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One man´s profit another man´s loss: the incomparable power of generic medicines leading to an interplay between intellectual property law and competition law. Controversies surrounding pay- for- delay deals.

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SAŽETAK

Svrha rada pod naslovom ""Nekima profit, drugima gubitak: neusporediva moć generičkih lijekova koja dovodi do interakcije prava intelektualnog vlasništva i prava tržišnog natjecanja. Kontroverze koje okružuju pay-for-delay sporazume." (autorica: Lucija Jurlina) je razumijevanje parametara iznimno snažnog utjecaja generičnih lijekova te motiva za nekonkuretno ponašanje proizvođača originalnih lijekova, radi analize zlouporabe prava intelektualnog vlasništva s ciljem odgađanja izlaska generičnih lijekova na tržište. Kombinacijom različitih strategija vezanih uz patente, od kojih neke dolaze do same granice ilegalnog, nastoji se produžiti patentna zaštita i očuvati monopolski položaj. Rad detaljno analizira najinteresantniju patentnu strategiju čiji je pravni status vrlo "vruća tema". Iako se zlouporaba nagodbe u sporovima o patentima, u vidu takozvanih "pay-for-delay" ugovora smatra ilegalnom prema europskom pravu tržišnog natjecanja, još uvijek postoje određene kontroverze glede neriješenih pravnih pitanja proizašlih tijekom provođenja "antitrust" aktivnosti. Rad analizira formiranje smjera budućeg provođenja "antitrust" mjera kroz dvije ključne presude Sudova EU u slučajevima Lundbeck i Paroxetine u potrazi za temeljnim odrednicama za tretiranje "pay-for-delay" sporazuma u kontekstu prava tržišnog natjecanja.

KLJUČNE RIJEČI: generički lijekovi, pay-for-delay sporazumi, EU, pravo intelektualnog vlasništva, patenti, antitrust, Lundbeck, Paroxetine

SUMMARY

The purpose of the paper named "One man´s profit another man´s loss: the incomparable power of generic medicines leading to an interplay between intellectual property law and competition law. Controversies surrounding pay- for- delay deals." (author: Lucija Jurlina) is to understand the greatness of generic effect and the motive behind the originator companies´ anticompetitive behaviour in order to analyse the ways of abuse of intellectual property law with the aim of delaying generic entry. Combination of different patent related strategies, some of them reaching the very boundaries of what is legal, is used to create the longest possible patent protection, and thus preserve monopolistic position. The paper will provide an in- depth analysis of the most interesting patent related strategy, legal status of which presents a very hot topic. Patent settlement agreements used as pay- for- delay agreements are found illegitimate under EU competition rules, however there seem to be a lot of controversies regarding the fundamental points of law points raised during the antitrust enforcement activities. The paper will analyse the forming direction of the future antitrust enforcement through 2 landmark judgments of the EU Courts, in Lundbeck and Paroxetine cases, in search for foundation for the treatment of pay- for- delay deals in the context of competition rules.

KEY WORDS: generic medicines, pay-for-delay agreements, EU, IPRs, patents, antitrust, Lundbeck, Paroxetine

ABBREVIATIONS

Agreement on a Unified Patent Court- UPCA

Competition Appeal Tribunal- CAT

Competition and Markets Authority- CMA

European Union- EU

European Economic Area- EEA

European Court of Justice -ECJ

European Patent Office- EPO

Federal Drug Agency- FDA

GlaxoSmithKline- GSK

Intellectual property rights- IPRs

Marketing Authorization- MA

Research and development- R&D

Supplementary product certificate- SPC

Treaty on the Functioning of the European Union- TFEU

Unified Patent Court- UPC

United States- US

I. INTRODUCTION

In the modern business world there are no many things comparable to the effect created by the entry of generic versions of medicines to the market. By being a perfect substitute for the originator medicines due to their bioequivalence and significantly lower prices as they do not require investment in the research and development, generic medicines create enormous competitive pressure and are regarded as a vicious threat by the originator companies. Purely by entering the market they cause drop of the prices which leads to significant savings for the national health budgets. But they are not just cost-effective, they improve overall access to pharmacotherapy, enable medication in the earlier stages of treatment, and reduce inequalities between patients and offer treatment to a substantially bigger number of patients. All these benefits trigger policy makers to introduce regulations to ease the generic entry, stimulate growth in generic volume use and lower the overall prices, which in the end again leads to the more intensive rise of competitive pressure on originator companies. If one takes into account the consequences that generic entry can have on originator companies, it could be safe to say that the fear of their entry is not excessive at all. The generic effect on originator companies could be fatal, as prices of the originator medicine drop drastically, they lose their market shares and face significant sales erosion, and consequently experience dramatical drops in profit which could lead to a point with no chances of survival. In order to avoid these catastrophic effects, originator companies are prepared to do everything in their power to block or at least delay generic entry. Some measures are on the very verge of illegality in the context of competition law, while others are proven to be illegal. As any delay of the generic market entry disrupts all the benefits that generic entry could bring, and thus has negative effects towards the healthcare systems and patients, there is a great need for antitrust scrutiny and monitoring potentially hindering practices of pharmaceutical companies.

A. Method and purpose

The main purpose of the paper is, by understanding the greatness of generic effect and the motive behind the originator companies´ anticompetitive behaviour, to analyse the ways of abuse of intellectual property law in order to delay generic entry. Originator companies seek to combine various measures to extend patent protection of their medicines and to preserve their market position and revenue streams. It is precisely the use of different patent strategies that can lead to the creation of the longest possible patent protection. The most

interesting part of these strategies is that they are perfectly legitimate under patent law. However, some of them are considered problematic under EU competition rules and attract antitrust scrutiny. The specific purpose of the paper is to deepen the analysis of patent settlement agreements used as pay-for-delay agreements which are found to be illegitimate under EU competition rules. This is currently a very hot topic as this is still a blurred legal area waiting for the ECJ´s judgments to shed some light on the problem. Forming direction of the future antitrust enforcement will be analysed through 2 landmark judgments of the EU Courts in search for foundation for the treatment of pay- for- delay deals in the context of competition rules.

The paper is based on different secondary sources, among which prevail the ones with the most recent nature. The author has analysed different research and scientific papers, publications, regulations, directives, reports, statistical data and EU Court´s judgements to create an in-depth analysis of generic effect and the status of antitrust enforcement in this legal field.

II. PHARMACEUTICAL SECTOR CHARACTERISTICS - HOW DOES IT WORK?

In order to understand the role and objective of competition policy and competition enforcement activities it is necessary to contextualize the main characteristics of the pharmaceutical sector. Understanding of various factors that affect competition in pharmaceutical markets such as interests of the stakeholders, R&D, life cycle of the product, IPRs and impact of the generic medicine entry is crucial in assessing potential anti-competitive behaviour.

A. Specific market structure

There are some specific factors that distinguish pharmaceutical sector from other regulated sectors in the internal market. Pharmaceutical sector is characterised by the multiplicity of stakeholders with often different or opposite interests, including a very important role of policy makers who are trying to balance different goals, such as ensuring the high quality of pharmaceuticals, making them affordable and maintaining low costs for the society and in the same time optimize innovative efforts to bring new products to the market.[1]

[1] European Commission*, Report from the Commission to the Council and the European Parliament, Competition Enforcement in the Pharmaceutical Sector (2009-2017), European competition authorities working together for*

The sector is R&D driven, highly regulated and is based on increasing level of product complexity and quality requirements.[2] The main factors shaping the sector are the demand for the new and better treatments for patients, life-cycles of medicines and threat of competition as patients switch to new and improved treatments or more affordable versions of the same drug, forcing companies to innovate so they are not surpassed by rivals.[3]

Pharmaceutical sector has an interesting structure regarding supply and demand. Supply side can be characterized by a two tier structure[4] which is composed of two different types of companies with diverse business strategies. The first tier consists of large multinational companies which are R&D proactive and dominate the markets for patented drugs.[5] For these originator companies, IPRs are a form of compensation for the high investment in innovation, but on the other hand, these rights result in making information about innovations public.[6] Competition among these companies is based on innovation, which is stimulated by the time limitation of the patent period protection as they cannot hold on to their patents indefinitely.[7] The second tier consists of smaller companies which produce generic medicines corresponding to the original product.[8] Generic products usually enter the market upon the loss of exclusivity of the original medicine and are usually much cheaper which results in savings for public health budgets.[9] They compete in price, service and efficiency for the market share.[10]

Demand in the pharmaceutical sector diverse from the typical demand in which the consumer pays for the product reflecting their optimal consumption level. The end consumer, i.e. the patient is not a decision maker in regard to prescribed medicine.[11] Instead demand is

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affordable and innovative medicines, Brussels, 2019, COM(2019) 17 final, https://ec.europa.eu/competition/sectors/pharmaceuticals/report2019/report_en.pdf,16 Jan. 2020, p. 20

[2] Grabowski, H., *Are the Economics of Pharmaceutical Research and Development Changing? Productivity, Patents and Political Pressures*, PharmacoEconomics, vol. 22, no Suppl.2, 2004, pp. 15-24

[3] *European competition authorities working together for affordable and innovative medicines,* loc.cit. (f.n. 1)

[4] Gunther, J.P.; Breuvart, C., *Misuse of Patent and Drug Regulatory Approval Systems in the Pharmaceutical Industry: an Analysis of US and EU Converging Approaches,* European Competition Law Review, vol. 26, no. 12, 2005, p. 669

[5] Ibid.

[6] European Commission, Communication from the Commission, *Executive Summary of the Pharmaceutical Sector Inquiry Report,* available at https://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/communication_en.pdf, 16 Jan. 2020, p. 7

[7] Ibid.

[8] Gunther; Breuvart, loc.cit. (f.n. 4)

[9] *Executive Summary of the Pharmaceutical Sector Inquiry*, loc.cit. (f.n. 6)

[10] Gunther; Breuvart, loc.cit. (f.n. 4)

[11] Ibid.

shaped by the choice of the physician who prescribes the product and the pharmacist who dispenses it.[12] Consequently, demand might not reflect patients' budgets, since the physician´s choice might reflect its own direct financial and nonfinancial incentives.[13] The physician is therefore an imperfect agent for the patient as he makes the choice of product but does not actually pay.[14] Furthermore, national health insurances schemes play an important part, as they are the ones covering or reimbursing most of the cost of the medicine and not the patients, prescribers or dispensers.[15] Co-payments should in theory make demand more elastic, but since they are not significant compared to the total cost they affect the demand only on the margin.[16] In regard to off-patent drugs, some countries give a role to the pharmacists by allowing them to substitute a prescribed product in case of generically written[17] prescription.[18]

B. Product life cycle

Discovery of a new chemical compound by originator manufacturers marks the start of the life cycle of the product. The life cycle can generally be divided into three phases. First is the pre-launch period which consists of extensive R&D, through a laboratory setting (pre-clinical trials) and then in a clinical setting (clinical trials)[19] which consist of assessing efficacy and safety of a medicinal product.[20] Then follows a regulatory approval, i.e. the MA for which companies can apply to the regulatory agency, i.e. to European Medicine Agency or

[12] Danzon, P.M.; Chao, L.W., *Does Regulation Drive Out Competition in Pharmaceutical Markets?*, The Journal of Law and Economics, vol. 43, no.2, 2000, p. 314
[13] Ibid., p. 315
[14] Ibid.
[15] Ibid.
[16] For more on co-payments and demand elasticity see here: Winklemann,R., *Co-payments for prescription drugs and the demand for doctor visits: Evidence from a natural experiment*, Working Paper, no. 0307, 2003, University of Zurich, Socioeconomic Institute, Zurich, https://www.econstor.eu/bitstream/10419/76241/1/372726909.pdf, 20 Jan. 2020
[17] Generic prescribing allows for any suitable drug to be dispensed and not just the branded one. For example, with the use of the recommended International Non-proprietary Name (rINN) a brand name Summamed becomes Azythromycin which is the non-proprietary name for the active ingredient of the drug and now any suitable drug with this active ingredient can be dispensed. This can lead to cost savings as it allows for cheaper generic versions to be dispensed.
[18] Danzon; Chao, op.cit. (f.n. 12), p. 316
[19] Pre-clinical trials include laboratory and animal testing and clinical trials include testing on humans. See more about R&D phases at European Commission, Competition DG, *Pharmaceutical Sector Inquiry, Final Report,* 2009, available at https://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/staff_working_paper_part1.pdf , 16 Jan 2020, pp. 50-53
[20] Ibid., p. 49, par. 128

a national authority.[21] Second phase starts with the product launch into the market followed by marketing and sales period, during which the product enjoys exclusivity rights. Final period begins with the loss of exclusivity, creating space for generic competition.[22]

Developing pharmaceuticals is a lengthy and costly process with a high risk rate. It takes approximately 10 years and at least $1 billion to successfully develop a new blockbuster drug[23] and to get a market approval.[24] Therefore, each phase requires patent protection for successfully shaping the business strategy of the originator company. It is common to apply for the patent already in the first phase, in order to prevent competitors from filing for a patent for the same invention, or from publishing it.[25] Moreover, patent applications are usually filed throughout the entire life cycle.[26] Period between launch and the loss of exclusivity, i.e. the second phase, is the chance for originator companies to recover the investments made in R&D and to make a positive return.[27] In order to maximize their profit, patent holders use well their privilege to charge a price often much higher than its marginal cost of production and take the opportunity to conclude licence contracts or cross-licence contracts. [28]

C. Product protection

In Europe, patent protection entitles originator up to 20 years[29] of exclusive commercial exploitment of the invention from the date of filing application at the patent office of the territory concerned, which determines the final date of patent protection for that territory. It is believed that the set time frame marks the point in which the cost to society, caused by reaping extra profits as a result from exclusive position, starts exceeding benefits.[30] Since the patent protection usually starts long before a medicine enters the market, patent protection can be extended with the SPC for medicinal products. The role of the SPCs is to

[21] Ibid., p. 54, par. 144
[22] Ibid., p. 49, par. 128
[23] A blockbuster drug is an extremely successful and popular drug that generates annual sales at least $1 billion for the company. See for details: Chen, J., *Blockbuster drug,* Investopedia, https://www.investopedia.com/terms/b/blockbuster-drug.asp, 20 Jan. 2020
[24] Song, C. H., Han, J.W., *Patent Cliff and Strategic Switch: Exploring Strategic Design Possibilities in the Pharmaceutical Industry*, SpringerPlus, vol.5., no1., 2016, pp.1-14
[25] *European competition authorities working together for affordable and innovative medicines,* op..cit. (f.n. 1), p. 21
[26] See infra section III., subsection A.
[27] *Pharmaceutical Sector Inquiry, Final Report*, op.cit. (f.n. 20), p. 49, par. 129
[28] Ibid., p. 96, par. 252
[29] Agreement on Trade- Related Aspects of Intellectual Property Rights (TRIPS), Article 33; European Patent Convention (EPC), Article 63
[30] *Pharmaceutical Sector Inquiry, Final Report*, op.cit. (f.n. 20), pp. 96-97, par. 252

compensate for the time between a patent application and the time when MA is granted and the product can for the first time be marketed in EEA.[31] SPCs aim to offset the patent protection due to the compulsory lengthy testing and clinical trials required prior to obtaining the MA.[32] The certificate can extend the patent protection up to 5 years and takes effect at the end of the lawful term of the basic patent.[33] It enables the holders of both patent and SPC to enjoy a period of maximum 15 years of effective protection[34] in every EU Member State from the time the medicinal product first receives a MA in the EEA and enters the market.[35]

Furthermore, originator companies benefit from market and data exclusivity. Original holder of MA can obtain 8 years of exclusivity over the data on pre-clinical and clinical studies previously submitted to MA authority.[36] Data exclusivity period affects generic producers in a way that they cannot rely on pre-clinical and clinical documentation previously submitted by the originator company for the reference drug, while applying for a MA by an abbreviated MA procedure.[37] Market exclusivity implies that generics authorised on the base of abridged procedure cannot be placed on the market until 10 years have passed from the date of MA for the reference medicine.[38]

All these protection layers create a shield over the originator medicine which prevents generic medicine entry and allows the innovator to reap the profit for the research. During that time, originators have the sole right to sell the product, and it is only after protection period

[31] Ibid., p. 112, par. 293

[32] European Commission, Internal Market, Industry, Entrepreneurship and SMEs, *Supplementary protection certificates for pharmaceutical and plant protection products*, available at: https://ec.europa.eu/growth/industry/policy/intellectual-property/patents/supplementary-protection-certificates_en, 20 Jan. 2020

[33] Regulation (EC) No 469/2009 of the European Parliament and of the Council of the 6 May 2009 concerning the supplementary protection certificate for medicinal products amended by the Regulation (EU) 2019/933 of 20 May 2019, Official Journal of the European Union, Article 13

[34] For example, if the patent application was made in 2000, the patent expiration would occur in 2020. However, the medicine will not be effectively on the market though the entire period of patent protection, as it has to receive the MA first. If the MA is obtained in 2005 there will be no grant od SPC, as the drug is covered with remaining 15 years of basic patent protection, but if the MA is granted in 2010, the remaining patent protection period will be 10 years, so the SPC will be granted for the period of 5 years leading to the total protection period of 15 years.

