Unlike the Italian Competition Authority, the Council of State refrained from commenting on the legitimacy of the patent protection obtained by the divisional patent and the SPC thereof and pointed out that patent rights granted or their application as such is not the conduct under dispute but the intention why those rights were obtained and the manner which they were enforced to exclude competitors from the market. The existence of the parent patent and the protection it provided for the same product on the market was the key element in the decision suggested that the divisional application was not filed with "the intention of patent protection" but to delay generic entry combined with the conduct of using this protection to initiate litigation and demand further pediatric extension.[41]

3.1.4 Humira

The plaintiffs in the case of Humira alleged that the broad portfolio of patents and patent applications AbbVie owned and enforced was anticompetitive and AbbVie used its broad portfolio as a leverage to force competitors to enter settlement agreements to delay their market entry in US in exchange of earlier market entry in Europe.[42] According to the District Court AbbVie`s broad patent portfolio contained 20 patent trees and over 200 patent applications, and over 100 of those applications were issued and a similar strategy was used in Europe according to the Court, where AbbVie abandoned or withdrew its patents when faced with validity challenges and used pending applications in order to file new divisional applications covering the same invention.[43]

The District Court found that "AbbVie has exploited advantages conferred on it through lawful practices"[44] and "AbbVie`s petitioning was protected by the Noerr-Pennington doctrine".[45] The Court pointed out that alleged anticompetitive conduct did not involve

[39] Decision of the Tribunale Amministrativo Regionale per il Lazio 7467/2012 of 3 September 2012 *Pfizer Italia srl.*
[40] Decision of the Consiglio di Stato (Italy) 693/2014 of 12 February 2014 *Pfizer Italia srl.*
[41] Ibid.
[42] In Re: Humira (Adalimumab) Antitrust Litigation, No. 19-cv-01873, Slip. Op. (N.D. Ill. Jun. 8, 2020).
[43] Ibid.
[44] Ibid.
[45] Ibid.

obtaining a broad portfolio of patents, obtaining those patents by knowing and willful fraud nor "objectively baseless" petitioning, which falls outside the protection of Noerr-Pennington doctrine.[46] The Court observed that the complaint was based on obtaining and asserting "swaths of invalid, unenforceable, or non-infringed patents without regard to the patent`s merits" by "repeatedly and aggressively asserting this patent thicket during a lengthy, detailed regulatory process (and subsequent infringement litigation).[47]

In its application of Noerr-Pennington doctrine, the Court observed that "immunized conduct cannot be aggregated with nonimmunized conduct without nullifying the immunity, it is necessary to identify protected and unprotected conduct"[48] and analysed AbbVie`s combined acts of prosecution of patents, FDA approval application acts and litigation before courts separately in view of antitrust immunity.

Referring to PRE[49], the Court observed that AbbVie`s act of obtaining a broad portfolio of patent applications and their prosecution, thus petitioning activity before the USPTO, have antitrust immunity by Noerr-Pennington doctrine and AbbVie`s petitioning was not objectively baseless due to the fact that more than half of those applications became issued patents.[50]

3.2 Comparison and analysis

Even though, the issue of divisional applications has not been addressed yet in the pharmaceutical industry by higher courts, the European Commission seems to have directed its attention on the matter.

Divisional applications have the potential of creating a legal uncertainty by extending the prosecution time and creating additional obstacles for generic entry. They can be used as tools to "artificially extend" patent protection and European competition authorities raise concerns for abuse of dominant position and violation of Article 102 TFEU.

[46] In Re: Humira (Adalimumab) Antitrust Litigation, No. 19-cv-01873, Slip. Op. (N.D. Ill. Jun. 8, 2020), p.19.
[47] Ibid, p.19.
[48] Ibid.
[49] Professional Real Estate Investors, Inc. v. Columbia Pictures Industries, Inc., 508 U.S. 49 (1993).
[50] In Re: Humira (Adalimumab) Antitrust Litigation, No. 19-cv-01873, Slip. Op. (N.D. Ill. Jun. 8, 2020), p.25.

In their assessment, European Competition Authorities focus on the lawfulness of the rights obtained by divisional applications, the intention behind filing divisional applications, the effect they have over the generic entry on the market, as well as their potential to exclude competition of other originator companies.

From the US perspective, filing of a broad portfolio of patents including divisional applications is evaluated under Noerr-Pennington Doctrine for antitrust immunity. US Courts focused on the "success" of filed applications to assess objectively baseless petitioning under Noerr-Pennington Doctrine.

Even though the approaches applied by both jurisdictions are different, both jurisdictions seem to agree on a potential anticompetitive effect of misuse of patent procedures and patent systems.

4. MISUSE OF REGULATORY PROCEDURES

4.1 Misleading representations before Patent offices and regulatory authorities

One form of misuse of regulatory procedures is via obtaining exclusivity rights by misrepresentations and fraud. The regulatory exclusivities and the patent term extensions such as SPCs, provide originator companies lawful tools to delay and prevent generic entry. However, competition and antitrust law sanctions conducts, where such rights are obtained by misrepresentations or fraud.

4.1.1 Astrazeneca v. Commission

A Supplementary Protection Certificate "extends the protection conferred by a patent for an additional maximum period of five years".[51] The period is calculated based on the filing date of the patent application and the filing of the Marketing Authorisation and is envisaged to compensate the time spent for clinical trials between those dates.

In the case of *Astrazeneca v. Commission*[52], AZ was sanctioned by two practices that was held by Commission and later upheld by the General Court[53] and the Court of Justice[54]. One of these anticompetitive practices was the way AZ has obtained SPCs in various European Countries by presenting misleading information to regulatory and patent authorities. Later, granted SPCs were in revoked in some countries and corrected in others. The Commission sanctioned AZ for abuse of dominant position, and the General Court and the Court of Justice upheld that decision. The element of presentation of misleading information were the dates to be used in the calculation of the SPC periods and in some countries, it was also directly relevant if SPCs were to be granted or not.

[51] Council Regulation (EC) 469/2009 concerning the supplementary protection certificate for medicinal products [2009] OJ L 152/1.
[52] Case C-457/10 P *AstraZeneca AB and AstraZeneca plc v European Commission* [2012] EU:C:2012:770; Case T-321/05 *AstraZeneca AB and AstraZeneca plc v European Commission* [2010] ECR II-02805; Case COMP/A.37.507/F3 – AstraZeneca.
[53] T-321/05 *AstraZeneca AB and AstraZeneca plc v European Commission* [2010] ECR II-02805.
[54] Case C-457/10 P *AstraZeneca AB and AstraZeneca plc v European Commission* [2012] EU:C:2012:770.

The Court of Justice approved General Court`s finding that the practice of misleading representations itself was not an abuse of dominant position nor an anticompetitive practice, but acquirement of exclusive intellectual property rights (SPCs) unlawfully via misleading representations was found to be an abuse of dominant position[55], and the effect it had on the competition was the determining factor in the assessment of such abuse.[56]

SPC granted in Germany was revoked before they came into force, i.e. the expiry of patents. The General Court held that the establishment of abuse of dominant position did not indeed require that the exclusive rights obtained was not subsequently enforced. The Court of Justice agreed with the General Court`s decision that the possession of SPCs is enough to "potentially" effect the competition even before the expiry date of the corresponding patents, and generally third parties cannot always be informed if the right was obtained unlawfully or not.[57]

This was a case in which, the rights provided by SPC regulation extending the protection of the patent, were unlawfully obtained by filing misleading representations that lead regulatory authorities to grant the exclusive SPC right.