[35] Ibid., preamble

[36] Directive 2004/27/EC of the European Parliament and of the Council of the 31 March 2004 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use, Official Journal of the European Union, Article 10; Regulation 726/2004 of the European Parliament and of the Council of the 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing European Medicines Agency,Oficial Journal of the European Union, Article 14(11)

[37] Ibid.

[38] Ibid.

expiration that generics can be placed on the market. Granting a monopoly status to the originator company has a purpose of rewarding them for their innovation and to stimulate future R&D[39]. This requires a tradeoff between encouraging dynamic competition for the market among innovators and restricting competition on the market for the active ingredient.[40]

D. Experiencing competition-generic effect

1. Rise of competitive pressure

When a certain medicine enters the market, competitive pressure primarily comes from the other similar originator medicines, with different molecules, which are already on the market or in the process of entering.[41] But, when the originator medicine is slated to lose exclusivity, competitive pressure rises, as the generic versions of the same drug are on the verge of entry.[42] Competition between generic and originator medicines may on occasion start even before patent expiry. Early entry, i.e. entry at risk usually happens if the generic company finds a way of entering the market without patent infringement, or it believes that patents of originator companies are not valid, in particular if annulled prior to the formal patent expiry date.[43]

Competitive pressure from generics is more intensive than the pressure from other originator medicines. Having the same active ingredient, generics represent competition between homogeneous products with same dosage form, safety, strength, route of administration, quality, performance characteristics and intended use.[44] Moreover, generic companies do not need to invest a fortune in R&D and repeat all the pre-clinical and clinical studies that were required for the original drug, as they can rely on the data previously submitted by the originator producer of the reference medicine in question.[45] The reduction in upfront research affects the selling price of the generic medicine, which is usually sold at a

[39] Sauter, W.;Hancher, L., *A Dose of Competition: EU Antitrust Law in the Pharmaceuticals Sector*, Journal of Antitrust Enforcement, vol. 14, no.2, 2014, p. 383
[40] Ibid.
[41] *Pharmaceutical Sector Inquiry, Final Report*, op.cit. (f.n. 20) p. 181, par. 464; p. 35, par. 89
[42] Ibid.
[43] Ibid.
[44] *European competition authorities working together for affordable and innovative medicines,* op.cit. (f.n. 1) p. 21; U.S. Food and Drug Administration, *What are generic drugs?* Available at: https://www.fda.gov/drugs/generic-drugs/what-are-generic-drugs 15 Feb 2020
[45] Dehns Patent and Trade Mark Attorneys, *The European Bolar Exemption from Infringement,* 2014, available at: https://www.lexology.com/library/detail.aspx?g=4c4c2131-b897-44c2-8651-60bec32c6f50 , 1 March 2020; loc.cit (f.n. 36)

substantially lower cost than the originator drug.[46] In addition, the precondition for the abridged procedure for obtaining MA is to demonstrate bioequivalence of the generic medicine to the reference drug which has been previously authorized.[47] Bioequivalence is determined through appropriate bioavailability studies[48] and it must be comparable within margins of tolerance to the reference drug, proving that generics are completely safe and effective.[49] Substantial price difference in combination with guaranteed quality make generic medicine a perfect substitute, positioning it as a strong threat to originator producers that is seen as trouble.

2. Price reduction effect causing significant savings

Generic medicine entry to the market creates a competitive environment which lowers average market prices dramatically, resulting in significant savings in the public health budget.[50] A study prepared for the Commission [51] has discovered that generic drugs are upon their entry cheaper than the originator drugs for approximately 40% to 50% and furthermore, cause fall of the originator prices for about 20% in just first 5 quarters. Numbers are even more impressive in the cases of blockbuster medicines. The Commission has found in the Lundbeck case that the prices of generic citalopram dropped on average by 90% in the United Kingdom within 13 months of generic entry on a wide scale.[52]

Moreover, price reductions have a major impact by translating directly into national healthcare savings. In the EU Pharmaceutical Sector Inquiry Commission found that savings to the public health funds were about 20% one year after the first generic entry, and about 25% after two years, depending on a Member State and the type of medicine.[53] More recently,

[46] U.S. Food and Drug Administration, *Generic drug facts*, available at: https://www.fda.gov/drugs/generic-drugs/generic-drug-facts, 15 Feb 2020

[47] Posner, J.; Griffin, J.P., *Generic substitution*, British Journal of Clinical Pharmacology, vol. 72, no.5, 2011, p. 731

[48] Bioequivalence is estimated by measuring the rate of absorption, or bioavailability, i.e., time in which a generic drug reaches the bloodstream in a certain number of healthy volunteers. See more at: Jawahar, N.; Datchayani, B., *Comparison of Generic Drug Application and their Approval Process in US, Europe and Japan*, Journal of Pharmaceutical Sciences and Research, vol. 10, no.3., 2018, pp. 523, 527

[49] Posner, Griffin, op.cit. (f.n. 47)

[50] *European competition authorities working together for affordable and innovative medicines,* op.cit. (f.n. 1) p. 21

[51] Copenhagen Economics, *Study on the economic impact of supplementary protection certificates, pharmaceutical incentives and rewards in Europe*, *Final Report*, May 2018, available at: https://ec.europa.eu/docsroom/documents/29521, 20 Feb 2020, p. 293

[52] European Commission, Commission Decision C(2013)3803 final of 19 June 2013 in Case AT.39226 – Lundbeck, par. 726.

[53] *Executive Summary of the Pharmaceutical Sector Inquiry*, op.cit. (f.n. 6), p.9

IMS Institute has found in its research[54] that in 2014 generic entry reduced the EU region´s medicine bill by 61%, not only by introducing medicines at a lower cost but also by inducing competition that lowers the price of the off-patent originator drugs.[55] Strength of generic impact on pharmaceutical expenditure becomes undeniably evident by looking at the exact numbers. It is estimated that savings in EU have reached approximately €100 billion, which would not have been possible if prices had not been lowered with the entry of generics.[56]

3. Access to medicines

Apart from having an impact on cost reduction for healthcare system, generic medicines have another dimension of value by improving access to pharmacotherapy.[57] They are of immense contribution to an increased availability of essential medicines that are both high quality and affordable.[58] Around the globe impact of generics to the availability of essential medicines was emphasized in a study which estimated the median availability of essential medicines around 61.5%, of which approximately 53.3% were generics.[59] Furthermore, a research based specifically on clopidogrel utilization in European countries, found strong affordability constraints before the generic entry.[60] In approximately 5 years difference, utilization of clopidogrel, after generic entry, increased in lower-income countries by 116% and in average-income countries by 31%. In these countries third- party payers usually restrict utilization of expensive medicine with different cost-containment measures directed to various stakeholders. For example, not all patients receive the most optimal drug therapy due to volume limits for individual physicians or healthcare institutions. Moreover, patients accessibility to high-cost medicine can be limited not only by a significant co-payment obligation, but also by polices which determine that high-cost medicines will be reimbursed only as second-line therapies after the failure of first-line therapies. It was also

[54] IMS Institute for Healthcare Informatics, *The Role of Generic Medicines in Sustaining Healthcare Systems: A European Perspective,* 2015, available at: https://www.medicinesforeurope.com/wp-content/uploads/2016/03/IMS_Health_2015_-_The_Role_of_Generic_Medicines_in_Sustaining_Healthcare_Systems_-_A_European_Perspective.pdf

[55] Ibid., p. 21

[56] Ibid., p. 9

[57] Dylst, P.; et al., *Societal Value of Generic Medicines beyond Cost-Saving through Reduction of Prices*, Expert Review of Pharmacoeconomics & Outcomes Research, vol. 15, issue 4, 2015, p. 701

[58] Sheppard, A., *Generic Medicines: Essential Contributors to the Long- Term Health of Society*, IMS health, 2013, available at: https://www.hup.hr/EasyEdit/UserFiles/Granske_udruge/HUP-UPL/IMS.pdf, 25 Feb 2020, p. 3

[59] Bazargani, Y.T. ; et al., *Essential Medicines are More Available than Other Medicines Around the Globe,* PloS One, vol. 9, no.2, 2014

[60] Elek, P.; et al., *Policy Objective of Generic Medicines from the Investment Perspective: The Case of Clopidogrel*, Health Policy, vol.121, no. 5., 2017, pp. 558-565

found that being more cost-effective, generics offer treatments to more patients within the same budget, and furthermore, could be used in first-line therapies, thereby introducing medicines earlier in the treatment process. Another important conclusion was that generics have not only increased access to pharmacotherapy, but also reduced inequalities between European patients. Furthermore, a study with data from the Netherlands clearly demonstrated the severeness of impact that a generic entry can have on patients´ accessibility to essential medicines even in a higher-income country.[61] In the particular case of clopidogrel, number of users in 2013 was 127.923. The research showed that if the price remained the same, number would fall to 15.171, and if the generics enter the market the number users would be bigger by 112.752.

Generic drug policies can be used as means to improve patient access to overall pharmacotherapy without the need for additional health expenditures and therefore contribute to health gain. IMS Institute's research[62] has found that in the period from 2005 to 2014, the average price of treatment for seven therapeutic areas in Europe where generic medicines are available has declined more than 50% per treatment day, whereas prescription volumes have increased more than 100% due to a lower cost that has increased access. The overall cost of treatment remained flat in the period of 10 years, but substantially more patients were treated.

Generic medicine and their impact on access to pharmacotherapy have also an important role during pandemics or epidemics. In situations where there are no vaccines or treatment for the illness, studies and trials are conducted to question whether low-cost generic drugs can be used as treatment and all without a billion-dollar investment.[63] Furthermore, originator medicine usually comes from only one source, but generic medicines are multisourced, as number of generic manufacturers produces the same product.[64] Multiplicity of sources undeniably helps in maintaining the supply for certain medicines which are of great value at the times of increased demand, such as this unexpected need for anti-infectives.[65]

[61] Dylst, op. cit. (f.n. 57) , p. 708
[62] IMS Institute for Healthcare Informatics, op.cit. (f.n. 54), pp. 13-16
[63] During COVID-19 pandemics malaria treatment was tested in several countries as potential treatment for the illness. It was the affordability that enabled University of Minnesota Medical School to buy 1500 doses of hidroxychlorquine for a laughable amount of money. See more: Beasley, D. *Two generic drugs being tested in U.S. race to find coronavirus treatment*, Reuters, 2020, available at: https://www.reuters.com/article/us-health-coronavirus-usa-treatments/two-generic-drugs-being-tested-in-u-s-in-race-to-find-coronavirus-treatments-idUSKBN2161QQ
[64] Sheppard, op.cit. (f.n. 58), p. 5
[65] Ibid.

4. Influence of generic effect on EU and individual member states

Ageing population, changes in lifestyle and prolonged life expectancy in diseases once associated with high mortality significantly burden the healthcare system.[66] Public spending on overall healthcare in the EU has increased to between 5.7 % and 11.3 % of GDP in the last decades and is expected to grow further.[67] Spending on pharmaceuticals contributes significantly to government spending on healthcare all together. Therefore, many European governments seek to decrease pharmaceutical expenditures, but in the same time enlarge access to pharmacotherapy.[68] One of the solutions is the increased use of generic medicine as there is substantial evidence of their powerful impact. However, experts recommend that to achieve all the benefits of generics, growth in volume use should become a focal point of generic policies, rather than simply regulating the price.[69] Simply cutting the price of generic drugs in low volume markets could cause damage to sector´s sustainability, as generated revenues would not be high enough, opposed to the cost of maintaining infrastructure, registration costs and other legal requirements.[70] On the other hand, increasing the demand for generics will raise the level of competition which will lead to overall more affordable treatments.[71] The EU and individual Member States are therefore, continuously implementing various measures to ease the entry and stimulate prescription and dispension of generics.

a. Measures on the EU level

In order to expedite the entry of generics into the market after patent expiry, the European Union has implemented some important measures. Even though, the progress to which they have contributed is undeniable, they need to be pushed further to reach a greater breakthrough. One of the most important measures was the "Bolar exemption"[72], purpose of which was to exclude from infringement of patent rights or SPCs the necessary tests and trials

[66] Ibid., pp. 1-2
[67] *European competition authorities working together for affordable and innovative medicines,* op.cit. (f.n. 1), p. 5
[68] Sheppard, op.cit. (f.n. 58), pp. 1-2
[69] Ibid., p. 4
[70] Ibid.
[71] Ibid.
[72] After Bolar Pharmaceutical V Roche case, Hatch-Waxman Act allowed medicines manufacturers to use patented products when developing medicines in order to obtain regulatory approval from the US Food and Drugs Administration. See more at: Fabre, J., *Boradening of safe harbours and patent exemptions for farmaceuticals in Europe*, Pinsent Masons, Out-Law Analysis, 2020, available at: https://www.pinsentmasons.com/out-law/analysis/safe-harbours-patent-exemptions-pharmaceuticals-europe, 1 March 2020

necessary to use the abridged procedure for obtaining marketing authorisation.[73] Patent protection of the reference medicine could pose a risk of infringement that acts relating to that drug can cause, but due to the exemption, generic manufacturers can without fear conduct bioequivalence trials needed for the abridged procedure.[74] Use of patented products for conducting trials makes obtaining regulatory approval possible prior to patent expiry, allowing generics to compete in the market almost right after the loss of exclusivity.[75] However, Bolar exemption needs to be subjected to further harmonization and broadening, as the EU Member States have chosen various directions in implementation of the Directive 2004/27/EC[76], hence creating a cloud of uncertainty.[77] Some countries have a restricted understanding of the exemption, while others, have expanded the notion to studies and trials that are useful, but not necessary, or to ones related to a marketing authorisation application in non EU/ EEA countries, or furthermore, to ones not in relation to an abridged procedure.[78] Such discrepancy could mean that clinical trials will fall into the scope of the exemption depending on where they are conducted.[79] Also, the possibility of the UPCA entering into force will make the scope of exemption depend on the nature of the relevant patent, as will the unitary patents, European patents and SPCs litigated before the UPC be subjected to the narrow exemption[80], which seems dated in regard to the modern development of the Bolar provision.[81] Another gray area of the Bolar exemption regimen is the question of outsourcing. Some of the clinical trials rely on active pharmaceutical ingredient supply from third-parties

[73] Dehns Patent and Trade Mark Attorneys, op. cit (f.n.45)
[74] Ibid.
[75] Rainsford, E.,*Update on Bolar exemptions in Europe*, Maucher Jenkins,2017, available at: https://www.maucherjenkins.com/news-and-events/2017/update-on-bolar-exemptions-in-europe, 1 March 2020
[76] Directive 2004/27/EC, op.cit (f.n.36)
[77] European Commission, Commission Staff Working Document, *Summary of the replies to the public consultation on Supplementary Protection Certificates and patent research exemption for sectors whose products are subject to regulated market authorisations, Accompanying the document Proposal for a Regulation of the European Parliament and of the Council amending Regulation (EC) NO 469/2009 concerning the supplementary protection certificate for medicinal products*, available at: https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52018SC0242&from=EN, 1 March 2020, pp. 7-8
[78] See more: de Coster, C.; England, P., *Not all Bolars exemptions are the same- an update*, Taylor Wessing, Synapse Law for Life Sciences, 2014, available at: https://www.taylorwessing.com/synapse/ti_bolarexemptions.html; Fabre, op.cit (72)
[79] Fabre, ibid.
[80] Agreement on a Unified Patent Court, 2013/ C 175/1, Official Journal of European Union, Article 27 (d)
[81] England, P., *Upgrading the single market: Upgrading the Bolar exemption,* Taylor Wessing, Synapse Law for Life Sciences, 2015, available at: https://www.taylorwessing.com/synapse/ti-bolar-exemption.html, 1 March 2020

and it is questionable whether such supplies fall into the scope of the Bolar provision, as the third-party suppliers are not the ones conducting the trials.[82]

Despite this legal framework, generic entry to the market right after patent and SPC expiry remained theoretical. The main issue appeared to be lack of possibility to manufacture generic medicine during the SPC period of protection of the product in the EU. Generics could not be produced for any purpose, including for export outside the EU to countries where SPC protection has expired or does not exist.[83] Generic manufacturers were not therefore, in a position to build up production capacity which made it difficult for them to enter the market immediately after SPC expiry.[84] This problem created another consequence, as it has put EU manufacturers in unfavorable position in relation to manufacturers based outside EU, as in global markets, like in day-1 EU markets, which could result in moving the manufacture outside the Union.[85] Therefore, on the basis of the European Commission's proposal, European Parliament finally adopted a new Regulation (EU) 2019/933[86] that introduced a SPC manufacturing waiver which allows generic manufacturers to produce, in the territory of a Member State during the entire SPC lifetime, for the purpose of exporting to non-EU markets.[87] The waiver also solves day-1 entry issue, as it allows stockpiling for the day-1 entry to EU market during the last 6 months before SPC expiry.[88] However, the waiver will not affect SPC already in effect on 1 July 2019, and due to the transitional period, it will not become effective until mid-2022 for the SPC applications filed before that day.[89] Furthermore, the exemption only applies to SPCs, which means that exempted activities could remain at risk of infringement regarding secondary patents[90] that cover product aspects such as a particular process or dosage.[91]

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[82] Fabre,op. cit. (f.n. 72)

[83] European Commission, *Proposal for a Regulation of the European Parliament and of the Council amending Regulation (EC) No 469/2009 concerning the supplementary protection certificate for medicinal products*, Explanatory Memorandum, COM(2018) 317 final 2018/0161 (COD) , available at: https://eur-lex.europa.eu/resource.html?uri=cellar:7b79457a-6254-11e8-ab9c-01aa75ed71a1.0003.02/DOC_1&format=PDF, 16 January 2020, pp.1-6

[84] Ibid.

[85] Ibid.

[86] Regulation (EU) 2019/933 of the European Parliament and of the Council of the 20 May 2019 amending Regulation (EC) No 469/2009 concerning the supplementary protection certificate for medicinal products, Official Journal of the European Union

[87] Ibid., Article 5, par.2

[88] Ibid.

[89] Ibid., par. 10

[90] See infra section III, subsection A.

[91] Fabre, op.cit. (f.n. 72)

b. Measures on the national level

Numbers of the EU Member States have put a serious effort to enhance generic impact by increasing their market share volume with various policies affecting both supply and demand side. Supply-side measures for boosting the uptake of generics usually consists of regulating launch prices, or regulating reimbursement of pharmaceuticals through reference pricing which involves grouping similar drugs, usually both originator and generic, and defining the price, lowest or the average price in the cluster that will be reimbursed by health insurance fund.[92] If a product is priced above the reference price, the insured patient has to pay the difference in price, which also affects the demand side.[93] Demand-side measures for encouraging prescription and dispension of generics usually include policies directed at primary care physicians, pharmacists and patients. [94] For example, physician fixed budgets can be structured as rewarding to those who underspend or penalize ones that overspend.[95] Furthermore, doctors can be obliged to prescribe the cheapest medicine in a certain percentage of treatments.[96] In regard to pharmacists, implementing a regressive margin can ensure profitability by paying them a greater percentage of the cost on lower priced pharmaceutical products, causing better generic dispension.[97] Also, by introducing the policy of generic substitution a pharmacist could dispense the generic version even when a general practitioner has prescribed brand name medication.[98] Choosing an appropriate policy depends on local demographic, cultural, economic and institutional constraints.[99] However, experience across countries has shown that different policies, that either facilitate early entry or provide financial incentives for generic use, have best effect if used in combination.[100]

Differences in generic uptake across countries may reflect different patent expiry dates, however generic uptake depends significantly on policies implemented at national level.[101] In the last decade, European countries have actively combined different policies in

[92] King, D.R.; Kanavos, P., *Encouraging the Use of Generic Medicines: Implications for Transition Economies*, Croatian Medical Journal, vol.43, no.4, 2002, pp. 463-465
[93] Ibid.
[94] Ibid.
[95] Ibid.
[96] Copenhagen Economics, op.cit. (f.n. 51), p. 152
[97] King; Kanavos, op.cit. (f.n. 92), p. 466
[98] Ibid.
[99] Simoens, S., *Sustainable provision of generic medicines in Europe*,2014, available at: https://www.quotidianosanita.it/allegati/allegato3090824.pdf, 15 March 2020, p. 4
[100] King; Kanavos, op.cit. (fn. 92), p. 467
[101] OECD, *Health at a Glance: Europe 2018, State of Health in the EU Cycle,* available at: https://www.oecd-ilibrary.org/docserver/health_glance_eur-2018-

effort to increase generic uptake, however, there are still some countries that need to establish measures that will improve their status.[102] Countries with a mature generic market have further increased the volume of generics, like United Kingdom and Germany, but it is more important to point out the big volume jumps occurring in a developing generic market countries.[103] For example, Belgium has established an internal reference pricing system that covers generics and original branded pharmaceuticals sold at the price of generics.[104] Furthermore, it has implemented financial incentives to purchase generics, established prescription quotas for doctors and mandatory substitution by pharmacists for some categories of drugs.[105] As a consequence of these measures generics market share has jumped in volume from 17 % in 2005 to 37 % in 2017.[106] In Spain the Ministry of Health, Consumption and Social Welfare sets the maximum price at which a drug could be financed by the public sector, physicians have to prescribe using the active principle and there is mandatory pharmacy substitution with the cheapest generic.[107] Spain´s generic medicine market share by volume doubled from 24 % to 48% between 2009 and 2014.[108] Countries that have also achieved impressive improvement are the Netherlands and Denmark. The Netherlands´ penetration of generics is encouraged with generic substitution and it has contributed to market share by volume growth over 70 %.[109] Denmark has promoted development of generic market through series of measures targeting physicians, pharmacists and patients resulting increased the generic market share by volume from less than 40 % in 2007 to over 60 % in 2015.[110] It is expected that countries will keep implementing more policies in the future,

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en.pdf?expires=1598490267&id=id&accname=guest&checksum=4375CC90B67B7405DDFA483884D9B67A, 15 March 2020, p. 63

[102] Ibid., p. 64

[103] Simoens, loc. cit. (f.n. 99)

[104] OECD, *State of Health in the EU, Belgium: Country Health Profile 2019*, available at: https://www.oecd-ilibrary.org/docserver/3bcb6b04-en.pdf?expires=1598490526&id=id&accname=guest&checksum=6D097779D2BF877242D5B11DEFD942BE,15 March 2020, p. 19

[105] Ibid.

[106] Ibid.

[107] OECD, *State of Health in the EU,Spain: Country Health Profile 2019,* available at: https://www.oecd-ilibrary.org/docserver/8f834636-en.pdf?expires=1598490783&id=id&accname=guest&checksum=9FA5BD0AB64C5F358BD260CAA80BDF58, 15 March 2020, p. 21

[108] Ibid.

[109] OECD, *State of Health in the EU, Netherlands: Country Health Profile 2019, available at:* https://www.oecd-ilibrary.org/social-issues-migration-health/netherlands-country-health-profile-2019_9ac45ee0-en, pp. 20-21, figure 23

[110] OECD, *State of Health in the EU, Denmark : Country Health Profile 2019,* available at: https://www.oecd-ilibrary.org/docserver/5eede1c6-en.pdf?expires=1598491029&id=id&accname=guest&checksum=00BB6CAA0452D53A8F5F6655ABA614A9, 15 March 2020, p. 20

resulting in even bigger generic expansion. The very recent calculation from the Copenhagen Economic study[111], that just a 10% change in overall spending on pharmaceuticals from originator to generic products would result in a total saving of 0.7% of amount spent on health within the EU, is definitely going to create even bigger incentive for governments in their future decision-making regarding generics.

5. Impact on originator companies

For some, generics represent the future of pharmaceutical industry, while in the eyes of others they are a draining profit nightmare. Generic producers seek to attract suppliers, pharmacists, patients and health insures with lower prices, resulting in not just lower average market prices,[112] but in severe sales erosion of the originator medicine and decline of the originator market share.[113] Calculation based on US data[114] showed that new originator medicine which faced first generic entry in 2013-2014 retained an average of only 12% units sold during patent exclusivity one year after generic entry. Erosion was even more significant for the drugs with sales greater than $250 million in a year before generic entry, for which originator retained 7% of units sold during patent exclusivity. Market share drop of the originator medicine was highlighted in the Sector Inquiry of the European Commission, which found that market share of generic companies was about 30% at the end of the first year of entry and 45% after two years.[115] Therefore, the profit margin of the originator product drops drastically after the loss of exclusivity rights and generic market entry.[116]

Industries relying on the blockbuster model face an increased financial risk.[117] EvaluatePharma calculations[118] show the severity of the consequences coming after the loss of patent protection of the blockbuster medicines and generic entry, i.e. the pending patent

[111] Copenhagen Economics, op.cit. (f.n.51), p. 163
[112] See supra section II, subsection D. 2.
[113] Figueroa, P.; Guerrero, A., *EU Law of Competition and Trade in the Pharmaceutical Sector*, Cheltenham, UK; Northampton, USA, 2019, par. 2.34
[114] Grabowski, H.;et. al., *Updated Trends in US Brand-Name and Generic Drug Competition*, Journal of Medical Economics, vol 19, no. 9, 2016, pp. 836-844
[115] *Executive Summary of the Pharmaceutical Sector Inquiry*, op.cit. (f.n. 6), p. 9
[116] Figueroa; Guerrero, op. cit. (f.n. 113), par.2.34
[117] *Can pharma meet the generic challenge?*, Pharmafile, 2007, available at: http://www.pharmafile.com/news/can-pharma-meet-generic-challenge, 20 March 2020
[118] *World Preview 2019, Outlook to 202* ,12th Edition, EvaluatePharma,2019, available at: https://info.evaluate.com/rs/607-YGS-364/images/EvaluatePharma_World_Preview_2019.pdf, 20 March 2020

cliff.[119] The report forecasts that a second patent cliff happening during 2019-2024 will put at risk $198 billion worth of sales, with $114 billion dollars of revenue expected to be lost worldwide.[120] Blockbuster medicines can even lose a greater market share, like it was in the case of Eli Lilly´s Prozac which lost about 70% of the market share during first 20 weeks from generic entry.[121] Furthermore, losing a best-selling drug often puts to test the integrity of the R&D-based company.[122] Companies are having trouble developing and marketing products that are effective enough to compete with already existing products, that can meet regulatory requirements, that are affordable to manufacture and cost-effective to meet payers´ demands.[123] Rising costs of replacing a blockbuster with a new high profit product and a very high rate of discovered molecules that are not successfully commercialized result in revenues from a successful blockbuster product covering not just the development of the product itself, but also the costs of such development of the new drugs and neutralizing the consequences of underperforming ones.[124] Moreover, sales generated from new products often cannot replace sales lost to a generic medicine.[125] Therefore, declining revenues due to generic entry could consequently result with a disaster. In order to save themselves and reduce debt, many companies change their strategies and divest their generics divisions to fully focus on proprietary business, while some R&D-based companies change their direction entirely and focus on the growth of generics.[126] However, sometimes mergers and acquisitions are the only option.[127] One of the most painful examples, accurately representing the destructive impact of generic entry that led to devourment of a company, is the story of Croatian pharmaceutical company Pliva.

[119] Patent cliff is a colloquialism that expresses the potential sharp decline in revenues upon patent expiry of one or more products, i.e. the case when a firm´s revenues could "fall off a cliff" when one or more prominent products goes off-patent, since they are now exposed to generic entry. See more: Kenton, W., *Patent Cliff*, Investopedia, available at: https://www.investopedia.com/terms/p/patent-cliff.asp, 20 March 2020

[120] Doughman, E., *Impending Patent Cliff Threatens Billions of Global Prescription Drug Sales*, Pharmaceutical Processing World, 2019, available at: https://www.pharmaceuticalprocessingworld.com/impending-patent-cliff-threatens-billions-of-global-prescription-drug-sales/, 20 March 2020

[121] Druss, B.G.; et al., *Listening to Generic Prozac: Winners, Losers and Sideliners*, Health Affairs, vol.23, no.5, 2004, pp. 210-215

[122] loc. cit. (f.n. 117)

[123] Mittra, J.; Tait, J., *Analysing stratified medicine business models and value systems: innovation- regulation interactions*, N Biotechnol, 2012, vol.29, no.6, pp. 709-719

[124] Figueroa; Guerrero, op. cit. (f.n. 113), par. 2.32

[125] Sheppard, op. cit. (f.n.58), p. 11

[126] loc.cit. (f.n. 117)

[127] Ibid.