4.1.2 Buspirone

In the Buspirone[58] case, antirust allegations were raised against Bristol-Myers Squibb Company that it by "fraudulently" listing a newly obtained patent in the Orange Book - knowing that it did not cover the use of buspirone- before one day the basic patent expired, brought infringement lawsuits against generic companies in order to trigger the 30-months stay of FDA approval for generic marketing authorisation and prevent generics from entering the market in violation of Section 2 of the Sherman Act.[59]

Bristol-Meyer Squibb`s motion to dismiss and its defense for listing the patent and filing infringement lawsuits was based on Noerr-Pennington doctrine. Regarding the conduct of

[55] Ibid.
[56] Ibid, para 62.
[57] Case C-457/10 P *AstraZeneca AB and AstraZeneca plc v European Commission* [2012] EU:C:2012:770, paras 108, 112.
[58] In re Buspirone Patent Litigation, 185 F. Supp. 2d 363 (S.D.N.Y. 2002).
[59] Ibid 366.

listing the patent in Orange Book, the District Court referred to *Litton Systems, Inc. v. AT & T Co.*[60], and observed that "Noerr-Pennington doctrine is not applicable to conduct through which private parties seek to achieve anticompetitive aims by making representations to the government in circumstances where the government does not perform any independent review of the validity of the statements, does not make or issue any intervening judgment and instead acts in direct reliance on the private party's representations"[61]. The District Court decided that Bristol-Meyer Squibb`s listing of its patent in Orange Book is not a petitioning activity under Noerr-Pennington, since FDA does not check the validity of the listed patent information and relied on the applicant`s representations.

4.2 Product hopping

Product hopping is the fruit of "Life Cycle Strategies for Follow-on Products" as described in the European Commission`s Pharmaceutical Sector Inquiry Report[62]. Pharmaceutical Companies introduce follow-on or "second generation products" on the market resulting from follow-on research and development.[63] European Commission refers to it as "switch" and explains the timing and practice of the switch and its effects on generic entry.[64]

There have been some cases concerning product hopping both in US and Europe. These cases will be discussed further to analyse how courts and competition authorities approached the act of product hopping or product switches, which are otherwise allowed by patent law and pharmaceutical regulations.

Product hopping or switches may happen in different forms. The timing of most of these cases are mostly related to the patent term expiry. Launch of the second generation products can be a tool to prevent or delay market entry when combined with the unique regulatory framework of the pharmaceutical industry and patent protections.

[60] Litton Systems, Inc. v. AT & T Co., 700 F.2d 785 (2d Cir.1983).
[61] In re Buspirone Patent Litigation, 185 F. Supp. 2d 363, 370 (S.D.N.Y. 2002).
[62] European Commission, `Executive Summary of the Pharmaceutical Sector Inquiry Report` COM(2009) 351 final.
[63] Ibid 3.2.6.
[64] Ibid.

4.2.1 Astrazeneca v. Commission

In the case of *Astrazeneca v. Commission*[65], Astrazeneca was sanctioned by two practices that was held by Commission and later upheld by the General Court and the Court of Justice. One of those practices regards the removal of old products from the market and introduction of newer ones.[66] In *Astrazeneca v. Commission*[67], European Competition Authorities refer to practice of introducing a new formulation (Losec MUPS tablets) on the market and to stop marketing the old formulation as "switch"[68]. A term which later will be also used by US Courts.

Astrazeneca has introduced new formulation of Losec MUPS tablets on the market and removed the old formulation from the market in some countries before the patent expiry date for Losec capsules. In addition, in three European countries (Denmark, Norway and Sweden) Astrazeneca has deregistered and withdrew its marketing authorisations of Losec MUPS tablets.[69] For generic companies, in order to be granted a marketing authorization relying on the clinical and safety data of the originator`s product (in this case Losec capsules), the original product needed to have a valid marketing authorisation. By deregistering the marketing authorisations in Denmark, Norway and Sweden, Astrazeneca created obstacles in the market entry of the generic products in those countries[70]. Astrazeneca was sanctioned by the European Commission for "selective" deregistration of marketing authorisations of Losec capsules in some European countries (Denmark, Norway and Sweden) in combination with the practice of introducing Losec MUPS tablets on the market while withdrawing Losec capsules from the market[71].

Both the General Court and the Court of Justice agreed that the practice of "switch" itself is not an abuse of dominant position. However, unlike the Commission`s decision, the

[65] Case C-457/10 P *AstraZeneca AB and AstraZeneca plc v European Commission* [2012] EU:C:2012:770.
[66] Ibid.
[67] Case T-321/05 *AstraZeneca AB and AstraZeneca plc v European Commission* [2010] ECR II-02805; Case COMP/A.37.507/F3 – AstraZeneca.
[68] Ibid.
[69] COMP/A.37.507/F3 – AstraZeneca.
[70] Case T-321/05 *AstraZeneca AB and AstraZeneca plc v European Commission* [2010] ECR II-02805, para 688-689.
[71] COMP/A.37.507/F3 – AstraZeneca.

General Court and the Court of Justice held that the deregistration of the marketing authorizations is an abuse of dominant position by Astrazeneca as an "undertaking engaged in competition on merits and in the absence of an objective justification" [72]. The General Court observed that even though an undertaking can take necessary actions to protect its commercial interests, misuse of regulatory procedures with the intention of "preventing competitors to enter the market or making it more difficult them to do so" cannot be considered as "competition on the merits" in the absence of "grounds relating to the defence of the legitimate interests" or in the absence of "objective justification".[73]

Astrazeneca argued that maintaining a marketing authorization caused pharmacological safety obligations, and it had no obligations to protect the interests of its competitors and this was an act of competition on merits with an objective justification. The Court of Justice observed that pharmacovigilance obligations could have been considered as an objective justification[74]. However, neither the General Court nor the Court of Justice agreed with Astrazeneca`s plea, because by selectively deregistering the marketing authorizations in three countries and continuing to market the Losec capsules in some other European countries, Astrazeneca failed to demonstrate that pharmacological safety obligations were "legitimate protection of an investment which came within the scope of competition on merits" or an objective justification.[75]

The originator company`s right to deregister its product without having to present any justification for it (unless for public health and safety concerns) has already been accepted by the Court of Justice.[76] In *Astrazeneca v. Commission* the General Court and the Court of Justice once more emphasized that the deregistration in this case was not an act of abuse nor withdrawing a product from the market to replace it with another. However, the "selective" deregistration practice resulted with anticompetitive effects. Also, General

[72] Case C-457/10 P *AstraZeneca AB and AstraZeneca plc v European Commission* [2012] EU:C:2012:770 para 140; Case T-321/05 *AstraZeneca AB and AstraZeneca plc v European Commission* [2010] ECR II-02805, paras 811-817.
[73] Case T-321/05 *AstraZeneca AB and AstraZeneca plc v European Commission* [2010] ECR II-02805, paras 672, 817.
[74] Case C-457/10 P *AstraZeneca AB and AstraZeneca plc v European Commission* [2012] EU:C:2012:770, para 135.
[75] Case T-321/05 *AstraZeneca AB and AstraZeneca plc v European Commission* [2010] ECR II-02805, paras 691-694.
[76] C-94/98 *Rhône-Poulenc Rorer and May & Baker* [1999] ECR I-8789 and Case C-172/00 *Ferring* [2002] ECR I-6891.