6. Pliva tragedy

After years of research, in the late 1970s, Pliva discovered an extremely efficient antibiotic Azithromycin (brand name Summamed).[128] Comparing to the leading multinational pharmaceutical companies, Pliva was at the time a small player without the essential capital to commercialize the drug internationally in order to properly reap the fruits of its research.[129] After patenting Azithromycin worldwide, American Pfizer Inc. offered Pliva a channel to commercialize its product which gave Pliva needed means to expand in US and Europe.[130] Under the licencing agreement, Pfizer acquired the right to sell Azithromycin worldwide and Pliva could continue to sell in Central and Eastern Europe and enjoy royalties on Pfizer´s sales.[131] Pfizer´s branded version of the drug was one of the bestselling antibiotics in the US and worldwide, with sales reaching $2 billion in 2005 before the loss of patent protection and generic entry.[132] Due to Azithromycin revenues Pliva was making approximately $150 million a year.[133]

However, 2005 seemed to be one of the most difficult years for Pliva due to the following changes and restructure. Firstly, Pliva was faced with a serious underperformance of its at the time newly-launched drug Sanctura in US market, and secondly patent expiry of the Azithromycin in the US in November 2005 was bringing Pliva major consequences.[134] Royalties from Pfizer drug were going to be extremely cut, and furthermore, the bulk price of the active ingredient was going to fall substantially, hitting Pliva´s pharmaceutical units.[135] Sanctura and the US market endeavor roughly hit Pliva´s profits and pushed it into considerable debt.[136] In anticipation of the downhill road, Pliva decided to restructure itself as a generic firm to counter the financial loss.[137] Attempting to recover, Pliva sold off Sanctura in the second quarter, and decided to do the same in the future with the rest of US subsidiary´s

[128] Ibid.
[129] WIPO, *Azithromycin: A worlds best-selling antibiotic*, 2009, available at: https://www.wipo.int/ipadvantage/en/details.jsp?id=906, 21 March 2020
[130] Ibid.
[131] Ibid.
[132] Ibid.
[133] Chu, W.L. ,*Pliva posts 9- months net loss of $34 million,* Outsorcing-pharma.com, 2005, available at: https://www.outsourcing-pharma.com/Article/2005/11/14/Pliva-posts-9-month-net-loss-of-34-million, 30 March 2020
[134] *Pliva exits branded drug business*, Outsorcing-pharma.com, 2005, https://www.outsourcing-pharma.com/Article/2005/05/16/Pliva-exits-branded-drug-business, 30 March 2020
[135] Ibid.
[136] Chu, loc.cit.(f.n. 133); ; Pliva Announces Q2 2005 Results, *A year marked by strategic change- Focus on generics,* 2005, https://zse.hr/userdocsimages/financ/PLVA-fin2005-1H-eng.pdf, 30 March 2020
[137] Chu, ibid.

branded drug portfolio, in order to focus on generic business which was still marking sale rises.[138] Pliva planned to launch a large number of generics to in the coming years to counterbalance the significant reduction of the Azithromycin royalty revenue.[139] Finalising the sales of its proprietary business in the fourth quarter, Pliva divested its manufacturing plant in Dresden to the Menarini Group and sold its research institute in Zagreb to GSK.[140] However, fourth quarter was not looking good. Pliva´s revenues were down by 19% which was a reflection of the 71% drop in Pfizer´s drug royalties to $18 million, as the blockbuster faced generic competition.[141] Profits were furthermore tackled by charges of the proprietary business sale, with asset impairment and restructuring costs amounting to $74 million.[142] Overall, Pliva posted a net loss of $41million.[143] Furthermore, results at the end of the year showed that all the divestments were just cushioning the blow in the net profit.[144] All the restructuring charges, lost sales from discontinued operations and drop in royalties led the net profits from $127.5 million in 2004 to a loss of $75.1 million.[145]

Furthermore, 2006 was set out to be equally hard, as the royalty revenue decline which came in November in 2005 would continue, but also through patent expiry in Western European markets and Japan in April. Proprietary R&D cost savings and a relatively small growth in Generics division were not able to neutralize the major loss of royalties and drop in the sales of the bulk Azithromycin.[146] In the first quarter profits took a massive dive of 61% year on year, as the patent expiry in the US dropped the royalties from the blockbuster to $8.3 million from $73 million.[147] Royalties streams cut off and poor results finally resulted in acquisition of Pliva by Barr Pharmaceuticals Inc. in October.[148] Later in 2008, Teva

[138] loc.cit. (f.n. 134)
[139] Chu, loc. cit. (f.n. 133)
[140] Roumeliotis, G., *Pliva´s transition to generics proves painful*, Outsorcing-pharma.com, 2006, https://www.outsourcing-pharma.com/Article/2006/03/10/Pliva-s-transition-to-generics-proves-painful,30 March 2020; Pliva Announces Q4 2005 Results, *A Challenging Year Marked by Significant Restructuring and Consolidation*, 2006, available at: https://zse.hr/default.aspx?id=15160, 30 March 2020
[141] *Pliva under pressure as the royalties slide*, PharmaTimes,2006, http://www.pharmatimes.com/news/pliva_under_pressure_in_2005_as_royalties_slide_996430, 30 March 2020
[142] Ibid.; Roumeliotis,loc. cit. (f.n. 140)
[143] PharmaTimes, ibid.
[144] loc.cit. (f.n. 140)
[145] Ibid.
[146] Ibid.
[147] Ibid.
[148] *Bar acquires Pliva dd. Following Official Closing of Tender Offers Processes,* https://zse.hr/default.aspx?id=15670, 30 March 2020

Pharmaceutical Industries Ltd. acquired Barr and Pliva along with it.[149] Management of questionable quality[150]along with the huge blow of the patent expiry effect shredded to pieces what was once a regional giant. Eastern Europeans' biggest manufacturer of drugs, present in more 30 countries and a leader in innovation, not only sold its proprietary business and turned to generic production, but ended up under a company that in the 1990s used to be incomparably smaller than Pliva, which is now a large multinational company and one of the biggest generic groups in the world.

III. ORIGINATOR COMPANIES USE ALL THEIR POWERS TO DELAY GENERIC ENTRY

Growth of generic medicine use is expected to continue even more in the future. With the measures adopted on the EU level and a large number of policies implemented by governments promoting the use of cheaper alternatives, generic threat is rising year by year.[151] Impressive volume jumps in low-volume markets in the last decade are the best evidence of the incentive driving generic competition and promoting expedite market entry. Intensive stimulation of generic entry and patent cliff waiting around the corner suggest that generic pressure is higher than ever.

To reduce the intensifying competitive pressure and rising R&D costs, originator companies seek to combine various strategies to extend patent protection of the active ingredients or pharmaceutical compositioning, and to maximize the commercial value of the product and protect their market position.[152] During the Pharmaceutical Inquiry, originator companies have even confirmed having life cycle management departments developing plans and strategies for specific products and markets in order to extend their market exclusivity

[149] *Teva completes acquisition of Bar*, Pharmaceutical Processing World, 2008, https://www.pharmaceuticalprocessingworld.com/teva-completes-acquisition-of-barr/, 30 March 2020

[150] Acquisition of unsuccessful firms that required big investments and transfer of successful medicine such as Polfa Krakow, entering the American market for which Pliva was too small, shady purchase of a new building for "the needs of the Board" that needed a complete renovation, investing only 450$ million out of approximately 3$ billion received from azithromycin to Croatian plants and the Research Institute, employing questionably qualified people on the management positions, nepotism, extreme investment in foreign experts employed on high positions for too big salaries which were later found in the center of money milking scandals. See more: Kirhmajer-Vujčić, D., *Pliva In Memoriam,available at:* https://www.slideshare.net/tzombix/pliva-in-memoriam?type=document; also: Šimićević,H., *Pismo Insidera: Kako su Plivu Poharali razuzdani menadžeri*, Nacional, available at http://arhiva.nacional.hr/clanak/53984/pismo-insidera-kako-su-plivu-poharali-razuzdani-menadzeri; Ilić, J., *Kronologija propasti Plive: Uzmi što možeš i zaradi što više*, Dnevnik.hr, available at: https://dnevnik.hr/vijesti/gospodarstvo/kronologija-propasti-plive-uzmi-sto-mozes-i-zaradi-sto-vise.html

[151] See supra section II., subsection D.2.

[152] Song; Han, op. cit. (f.n. 24)

without generic competition and prevent loss of profit.[153] These strategies include not only patent filing, patent litigation strategies and patent settlement agreements, but as well misuse of the patent regulatory framework, interventions before national authorities, life cycle strategies for follow-on products, disparagement practices, abuse of dominant position by charging excessive prices, increasing market power by mergers etc.[154] Some of these commercial strategies, despite being fully compliant with EU regulatory rules, are considered as problematic under EU competition rules and therefore, attract the scrutiny of competition authorities.[155] The list of hindering practices is endless and not exhaustive, as the creativity of pharmaceutical companies does not have boundaries. Therefore, authorities must remain vigilant in investigating potentially anti-competitive situations, especially concerning new practices or new trends used by companies in the industry.[156]

As the overview of all the anti-competitive practices goes beyond the scope of this paper, the following subsections will focus on strategies related to patents, which will be relevant for the analysis of the selected recent EU courts´ judgements.

A. Strategies related to patents

Having in mind rising R&D costs, accelerated entry and grown presence of the generics on the market, originator companies are trying to ensure, not just the uninterrupted enjoyment of exclusivity of the base patent[157] until the end of protection period, but they are searching for a way to preserve revenue streams even beyond patent expiry.[158] Originator companies have, therefore, used patent strategies which lead to the creation of the broadest and longest possible patent protection of their products.[159] Although, the bare use of such strategies is generally in line with the objectives of patent law, such strategies seem to be more oriented at preventing or distorting competition and less at protecting their own

[153] *Pharmaceutical Sector Inquiry, Final Report*, op.cit. (f.n. 20), p. 49, pr. 130; p. 60, par. 166; p. 181, par. 465; *European competition authorities working together for affordable and innovative medicines,* op.cit. (f.n. 1), pp. 27-28

[154] *Pharmaceutical Sector Inquiry, Final Report* ,ibid .

[155] Zulli, A.; et al., *The European Commission's Lundbeck Decision: A compass to navigate between Scylla and Charybidis* , Intellectual Property & Technology Law Journal, vol. 27, no. 6, 2015, p.4

[156] *European competition authorities working together for affordable and innovative medicines,* op.cit. (f.n. 1), p. 45

[157] Usually the first patent claiming the invention of the new active substance.

[158] *Pharmaceutical Sector Inquiry, Final Report*, op.cit. (f.n. 20), p.184, par.475

[159] Ibid., p. 184, par. 473

innovations.[160] Therefore, the basic principle of patent strategies lies in the use of legal measures in order to preserve the pre-generic-entry market position.

1. Patent clusters

Continuous research of the same medicine usually leads to further patent protection for improvements beyond the basic active ingredient.[161] These so called secondary patents[162] can cover new formulations, processes and new crystalline forms of the original compound.[163] For example, in the case where the manufacturing process was optimised in a way that has substantial and unforeseeable advantages over known processes, the relevant process patent, such as enhancing purity level can get protected at a later stage of the product lifecycle.[164] At first glance it may seem that the main purpose of patents may be the protection of incremental innovation, however, the secret aim appears to be a formation of several defense layers that will possibly delay and even block competition, i.e. generic entry.[165] The practice of forming patent network surrounding the base patent is known under the notion of patent clustering.[166]

Large number of product and process patents creates legal uncertainty for generic companies in terms of knowing if their product is going to infringe any patent.[167] Instead of facing a single patent expiration, generic companies are facing multiple secondary patents.[168] Even if generic companies manage to invalidate the base patent before its regular expiry, they still cannot enter the market, as there is still possibility of infringement of one of the many secondary patents covering aspects other than the main patent.[169] Creation of a broad patent portfolio basically allows the coverage of all economically interesting or viable salt forms, enantiomers or formulations of the compound.[170] Also, by protecting all efficient and more economical ways of manufacturing, generics manufacturer may have difficulty in sourcing

[160] Ibid., p. 195, par. 523
[161] Ibid., p. 187, par. 485
[162] Distinction between primary and secondary patents is irrelevant under patent law, but it is a part of terminology used by the stakeholders in the sector and is therefore relevant for understanding stakeholder´s behaviour. See more: Ibid., p. 189, par. 490
[163] Ibid. pp. 188-189, par. 489
[164] Hutchins, M., *Extending the Monopoly- How Secondary Patents Can Be Used to Delay or Prevent Generic Competition Upon Expiry of the Basic Product Patent,* Journal of Generic Medicines : The Business Journal for the Generic Medicine Sector, vol 1., no.1, 2003, p. 65
[165] *Pharmaceutical Sector Inquiry, Final Report*, op.cit. (f.n. 20), p. 187, par. 476
[166] Song; Han, op. cit. (f.n. 24)
[167] *Pharmaceutical Sector Inquiry, Final Report*, op.cit. (f.n. 20),p. 196. par. 525
[168] Song; Han, op. cit. (f.n. 24)
[169] Ibid.
[170] *Pharmaceutical Sector Inquiry, Final Report*, op.cit. (f.n. 20), p.187, par. 484

active ingredients of acceptable quality and at acceptable price, leaving ones made by less efficient processes.[171] Furthermore, originator companies strategically obtain multiple patents towards the end of the base patent protection with the aim of prolonging exclusivity period of the product as much as they can beyond expiry of the first patent.[172] Also, with the expiry date of the basic patent nearing, originator producers may seek to develop new dosage forms and line extensions to accommodate different market segments, such as liquid compositions, chewable or dispersible tablets, and transdermal patches etc., which present a new opportunity for obtaining new patents.[173] Also, recognition that the drug may have other therapeutic uses can lead to new patents emerging for novel therapeutic indications, dosage regimens, or combination therapies with other drugs.[174] European Commission Sector Inquiry found that the ratio of primary to secondary patents is 1:7.[175] The denser the web created by the patent clusters, the more difficult it is for a generic company to bring its generic version of the reference drug to the market.[176] Therefore, generic companies have to struggle to find a way to bypass all the patents, so the lack of the solution can act as a competition limiting factor.[177]

2. Secondary patents used as a part of a broader strategy

Due to the uncertainty for legitimate and viable generic entry, patent clusters can merely by their existence, prevent generic producers in entering the market, at least until the patent situation is clearer, as opposed to more risk sensitive generic companies which will probably not enter at all.[178] Even though, originator companies argue that generics are not forced to abandon their projects, as there is the possibility of opposition and litigation procedures, these however, proved to be time consuming and costly.[179] Just the threat of incurring litigation cost or issuance of an interim injunction which prevents the sale of generics can deter their entry even if they believe that there is no infringement on their side.[180] Larger generic companies are usually financially prepared for long and costly litigation, while smaller companies could be drowned by the cost burden.[181] Generic companies start to

[171] Hutchins, op. cit. (f.n. 164), p. 64
[172] *Pharmaceutical Sector Inquiry, Final Report*, op.cit. (f.n. 20), p. 185, pars. 475, 477
[173] Hutchins, op.cit (f.n. 164) p. 67
[174] Ibid., p. 66
[175] *Pharmaceutical Sector Inquiry, Final Report*, op.cit. (f.n. 20), p.188, par. 489
[176] Ibid., p.196, par. 525
[177] Song; Han, op. cit. (f.n. 24)
[178] *Pharmaceutical Sector Inquiry, Final Report*, op.cit. (f.n. 20), p.197, par. 528
[179] Ibid., p. 198, par. 536
[180] Ibid.,pp. 200, par. 544
[181] Ibid.,p. 200, par. 545

struggle as interim injunction are obtained against generic product being put on the market, resulting in lack of revenues which could cover rising litigation costs, whereas the originator company continues collecting revenues from its product.[182] One of the greatest examples on how secondary patents can be used to delay generic entry to the market beyond basic patent expiry is the case of GlaxoSmithKline's patents for its anti-depressant product paroxetine.[183] Paroxetine somehow managed to get from the expiry of the basic patent in the US in the mid-1990s to no generics and a list of 13 separate patents that GlaxoSmithKline declared relevant for various Paxil products in the FDA Orange Book in 2003.[184] The process patent for making paroxetine was the last on that list and it was expiring in 2018.[185] Furthermore, the European Commissions' inquiry found that blockbuster medicines are protected by up to nearly 100 product-specific patents and patent applications, which can lead to 1,300 patents and applications across all EU Member States.[186] Despite the lower number of underlying patent families based on EPO applications, in the absence of the Community patent, a generic competitor will then need to challenge all existing patents and pending patent applications in those Member States in which it wants to enter.[187]

Even though, secondary patents can be used to protect real innovation, their lack of strength in number of cases could be the evidence that these are often of questionable validity, consequently with a purpose to delay generic entry. During the public consultation as a part of European Commission´s sector inquiry in 2009, generic companies reiterated that originator companies obtained "weak patents", in particular for secondary patent applications, since their novelty and inventive step requirements were too easily met by the EPO.[188] Also, number of inspection documents of the originator companies showed that they were aware of their patents not being as solid, however, as all patents create a problem for competitor it was better to have any patent than no patent at all.[189] Furthermore, the Inquiry found that the 60% of opposition and appeal procedures against originator company's patents, almost all involving secondary patents, ended in revocation of the disputed patent, and in 55% of the patent litigation cases involving question of the disputed patent's validity ended in annulment of the

[182] Ibid.
[183] Hutchins, op.cit. (f.n. 164), pp. 67-68
[184] Ibid.,p. 68
[185] Ibid.
[186] *Pharmaceutical Sector Inquiry, Final Report*, op.cit. (f.n. 20),p. 188, par. 488
[187] Ibid.
[188] Ibid., p. 190, par. 499
[189] Ibid., pp. 189-192

patent.[190] Even if generic producers have strong indication that only few patents in the bundle will be valid, patent clusters make it impossible for them to know for certain that their product will not infringe any patent, while challenging patents for majority of generic firms represents a financial overburden.

However, braver generic companies may still enter the market at risk. In such cases, patent clusters become an important means in executing originator companies´ procedural enforcement strategies which typically start with patent litigation and potentially continue with patent settlement agreements which will be discussed in the later subsections. Original brand manufacturers apart from signaling[191] generic companies that they are ready to defend their intellectual property, are well aware that they can prolong their exclusivity time by initiating patent litigation and filing for the interim injunction which prevents the sales of generic products until the end of the main proceeding.[192] They file a suit against generic manufacturers claiming patent infringement on one or more patents often related to various and insignificant elements of the drug.[193] Initiating litigation has the benefit of extending the length of time the originator medicines can exclusively occupy the market, and therefore maximize the originator producer´s profit.[194] Assured time for enjoying undisturbed market position seems quite generous, as patent litigation can take several years. Average time of the ensuing litigation took 2.8 years in the examined period in the Sector Inquiry, but between Member States varied from just over six months to more than six years.[195] In certain cases an originator company may bring numerous patent infringement actions against a generic company in several Member States, even where the originator company does not believe to have a chance of being successful. Practice of instigating litigation with the collateral purpose of inflicting anticompetitive injury is not uncommon among originator companies.[196] What constitutes a restriction of competition here is the abuse of litigation processes and not their legitimate use.[197] This type of conduct is known under the notion "vexatious litigation" in Europe and "sham litigation" in the US. It is not easy to determine circumstances in which the use of the litigation process will constitute an abuse that might be considered anticompetitive

[190] Ibid.,p. 191, par. 501
[191] Ibid., pp. 199-200, pars. 542-534
[192] Ibid., pp. 211-212, pars. 583-584
[193] Glasgow, L.J., *Stretching the Limits of Intellectual Property Rights: Has the Pharmaceutical Industry Gone Too Far?* , Idea (Concord N.H.), vol. 41, no.2, 2001, p. 235
[194] Ibid.
[195] *Pharmaceutical Sector Inquiry, Final Report*, op.cit. (f.n. 20), p. 228, figure 82
[196] Lianos, I.; Regibeau, P., *Sham Litigation: When Can it Arise and How Can it Be Reduced?*, Antitrust Bulletin, vol. 62, no. 4, pp. 647-648
[197] Ibid.

if the other conditions for the implementation of the specific competition law provision are satisfied.[198] Vexatious litigation can be identified by the subjective test which focuses on the intent of the litigant. The test defines sham litigation as a pattern of baseless claims or a single claim made without regard to their merits only to delay and tie up the judicial process, i.e. the litigation in which the litigant does not expect to be successful.[199] Another test is the objective one which explains sham litigation through the real motive of the litigant by the cost benefit analysis of his economic interest to bring suit.[200] It characterizes as sham even those claims with probable cause, if the benefits of the litigation discounted by the probability of success would be too low to repay the costs.[201] However, profound analysis of the established circumstances defining vexatious litigation through EU case law would go beyond the scope of this paper.

3. Patent settlement agreements as pay-for-delay agreements

Patent settlement agreements are commercial agreements to settle patent-related disputes.[202] Disagreement regarding the outset of the patent litigation, dispute or opposition procedure, about validity of the originator company´s patent or whether the generic company´s commercial activities infringe the originator company's patent, can be a motive to settle.[203] As already mentioned, opposition procedures or litigations tend to be very costly, time-consuming and above all unpredictable in their outcome.[204] Both the players face the risk of such uncertainty.[205] For the originator company the risk lies in different outcomes in different jurisdictions regarding the patent validity.[206] Even a single judgment declaring the patent invalid could negatively affect the originator´s reputation and overall commercial value of the drug.[207] This could be even more obvious if the patent dispute is based on infringement

[198] Ibid.
[199] Ibid. 655
[200] Ibid.
[201] Ibid.
[202] European Commission, Competition DG, *8th Monitoring Report on Patent Settlements (period January-December 2016)*, 2018, available at: https://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/patent_settlements_report8_en.pdf, 16 Jan 2020, p.1, par. 2
[203] *Pharmaceutical Sector Inquiry, Final Report*, op.cit. (f.n. 20), p.255, par. 707
[204] *8th Monitoring Report on Patent Settlements,* op.cit. (f.n. 203) ,p.2, par.3
[205] Zinmeister, U., Held, M., *Pay- for-Delay or Reverse Patent Settlements- A War of Roses between Competition and Patent Law in Europe and in the US? European Commission Fines Lundbeck and Other Pharma Companies for Delaying Market Entry of Generic Medicines.*, European Competition Law Review, vol. 34, no. 12, 2013, pp. 622-623
[206] Ibid.
[207] Ibid.

of secondary patents. If we look at above mentioned statistics,[208] it can be concluded that secondary patents have quite a chance to be declared invalid as they often are not as strong, suggesting that originators will have a firm incentive to settle. The generic company, as already mentioned risks interim injunctions and high damage claims. It is therefore, understandable that from economic point of view, parties have legitimate interest to discontinue the dispute or litigation and reach a mutually acceptable compromise through a settlement, if a final judgement has not been handed down.[209]

However, patent settlements can be misused. In regular patent settlements, normal direction of value transfers is supposed to move from patent infringer to the patent holder.[210] However, there seems to be a pattern in settlement agreements in the pharmaceuticals sector, where payments are transferred from patent holders to generic companies.[211] Such transfers raise a suspicion that patent settlements are used as a veil for paying off generic manufacturers to delay or refrain from entering the market with a competing drug.[212] These reverse patent settlements would therefore, constitute a subcategory of pay-for-delay agreements.[213] Such agreements allow the originator to continue reaping monopoly profits even after its patent has expired, hindering the generic entry effect of price falling.[214] Nonetheless, these agreements are conveniently beneficial for the generic company as well, as it receives significant earnings by sharing a part of the originator's profits from exclusivity, i.e. artificially high prices, and all without even entering the market.[215] If the originator company assures to the generic company a profit lower in the amount than the originator´s possible loss in profits occurring in the case of generic entry, originator company will be able to afford to pay off one or couple generic companies to prevent their entry.[216]

Unlike above mentioned, not per se illegitimate delaying strategies, such as strategic patenting strategies and patent enforcement strategies which are a matter of intellectual property law and can only be questioned by patent offices and courts, pay-for-delay settlements may be illegitimate in the eyes of competition law and attract antitrust scrutiny.

[208] See supra section III, subsection A.2.
[209] *8th Monitoring Report on Patent Settlements,* loc.cit. (f.n. 204), p.2, par.3
[210] Sauter; Hancher, op.cit. (f.n. 39), p. 400
[211] Ibid.
[212] Glasgow, op.cit.(f.n. 193) , p. 239
[213] Sauter; Hancher, op.cit (f.n.39) p. 402
[214] Friend, M., *Reverse Patent Settlements and EU Competition Law*, Cambridge Law Journal, vol.76, no. 1, 2017, p. 29
[215] *European competition authorities working together for affordable and innovative medicines,* op.cit. (f.n. 1), pp.2, 25
[216] Ibid.

Bearing in mind the significant price reductions caused by generics,[217] pay-for-delay agreements seem to be problematic in the economic sense, as the benefits of generic market entry that might have accrued to consumers and to providers of health insurance or single buyers in national health systems, are shared by the conspiring originator and generic companies.[218] Therefore, pay-for-delay settlements could act as restriction of competition between actual or potential competitors, and in more serious cases even as a form of market sharing constituting the one of the most serious competition law infringements that leads to enormous consumer harm.[219] Consequently, they fall under Article 101 TFEU and equivalent provisions in national competition laws.[220] Article 101 TFEU prohibits agreements between undertakings, decisions by associations of undertakings and concerted practices which may affect trade between Member States and which have as their object or effect the restriction of competition. Even though, pay-for-delay settlements resemble at first sight to classic restrictions by object as they block generic entry to the market, conclusion that they should always be classified as such needs to be taken with precaution.[221] Blocking the entry of an infringing competitor is at the core of the patent right, so one could argue that pay-for-delay settlements only fall within this category if they go beyond patents right.[222] In addition to infringing Article 101 TFEU, in the case where the originator holds a dominant position and the agreements are part of a strategy to delay generic entry, pay-for-delay agreements can also infringe Article 102 TFEU. This has been one of the topics in the most recent ECJ´s judgement that will be analysed later in the text. Pay-for-delay agreements are interesting due to all the controversy around the fundamental elements of Article 101 and the involvement of the intellectual property rights which make the analysis very complex and challenging even for the best experts.

[217] See supra section II. Subsection D.2.
[218] Sauter; Hancher, op.cit (f.n.39), p. 401
[219] Ibid.
[220] *European competition authorities working together for affordable and innovative medicines,* op.cit. (f.n. 1), p.25
[221] Schroder, V., *Pay- for- Delay Settlements in the EU: Did the Commission Go Too Far?*, European Competition law Review, vol.38, no. 12, 2016, p. 728
[222] Ibid.

a. Classification of patent settlement agreements

As a result of the analyses of the patent settlement agreements, in its Final Report of the Pharmaceutical Sector Inquiry, European Commission proposed a categorisation,[223] purpose of which is the indication on what kinds of settlements may fall under further competition rules scrutiny.[224] However, this categorisation does not suggest that falling into a particular category will mean immediate incompatibility with EU competition law, as every case will have to be examined under its own individual circumstances and merits.[225]

Two main criteria are used to determine if a settlement agreement is problematic under competition law perspective. First criteria are the limitation of generic company's ability to place its product in the relevant market. The Commission pointed out several ways of potential limitation of generic entry to the market with the list not being exhaustive. The most straightforward limitation occurs when a patent settlement agreement contains a so called "non-challenge clause" which is in its essence an explicit provision that the generic company will refrain from challenging the validity of the originator company's patent, or a so called "non-compete clause" which obligates generic company to refrain from entering the market until the patent has expired. Furthermore, a licence and distribution agreements can also be categorised as limiting if a generic company cannot enter the market with its own product or freely set the conditions for the commercialisation. Second classification criteria is the existence of a value transfer, and it refers to the agreements which limit generic entry. The most evident value transfer is a direct monetary transfer such as payment of a lump sum from the originator company to the generic company. Depending on the settlement terms, such monetary transfer can take the form of compensation for the generic company's legal costs in the patent dispute or it can occur as a result of the purchase of an asset, such as generic company's stock of own products. However, such transfers are considered to possibly have another hidden purpose, the one of paying the generic company for agreeing to delay the product launch or for discontinuing the patent challenge.

Overall, the Commission considers patent settlements that do not restrict the generic company´s ability to market its own product unproblematic from a competition law

[223] *Pharmaceutical Sector Inquiry, Final Report*, op.cit. (f.n. 20),pp. 268-269; *8th Monitoring Report on Patent Settlements,* op.cit. (f.n. 204), pp. 2-4
[224] *Pharmaceutical Sector Inquiry, Final Report*, op.cit. (f.n. 20), p. 254, par. 703
[225] *Pharmaceutical Sector Inquiry, Final Report*, ibid.; *8th Monitoring Report on Patent Settlements,* op.cit. (f.n. 204), p.2, par.7

perspective.[226] Usually, the same applies to patent settlements which might limit generic entry but do not include a value transfer from the originator to the generic company.[227] However, settlement agreements in this category could still end up under competition law scrutiny if they are concluded outside the exclusionary zone of the patent, meaning that they would reach beyond its geographic scope, its period of protection or its exclusionary scope.[228] For example, a settlement agreement related to the process patent, which foresees a complete launch ban of generic products even with non-infringing processes, goes beyond of what a process patent can prevent.[229] It is the same in the case of settlement agreements in which the patent holder or both parties know that the patent does not meet the patentability criteria, for instance in cases where the patent was granted on the grounds of incorrect, misleading or incomplete information.[230] Settlements which limit generic entry and also include a value transfer are the ones usually attracting the highest degree of antitrust scrutiny.[231] Such settlement will be considered in the eyes of European Commission as a potential restriction of competition, as its purpose is presumably to share monopoly profits, unless the company can provide a believing explanation to justify the value transfer.[232] However, as this Commission´s classification is more descriptive than concrete, for further guidance on legality of the reverse patent settlement agreements one must consult the developed case law.

IV. ANTITRUST ENFORCEMENT

A. Importance of enforcement of competition rules

To reward pharmaceutical companies for their innovations and to stimulate further R&D, they are publicly granted a temporary monopoly for their results through intellectual property rights.[233] However, pharmaceutical companies often strategically use intellectual property rights to ease the competitive pressure, which invokes the necessity for striking a balance between the enforcement of the intellectual property rights and of antitrust law.[234] Any delay in market entry, due to the hindering practices of pharmaceutical companies, has a

[226] *8th Monitoring Report on Patent Settlements,* op.cit. (f.n. 204), p. 4, par. 15
[227] Ibid., par.16
[228] Ibid.
[229] Hawk, B.E., *International Antitrust Law& Policy: Fordham Competition Law 2009,* New York, USA, 2010, p. 468
[230] *8th Monitoring Report on Patent Settlements,* op.cit. (f.n. 204), par.16
[231] Ibid., par. 17
[232] Hawk, loc.cit. (f.n. 229)
[233] Sauter; Hancher, op.cit. (f.n. 39) , p. 383
[234] Ibid.

negative effect not just towards the healthcare systems but towards the end-consumer. The Pharmaceutical Sector Inquiry showed that entry of generic drugs takes on average more than 7 months after the expiration of a patent for a branded drug, a delay leading to the loss of 20% cost savings to the European health system.[235] This explains the need for the close competition law scrutiny of the pharmaceutical sector, so that enforcing competition law could help safeguard EU patients' access to affordable and innovative medicines.[236] The European competition authorities have adopted number of decisions that addressed anti-competitive practices which had previously not been addressed under EU competition law.[237] However, they gave guidance on the application of EU competition law in novel issues only to some extent. There are still some murky waters left to be navigated, such as the blurred legal area of pay-for-delay deals. In order to analyse the forming direction of the future antitrust enforcement in this area, the following subsections will address 2 landmark judicial decisions of the EU courts that were supposed to lay the foundation for the treatment of pay-for-delay agreements under the Article 101 and 102, however they still left some questions open.

B. Lundbeck case

The legality of the reverse patent settlement agreements under EU competition law has not been discussed before an EU Court until 2016. It was the General Court´s judgement in the Case T-472/13, *Lundbeck v Commission* EU:T:2016:449 which first addressed the issue in this area of antitrust enforcement. The judgement confirms application of Article 101 TFEU to agreements that restrict potential competition and tries to establish the conditions which elevate reverse patent settlements to a restriction by object. However, it is questionable how much concrete guidance on distinguishing lawful and unlawful stems from the judgement for the parties concluding patent settlement agreements.