Court refers once more in the decision that most abuse of dominant position cases relate to practices that are otherwise allowed by other legal rules.[77]

The General Court argued the anticompetitive effects resulted from the additional obstacles created on the generic companies due to deregisterations. The General Court said that generic companies would not have had enough time to prepare after finding out about the deregistrations. However, this was due to the fact that Astrazeneca has deregistered the marketing authorisations right after/before the patent expiry. If it had done that before, theoretically generic companies might have had time to prepare. The decision remains silent on Astrazeneca`s choice of timing of deregistrations. However, from a legal perspective it could be argued that the decision would have been different if there was enough time for generics to prepare.

4.2.2 Reckitt Benkiser - Gaviscon

The Office of Fair Trading (OFT) has sanctioned Reckitt Benkiser for withdrawing and de-listing its Gaviscon liquid formulation and decided that Reckitt Benkiser has abused its dominant position since the "withdrawal tended to restrict the competition or was capable of having that effect"[78].

In this case, Reckitt Benkiser withdrew its product from the market and de-listed corresponding product just before the generic name was to be published, which according to the OFT had an anticompetitive effect because it prevented "full generic competition". The generic name enables generic practitioners to prescribe an open script, which then enables the pharmacies to choose any product linked to that generic name. Thus, without the generic name the General practitioners prescribe the product brand name and pharmacies are obliged to sell that product instead of choosing from products linked to the generic name. OFT observed that Reckitt Benkiser´s intent and expectation was exactly to use this framework of generic name publication and its consequences and prevent full generic competition.

[77] Case T-321/05 *AstraZeneca AB and AstraZeneca plc v European Commission* [2010] ECR II-02805, para 675.
[78] Case CE/8931/08 Reckitt Benckiser Healthcare (UK) Ltd (OFT Decision of 12 April 2011 CA98/02/2011), para 6.162.

OFT referred to the Astrazeneca case[79], and observed that Reckitt Benkiser`s action cannot be considered as "competition on the merits" since the withdrawal was not economically feasible[80] and the objective was to prevent full generic competition as stated by Reckitt Benkiser`s internal documents[81]. OFT pointed out that bad faith and intent of the dominant firm is not necessary to establish abuse of dominant position[82]. However, it may be used to interpret the nature of the conduct. [83]

4.2.3 Abbott Laboratories v. Teva Pharmaceuticals USA, Inc.

In *Abbott v. Teva*[84], generic companies lodged antitrust allegations against Abbott. Abbott changed the formulation of the Tricor product from capsules to tablets during the patent litigation stage before generic entry, withdrawing Tricor capsules from the market and changing the code in the National Drug Data File to "obsolete", which prevented Tricor capsule prescriptions to be substituted with generic versions by the pharmacists.[85] Later, Abbott changed the tablet formulation to another new tablet formulation again, with an additional change in the label that tablets "no longer had to be taken by food", followed by withdrawal from the market and changing the code in the National Drug Data File again.[86]

Both these product switches happened during the litigation stage, after Abbott filed infringement lawsuits triggering the "thirty-month Hatch-Waxman stay" period, during which FDA does not approve any generic products. After the litigation, generic companies could then market their products, however, they marketed their products with "modest" sales as they were not eligible for generic substitution.

[79] Case T-321/05 AstraZeneca AB and AstraZeneca plc v European Commission [2010] ECR II-02805.
[80] Case CE/8931/08 Reckitt Benckiser Healthcare (UK) Ltd (OFT Decision of 12 April 2011 CA98/02/2011), para 6.162.
[81] Ibid, paras 6.112-6.119, 6.163.
[82] Ibid.
[83] Ibid.
[84] Abbott Labs. v. Teva Pharm. USA, Inc., 432 F. Supp. 2d 408 (D. Del. 2006).
[85] Abbott Labs. v. Teva Pharm. USA, Inc., 432 F. Supp. 2d 408, 415 (D. Del. 2006).
[86] Ibid 418.

Generic companies Teva and Impax claimed that the second switch from original tablet formulation to the new tablet formulation "was not an actual improvement over the previous tablets but was developed simply to prevent generic substitution".[87]

In the motion to dismiss stage, the District Court referred to *Berkey Photo, Inc. v. Eastman Kodak Co.*[88] and *Foremost Pro Color, Inc. v. Eastman Kodak Co.*[89] and observed that Sherman Act was meant to promote competition via innovation and new products, and improved products are actually one of the advantages of competition.[90]

The District Court pointed out that the "rule of reason" test should be applied, which was established by the Supreme Court in *Standard Oil Co. v. United States*[91], to determine if the "anticompetitive conduct of formulation changes outweighs the pro-competitive effect".

The District Court dismissed Abbott`s motion to dismiss, observing that the allegations of product removal and NDDF code changes resulted in "consumer coercion" and are potentially anticompetitive.[92]

4.2.4 Walgreen Co v AstraZeneca Pharma LP

In the case of *Walgreen Co v AstraZeneca Pharma LP*[93], the District Court granted AstraZeneca`s motion to dismiss for the allegations brought by Walgreen, that AstraZeneca violated Section 2 of the Sherman Act, 15 U.S.C. § 2, by switching its Prilosec product with the new product Nexium. [94]

Before AstraZeneca`s Prilosec patents expired, AstraZeneca introduced a new product on the market, i.e. Nexium. Nexium contained (S)-omeprazole as active ingredient and Prilosec contained equal parts of (S)-omeprazole and (R)-omeprazole. Plantiffs argued that

[87] Abbott Labs. v. Teva Pharm. USA, Inc., 432 F. Supp. 2d 408, 418 (D. Del. 2006).
[88] Berkey Photo, Inc. v. Eastman Kodak Co., 603 F.2d 263, 286 (2d Cir.1979).
[89] Foremost Pro Color, Inc. v. Eastman Kodak Co., 703 F.2d 534, 546 (9th Cir.1983).
[90] Abbott Labs. v. Teva Pharm. USA, Inc., 432 F. Supp. 2d 408, 420 (D. Del. 2006).
[91] Standard Oil Co. v. United States, 221 U.S. 1, 61-62, 31 S.Ct. 502, 55 L.Ed. 619 (1911).
[92]
[93] Walgreen Co v AstraZeneca Pharma LP, 534 F Supp 2d 146 (DDC 2008).
[94] Ibid.

Nexium and Prilosec were essentially identical and Nexium did not provide any advantage over Prilosec.[95] However, AstraZeneca did not withdraw Prilosec capsules from the market and the generic substitution was not prevented. Only some of the market share switched to Nexium which resulted generic sales to be less, if Nexium was not introduced in the market.[96]

The District Court referred to *Abbott v. Teva*[97] and pointed out that elimination of consumer choice by removing the old product from the market was the critical element in that case, whereas in this case Prilosec capsules were continued to be marketed and AstraZeneca merely added a new product to compete with the other products that were already on the market including its own product.[98]

4.2.5 New York v Actavis

New York v Actavis[99] is the first case in which the product hopping was addressed by circuit courts as an antitrust violation.[100] State of New York brought an antitrust action against Actavis, alleging that by its planned withdrawal of its Namenda IR product (tablet formulation to be administered twice daily) from the market before generic entry and introduction of the new product Namenda XR (capsule formulation to be administered once daily), Actavis violated antitrust laws since generic substitution for Namenda would only be available for Namenda IR and not Namenda XR which had exclusivity for another 14 years and sought preliminary injunction to stop Actavis`s planned withdrawal of Namenda IR during litigation. Actavis appealed to the District Court`s decision to grant the preliminary injunction and the appeal was addressed by the United States Court of Appeals, Second Circuit.[101]

The Second Circuit stated that "neither withdrawal nor product improvement alone is anticompetitive" and referred to the standard set out in *Berkey Photo, Inc. v. Eastman*

[95] Walgreen Co v AstraZeneca Pharma LP, 534 F Supp 2d 146, 149 (DDC 2008).
[96]
[97]
[98] Walgreen Co v AstraZeneca Pharma LP, 534 F Supp 2d 146, 151 (DDC 2008).
[99] New York ex rel. Schneiderman v. Actavis PLC, 787 F.3d 638 (2d Cir. 2015).
[100] Ibid 643.
[101] New York ex rel. Schneiderman v. Actavis PLC, 787 F.3d 638 (2d Cir. 2015).