1. Case background

Lundbeck´s patents for the active ingredient citalopram and two processes ("the original patents") were granted between 1977 and 1985. As they were about to expire, Lundbeck reacted with defensive patent filing strategy for various secondary manufacturing

[235] *Pharmaceutical Sector Inquiry, Final Report*, op.cit. (f.n. 20), p. 94
[236] *European competition authorities working together for affordable and innovative medicines,* op.cit. (f.n. 1), pp.1,6
[237] Ibid.

processes. Later on, under generic threat, Lundbeck started patent litigation proceedings on the account of infringement of the secondary patents and consequently entered into various settlement agreements with generic companies Merck, Alpharma, Arrow and Ranbaxy. Under the agreements, the generic companies committed not to compete with Lundbeck, to sell the generics' stock of generic medicine to Lundbeck, and resell Lundbeck citalopram with guaranteed profit, and to receive a significant sum of money in lieu of litigation costs or damages.

After thorough investigation the Commission adopted the decision that the settlement agreements constituted restrictions of competition by object, therefore infringing Article 101 (1) TFEU. The Commission's by object thesis was constituted on following factors: 1) the generic companies and Lundbeck were at least potential competitors; 2) generic entry to one or more EEA markets was limited for the relevant period; and 3) the agreement involved a transfer of value from Lundbeck, which was linked to generic companies´ acceptance of the limitation on entry to the markets. [238] Commission also relied on some additional factors: 1) the sum paid by Lundbeck to the generic companies was based on the generic company's expected turnover or profit, had it successfully entered the market; 2) Lundbeck could not have obtained those limitations on entry through the enforcement of its process patents, since obligations on the generic companies went beyond the rights usually granted to holders of process patents; and 3) the agreements did not contain any commitment from Lundbeck to refrain from infringement proceedings if the generic company entered the market with generic citalopram products after expiry of the agreement.[239] On the account of the seriousness of the infringement Commission fined Lundbeck and the generics approximately €150 million. Lundbeck and the generics appealed. The General Court dismissed the appeals and upheld the Commission's decision, resulting with some questionable conclusions. The General Court´s judgement is currently under appeal. Following subsections will address findings that are presumed to be inevitable along with the findings that make Lundbeck case so controversial.

2. Restriction by object controversy in regard to trending case law

As already mentioned Article 101 TFEU prohibits agreements which have as their object or the effect the restriction of competition. Restriction of competition by object

[238] Judgement of 8 September 2016, Case T- 472/13, *Lundbeck v Commission*, EU:T:2016.449, pars.63, 65-67
[239] Ibid.

includes such behaviour which is by its very nature anticompetitive.[240] The classification by object removes the examination burden of the actual or potential effects of an agreement on the market, from the competition authority, once its anti-competitive object has been established.[241] In light of that, the Commission has been criticised in recent years for overly pursuing cases under by object test, rather than applying by affect one, under which it has to outline the anticompetitive effects of the agreements in question.[242] Interestingly, the core finding of the Commission in the *Lundbeck* decision, opposed by the defendants, was that pay-for-delay agreements are amount to market sharing and represent restriction by object. Strangely, the Commission´s decision was upheld by the General Court, contrary to case law of the time. The Commission´s pattern of pursuing more challenging cases under by object test was supposed to be finally restricted by the CJEU in *Cartes Bancaires*. In the judgement the Court for the first time stated that the concept of the restriction of competition by object must be interpreted restrictively.[243] According to the judgement, the concept of restriction of competition 'by object' can be applied to the types of coordination between undertakings which reveal a sufficient degree of harm to competition that it may be found that there is no need to examine their effects.[244] Furthermore, when assessing whether such coordination is sufficiently harmful, the nature of the services at issue, as well as the real conditions of the function and structure of the markets should be taken into consideration, as well as all relevant aspects of the economic and legal context in which that coordination takes place, it being immaterial whether or not such an aspect relates to the relevant market.[245] Court considers that non-exhaustive list of collusions that would be caught under Article 101 irrelevant,[246] and rather stresses that certain collusive behaviour, such as price-fixing by cartels, may be considered a restriction by object as the experience shows that such behaviour leads to falls in production and price increases, resulting in poor allocation of resources to the detriment, in particular, of consumers.[247] Patent settlements are assumed to be an efficient extrajudicial method of settling costly and time-consuming disputes, and thus, do not create a

[240] Communication from the Commission, *Guidelines on the applicability of Article 101 of Treaty on the Functioning of the European Union to horizontal co-operation agreements*, Official Journal of the European Union, p. 8
[241] Ibid.
[242] See more at: Witt, A.*C., The Enforcement of 101 Article TFEU- What Has Happened to the Effect Analysis?,* Common Market Law Review, vol. 55, no.2, 2018, pp. 417-448
[243] Judgement of 11 September 2014, Case C-67/13 P, *Groupement des cartes bancaires V European Commission,*EU:C:2014:2204, par. 58
[244] Ibid., para 58
[245] Ibid., para 53, 78
[246] Ibid., para 58
[247] Ibid., para 51

reason for general presumption that antitrust issues and harm to consumer interest are involved.[248] As cases should be classified as restriction by object where there is existing experience of such agreements being harmful to consumers and society, patent settlements do not seem as an obvious by object restriction.

3. Exceeding the scope of patent protection - justification in light of the correct by object infringement constitution in the context of these particular agreements

Commission concluded during its research that Lundbeck's process patents were not capable of blocking all possibilities of market entry open to the generic undertakings.[249] The argument that particularly stands out is that processes protected by the patents were not the only possible way to manufacture the drug. In its decision, Commission explained that Lundbeck itself confirmed that its process patents were not capable of blocking all possible routes to the market and that generic companies could have produced citalopram by using the process described in Lundbeck's original compound patent filed in 1977, even though it could be a potentially less efficient method of purification, or they could have invented an entirely new process.[250] This leads to a conclusion that the settlements are preventing generic companies from entering the market beyond the scope of the patent, by forbidding the entry to the market even by other possible ways.[251] So, the patent invoked by the originator could not prevent generic producers from entering the market even when declared valid.[252] If the generic producer agrees not to enter the market for a given period of time, the settlement, and not the intellectual property system, would be protecting the right holder from competition.[253]

Therefore, it could be concluded that the object of these arguments was not to solve an intellectual right question, rather to restrict competition that otherwise existed.[254] As such, the agreements would be contrary, by their very nature, to Article 101 TFEU.[255] In order to show that an agreement restricts competition, an authority would need to show that generic entry would be likely within a short period of time, making the argument raised in the case, that

[248] Sauter; Hancher, op.cit. (f.n. 39), p. 400
[249] Lundbeck v Commision judgement, op. cit. (f.n. 238), pars. 96, 97
[250] European Commission, Commission's decision of June 19, 2013, in Case 39.226 *Lundbeck,* par. 634
[251] See supra section III, subsection A.3.a.
[252] Colomo, P.I., *Pay- for- Delay and Structure of Article 101(1) TFEU: Points Raised in Lundbeck and Paroxetine*, Journal of European Competition Law & Practices, vol. 10, no.10, 2019, p. 604
[253] Ibid.
[254] Ibid.
[255] Ibid.

generic products were infringing, irrelevant.[256] The main discussion in this case should therefore be whether the settlement is capable of restricting competition that would otherwise existed, and not whether the dispute relates to an infringing product.[257] To add on, it was confirmed by the Court that the settlements were not settlement agreements per se because they just postponed both generic company's entry and litigation, without settling it, in return for a payment, without providing that at the end of that period generics could enter the market free off infringement actions raised by Lundbeck.[258] All this leads to an inevitable conclusion that these particular settlements have indeed as their object the restriction of competition. It is therefore not the outcome that is questionable in this case, but it is the argument that there would be restriction by object infringement even where generic companies do not have another way of entering the market besides using a patented process, i.e. in patent settlements which are not exceeding the scope of the patent.[259]

4. Potential competition question

a. Blocking position due to Lundbeck´s patent protection

The applicants contested Commission's decision claiming that generics´ processes of manufacture infringed Lundbecks patents, claiming that Article 101 TFEU protects only lawful competition, which cannot exist where a patent precludes a way, in law or in fact.[260] Furthermore, basing the existence of potential competition merely on possibility of entering the market with the risk of infringement of the patent is incompatible with the patent protection.[261] So entry at risk cannot express potential competition under Article 101, as it infringes the third parties' intellectual property rights.[262] Their argument seems supported by the earlier case law determing that a company cannot be described as a potential competitor if it is not able to enter the market, i.e. there need to be real possibilities to compete or to enter the market in the light of the structure of the market and the economic and legal context.[263]

[256] Ibid.
[257] Ibid.
[258] Lundbeck v Commission judgement, op. cit. (f.n.238), par. 460
[259] Ibid., pars. 401, 515
[260] Ibid., par. 115
[261] Ibid.
[262] Ibid.
[263] Judgments of 15 September 1998 in *European Night Services and Others* v *Commission*, T-374/94, T-375/94, T-384/94 and T-388/94, ECR, EU:T:1998:198, par.137; 14 April 2011 in *Visa Europe and Visa International Service* v *Commission*, T-461/07, ECR, EU:T:2011:181, par. 68, and *E.ON Ruhrgas and E.ON* v *Commission*, T-360/09, EU:T:2012:332, par. 85

Interesting question posed is whether there can be competition if the market entry is blocked by intellectual property rights.

In response the Court noted that the applicants' argument is based on the premises that the generic company undoubtedly infringed the relevant patent and that those patents would certainly have withstood the claims of invalidity that would have been raised by the generic undertakings in infringement actions.[264] The Court agreed that patents are presumed valid until revoked or invalidated, and therefore they constitute a block of competition.[265] However, it stated that presumption of patent validity cannot be equated with a presumption of illegality of generic products placed on the market, as the risk entry is not unlawful in itself.[266] The Court considers entry at risk as the one of the expressions of potential competition and that the generics were ready to enter the market and accept the risk based on the following factors: 1) Lundbeck´s compound patent and two main manufacturing process patents have expired; 2) there were other processes allowing the production of generic citalopram that had not been found to infringe other Lundbeck patents, which the applicants were aware of; 3) steps taken and investments made by the generic undertakings in order to enter the citalopram market before concluding the agreements at issue, such as obtaining the active ingredient, applying for the MA or even making sales, showing that they are ready to enter and accept the risks.[267] Therefore, the Court supports the Commission in concluding that Lundbeck´s process patents did not necessarily constitute insurmountable barriers for the generic companies.[268]

The Courts conclusions lead to potential broadening of the scope of Article 101.[269] It seems that there is a strong suggestion that potential competition exists even where the patent blocks the entry, in sense that potential competition exists until a final ruling declares patent infringement.[270] What the Court is basically saying is that generic product is presumed to be lawfully on the market until proven the opposite, despite the fact that patent is in the same time presumed valid, and leading to the conclusion that uncertain probability of lawful market entry is amounted to real possibility of market entry.[271] It leaves the question, whether the

[264] Lundbeck v Commission judgement, op.cit. (f.n. 238), par.120
[265] Ibid., par. 121
[266] Ibid., pars. 121, 122
[267] Ibid., pars.129,131
[268] Ibid., par. 124
[269] Colomo, op. cit. (f.n.252) , p. 606
[270] Ibid.; Lundbeck decision, op.cit.(f.n. 250) , par.624
[271] Colomo, ibid.

products are legally on the market or not, open.[272] Also, declaring the entry at risk as the expression of the competition leads to a conclusion that all the patent settlement agreements, even genuine ones which have not exceeded the scope of the patent, distort such an entry and restrict competition that would otherwise existed.[273] Later on, the Court also fails to give clarity on a legal status of such settlements by stating that even a settlement within exclusionary scope of the patent can still amount to by object violation.[274] If we bear in mind that Commission has stressed out in its Sector Inquiry that not all limiting agreements are necessarily incompatible with Article 101[275], which was also confirmed in the Lundbeck decision,[276] then this seems to give a little guidance on what is lawful. It is not clear in which situation would these settlements be prima facie prohibited and those in which they would not.[277]

b. Process patent validity question

Lundbeck´s crystallization process patent being annulled at first instance by the EPO before being finally upheld by the EPO Board of Appeal in 2009.[278] According to the Commission the fact that the patent settlements were concluded 2001-2002 means that patent settlements were concluded when Lundbeck was uncertain about the patent´s validity and it was possible that a national court declared it invalid.[279] So in order to prove patent validity, since entry at risk is not unlawful, the Court said that it was for Lundbeck to prove before the national courts, in the event that generics entered the market, that those generics infringed one of the process patents.[280] However, settling a dispute made a court ruling unnecessary.[281] In the circumstances that there was no court ruling and that the ex-post evidence of validity is not accepted, it is questionable how can the applicant satisfy the Court´s legal test.[282] Having the ex-post evidence on validity, there is a danger of sanctioning a patent holder for doing something which is perfectly legal under patent law and should as a consequence possibly be legal under competition law, at least in the context of use of the question of validity as a factor

[272] Batchelor, B.; et al., *Lundbeck raises More Questions than Answers on Pay-for- Delay Settlements; Creates Damaging Divergence from the US Law*, European Competition law Review, vol.38, no.1, 2017,p.4
[273] Colomo, op.cit. (f.n. 252), p. 607
[274] Ibid.; Lundbeck v Commission judgement, op.cit. (f.n.238), pars. 401, 515,
[275] See supra section III, subsection A.3.a
[276] Lundbeck decision, op.cit. (f.n.250), par. 638
[277] Colomo, op.cit. (f.n. 252), p. 607
[278] Lundbeck v Commission judgement, op.cit. (f.n.238), par. 145
[279] Ibid.,par. 145
[280] Ibid., par. 122
[281] Batchelor, op.cit.(f.n.272), p. 5
[282] Ibid.

in the analysis.[283] Furthermore, the Court also stated that if the applicants were so convinced of the validity of their patents and that generic products would infringe them, they could have obtained orders to prevent market entry before the competent national courts, or, seek damages in case of unlawful early entry.[284] Also, the Court claims in the context of the infringement action brought by Lundbeck that the generic companies could have contested the validity of the patent on which Lundbeck relied by raising a counter-claim, on the basis of the evidence found in the contested Commission's decision where Lundbeck itself estimated the probability that its crystallisation patent would be held invalid up to 60%.[285]

Such a reversal of the burden of proof does not seem justified or reasonable and it raises a question whether the Court along with the Commission should have gone as far as it did in discussing invalidity concerns.[286] Bearing in mind that EU law does not question existence of intellectual property rights, [287] pointing out the potential weakness of the patent does not seem relevant, as the analysis under Article 101 should be based on the patent validity presumption. It is questionable whether the Commission is the right authority to assess the issue of patent validity, as it is a very demanding question where both legal and technical aspects are of pivotal relevance.[288] It could be concluded that Commission's analysis presents patents as probabilistic rights, thus indicating a new relationship between intellectual property law and competition law.[289] Also, it feels like the Commission is trying to stay consistent with the Sector Inquiry findings about the weakness of the secondary patents[290] by pushing the conclusion that in case of the secondary patents which are potentially weak, a patent validity should always be contested in court to a final judgement and therefore depriving the parties of possibility to settle in cases of secondary patents.

c. Existence of potential competition

Finally, the Court accepted Commission´s opinion that several factors together set the existence of potential competition, such as the significant efforts made by generic companies

[283] Schroder, op.cit. (f.n.221), p. 730
[284] Lundbeck v Commission judgement, op.cit. (f.n.238), par.384
[285] Ibid., par. 122
[286] Schroder, op.cit. (f.n. 221), p. 730
[287] The existence/ exercise of dichotomy was first mentioned in the Judgement of 13 July 1966, Cases 56 & 58/64 *Consten & Grundig*,EU: C:1966: 41, which means that EU competition law can only impact on national IP law when it comes to exercise of IPRs.
[288] Schroder, op.cit. (f.n. 221), p. 730
[289] Colomo, op. cit. (f.n.251) , p. 606
[290] See supra section III., subsection A.2.

in order to prepare their entry to the market, the fact that they had obtained MAs or had taken necessary steps to obtain one, the number of processes available to produce citalopram without infringing their patents, the fact that no court had found the generic products to be infringing, that there was a non-negligible possibility that some of Lundbeck's process patents might be declared invalid, and that applicants paid significant amounts to the generic companies in order to keep them out of the market, which shows that those generic companies were perceived as potential competitors.[291] Also, it was pointed out that a simple fact that Lundbeck decided to conclude reverse patent settlement agreements was an indicator that generics were seen as a threat.[292]

The Court did not take into consideration the applicants´ claim that Commission confuses market entry with the investments made that allow entry.[293] According to them possibilities of making investments that if successful could allow market entry do not satisfy the test set by the case-law that requires establishing real concrete possibilities of entering the market and that market entry is sufficiently rapid.[294] This leads to the conclusion that even in a case like this, where some applicants have experienced barriers[295] like not receiving a MA, or found it difficult to access the API, or had technical difficulties or required regulatory approvals to change their manufacturing process, are included in the Court´s legal standard for potential competition.[296] All generic companies can take preliminary steps, but that does not necessarily mean that occurring challenges will be resolved.[297] Furthermore, as already mentioned above, the standard requiring no court ruling that generics have infringed the patent is irrelevant since the patent settlements erase the need for one.[298] Also, non-negligible possibility of patent invalidity feels vague as it basically applies to almost all patents.[299]

5. Value transfer question

Lundbeck concluded a variety of agreements at the same time as the patent settlement that are regarded as value transfers. These include distribution agreements, stock purchases and lump sum payments for avoided litigation costs and damages. The question was whether

[291] Lundbeck v Commission judgement, op.cit. (f.n.238), par. 157
[292] Ibid., par. 181
[293] Ibid., par. 150
[294] Ibid., pars.104, 15;, *E.ON Ruhrgas and E.ON* v *Commission* judgement, op.cit.(f.n. 263), pars. 106 , 114
[295] Lundbeck v Commission judgement, op.cit. (f.n.238), pars. 168-206
[296] Batchelor, op.cit. (f.n.272) p. 5
[297] Ibid.
[298] Ibid.
[299] Ibid.

they were justifiable. The applicants argued that the Commission had to show that the only plausible explanation for the payment was the restriction of competition.[300] However, the decisive factor for Court was the size of the payments which is considered to be disproportionate and therefore led generics to stay off the market constituting a restriction by object.[301] Furthermore, payments were considered to correspond to the anticipated profits that the generics could have expected after entering the market during the time of the agreements.[302] Also, on account that Lundbeck had doubts about the validity of its patents it is considered that the agreements were concluded in order to replace that uncertainty for the certainty that the generics would not enter the market.[303]

The Court did not accept the arguments that the agreements were concluded to avoid significant litigation costs on the account that most of the agreements made no reference to those costs.[304] Furthermore, the Court believed that the level of payments removed the incentive to contest Lundbeck´s patents.[305] As the size of the payment corresponded to the anticipated profit, it induced generic companies to limit their commercial autonomy, despite the absence of a no-challenge clause.[306] The Court also suggests that the size of the sum could be lower as it could constitute immediate profit, without necessitating the risk that the market entry would have entailed.[307] However, the Court´s argumentation does not explain how large a size of a payment has to be to amount to a restriction by object, and if the payment corresponded to the amount of the litigation costs would that imply compatibility to Article 101.[308]

C. Paroxetine case

It is precisely the year 2020 that brought a major landmark judgement in the EU competition law. European Court of Justice´s judgment in the Case C-307/18 Generics (UK) and others v CMA (Paroxetine) answered many questions in great depth and breadth and contributed to understanding some of the fundamental principles stemming from Article 101 and Article 102. Shaped by the narrow questions posed by the referring court and leaving

[300] Lundbeck v Commission judgement, op.cit. (f.n.238), par. 365
[301] Ibid., pars. 354, 366
[302] Ibid. , par.362
[303] Ibid., par. 369
[304] Ibid., par. 388
[305] Ibid., par. 398
[306] Ibid., pars.398, 399
[307] Ibid., par. 399
[308] Friend, op.cit. (f.n. 214), p. 32

number of questions open to be resolved in other cases, the ruling confirms that analysis of each patent settlement depends on the individual context of the agreement.

1. Case background

In 2016, CMA fined GSK, Alpharma Ltd. and Generics (UK) Ltd. £44.99 million for entering into patent settlement agreements in relation to the court proceedings regarding the process patent for producing a form of antidepressant Paroxetine.[309] Generic manufacturers agreed not to enter the market with their generic versions of the drug for the term of the agreement, and in return GSK made payments to the generic manufacturers and bought of their generic stock, generics also undertook to enter into distribution deals regarding the paroxetine made by GSK.[310] Also, the agreements between GSK and Alpharma, and GSK and Generics (UK) only deferred resolution of the disagreement until after the expiry of the agreements, only pausing the court proceedings without creating a real solution.[311] The CMA considered these agreements breaching Article 101 and the equivalent prohibition under Chapter I of the Competition Act 1998 (CA98), and also that GSK held a dominant position in the market for paroxetine, and abused that position by entering into agreements with the generic manufacturers.[312] GSK and the generic manufacturers appealed to the CAT and in 2018 it handed down a preliminary judgment but decided to request the ECJ for a preliminary ruling. Following subsections will analyse only the relevant elements of the judgement, analysing the entire judgement would go beyond the scope of the paper.

2. ECJ´s ruling

a. Potential competition question

The CAT's question to the ECJ was whether a patent holder and a generic manufacturer can be considered potential competitors if there is a dispute regarding patent validity or patent infringement. Also, the national court also seeks to ascertain whether pending proceedings on the matter, or obtained an interim injunction or the fact that patent holder regards generics as potential competitors constitute factors that may influence the

[309] Judgement of 30 January 2020, Case C-3017/*18 Generics (UK) Ltd and Others v CMA*, EU:C:2020:52, par. 16
[310] Ibid., pars. 12-14
[311] Opinion of Advocate General Kokott (AG Opinion), Case C-3017/18 *Generics (UK) Ltd and Others v CMA*, para. 135.
[312] Generics(UK) and Others v CMA judgement ,op. cit. (f.n.311), para 15

response to the question of the existence of potential competition. The main argument in the case was that the patent proceedings were impossible to predict and that the generic manufacturers could not be characterised as potential competitors as it was impossible to know whether the generic manufacturers had real concrete possibilities to enter the market.[313]

As seen in the Lundbeck case assessment of existence of potential competition could be quite tricky in pay-for-delay cases. As already noted by the General Court patents are presumed valid, however, entry at risk is not illegal per se as there is no presumption that new entrant will infringe the patent. The main question is whether it is possible to establish the existence of potential competition prior to deciding on the validity of patent or on patent infringement.[314] The ECJ concludes that the relevant factor in assessing potential competition is the determination of real and concrete possibilities for generics to enter and compete with undertakings on the market in the absence of relevant settlement agreements.[315] One might ask how is it possible to establish these real and concrete possibilities if there is uncertainty of the ability to enter due to the pending proceedings on the patent validity/infringement question. The Court provides an answer without undermining the principle under which the EU competition law does not question the existence of the intellectual property rights. The Court points out that potential competition cannot be found where there is just hypothetical possibility of such entry or a mere wish or desire of the generic manufacturer to enter the market.[316] Also, there is no requirement to show that it was certain that the generic manufacturers would in fact enter.[317] Potential competition needs to be assessed through the structure of the market and the relevant economic and legal context.[318] The ECJ makes it clear that it is necessary to consider regulatory constraints that are characteristic of the medicine sector, stressing out that only lawful entry counts as competition, i.e. no medicine can be placed on the market without obtaining a MA.[319] The Court also noted that full account must

[313] AG Opinion, op. cit. (f.n. 311), pars. 64-65
[314] Colomo,P.I., *Case C-307/18 Generics (UK) and Others v CMA (Paroxetine), a MajorLlandmark in the CaseLlaw (II): Pay-for-Delay,*Chillin´ Competition (BLOG), 2020,pp. Chillin´ Competition (BLOG),2020-02-08, Brussels: Newstex, available at: https://chillingcompetition.com/2020/02/28/case-c-307-18-generics-uk-and-others-v-cma-paroxetine-a-major-landmark-in-the-case-law-ii-pay-for-delay/
[315] Generics(UK) and Others v CMA judgement , op.cit. (f.n.309), pars. 36-37, confirming the established case law, the Judgement of 28 February 1991, C-234/89 *Delimitis*, EU:C:1991:91
[316] Generics (UK) and Others v CMA judgement , op.cit. (f.n.309),par.38
[317] Ibid.
[318] Ibid., par. 39
[319] Ibid., par. 40

be taken on the intellectual property rights, meaning that patents should be accorded a high level of protection.[320]

According to the Court the first element when analysing potential competition is establishing whether a generic company had taken sufficient preparatory steps to enter the market within such a period of time that would impose competitive pressure on the originator company. [321] Such steps may include measures taken to gain MAs, creating adequate stocks of the generic either by production or by the supply from the third party and taking legal steps with a view to challenging the process patents held by the patent-holder, or adopting a range of marketing initiatives.[322] These steps should point to a conclusion that a generic company has a firm intention and ability to enter the market even where there are process patents held by the originator company.[323] This leads to the second important element analysed, consideration of process patents an insurmountable barrier to entry. The Court now confirms that manufacturing process cannot be regarded as an insurmountable barrier and does not mean that a generic company with a firm intention and ability to enter the market, and who, by the steps taken, shows readiness to challenge the validity of that patent, and takes the risk upon entering of being subject to infringement proceedings brought by the patent holder, cannot be characterised as potential competitor.[324] It is confirmed that no matter if the patent dispute outcome is uncertain or if the interim injunction has been obtained, the presumption of patent validity does not constitute an absolute bar to the generic manufacturers entering the market.[325] ECJ follows AG Kokott´s Opinion[326] confirming that even though, patents are part of the economic and legal context, competition authorities should not review the strength of the patent or the probability of winning a patent dispute and that assessment should rather consist of finding real possibilities of entering the market at the relevant time.[327] This should be based on taking into account that uncertainty as to patent validity is a fundamental characteristic of pharmaceutical sector, there is no such thing as presumption of infringement, patent does not guarantee protection against patent challenges, entry at risk and consequent proceedings are common in the sector, there is no such thing as patent linkage,[328] and

[320] Ibid., par. 41
[321] Ibid., par. 43
[322] Ibid., par. 44
[323] Ibid.
[324] Ibid., par. 46
[325] Ibid., par. 47
[326] AG Opinion, op.cit. (f.n. 311), point 83
[327] Ibid., par. 50
[328] In order to obtain a MA there is no requirement to prove that marketing does not infringe any patent rights.

existence of potential competition before the expiry of a patent since generics want to be ready to enter as soon as patent expires.[329] The Court also noted even if the patent litigation is in fact genuine one, this can also serve as evidence that there is a potential competitive relationship.[330] Also, conclusion of agreements between undertakings at the same level of production chain, especially those who have not entered the market yet, could be a firm indication that there is a competitive relationship between them, and moreover, the existence of a value transfer to the generic manufacturers could be a further indication.[331] The greater the size of the value transfer, the stronger the indication that there is potential competition.[332] Third element of analysis is the originator companies´ subjective perception of generic manufacturers as competitors. The subjective consideration may be relevant when it affects the conduct on the market of the originator manufacturer.[333] The subjective perception forms as a consequence of rising competitive pressure and basically points to the ability of a firm to enter the market.

b. Restriction by object question

The CMA also requested from the ECJ to consider if the reverse patent settlement agreements whit the non-compete and non-challenge clause constituted agreements that had as their object the prevention, restriction or distortion of competition, contrary to Article 101(1) TFEU. The referring court also seeks to ascertain if the answer to the question differs if the outcome of the pending proceeding is impossible to determine; the restriction of competition imposed on generic manufacturer does not exceed the patent; the transferred sum is higher than legal cost, but lower than profits that would have been made if the generic would have succeeded in the proceedings and entered the market; and what is the effect of pro-competitive benefits.

ECJ´s judgement turned out to be consisted with modern case law like already mentioned *Cartes Bancaires.* The judgement confirms that the concept of a restriction by object must be interpreted strictly, in the light of the economic and legal context and it only applies to conduct which has sufficient degree of harm to competition that it is not necessary to assess their effects, since some forms of coordination can be regarded as being harmful to

[329] Generics(UK) and Others v CMA judgement , op.cit. (f.n.309), par. 51
[330] Ibid., par. 52
[331] Ibid., pars. 55-56
[332] Ibid., par. 56
[333] Ibid., pars. 42, 57

the proper functioning of normal competition by their very nature.[334]The ECJ´s judgement has brought clarity to that statement making it more understandable.

It was finally explicitly said that a patent settlement between the patent holder and generic manufacturer, who after assessing its chances in the court proceedings may decide to abandon entry to the market, cannot in all cases be considered a restriction by object.[335] Furthermore, the fact that such an agreement involves a value transfer made by the originator company is not sufficient to classify it as a restriction by object, since those transfers may prove to be justified, appropriate and strictly necessary having regard to the legitimate objectives of the agreement.[336] The Court even gave an example when such a payment would fall outside of the scope of Article 101. This could be the case where the value transfer corresponded to the litigation costs or the value of goods or services supplied by the generic manufacturer to the originator.[337]

According to the Court agreements restrictive by object are first and foremost ones bringing to end entirely fictitious disputes, or designed with the sole aim of disguising a market-sharing agreement or a market-exclusion agreement. [338] Furthermore, where it is clear from the analysis of the agreement that the value transfers could not have any explanation other than the commercial interests of the parties not to engage in competition, characterisation as restriction 'by object' needs to be adopted.[339] According to the Court, if there is no other plausible explanation for the settlement than the motive of substantial payment, such as the perception of patent strength, the agreement amounts to restriction by object.[340] Meaning that another plausible reason could lead to exclusion of by object classification, creating the need for through analysis of the purpose of the agreement and its context. In that regard, the value transfer must be sufficiently beneficial to act as an incentive to refrain from the market entry, however, there is no requirement that the transfer should be greater than the profits that would have been made if a generic company had been successful in the patent proceedings.[341]

[334] Ibid., pars. 66-67
[335] Ibid., par. 84
[336] Ibid., par. 85
[337] Ibid., par. 86
[338] Ibid., par. 76
[339] Ibid., par. 87
[340] Ibid., par. 89
[341] Ibid., par. 94

One of the most groundbreaking elements of the judgement was that the Court has rejected the argument that agreements that do not exceed the scope of the patent could not constitute a restriction by object, as the patent does not permit the holder to enter into contract which are contrary to Article 101.[342] Also, the fact that there is uncertainty as to the validity of the patent, because of a genuine dispute or the existence of court proceedings prior to the conclusion of the agreements or the grant of an interim injunction, has no relevance to the question of whether characterisation of the agreements as restriction by object can be ruled out.[343] It is actually the uncertainty of the outcome in reaction to the validity of the patent or the infringement of the generic drug that contributes to existence of potential competition as long as it lasts.[344] The Court also emphasised that presumption of validity, existence of a court proceeding or interim injunction do not shed a light on the outcome of the patent related dispute, moreover, that cannot ever be known as a result of the conclusion of the agreement.[345] This all leads back to the conclusion that it is necessary to analyse an agreement thoroughly in search for the real purpose of the agreement, as even though an agreement may not exceed the scope of a patent, it could still amount to by object restriction if there is no other plausible explanation.