Kodak Co.[102] to point out that consumer coercion is a factor then product innovations and new products are anticompetitive.[103]

The Second Circuit distinguished between a "soft switch", i.e. to promote Namenda XR while Namenda IR was still on the market, and a "hard switch", i.e. withdrawing Namenda IR from the market and introducing the new product Namenda XR.[104] The Second Circuit held that hard switch was anticompetitive and observed that "by removing Namenda IR from the market prior to generic IR entry, Defendants sought to deprive consumers of that choice" and that "hard switch crosses the line from persuasion to coercion".[105]

Actavis` argued that the withdrawal of Namenda IR was procompetitive because "it would have maximized their return on investment in Namenda XR".[106] The Second Circuit referred to *In re Adderall*[107] and observed that anticompetitive behaviour was evident in "willing to forsake short-term profits to achieve an anticompetitive end" since withdrawing Namenda IR would have resulted in loss of profits.[108]

The Second Circuit decided that "the combination of withdrawing a successful drug from the market and introducing a reformulated version of that drug, which has the dual effect of forcing patients to switch to the new version and impeding generic competition, without a legitimate business justification, violates § 2 of the Sherman Act".[109]

Furthermore, the Second Circuit rejected Actavis` arguments that they "their patent rights under Namenda IR and Namenda XR shield them from antitrust liability"[110], observing that patent law provides a monopoly on Namenda XR only and Actavis tried to extend this protection to all of its memantine-therapy drugs thus putting its combined action of withdrawal of Namenda IR and introduction of Namenda XR in the market beyond the scope of patent rights.[111]

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[102] Berkey Photo, Inc. v. Eastman Kodak Co., 603 F.2d 263 (2d Cir.1979).
[103] New York ex rel. Schneiderman v. Actavis PLC, 787 F.3d 638, 654 (2d Cir. 2015).
[104] Ibid.
[105] Ibid 655.
[106] Ibid 659.
[107] La. Wholesale Drug Co. v. Shire LLC (In re Adderall XR Antitrust Litig.), 754 F.3d 128 (2d Cir. 2014)
[108] New York ex rel. Schneiderman v. Actavis PLC, 787 F.3d 638, 659 (2d Cir. 2015)
[109] Ibid.
[110] Ibid.
[111] Ibid 660.

4.2.6 Mylan v. Warner Chilcott

In the case of *Mylan v. Warner Chilcott*[112], the act under antitrust law scrutiny consists of several product hops, i.e. several changes in the product, where Mylan`s access to the market as generic substitution was not completely prevented. Warner Chilcott removed the Doryx capsules from the market to introduce tablet versions, followed by other changes where the dose was changed and tablets were marketed with scores which enabled patients to divide the tablet.[113] Doryx capsules were on the market without patent protection for a long time before they were withdrawn and generic versions were also available on the market.[114] Furthermore, the changes in the tablet did not prevent Mylan to enter the market but Mylan had to go through additional regulatory procedures by filing new marketing authorizations for each change.[115]

The Third Circuit agreed with the District Courts decision that Mylan failed to prove anticompetitive conduct because generic competition was available and generic companies were not barred from the market[116]. Referring to *New York v Actavis*[117], the Third Circuit observed that this case was different since it did not involve a "patent cliff" and generic competition was not prevented completely.[118]

4.3 Comparison and analysis

Both jurisdictions seem to focus on the anticompetitive effects of product hopping, i.e. delay or prevention of generic market entry. Both in Europe and US, courts have explicitly stated that neither withdrawal nor introduction of second generation product is considered to be anticompetitive. However, the combination of the withdrawal of the first generation product from the market with the introduction of the second generation product is the

[112] Mylan Pharm. Inc. v. Warner Chilcott Pub. Ltd., 838 F.3d 421 (3d Cir. 2016), Mylan Pharms., Inc. v. Warner Chilcott Pub. Ltd., Civ. No. 12-3824 (E.D. Pa. Apr. 16, 2015).
[113] Ibid.
[114] Mylan Pharm. Inc. v. Warner Chilcott Pub. Ltd., 838 F.3d 421, 429-430 (3d Cir. 2016).
[115] Ibid 431.
[116] Ibid 438-439.
[117] New York ex rel. Schneiderman v. Actavis PLC, 787 F.3d 638 (2d Cir. 2015).
[118] Mylan Pharm. Inc. v. Warner Chilcott Pub. Ltd., 838 F.3d 421, 439-440 (3d Cir. 2016).

common element in both jurisdictions. Even though in *Astrazeneca v. Commission*[119], Court of Justice set EU`s approach to include delay of generic entry on the market as anticompetitive effect, the Third Circuit excluded it *Mylan v. Warner Chilcott*[120]. Both jurisdictions also acknowledge the timing of the withdrawal and if it had allowed any time for the generic entry and that patent rights cannot be a "shield" from antitrust law.

Both jurisdictions acknowledge the conflict between competition law and patent law, one overseeing monopoly and the other providing monopoly. However, in all cases both jurisdictions seem to have the approach not to limit any "patent rights" when it comes to product hopping but rather sanction actions of originator companies which abuse the pharmaceutical regulatory framework, where patent protection is a tool for originator companies to prevent or delay generic entry which also is regulated by the same pharmaceutical regulatory framework.

[119] Case C-457/10 P *AstraZeneca AB and AstraZeneca plc v European Commission* [2012] EU:C:2012:770.
[120] *Mylan Pharm. Inc. v. Warner Chilcott Pub. Ltd.*, 838 F.3d 421 (3d Cir. 2016), *Mylan Pharms., Inc. v. Warner Chilcott Pub. Ltd.*, Civ. No. 12-3824 (E.D. Pa. Apr. 16, 2015).

5. CASES RELATED TO ENFORCEMENT OF PATENTS

5.1 Exhaustion Principle and Parallel Imports - Centrafarm v Sterling

In *Centrafarm v Sterling*[121] case, the Court of Justice apply the exhaustion principle to patent cases. In cases where the patent holder itself or third parties with patent holders consent is marketing and selling a patented drug in a member state, patent holders rights are exhausted such that the parallel import of those products to another member state where the product is patented is allowed.

The Court of Justice further observed that even though Article 85 EEC does not affect recognition of industrial property rights (patent rights in this case) in a member state, but the circumstances in which those rights may be exercised may still be in violation of that article's prohibitions if the exercise of a right of this nature appears to be the purpose, means, or outcome of an agreement (license agreement in this case).[122]

This was one of earlier cases, where Court of Justice ruled on parallel import of pharmaceutical products. Even though parallel imports are mostly judges according to the internal market rules and free movement of goods, the Court of Justice also commented on limits competition law sets on the exercise of patent rights, i.e. license agreements in this case.