What is also refreshing is this judgement that the Court acknowledged that the pro-competitive effects of an agreement, as elements of the context, must be taken into account in the overall assessment of whether the concerted practice reveal a sufficient degree of harm to competition and whether it should be characterised as restriction by object.[346] Taking account of those pro-competitive effects is intended not to undermine characterisation as a 'restriction of competition' within the meaning of Article 101(1) TFEU, but merely to appreciate the objective seriousness of the practice concerned.[347] However, the mere existence of such pro-competitive effects cannot preclude characterisation as a restriction by object.[348] If they are demonstrated, relevant and specifically related to the agreement concerned, they must be sufficiently significant, so that they justify a reasonable doubt as to whether the settlement

[342] Ibid., pars. 96-97
[343] Ibid., par. 98
[344] Ibid., par. 100
[345] Ibid., par. 102
[346] Ibid., par. 103
[347] Ibid., par. 104
[348] Ibid., par. 106

agreement concerned caused a sufficient degree of harm to competition to constitute a restriction by object.[349]

c. Restriction by effect

The judgement has an additional value as it also discusses by effect restrictions, although in a very narrow way due to the question posed. The CAT asked whether establishing the existence of by effect restriction needs to be supported by a 50% probability that the manufacturer of generic medicines would have succeeded in a patent dispute or that there would have been a less restrictive form of settlement agreement.[350]

The ECJ noted that the establishment of counter-factual does not imply any definite finding of chances in regard to winning in the patent dispute or to the probability of the conclusion of a less restrictive argument.[351] The sole purpose of counter-factual is to establish realistic possibilities in the absence of the agreement at issue, so factors such as chances of success in a patent dispute or probability of conclusion of a less restrictive agreement are only some among many to be taken into consideration in order to determine the structure of the market.[352] The restrictive effect should be assessed through the actual context in which it would occur in the absence of the agreement, taking into consideration legal and economic context, the nature of goods or services affected and market conditions.[353] Also, the restrictive effects must be sufficiently appreciable.[354] However, the Court did not clarify the meaning of this aspect.

[349] Ibid., par. 107
[350] Ibid., par. 113
[351] Ibid., par. 119
[352] Ibid., par. 120
[353] Ibid., pars. 116, 118
[354] Ibid., par. 117

d. Abuse of dominance

One of the most interesting questions posed by the referring court was one relating to the notion of the abuse. The CAT asked whether the dominant undertaking that is the holder of a process patent, abuses its dominant position within Article 102 by using a strategy of concluding a series of settlement agreements, the effect of which is to keep outside the market generic competitors, even though some agreements have not been found to breach Article 101.[355] The Court already established that anticompetitive agreements may at the same time constitute an abuse of dominance,[356] however the relevant question targeted the overall strategy of concluding pay- for-delay agreements.

According to the documents available to the Court, the CMA and the CAT found that the set of the settlement agreements that GSK concluded were part of an overall strategy which had, if not as its object, at least the effect of delaying generic entry.[357] The Court confirmed that such contract-oriented strategy impedes the growth of competition while adversely affecting both national health systems and final consumers.[358] Furthermore, the anticompetitive effects of such strategy are liable to exceed the effects of individual agreements, as it has a significant foreclosure effect on the market, depriving the consumers of the benefits of generic entry.[359] Relying on this finding, the ECJ concluded that where the overall strategy was capable of restricting competition and has exclusionary effects going beyond the specific anticompetitive effects of the individual agreements, there is abuse of dominance under Article 102.[360]

Furthermore, it remains immaterial if the agreement was entered into not to settle but to avoid proceedings, or if the agreements might have led to substantial savings or that a certain agreement could not be penalised under national law which is in accordance with Article 101.[361] Such arguments cannot question the finding that the overall strategy constituted an abuse, as all the agreements taken together might generate cumulative anticompetitive effects that were liable to strengthen GSK´s dominant position.[362] It was

[355] Ibid., par. 145
[356] Judgement of 13 February 1979, Case 85/76, *Hoffmann-La Roche* v *Commissio*n, EU:C:1979:36, pars.116, 120
[357] Generics(UK) and Others v CMA judgement , op.cit. (f.n.309),par. 155
[358] Ibid., par. 156
[359] Ibid., par. 157
[360] Ibid., par. 172
[361] Ibid., pars. 158-160
[362] Ibid., par. 161

recognised earlier, that the anticompetitive intent can be a relevant factor to determine that there is an abuse[363] however the Court now noted that the intent of a dominant undertaking must be taken into account when assessing the conduct of the dominant undertaking. [364] Also, as it is open to a dominant firm to provide justification for potentially anticompetitive behaviour, the weighing of the favorable and unfavorable effects on competition needs to be done objectively, no matter if they were deliberate or only accidental.[365]

V. CONCLUSION

It seems today that the competitive pressure stemming from generic market entry is higher than ever. Impressive volume jumps in generic use occurring in European countries due to all the measures implemented on the EU and national level to promote generic entry, alongside with the patent cliff around the corner announcing the loss of billions of dollars, suggest that all eyes should be pointed directly at the originator companies. Loss of exclusivity is the strongest motive for originator companies to engage in every possible tactic to delay or block generic entry, and with all the generic-friendly measures now in force this motive seems to be at its peak. Particularly interesting are the commercial strategies which are fully compliant with the EU regulatory rules and at first glance do not raise any suspicion, but could have a deterrent effect on generic enthusiasm and attract antitrust scrutiny.

Although dancing on the verge of illegality in the eyes of EU competition law due to their potentially distorting effect, by being in line with the objectives of patent law, some patent strategies are left unscratched, as EU competition law does not question the existence of intellectual property rights. Patent strategies are proven to be a convenient way to create the longest possible patent protection in order to preserve monopoly position and revenue streams even beyond patent expiry, under the paravan of alleged protection of innovations. One of the best ways to delay generic entry and in the same time stay under the antitrust scrutiny radar, is the creation of the patent network surrounding the base patent, i.e. patent clustering. By creating a large number of secondary patents for new formulations, processes or new crystalline forms of the compound, originator companies create legal uncertainty for generic companies in terms of knowing whether their product would infringe any patent. Even if they manage to invalidate the base patent, there is still possibility of infringement of one of

[363] Judgement of 12 April 2012, C-549/10, Tomra Sytems and Others v Commission, EU:C:2012:221, pars. 20, 21,24
[364] Generics(UK) and Others v CMA judgement, op.cit. (f.n.311), par. 164
[365] Ibid., pars. 165-169

many secondary patents in the pile. The thicker the patent web the greater is the struggle to bypass all the patents. Conveniently, originator undertakings usually obtain multiple patents towards the end of the base patent protection with the goal of extending the exclusivity period. This uncertainty allows that patent clusters merely by existence prevent generic entry. Just the threat of litigation cost or the interim injunction is enough for risk sensitive generic companies to stay out, even if they have strong indication on patent invalidity. In case that there is a risk taker among generics, secondary patents become important means in executing procedural enforcement strategies. Originator companies are well aware that they can prolong their exclusivity time by initiating patent litigation and filing for the interim injunction which prevents the sale of generic products until the end of main proceeding which could conveniently last for couple of years. This tactic has the benefit of extending the length of permitted time for exclusive occupation of the market and ensuring monopoly profits. In certain cases originator company may even bring numerous patent infringement actions aware of non-existent chances of success. Such behavior could form an abuse of litigation processes, i.e. vexatious litigation, constituting a restriction of competition under Article 102. The most interesting patent related strategy for delaying generic competition is the use of patent settlement agreements as pay-for-delay deals. Patent settlement agreements are perfectly legitimate means of ending a costly dispute unpredictable in its outcome. However, they can be misused to pay off generic companies to delay or refrain from entering the market. These types of deals allow the continuity of reaping monopoly profits while hindering generic effect of price falling. They are also conveniently beneficial for the generic company as well, as they receive a piece of monopoly cake without the trouble of entering the market. Pay-for-delay deals are problematic in the economic sense as the benefits from generic entry that might have accrued to consumers or national health systems, are shared between the originator and generic manufacturer. Therefore, they could act as restriction of competition between actual or potential competitors, and in more serious cases even as a form of market sharing constituting the one of the most serious competition law infringements that leads to enormous consumer harm. Consequently they fall under Article 101 TFEU which prohibits agreements between undertakings, decisions by associations of undertakings and concerted practices which may affect trade between Member States and which have as their object or effect the restriction of competition. In addition to this, where the originator holds a dominant position and the agreements are part of a strategy to delay generic entry, pay-for-delay agreements can also infringe Article 102 TFEU. Due to all the controversy around the fundamental elements

of Article 101 and the involvement of the intellectual property rights, analysis of the pay- for-delay agreements is very complex and challenging even for the best experts.

Bearing in mind the upcoming patent cliff, it is only logical to expect an increased number of patent settlements. Although not all patent settlements are deemed anticompetitive, it would be desirable to have a concrete regulative framework which would be able to clearly distinct those which are anticompetitive from those which are not. This is of great importance not just for the companies in order to know which agreements attract antitrust scrutiny, but also for the antitrust enforcement bodies to increase their efficiency. Legal status of patent settlement agreements is still blurred and the hopes are up that ECJ will shed some light on the matter after deciding on the judgements on the appeal. Maybe then we will have a consolidated framework with clear foundations. Until then there is only the option of analysing the selected judgement from the General Court and the most recent ECJ´s judgement, while seeking to foresee the future antitrust enforcement development.

Major controversy in the Lundbeck judgement was caused by amounting patent settlement agreements to by object restriction. It is considered that by object restrictions should be reserved for behaviors for which experience shows that they lead to falls in production and price increases, resulting in poor allocation of resources to consumers. It is therefore, hard to believe that patent settlements which are assumed as en efficient method of settling costly and time-consuming disputes, could create a reason for such general presumption. Another controversial conclusion was the establishment of the ground for potential competition. The Court did not give a clear standard as to the blocking position of the patent. Even though the patents are presumed valid, the entry at risk is not unlawful itself, leading to the conclusion that uncertain probability of lawful entry could amount to real possibility of market entry. It combines the notion of potential competition with the fact that entry at risk is not unlawful, relaying the existence of potential competition on possible lawful entry. Such notion of potential competition could lead to a conclusion that if the entry at risk is the expression of potential competition than all the patent settlements, even genuine ones, distort such an entry and restrict competition that would otherwise existed. Furthermore, the Court made an impression that patents are probabilistic rights especially in the case of secondary patents, and thus indicated a new relationship between competition law and intellectual property law. The competition law cannot question the existence of patents as patents are presumed valid, however this is exactly what the Court is doing by insisting that the validity question could and should always be discussed before a court, resulting in

deprivation of possibilities of the parties to settle. Also, factors that were concerned when establishing potential competition felt lacking. Do generic companies which face certain barriers in their effort to enter the market, such as experiencing technical difficulties, satisfy the requirement of real and concrete possibilities of market entry? Also, pointing out the non-negligible possibility that some Lundbeck´s patents might be declared invalid, as an argument for establishing the potential competition, feels vague as it basically applies to almost all patents. Another questionable point made by the Court was that the decisive factor for concluding that settlements restrict competition by object is the size of the value transfer. According to the Court as the size of the payment corresponded to the anticipated profit it induced generic firms to limit their commercial autonomy. However, the Court does not give any particular guidance in cases that the size really amounts to litigation costs and would that imply a plausible explanation other than the restriction of competition.

It was the very recent Paroxetine case that finally made understandable the fundamental principles of Articles 101 and 102. One of the greatest contributions of the ECJ´s judgement was answering the question if it is possible to establish the existence of potential competition prior to deciding on the validity of patent or on the patent infringement. The ECJ noted that the relevant factor in assessing potential competition is the determination of real and concrete possibilities for generics to enter and compete with undertakings on the market in the absence of relevant settlement agreements, and provided an explanation of this standard without undermining the principle of not questioning the existence of intellectual property rights. According to the Court potential competition exists if a generic company has taken sufficient steps to enter the market within a period that would impose competitive pressure on the originator company. Hypothetical possibility of entering is not enough, these steps should point to a conclusion that the company had a firm intention and ability to enter. Argumentation led to another significant conclusion that manufacturing process cannot be regarded as an insurmountable barrier, meaning that a generic company in light of the steps taken, showing readiness to challenge the validity of that patent, and taking the risk upon entering of being subject to infringement proceedings brought by the patent holder, can be characterised as potential competitor. Just the fact that there is a genuine patent litigation or that the parties have concluded an agreement could be an indication that there is potential competition. Also subjective perception can be of relevance if it affects the conduct of the originator company. However, it is noted that competition authorities should not review the strength of the patent or probability of winning patent dispute, and should instead focus on

finding the real possibilities of entering the market. On the notion of restriction by object it was finally explicitly said that a patent settlement cannot be considered in all cases as restriction by object. Furthermore, it was noted that mere existence of a value transfer is not enough to classify an agreement as a restriction by object, as this transfer may prove to be justified, for instance in cases where value transfer corresponds to litigation costs or services supplied by the generic company. First in line to be considered as by object restrictions are the settlements bringing to an end entirely fictitious disputes, sole aim of which is to disguise a market-sharing or a market-exclusion agreement. Furthermore, agreements that include a value transfer which could not have any other plausible explanation than the commercial interest of not engaging in competition will be classified as by object restriction. In that regard value transfer must be sufficiently beneficial, but it does not need to be greater than the expected profits of the generic firm. Furthermore, the Court has rejected the argument that agreements not exceeding the scope of the patent could not constitute a restriction by object, as the patent does not permit the holder to enter into contract which are contrary to competition rules. Presumption of validity, existence of a court proceeding or interim injunction do not shed a light on the outcome of the patent related dispute. Moreover, that cannot ever be known as a result of the conclusion of the agreement, so in the absence of a plausible explanation, such agreements could still amount to by object restriction. Refreshing notion of this judgement is that pro-competitive effects must also be taken into consideration in the overall assessment of the restriction by object. However, they need to be sufficiently significant to justify a reasonable doubt as to whether the settlement caused a sufficient degree of harm to competition to be classified as restriction of competition. Additional value of the judgement is that it discusses also the notion of restriction by effect. The Court now confirmed that when establishing the existence of restriction by effect, counter-factual does not need to be supported with any definite findings of chances of winning in the proceeding or the probability of conclusion of a less restrictive argument. The purpose of counter-factual is to establish realistic possibilities in the absence of the agreements at issue, so factors such as chances of success in a patent dispute or probability of conclusion of a less restrictive agreement are only some among many to be taken into consideration in order to determine the structure of the market. Another particularly interesting notion brought by the Court was that the overall strategy of concluding a series of settlement agreements, capable of restricting competition and having exclusionary effects going beyond the specific anticompetitive effects of an individual agreement can constitute abuse of dominance under Article 102. The fact that some agreements may have led to substantial savings or that a certain agreement is not in the

breach of Article 101 cannot question the finding that the overall strategy constituted an abuse, as all agreements might generate cumulative anticompetitive effects. With all these landmark findings there is at least some guidance on what is lawful. However, the judgement is framed by the narrow questions posed by the referring court and given background facts, so many issues are left open for discussion. It will be interesting to see how the ECJ will decide on Lundbeck case and how the Paroxetine case will affect that judgement. As the case law develops there will be more clarity on the subject matter.

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