The next ruling of the Court of Justice after *Centrafarm v Sterling* was in *Merck v Stephar*[123], which again judged parallel imports and set limits to patent rights and patent exhaustion principle.

[121] Case 15/74 *Centrafarm BV and Adriaan de Peijper v Sterling Drug Inc.* [1974] ECR 1147.
[122] Ibid, para 39-40.
[123] Case 187/80 *Merck & Co. Inc. v Stephar BV and Petrus Stephanus Exle*r [1981] ECR 2063.

5.2 Consent and Compulsory Licenses

Even though there are no cases of compulsory licenses in the pharmaceutical field, where Court of Justice held judgements, Europe has established case law of essential facilities doctrine applied to refusal to license practices.

In the case of Magill[124], the Court of Justice held that by refusing to grant licenses of their weekly television listings for the publication of television guides, the undertaking holding the dominant position "denied access to the basic information which is the raw material indispensable for the compilation of such a guide".[125] Although this decision concerned deny of access to information protected by copyrights, this formed the essential facilities concept in the Intellectual Property field, whereby the Court decided that act of refusing to deal by refusing to grant a licence for the IP rights without justification constitutes an abuse of dominant position, where the access to the IP (weekly television listings in this case) is "indispensable" for the third party to introduce a new product on the market, and such refusal results in excluding all competition. This decision of the Court formed the essential facilities doctrine in the IP field acknowledging that although IP deserves a special protection, when these aforementioned four conditions are satisfied, a refusal to grant IP licences constitutes abuse of dominant position prohibited by Article 102. Furthermore, refusal to supply access to IP rights might result with compulsory licensing orders as it was the case in the Microsoft[126] case.

These principles might as well apply to patents and to pharmaceutical industry in the future, where instances of compulsory licence orders might be issued.

When it comes to refusal to deal in the IP field the US approach is that "refusals to deal are rarely anticompetitive, whether or not they involve patents".[127] The liability for mere refusals to license is not considered to have an essential role in the relationship between

[124] Joined Cases C-241/91 P and C-242/91 Radio Telefis Eireann (RTE) and Independent Television Publications (ITP) v Commission [1995] ECR I-743.
[125] Ibid, para 56.
[126] Case T-201/04 Microsoft v Commission [2007] ECLI:EU:T:2007:289.
[127] U.S. Department of Justice & Federal Trade Commission, `Antitrust Enforcement and Intellectual Property Rights: Promoting Innovation and Competition` (justice.gov, 2007) <https://www.justice.gov/atr/chapter-1-strategic-use-licensing-unilateral-refusals-license-patents> accessed 18 December 2021.

patent rights and antitrust protections, however situations where a patent owner refuses to continue a licence is considered as a potential antitrust violation.[128]

[128] U.S. Department of Justice & Federal Trade Commission, `Antitrust Enforcement and Intellectual Property Rights: Promoting Innovation and Competition` (justice.gov, 2007) <https://www.justice.gov/atr/chapter-1-strategic-use-licensing-unilateral-refusals-license-patents> accessed 18 December 2021.

5.3 Pay for delay/Reverse Payment Agreements

This kind of arrangement can be beneficial to both the originator and the generic companies. The originator company pays the generic company and the generic company delays market entry for a period of time. If the payment to generic company compensates the profits, which the originator company makes during the time to generic company stays out of the market, then this will be beneficial for the originator company. On the other hand, if the payment the generic company receives from the originator company is greater than the profit, which generic company would have made if it had entered the market, then the generic company profits as well.[129]

Since the price reduction induced by the entry of generics in the market is hindered, healthcare systems pay higher values for longer time.[130] According to UNDP pay for delay agreements "enrich patent owners and generic producers at the expense of the public" and should be prevented by legislation. [131]

These agreements usually involve patent disputes and payments can also be in other forms of exchange of value between the companies.[132]

Pay-for-delay or reverse payment agreements which entail coordination between rival companies are covered by Article 101 TFEU in Europe and Section 1 of the Sherman Act. However, these can also be a violation of Article 102 TFEU in Europe as discussed below.[133]

[129] European Commission, Directorate-General for Competition `Competition enforcement in the pharmaceutical sector (2009-2017) : European competition authorities working together for affordable and innovative medicines` Publications Office (2019).
[130] Ibid.
[131] Frederick Abbott and others, *Using Competition Law to Promote Access to Health Technologies: A Guidebook for Low- and Middle-Income Countries* (2014) United Nations Development Programme.
[132] European Commission, Directorate-General for Competition `Competition enforcement in the pharmaceutical sector (2009-2017) : European competition authorities working together for affordable and innovative medicines` Publications Office (2019).
[133] Ibid.

5.3.1 Generics UK

This was the first case where the Court of Justice established a test for patent settlement agreements and their anticompetitive nature. The Competition and Markets Authority of United Kingdom issued a decision that Generics (UK) Ltd, GlaxoSmithKline plc, Xellia Pharmaceuticals ApS, Alpharma LLC, formerly Zoetis Products LLC, Actavis UK Ltd and Merck KGaA have entered into settlement agreements and concerted practices and that GSK had abused its dominant position. The companies then appealed the Competition and Market Authority`s decision before the Competition Appeal Tribunal, which later referred the case to the Court of Justice[134].

In its judgement, the Court of Justice made important remarks about the relationship of patent law and patent rights in the competition law context. The Court pointed that competition authorities cannot assess the validity of rights conferred by a patent such as the validity of a patent, or the strength of it, however, competition authorities cannot disregard the influence of such issues on competition and they should assess the effect of the existence of a patent on the generic market entry.[135]

The Court of Justice further observed that Article 101 TFEU makes no distinction between settlement agreements and those which were concluded for different goals and challenges to the validity and scope of a patent is an integral part of the competition.[136] Therefore, given the legal and economic environment, a condition in an agreement stating that a patent will not be challenged may restrict competition within the meaning of Art 101 TFEU.[137]

However, a generic company may also decide not to enter the market after evaluating the chance of success in the litigation proceedings and may enter into a settlement agreement with the originator company. It does not follow that these types of agreements are always to be considered as "restriction by object" under Article 101 TFEU, even if there is "transfer of value" from the originator company to the generic company. [138]

[134] Case C-307/18 *Generics (UK) Ltd and Others v Competition and Markets Authority* [2020] ECLI:EU:C:2020:52.
[135] Ibid para 50.
[136] Ibid paras 80-81.
[137] Ibid para 82.
[138] Ibid para 84-85.

The Court focused on the amount of "transfer of value" as the decisive factor in such agreements, that "in the absence of any other plausible explanation, … it is "the transfer of value which has induced" the generic company to not enter the market and stop the litigation proceedings relating to the invalidity of the patent.[139]

The Court of Justice further approves General Court`s observation that in such agreements the transfer of value might be in form of other arrangements providing the generic company other opportunities to capitalize.[140]

Regarding the possibility of an Article 102 TFEU violation, the Court of Justice further held that if an originator company enters into settlement agreements to end the litigation proceedings for the validity of the patent in order to delay the entry of generic companies, such a practice may be an abuse of dominant position if it is determined that it has the ability to restrict the competition.

5.3.2 Lundbeck

The Court of Justice in *Lundbeck*[141] referred to the *Generics*[142] judgement on most points of law since both cases were similar in facts, i.e. Lundbeck had entered into settlement agreements with generic companies and a reverse payment was involved as part of those agreements.

Applying the standard set out in *Generics*[143], the Court of Justice made additional remarks stating that an agreement concluded where potential or actual competitors were prevented to enter the market via a payment is not covered by the intellectual property rights, patent rights in this case. [144]

[139] Ibid para 88.
[140] Ibid para 90-91.
[141] Case C-591/16 P *H. Lundbeck A/S and Lundbeck Ltd v European Commission* [2021] ECLI:EU:C:2021:243.
[142] Case C-307/18 *Generics (UK) Ltd and Others v Competition and Markets Authority* [2020] ECLI:EU:C:2020:52.
[143] Ibid.
[144] Case C-591/16 *P H. Lundbeck A/S and Lundbeck Ltd v European Commission* [2021] ECLI:EU:C:2021:243, para 122.

Lundbeck`s agreements did not have no-challenge clauses unlike those in Generics case, and the Court of Justice observed that the fact agreements did not have no-challenge clauses does not exclude them from being restriction by object, because the amount of value of transfer was high enough to cover the potential profits they had expected to make if they had entered the market, also covering additional potential litigation damages.[145]

5.3.3 Servier

After the patent challenge lawsuits and infringement lawsuits have been initiated, Servier (originator company) has concluded 2 agreements with Krka (generics company), first of which was a license agreement which allowed Krka to market its generic products in some of EU countries, whereas the second agreement was a settlement agreement, where Krka agreed to refrain from marketing in the rest of the EU market.[146]

With a third assignment and license agreement Krka licensed its alternative method of production for Servier`s marketed active ingredient to Servier in exchange of €30 million. This agreement furthermore prevented assignment of this alternative method of production to other generic companies.[147]

The Commission decided that the settlement and first license agreement is a "market sharing agreement" in violation of Article 101 TFEU.[148] However, according to the Commission`s assessment the assignment and license agreement constituted another violation because combined with the first license and settlement agreement, Servier was able to secure that Krka could not provide other generic companies a license to produce the active ingredient by Krka`s alternative method. Another point for the Commission was that Servier had not made any assessments for Krka`s licensed patents before entering the agreement and Servier could not produce any documentation how the licensed technology would be implemented[149] and the value of €30 million was economically more than it was

[145] Case C-591/16 *P H. Lundbeck A/S and Lundbeck Ltd v European Commission* [2021] ECLI:EU:C:2021:243, para 133-135.
[146] Ibid, para 822.
[147] Perindopril (Servier) (Case AT.39612) Commission Decision [2014] C(2014) 4955 final.
[148] Ibid, para 1857-1859.
[149] Ibid, para 1767.

in the interest of both parties in such an agreement[150]. Commission`s conclusion was therefore, that Servier had licensed and obtained rights for Krka`s alternative production method in order to block other generics from being able to license this alternative method.[151]

However, Commission`s decision was annulled[152] by the General Court because the General Court did not agree that the settlement and license agreement resulted with market sharing[153].

Furthermore, the General Court did not agree that the assignment and license agreement was a "side deal", because they were not concluded on the same day and they were not legally linked.[154]

The Commission then appealed the General Court`s decision[155] and the Court of Justice has not yet issued a decision on this case. It should be pointed out that by the time General Court decided on this case the Court of Justice` judgements of Generics and Lundbeck have not been yet issued. Advocate General in its opinion[156] referred to the previous cases in its opinion for the appeal lodged against the judgement of the General Court, who has annulled Commission`s Decision[157] that Servier`s licence agreement was in violation of Article 101 TFEU and the collective settlement and licence agreements was an abuse of dominant position in violation of Article 102 TFEU.

So, it remains yet to be seen if the General Court`s decision will be annulled by the Court of Justice. Following the standards set in Generics UK and Lundbeck it is likely that the Court of Justice might annul General Court`s decision and agree with the Commission as it is suggested by the opinion[158] of the Advocate General.

[150] Perindopril (Servier) (Case AT.39612) Commission Decision [2014] C(2014) 4955 final, para 1795-1796.
[151] Ibid, para 1806- 1807.
[152] Case T-691/14 *Servier SAS and Others v European Commission* [2018] ECLI:EU:T:2018:922.
[153] Ibid, para 1014, 1054.
[154] Ibid, para 798, 1056.
[155] Case C-201/19 P - *Servier and Others v Commission* [2022] ECLI:EU:C:2022:577.
[156] Ibid.
[157] Perindopril (Servier) (Case AT.39612) Commission Decision [2014] C(2014) 4955 final.
[158] Case C-201/19 P *Servier and Others v Commission* [2022] ECLI:EU:C:2022:577.

5.3.4 FTC v. Actavis

FTC v Actavis[159] was the first case when Supreme Court set a standard for pay for delay agreements in US. Actavis filed an application for its generic version of AndroGel certifying that Solvay`s listed patents in Orange Book were invalid and that Actavis did not infringe them. Solvay the originator company of the drug AndroGel, filed infringement lawsuits and initiated Paragraph IV litigation, later even though Actavis received an approval of marketing authorisation for its generic product, Actavis and Solvay entered into a reverse-payment settlement agreement. Actavis agreed to stay out of the market for a specified time period in exchange of millions of dollars and Solvay entered into similar settlements with other generic companies as well.[160]

Federal Trade Commission alleged that all parties violated antitrust laws by agreeing "to share in Solvay's monopoly profits, abandon their patent challenges, and refrain from launching their low-cost generic products to compete with AndroGel for nine years"[161]. The District Court held that FTC`s allegations were not antitrust violation.[162]

The Supreme Court referred to Watsons[163] and pointed out that "anticompetitive effects fall within the scope of the exclusionary potential of the patent" agreeing with District Court`s reasoning in rejecting FTC`s allegations. However, the Supreme Court disagreed that this can immunize the agreement from antitrust attack.[164] The Court pointed out that a valid patent may give patent holder rights, but an invalidated patent does not, and the paragraph IV litigation challenges the validity and its scope.[165] The Supreme Court observed antitrust immunity conferred by a patent and its monopoly must be assessed by evaluating settlement`s anticompetitive effects against patent law as well as procompetitive antitrust policies.[166]

[159] FTC v. Actavis, Inc., 570 U.S. 136 (2013).
[160] Ibid B1.
[161] Ibid B2.
[162] Ibid.
[163] Fed. Trade Comm'n v. Watson Pharms., Inc., 677 F.3d 1298, 1312 (11th Cir. 2012)
[164] FTC v. Actavis, Inc., 570 U.S. 136 (2013).
[165] Ibid.
[166] Ibid.

The Supreme Court further referred to previous instances[167] where it has ruled before resolving the issue of "lawful restraint on trade of the patent monopoly and the illegal restraint prohibited by the Sherman Act", that improper use of patent monopoly is an antitrust violation.[168]

Furthermore, Hatch-Waxman Act has a procompetitive character and makes it easier to challenge a patent`s validity, and filing of paragraph IV certification triggers the patent dispute with additional requirements for filing corresponding settlement terms ending such disputes with the FTC.[169] According to the Supreme Court this legal framework also did not support the District Court`s reasoning in rejecting FTC's antitrust allegations.

The court held that in some cases legitimate justifications may be present regarding the payment and have such payments might reflect traditional settlement conditions to cover the costs of litigation. However, "an unexplained large reverse payment itself would normally suggest that the patentee has serious doubts about patent`s survival. And that fact, in turn suggest that the payment`s objective is to maintain supra-competitive prices to be shared among the patentee and the challenger rather than face what might have been a competitive market".[170]

The Supreme Court pointed out that antitrust liability which might arise because of unjustified reverse payments, does not prevent the parties from settling in other ways that would allow the generic company to enter the market before the expiry date of the originator company`s patent.

The Supreme Court opinion thus can be summarised that large and unjustified reverse payments do not fall within the scope of the exclusionary rights of a patent application and such payments might risk producing anticompetitive effects and thus inducing antitrust injury in absence of justified reasons and set a standard for alternative means of settlement which would allow the generic company to enter the market before the expiry date of the patent.

[167] United States v. Line Material Co., 333 U.S. 287, 310 (1948).
[168] Fed. Trade Comm'n v. Watson Pharms., Inc., 677 F.3d 1298, 1312 (11th Cir. 2012), Part II A.
[169] Ibid.
[170] Ibid.

After the Supreme Court decision, US courts have ruled over reverse payment settlements in other cases. In Humira[171], the District Court ruled that even though considerable reverse payments were made by the originator company AbbVie, the conditions of the settlement agreement which allowed the generic companies to enter the market before the expiry date of the patent increased competition.

5.4 Comparison and analysis

Both Europe and US have a similar approach when it comes to pay for delay agreements. Both jurisdictions agree that this type of agreements are not covered by the patent rights or the monopoly conferred by such rights. Furthermore, both jurisdictions agree that challenges to a patent`s validity is part of competition.

Although both jurisdictions seem to accept that not all settlement agreements are anticompetitive and generic companies have a right to decide not to continue the patent invalidity lawsuits, no-challenge clauses have anticompetitive effects.

When it comes to the reverse payment made by the originator company, "unjustified large sums" are anticompetitive, however, side deals or other types of agreement seem to be viewed differently by Europe and US depending on the facts of the case and no consistent case law exists yet.

[171] In Re: Humira (Adalimumab) Antitrust Litigation, No. 19-cv-01873, Slip. Op. (N.D. Ill. Jun. 8, 2020).

5.5 Patent Litigation

The sector inquiry[172] of the European Commission points litigation as one the tools they can use to delay or prevent generic entry. Sham litigation (as referred in US) and vexatious litigation (as referred in EU) is an "anticompetitive use of the judicial process to enforce intellectual property rights"[173].

In sham litigation, US applies the Noerr-Pennington Doctrine[174]. There are many cases in pharmaceutical industry where generic companies have raised antitrust allegations of sham litigation.

In EU the legal standard for vexatious litigation was established in ITT Media case[175]. Unlike US, there have not been any cases of vexatious litigation in pharmaceutical industry, or in other industries that has been addressed by higher courts.

[172] European Commission, `Executive Summary of the Pharmaceutical Sector Inquiry Report` COM(2009) 351 final.
[173] Institute for Applied Economic Research (IPEA) `Study On The Anti-Competitive Enforcement Of Intellectual Property (IP) Rights: Sham Litigation` [2012] WIPO CDIP/9/INF/6 REV.
[174] Eastern R. Conference v. Noerr Motors, 365 U.S. 127 (1961); United Mine Workers v. Pennington, 381 U.S. 657 (1965).
[175] Case T-111/96 *ITT Promedia v Commission* [1998] ECR II-02937.

CONCLUSION

European competition law and US antitrust case law suggest that anticompetitive conducts in the pharmaceutical industry in most cases include practices which are otherwise lawful by patent rights and regulatory framework.

The anticompetitive conduct may sometimes be a combination of different practices and the anticompetitive effect on the competition is usually the result of the combination of such practices, each otherwise lawful. It can be observed that in some cases patents are used as a tool and are part of a combined anticompetitive conduct, whereas in others they are the core element that is found to be anticompetitive.

In most cases the effect of the conduct on the competition depends on the specific circumstances of the case. Every case is unique and standards or tests set up by courts may fail to be applied as a universal solution. This is due to the complicated legal framework that governs and links patent law and regulatory framework of pharmaceutical industry.

Usually, the originator company is in the dominant position has the position to manipulate the market via legal rights provided by patent law and regulatory framework. However, in some cases, the two key players of the market, i.e. generic and originator companies may also be accomplices in an anticompetitive conduct.

Even though it may seem that competition and antitrust law set limitations to patent rights and rights provided by regulatory frameworks, the analysis of the cases and the points of law applied by competition authorities and courts suggest that competition and antitrust law mostly sanction abuse of rights and anticompetitive effects created by such practices.

Both jurisdictions in US and EU seem to have a similar approach while assessing misuse of patent procedures and patent systems. One of the ways companies misuse patent system is filing of divisional patent applications and have been a practice to be considered to have anticompetitive effects by both jurisdictions. Even if such filings are lawful under patent law, they might be sanctioned under European competition law and US antitrust law.

Filing of divisional applications may in some cases be considered as “artificially extending” the protection conferred by a patent application in Europe. Furthermore, divisional applications may be used in some cases to create legal uncertainty for others.

European competition authorities and courts focus on the effect such applications and rights might have on the competition. It has been acknowledged by European competition authorities that the intention behind obtaining patent rights by divisional applications and the way they are enforced might be the key indicator of an anticompetitive conduct. Such anticompetitive intent is to exclude competitors from the market or to delay their entry in the market. However, lack of intent and bad faith does not immunize the violation of competition law and the effect which the conduct has on the competition.

Whereas, US courts apply a different approach. US Courts apply Noerr-Pennington doctrine to assess the antitrust immunity and view filing of divisional applications as petitioning before USPTO and analyse if such filings were objectively baseless or not. The success rate of such divisional filings or their issuance have been determined to be an indicator of not being objectively baseless and having antitrust immunity.

According to both US and EU, providing misleading information to government authorities and patent offices in order to obtain patent rights are not only unlawful but also are potentially anticompetitive. Similar misleading conduct and misrepresentations might also be viewed as anticompetitive when they occur during regulatory approval proceedings and applications.

However, there are other ways originator companies have been sanctioned because of misuse of the regulatory procedures. One of the most sanctioned practices is product hopping. Product hopping conduct results from a combination of practices all of which is lawful under the regulatory legal framework. It is a form of second generation products being introduced into the market via a “product switch”. This form of conduct depending on the facts of the conduct have been considered to be misuse of the regulatory regulations and laws by both European competition and US antitrust law.

European competition authorities and courts apply the legal principles of “competition on merits” in order to determine a potential abuse of dominant position regarding a product hopping case. In the absence of objective justifications for the product switch or legitimate interests of the dominant company. The effect of the switch on the competition is again the key element and that is also once again the generic entry on the market.

Product hopping cases in US have been assessed in terms of their pro-competitive effect as a product improvement and their anti-competitive effect on generic products and consumer choices. Rule of reason test has been applied by some courts to determine if the anti-competitive effect outweighs the pro-competitive. Withdrawal of previous product from the market has been determined by US courts as removal of consumer choice and as consumer coercion. The availability of generic competition is the key element in determining antitrust injury.

Both EU competition case law and US antitrust case law has acknowledged that the withdrawal of the product itself is not an anticompetitive conduct. In Europe, the deregistration of the marketing approval after withdrawal prevented the generic entry in the market having restricted competition. Thus, the combination of two practices has been determined to be anticompetitive. Also, the anticompetitive conduct has been analysed in view of competition on merits. US antitrust law also focuses on the effect withdrawal has on generic entry in the market. Even though product improvements as a rule are considered to be pro-competitive, withdrawal has been in some cases considered to be removal of consumer choice and forcing consumers to switch by US courts. Timing of the withdrawal and allowing generics enter the market is an additional element considered by both EU and US courts.

Another important practice that has been sanctioned by both jurisdictions is pay-for-delay or reverse payment agreements. European courts have ruled that this type of agreements are anticompetitive if they have the potential to restrict the competition. The validity of the patent according to the Court of Justice is not to be ruled by competition law but may be used to assess the effect of a settlement on the competition. No-challenge clauses, transfer of value beyond the scope of litigation are indicators for such agreements being anticompetitive. Transfer of value can be in different forms and does not have to be a monetary transfer of value. Side deals or what type of deals could also be considered to be anticompetitive in relation to pay-for-delay agreements are not well established.

US antitrust law also approaches pay for delay agreements as potential antitrust violations. Supreme Court decided that the antitrust immunity provided by patent rights must be assessed by weighing procompetitive effects against competitive effects and these agreements are not supported by the Hatch Waxman Act`s procompetitive goals. Large

unjustified sums indicate that the patent holder has doubts about the result of the litigation and patent`s validity.

US antitrust law and EU competition law approach pay-for-delay agreements similarly. In its essence ending litigation challenging the validity of the patent and agreeing not to enter the market in exchange of transfer of value might be anticompetitive. However, both jurisdictions state that not all settlements agreements about the validity of a patent challenge are anticompetitive. The difference of the approach between two jurisdictions and an issue to be cleared by other case law is the transfer of value and which form it could take.

Other differences between EU competition and US antitrust law can be observed in practices regarding parallel imports, compulsory licensing. These differences occur due to the fundamental differences between EU competition and US antitrust law. In other areas, both jurisdictions have similar approaches trying to balance patent law and competition law. Most practices relate to misuse of rights provided by patent law or regulatory legal framework.

EU competition law acknowledges that abuse of dominant position and anticompetitive practices mostly concern conduct which is otherwise lawful and focus on the effect on the competition. By applying points of law, EU competition law applies general principles such as “competition on merits” but accepts as a general principle that competition law has a overruling superiority. Whereas US antitrust law tries to weigh the procompetitive effects of patent rights against anticompetitive effects resulting from lawful conduct supported by rights provided by patent law. In cases concerning acts before regulatory authorities US antitrust law acknowledges antitrust immunity provided by Noerr-Pennington Doctrine and analyses the alleged injury applying those principles. This difference between US antitrus law and EU competition law seems to reflect on the sanctioned conducts and in rare cases EU competition law has a more restrictive approach compared to the US antitrust law, which acknowledges antitrust immunity provided by patent rights or Noerr-Penninggton Doctrine.

A common issue in both jurisdictions is that these practices are unique and need to be approached case by case. Clearly, pharmaceutical industry will continue to be sanctioned by EU competition law and US antitrust law in the future and more case law will develop

covering different aspects of anticompetitive practices in this industry and competition and antitrust law will continue to balance competition and innovation.

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21 U.S.C. 355

21 U.S.C. 505

ANNEX

ABSTRACT IN ENGLISH

In the pharmaceutical market competition starts when generic companies enter the market. However, exclusionary rights provided to the originator company by patent laws and regulatory laws set conditions for the generic entry in the market.

The aim of this work is to examine the limits set by competition and antitrust laws on rights provided by patent law and other rights provided by regulatory framework of the pharmaceutical industry. The work examines patent related conducts and practices that are considered to be “anticompetitive” by European competition law (national courts and competition authorities, European Commission and European Court of Justice) and US antitrust law. Competition and antitrust case law of higher Courts and authorities relating to pharmaceutical cases in both jurisdictions is analysed by focusing on the points of law applied.

Anticompetitive conducts in the pharmaceutical industry in most cases include practices which are otherwise lawful by patent rights and regulatory framework and the effect of the conduct on the competition depends on the specific circumstances of the case. The anticompetitive conduct may sometimes be a combination of different practices and the anticompetitive effect on the competition is usually the result of the combination of such practices, each otherwise lawful. It can be observed that in some cases patents are used as a tool and are part of a combined anticompetitive conduct, whereas in others they are the core element that is found to be anticompetitive. This makes legal standards or tests established by courts difficult to apply as a universal rule. This seems to be resulting from the complicated legal framework that governs and links patent law and regulatory framework of pharmaceutical industry.

Pharmaceutical industry will continue to be sanctioned by EU competition law and US antitrust law in the future and the challenge for competition authorities to continue to balance competition and innovation will continue.

ABSTRACT IN GERMAN

Auf dem Pharmamarkt beginnt der Wettbewerb mit dem Markteintritt von Generikaherstellern. Ausschlussrechte, die dem Originalpräparatehersteller durch Patentgesetze und Regulierungsgesetze gewährt werden, legen jedoch Bedingungen für den Markteintritt von Generika fest.

Ziel dieser Arbeit ist es, die durch Wettbewerbs- und Kartellgesetze gesetzten Grenzen von Patentrechten und anderen Rechten, die durch regulatorische Rahmenbedingungen der pharmazeutischen Industrie vorgegeben sind, zu untersuchen. Die Arbeit untersucht patentbezogene Verhaltensweisen und Praktiken, die nach europäischem Wettbewerbsrecht (nationale Gerichte und Wettbewerbsbehörden, Europäische Kommission und Europäischer Gerichtshof) und US-Kartellrecht als „wettbewerbswidrig“ gelten. Die wettbewerbs- und kartellrechtliche Rechtsprechung der höheren Gerichte und Behörden in Bezug auf pharmazeutische Fälle in beiden Jurisdiktionen wird analysiert, indem der Schwerpunkt auf die angewandten Rechtspunkte gelegt wird.

Wettbewerbswidriges Verhalten in der pharmazeutischen Industrie umfasst in den meisten Fällen Praktiken, die ansonsten durch Patentrechte und regulatorische Rahmenbedingungen rechtmäßig sind, und die Auswirkung des Verhaltens auf den Wettbewerb hängt von den spezifischen Umständen des Falls ab. Das wettbewerbswidrige Verhalten kann manchmal eine Kombination verschiedener Praktiken sein, und die wettbewerbswidrige Wirkung auf den Wettbewerb ist normalerweise das Ergebnis der Kombination solcher Praktiken, die ansonsten rechtmäßig sind. Es ist zu beobachten, dass Patente in manchen Fällen als Instrument genutzt werden und Teil eines kombinierten wettbewerbswidrigen Verhaltens sind, während sie in anderen Fällen das Kernelement darstellen, das als wettbewerbswidrig befunden wird. Dies macht es schwierig, gesetzliche Standards oder von Gerichten festgelegte Tests als universelle Regel anzuwenden. Dies scheint auf den komplizierten Rechtsrahmen zurückzuführen zu sein, der das Patentrecht und den regulatorischen Rahmen der pharmazeutischen Industrie regelt und verbindet.

Die Pharmaindustrie wird auch in Zukunft durch das EU-Wettbewerbsrecht und das US-Kartellrecht sanktioniert werden, und die Herausforderung für die Wettbewerbsbehörden, Wettbewerb und Innovation weiterhin in Einklang zu bringen, wird bestehen bleiben.